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APPENDIX M

SAE NARRATIVES

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Treatment Arm

Subject [redacted] enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
06-Feb-2006	**001**	**003**	**118 - Atrial Fibrillation**	**Likely not related**	**Likely not related**
07-Feb-2006	002	002	199 - Cardiac Other: 1st degree AV block	Likely not related	Likely not related
09-Feb-2006	004	001	818 - Pain	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 74-year-old Caucasian male with past medical history of hypertension. Medications at admission included: Atenolol, Allopurinol, Prilosec and Vitamin B12.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 09:30 on [redacted]-2006. Symptoms at presentation included aphasia, dysarthria, and right facial paresis. CT scan at admission revealed an area of low density in the right temporal parietal lobe, consistent with subacute infarct. CT perfusion scan showed a small area of reduced cerebral blood flow in the right posterior temporal area which correlated with the area of subacute infarct seen on the non-contrast images. Baseline NIHSS was 5. The subject was randomized to the treatment arm of the SENTIS trial at 13:23, [redacted]-2006, 3.9 hours from symptom onset.

NeuroFlo Procedure: The NeuroFlo procedure was initiated on [redacted]-2006 at 14:32. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2006 (post enrollment day 1), electrocardiogram revealed atrial fibrillation **(SAE #003).** (Due to prolonged hospitalization, event was adjudicated as serious.) Following consultation with Cardiology, the subject received Cardizem, Digoxin, Amiodarone, and Coumadin.

On [redacted]-2006 (post enrollment day 2), first degree atrial-ventricular block **(AE #002)** was diagnosed by electrocardiogram. This was attributed to the Amiodarone, and the dosage was decreased from 400mg to 200mg, with no further difficulties.

On [redacted] 2006 (post enrollment day 4) the subject complained of right knee pain **(AE #001)** which was treated with Celebrex and Tylenol.

The subject was discharged from the hospital on [redacted]-2006 to home.

Subject [redacted], enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
27-Apr-2006	**001**	**001**	**405 - HT, probably not contributing to mass effect**	**Unknown**	**Unknown**
15-Jul-2006	**080**	**002**	**411 - Transient ischemic attack**	**Likely not related**	**Likely not related**
21-Jul-2006	**086**	**003**	**115 - Patent foramen ovale (PFO) with closure**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 73-year-old Caucasian male with past medical history of hypertension, hyperlipidemia, myocardial infarction, coronary artery bypass graft, and smoking. Medications at admission included: Lipitor and antihypertensive agent.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 03:00 on [redacted]-2006. Symptoms at presentation included left-sided weakness with facial droop and slurred speech. CT scan at admission revealed acute thrombus involving the right supraclinoid internal carotid artery (ICA) as well as right middle cerebral artery (MCA). Baseline NIHSS was 10. The subject was randomized to the treatment arm of the SENTIS trial at 10:40, [redacted]-2006, 7.7 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 11:03, [redacted]-2006. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2006 (post enrollment day 1) the subject was noted to be lethargic. The 24 hour NIHSS increased to 12. NCT and CT perfusion indicated hemorrhagic transformation **(SAE #001)**. The subject's condition slightly worsened on [redacted]-2006 and NCT was repeated. It showed no change from the previous NCT.

The subject's 4 day NIHSS on [redacted]-2006 decreased to 8. He stabilized and was discharged on [redacted] 2006 to a skilled nursing facility and to home without assistance on [redacted] 2006.

At the time of the 30 day follow-up visit on [redacted] 2006, the subject's NIHSS was ranked as 3 with mRS of 2.

On [redacted]-2006 (post enrollment day 80) the subject was hospitalized for a transient ischemic attack **(SAE #002)**. He was discharged back to home without assistance on [redacted]-[redacted]-2006.

On [redacted]-2006 (post enrollment day 86) the subject was admitted to an outpatient facility for closure of his patent foramen ovale **(SAE #003)** that had been identified at the time of his index hospitalization. The procedure was tolerated by the subject and no complications were noted. The subject was discharged to home on the following day.

The 90 day NIHSS on [redacted]-2006 was ranked as 2; mRS remained at 2.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
08-Oct-2008	000	004	603 - Electrolyte imbalance	Likely not related	Likely not related
08-Oct-2008	000	006	103 - Hypertension	Likely not related	Likely not related
09-Oct-2008	**001**	**001**	**702 - Femoral artery occlusion/thrombosis**	**Likely related**	**Likely related**
09-Oct-2008	001	003	414 - Neurological worsening	Likely not related	Likely not related
11-Oct-2008	003	010	118 - Atrial Fibrillation	Likely not related	Likely not related
11-Oct-2008	003	901	818 - Pain	Likely not related	Likely not related
11-Oct-2008	003	902	409 - New ischemic stroke	Unknown	Unknown
12-Oct-2008	004	005	815 - Skin irritation	Likely not related	Likely not related
12-Oct-2008	004	013	809 - Diabetes mellitus	Likely not related	Likely not related
13-Oct-2008	**005**	**002**	**202 - Respiratory failure**	**Likely not related**	**Likely not related**
15-Oct-2008	007	007	699 - Lab/electrolyte Other: Increased LFTs	Likely not related	Likely not related
17-Oct-2008	009	012	811 - Depression	Likely not related	Likely not related
21-Oct-2008	013	009	303 - Urinary Tract Infection	Likely not related	Likely not related
23-Oct-2008	015	008	602 - Thrombocytopenia	Likely not related	Unknown
26-Oct-2008	**018**	**903**	**599 - GI Other: Peptic ulcer**	**Likely not related**	**Likely not related**
28-Oct-2008	020	011	399 - Renal Other: Fluid imbalance	Likely not related	Likely not related
Unk-Jan-2009		904	815 - Skin irritation	Likely not related	Likely not related
Unk-Feb-2009		**905**	**699 - Lab/electrolyte Other: Bacteremia**	**Likely not related**	**Likely not related**
Unk-Feb-2009		906	815 - Skin irritation	Likely not related	Likely not related
Unk-Feb-2009		907	504 - GI Motility Disorders	Likely not related	Likely not related
04-Mar-2009	147	014	303 - Urinary Tract Infection	Likely not related	Likely not related
04-Apr-2009	178	909	301 - Renal dysfunction	Likely not related	Likely not related
04-Apr-2009	**178**	**910**	**805 - Sepsis**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is an 80-year-old Caucasian female with past medical history of hypertension. She was a former cigarette smoker of 65 years. Medications at admission included: Lisinopril.

Current Stroke Onset and SENTIS Enrollment: The subject had sudden onset of symptoms at 11:30, [redacted] 2008. Symptoms at presentation included visual impairment, left-sided sensorimotor deficit and dysarthria. The subject was evaluated at an outlying hospital within the tPA time window but she refused tPA treatment. She was later transferred to the SENTIS site for further care. CT scan at admission revealed no acute intracranial abnormalities. Baseline NIHSS was 14. She was randomized to the treatment arm of the SENTIS trial at 17:15, [redacted]-2008, 5.8 hours from symptom onset.

NeuroFlo Procedure: Right femoral arterial puncture occurred at 18:13, 0[redacted] 2008, but the access was unsuccessful. The left femoral artery was accessed without difficulty. The subject had conscious sedation and tolerated the NeuroFlo procedure well. Hemostasis was achieved with the Starclose vascular closure device labeled for 6-Fr introducer sheath. The procedure note stated "there were no complications during or immediately after the procedure."

Post-Enrollment Course: On [redacted]-2008 (the day of enrollment), CTA showed signs in both lungs consistent with a history of asbestos exposure, and emphysematous changes. There was also a cavitary nodule (2.5x1.8cm) in the left upper lobe and an enlarged left pre-vascular mediastinal lymph node; it was confirmed by CTs of the chest on 24-Oct-2008 and [redacted] 2009. A closed bronchial biopsy was performed on [redacted]-2009; the cytology exam was negative for malignant cells. The nature of the lung mass had not been determined at the 90-day follow-up.

Also on [redacted]-2008, the subject's electrolytes were imbalanced **(AE #004).** Serum magnesium was 1.3; potassium and calcium were also low. Supplements were given. Electrolytes were within normal limits by 2[redacted]-2008. Her serum total protein and albumin levels were also below normal limits during the index hospitalization.

Although the subject had a history of hypertension, her blood pressure was significantly elevated intermittently over the next two weeks and was treated with Hydralazine, Labetalol, and Metoprolol **(AE #006)**. The subject was still on oral antihypertensives at the 90 day follow-up.

At 20:00 on [redacted] 2008, pedal pulses were palpable but faint bilaterally, and lower extremities were warm to touch with capillary refill <3 seconds.

On [redacted] 2008, bilateral pedal pulses were palpable in the post-anesthesia care unit (PACU) at 04:00. Venous duplex at 09:00 was negative for deep vein thrombosis (DVT). [Note: Nursing notes in the PACU between 06:00 and prior to the subject being transferred to the floor in the evening are unavailable. The site stated that they were lost. After multiple diligent searches, the notes have not been found.] It was documented at 20:49 that the subject's left foot was cold and cyanotic, the left dorsalis pedis (DP) and

posterior tibial (PT) pulses were not palpable and a hematoma had formed at the left groin puncture site with bloody drainage **(SAE #001)**. Vascular surgery was consulted. On [redacted]-2008, a CTA of the aorta with femoral run-off revealed multiple focal occlusions in the left popliteal artery, severe diffuse atherosclerotic disease and severe right renal artery stenosis, however, the nephrogram appeared symmetric at this time. Abdominal arteriogram prior to NeuroFlo treatment on [redacted]-2008 showed no evidence of stenosis in either of the bilateral renal arteries. [Note: No diagnosis regarding this was made in the progress notes or discharge summary.] The same scan also revealed evidence of chronic lung disease with right lower lobe anterior emphysema. The subject underwent an aortography/selective left leg arteriography and initiation of thrombolysis on the same day. The right femoral artery was accessed for the procedure. It confirmed that the left popliteal artery was abruptly cut off just above the knee. There was an indication of fresh thrombus. Subsequent angioplasty and repeated thrombectomy were marginally successful without residual improvement of reopening of superficial femoral, popliteal and tibial vessels; an infusion catheter was placed in the popliteal artery for tPA infusion. The subject was also given systemic low-dose heparin infusion.

Also on [redacted] 2008 the 24 hour NCT of the brain showed evolving bland infarct in the right MCA distribution with some local mass effect; no gross midline shift or hemorrhage transformation. NIHSS increased by 3 points from 14 to 17 **(AE #003)**.

On [redacted]-2008 (post enrollment day 3), the subject developed a rapid expanding hematoma in the left groin which was superficially tracking up the abdominal wall and down the thigh. Her hemoglobin and hematocrit dropped as low as 6.9 and 21.1, respectively. The subject was hypotensive for a brief period of time. She was minimally responsive during this episode, and the worsening mentation was thought to be multi-factorial **(cont. of SAE #001)**. She was intubated for airway protection. tPA was discontinued and heparin was held temporarily. The subject received 3 units of packed red blood cells (PRBCs) at the time and 3 additional units over the following week. The left foot remained cold without palpable pulses. It was determined that the leg salvage had failed and amputation was planned. The subject was also noted to have areas of ecchymosis on her upper extremities and abdomen.

Also on [redacted] 2008 and [redacted] 2008 the subject was documented to have episodes of tachycardia that spontaneously resolved. On 1[redacted]-2008, there was another episode of tachycardia after suctioning with good response with Lopressor. Atrial fibrillation **(AE #010)** with rapid ventricular response was captured on an ECG on [redacted]-2008.

Additionally, the subject complained of back pain **(AE #901)** on [redacted]-2008. Tylenol and Oxycodone were added to her regimen.

A follow-up CT of the brain on [redacted]-2008 showed a new finding of a large area of infarction now involving the right inferior and medial temporal lobe extending to occipital lobe, thalamus, and moderate mass effect **(AE #902).** NIHSS was 13.

On [redacted]-2008 (post enrollment day 4) the subject was extubated overnight and was hemodynamically stable. NIHSS was 15. Blisters and mottled skin were noted near the left groin site **(cont. of SAE** [redacted] and a left forearm skin tear was also noted **(AE #005)**. Both were treated with dressings.

The subject's blood glucose had been elevated (mid-upper 100s) since the day of enrollment on [redacted]-2008. Hyperglycemia was documented on [redacted]-2008, and insulin was started on [redacted]-2008 **(AE #013)**. At discharge on [redacted]-2008 she was formally diagnosed as diabetic. Oral medication and insulin were prescribed through the 90 day visit.

On [redacted]-2008 (post enrollment day 5) the subject developed left lung collapse overnight and respiratory failure **(SAE #002)**. Her oxygen saturation was in the low 90s. Left lung atelectasis was noted on chest x-ray with possible effusion. She was reintubated, and Lasix was administered. Moderate amount of thick yellow secretions was suctioned. A bronchoscopy was performed, no mucus or blood was seen; airways were open bilaterally. Chest percussion and bronchodilators were continued. (After multiple attempts to extubate the subject with repeated lung collapse and persistent pleural effusion, a tracheostomy was performed for her prolonged need for ventilator assistance on [redacted] 2008. The subject was weaned off the ventilator and remained stable on a tracheostomy collar for more than 5 days prior to discharge. She remained on a tracheostomy collar through the 90 day follow-up.)

Also on [redacted]-2008 the subject was diagnosed with rhabdomyolysis related to the left leg ischemia **(cont. of SAE #001)**. She had decreased urine output, positive for urine myoglobin, and significant generalized edema. Her creatine kinase-myoglobin (CK-MB) was 14.2 (<8.8ng/ml) and serum CK was 1855 (30-220U/L). The decreased urine output was responsive to Lasix. It resolved by [redacted] 2008.

On [redacted] 2008 (post enrollment day 6) the subject had an uncomplicated left above the knee amputation **(cont. of SAE #001)**.

On [redacted]-2008 (post enrollment day 7) the subject's liver function tests (LFT) were significantly increased (alanine transaminase (ALT) of 50 and aspartate transaminase (AST) of 57) **(AE #007)**. Lipitor was discontinued. LFTs remained elevated throughout her index hospitalization and were stable at the time of index discharge.

On [redacted]-2008 (post enrollment day 9) the subject was treated with Zoloft for withdrawn affect and depression **(AE #012)**. Treatment with Zoloft continued through the 90 day follow-up.

On 2[redacted]-2008 (post enrollment day 13) the subject was diagnosed with urinary tract infection (UTI) following positive urine culture and increased white blood cell (WBC) count **(AE #009)**. She was afebrile. Ciprofloxacin was administered for 7 days with good result.

Between [redacted]-2008 and [redacted]-2008 the subject's platelets dropped to the range of 43-95 with negative Platelet Factor-4 (PF-4). The platelet count was gradually improving but started dropping again on [redacted] 2008 (post enrollment day 15), and the repeated PF-4 was positive. Although the Heparin-Induced Platelet Aggregation Assay was negative, given the timing and exposure to heparin along with new thrombosis, heparin-induced thrombocytopenia (HIT) was considered **(AE #008)**. Also on [redacted] 2008, the subject had a positive ultrasound study for left femoral DVT **(part of AE #008).** Bivalirudin was started two days later.

On [redacted] 2008 (post enrollment day 16) a CT of the brain showed interval evolution of a very large infarct in the right MCA and right PCA distributions since [redacted]008 with interval improvement of the mass effect. An unconfirmed petechial hemorrhage along the cortex was also mentioned in the report. The Core Lab analysis showed no definite evidence of hemorrhage on this CT scan. There were similar findings on the follow-up CT on [redacted]-2008.

On [redacted] 2008 (post enrollment day 18), after 8 hours on Bivalirudin for the DVT, the subject had a large amount of loose bloody stool with hemoglobin of 6.1 and an 8-point drop in hematocrit to 19.3. Colonoscopy was negative except moderate diverticulae left colon. Bivalirudin was discontinued and the subject was transfused with total of 5 units of PRBCs and 2 units of fresh frozen plasma. An Esophagogastroduodenoscopy (EGD) on [redacted]-2008 revealed a gastric ulcer with active bleeding in a pulsate fashion and multiple duodenal ulcers **(SAE #903)**. Epinephrine injection and clip were applied. During the period of decompensation the subject was in respiratory distress and was re-intubated. Gastrointestinal (GI) bleeding continued and the subject subsequently underwent microcoil embolization of the gastroduodenal artery on [redacted] 2008. She was also treated with IV Nexium. There were a few additional episodes of GI bleeding (melena). Hemoglobin and hematocrit gradually became stable. On [redacted] 2008 repeated EGD showed no active bleeding in the stomach and duodenum.

On [redacted] 2008 (post enrollment day 19) the subject developed DVT in the right internal jugular and axillary veins **(part of AE #008)**, and an inferior vena cava filter was placed on [redacted]-2008. On [redacted] 2008 ultrasound of the upper extremity revealed DVT of the subclavian, axillary, brachial, and basilica veins **(part of AE #008)**. No treatment was administered for these DVTs. They had resolved at the time of the 90 day follow-up visit.

On [redacted]-2008 (post enrollment day 20) the subject had decreased urine output and 4+ pitting edema with weeping from the upper extremities **(AE #011)**. Generalized edema had been documented previously. The subject was treated with fluid bolus and Lasix and the Foley catheter was changed. The decreased urine output improved by [redacted]-2008. The fluid imbalance resolved by [redacted]-2009.

During the subject's index hospitalization, percutaneous endoscopic gastrostomy (PEG) tube was placed. The subject was discharged from the hospital on [redacted]-2008 to a long term care facility.

On [redacted]-2008 (post enrollment day 79) the subject was re-admitted to the hospital for shortness of breath and decreased oxygen saturation by pulse oximetry. She reportedly had low-grade fever while in the nursing home but was afebrile on this admission. She also had increased bronchial secretions. Chest CT showed left pleural effusion that was treated with thoracentesis; approximately 300ml of yellowish non-serosanguineous fluid was aspired without incidence. The subject was discharged back to the long term care facility on [redacted]-2009 in stable condition with the diagnosis of acute respiratory failure with underlying bronchopneumonia and chronic obstructive pulmonary disease (COPD) **(cont. of SAE #002).**

On [redacted]-2009 (post enrollment day 90) the subject was again re-admitted to the hospital for respiratory distress including increased secretions and respiratory rate. Chest x-ray showed left pleural effusion and consolidation. Tracheobronchitis was considered. She was treated with antibiotic and bronchodilators **(cont. of SAE #002)**. Per admission history and physical, the subject had generalized rash and was seen by dermatology during the previous hospitalization and was on topical cream **(AE #904)**. She was discharged back to the long term care facility in stable condition on [redacted] 2009.

On [redacted] 2009 (post enrollment day 105) the subject was seen in the emergency room (ER) for increased secretions and cough **(cont. of SAE #002)**. She was stabilized in the ER but not hospitalized. She returned to the long term care facility on the same day.

On [redacted] 2009 (post enrollment day 119) the nursing home staff noticed that the subject had respiratory distress with desaturation; she was cyanotic and diaphoretic. She had to be bagged and brought to the ER but became asymptomatic and hemodynamically stable upon arrival to the hospital. Chest x-ray showed left lung opacification, so she was hospitalized for further evaluation and treatment. Her WBC count was 11.5 on admission, and then was down to normal. Blood culture was positive for Coagulase-negative Staphylococcus growth **(SAE #905)**. The source was thought to be the Port-A-Cath device on the right chest wall. The subject was diagnosed with pneumonia with sputum culture positive for Klebsiella and Methicillin-resistant Staphylococcus, acute respiratory failure and tracheostomy infection **(cont. of AE #002)**. Antibiotics, breathing treatments and frequent suctioning were administered. She was discharged back to the long term care facility in stable condition on [redacted] 2009. At discharge, the subject was also diagnosed with pressure ulcer **(AE #906)** and Clostridium difficile- negative diarrhea **(AE #907)**.

On [redacted]-2009 (post enrollment day 147) the subject was re-admitted to the hospital for excessive secretion, shortness of breath, hypoxemia, and fever. Chest x-ray showed complete opacification of the left lung and mediastinal shift secondary to the left lung collapse **(cont. of SAE #002)**. Emergency bronchoscopy was performed allowing some aeration of the lung. Bronchoscopy culture was negative for microorganism growth. Blood culture showed gram-positive cocci in clusters; antibiotics were continued.

Also on [redacted]-2009 urine analysis showed significant amount of leukocyte esterase and WBC; urine culture was positive for Proteus Mirabilis **(AE #014)**. Treatment with Zosyn

and Vancomycin was continued. The subject was discharged back to the long term care facility in stable condition on [redacted]-2009.

On [redacted]-2009 (post enrollment day 178) she was once again admitted for recurrent respiratory distress and hypoxia **(cont. of SAE #002)**. Upon admission, she was febrile with WBC of 13, blood urea nitrogen (BUN) of 85, and creatinine of 2.05 **(AE #909)**. Her international normalized ratio (INR) was 6.3 **(cont. of AE #008).** She was hypotensive (SBP=88) in the ER. Her hemoglobin was 14.8 and hematocrit was 46.1 initially, and then went down to 10.1 and 32, respectively, after hydration; serum creatinine was down to 1.5. The subject had gross hematuria with clots via a Foley catheter. The renal CT scan read by the attending physician was negative for gross hydronephrosis or mass. She also had abdominal discomfort and heme-positive diarrhea. The existing PEG tube was noted to have some black aspirate. Per admission note, it was unclear whether her elevated BUN was related to an upper GI bleed or if her heme-positive stool was simply related to the diarrhea given her supratherapeutic INR. A test for Clostridium difficile was ordered (no result was mentioned). GI hemorrhage was the only GI-related diagnosis at discharge **(cont. of SAE #903)**. Urine culture was positive for Proteus Mirabilis which was the same bacteria found in the urine culture on [redacted] 2009 admission **(cont. of AE #014)**. The subject was diagnosed with UTI with sepsis at admission. Blood cultures were negative in the setting of prolonged antibiotic coverage. UTI and sepsis **(SAE #910)** were listed as separate diagnoses at discharge. Zosyn was continued and a single dose of Diflucan was added. Vitamin K and fresh frozen plasma were given to reverse anticoagulation.

The 90 day visit was originally scheduled within the window but was delayed several times due to the subject's multiple re-hospitalizations. It was finally done on [redacted] 2009 (post enrollment day 181), so adverse events occurring on/prior to that date are still considered as within the 90 day follow-up window.

At the 90 day visit on [redacted]-2009 the subject was still hospitalized. Her NIHSS remained at 14.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
23-Dec-2009	**001**	**001**	**499 - Neuro Other: Glioblastoma**	**Likely not related**	**Likely not related**
14-Jan-2010	023	002	816 - Oral thrush	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 54-year-old Caucasian male with past medical history of cholecystectomy in 1985. He was not on any medication at the time of admission.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 10:40 on [redacted] 2009. Symptoms at presentation included right-sided weakness, slurred speech, and transient blurred vision. CT scan at admission revealed no hypodensity and no hemorrhage. While in the emergency room, the subject had a seizure manifested by twitching of his face and tonic-clonic movements of his right hand. Ativan was given and the seizure stopped. The subject was loaded with Fosphenytoin. He was alert and oriented soon after the episode of seizure. Baseline NIHSS was 7 (post-seizure). The subject was randomized to the treatment arm of the SENTIS trial at 15:28, [redacted] 2009, 4.8 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 15:45, [redacted] 2009. Treatment was unremarkable.

Post-Enrollment Course: The 24 hour NIHSS on [redacted]-2009 decreased to 2. MRI of the brain showed no infarct and no hemorrhage, but did reveal a left frontal mass. A resection and biopsy on [redacted]-2009 was consistent with grade IV glioblastoma **(SAE #001)**. The subject's mild dysarthria with paraphrasic errors exacerbated post-operatively but these symptoms gradually improved. The subject was discharged from the hospital on [redacted]-2009 to home.

On [redacted] 2010 (post enrollment day 23), during his oncology office visit, oral thrush **(AE #002)** was noted and Clotrimazole was prescribed. Chemotherapy began on that day and radiation therapy began on [redacted]-2010 **(update to SAE #001)**.

The subject did not present as scheduled for his 30 day follow-up visit and withdrew consent for SENTIS participation on 1[redacted]-2010.

Subject [redacted], enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-Dec-2006	000	003	818 - Pain	Likely not related	Likely not related
28-Dec-2006	000	023	606 - Hyperglycemia	Likely not related	Likely not related
29-Dec-2006	**001**	**001**	**403 - Cerebral edema**	**Likely not related**	**Likely not related**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
29-Dec-2006	**001**	**014**	**499 - Neuro Other: Hydrocephalus with headache**	**Likely not related**	**Likely not related**
30-Dec-2006	**002**	**002**	**202 - Respiratory failure**	**Likely not related**	**Likely not related**
30-Dec-2006	002	902	603 - Electrolyte imbalance	Likely not related	Likely not related
02-Jan-2006	005	901	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
04-Jan-2007	007	016	899 - Other: Hiccups	Likely not related	Likely not related
10-Jan-2007	013	018	103 - Hypertension	Likely not related	Likely not related
12-Jan-2007	015	013	405 - HT, Probably not contributing to mass effect	Likely not related	Likely not related
23-Jan-2007	026	008	413 - Headache	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 45-year-old Caucasian male with past medical history of intravenous heroin abuse and Hepatitis C. He admitted to using heroin on the day of admission. He is a current smoker. Medications at admission: none.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 15:00 on [redacted] 2006. Symptoms at presentation included slurred speech, difficulty swallowing and right-sided weakness and clumsiness. CT scan at admission revealed no intracranial abnormality. Baseline NIHSS was 8. The subject was randomized to the treatment arm of the SENTIS trial at 22:30, [redacted] 2006, 7.5 hours from last known normal.

MRI at 22:50 showed a right cerebellar infarct involving the posterior inferior and superior cerebellar arteries territory. A protocol deviation has been received for enrolling a subject with acute infarct restricted to the brainstem/cerebellum.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 22:50, [redacted]-2006. During the procedure the subject complained of back, abdominal and right shoulder pain **(AE #003)**; Fentanyl was given.

Post-Enrollment Course: On 2[redacted]-2006 (the day of enrollment), the subject's admission glucose was 241 **(AE #023)**; insulin was given per sliding scale. The subject continued receiving insulin until [redacted]-2007.

Drug screen was positive for opiates and benzodiazepines. Tachycardia and a white blood cell count of 24.5 were also noted. The 4 hour NIHSS decreased to 4.

On [redacted]-2006 (post enrollment day 1), NCT showed a large right cerebellar stroke with associated mass effect, midline shift to the left, and mass effect upon the right side of the pons **(SAE #001).** There was also mass effect upon the fourth ventricle resulting in hydrocephalus; no hemorrhage was noted. The subject was agitated and complained of headache; these symptoms were attributed to the hydrocephalus **(SAE #014)**. Ventricular catheter was placed at 05:00 on [redacted] 2006. Post ventriculostomy, the subject's mental status improved and he started following commands.

On [redacted]-2006 (post enrollment day 2), NCT at 08:44 showed further evolution of the right cerebellar stroke with further cerebellar midline shift to the left and mass effect with obliteration of the forth ventricle. Hydrocephalus was unchanged. A small amount of intra-ventricular blood dependently in the lateral ventricles was thought be a result of the ventriculostomy. At 11:00 the subject had increased respiratory distress, a temperature of 100.6° F, and the oxygen saturation of the blood was 95%. Chest x-ray showed right lower lobe infiltrates. The subject became progressively agitated and confused and was unable to clear his airway **(SAE #002)**. At 17:25 the subject was intubated to protect his airway. Aspiration pneumonia was suspected and Zosyn was started. The subject's serum potassium level was 3.3 **(AE #902)**; replacements were given**.**

NCT on [redacted] 2006 was essentially unchanged from previous scan with an interval decrease in volume of the lateral ventricles post ventricular catheter placement. NCT on [redacted] 2007 showed a marked increase in hydrocephalus. The ventricular catheter had high attenuation debris around it and was likely clogged.

On [redacted] 2007 (post enrollment day 5) NCT showed a slight decrease in hydrocephalus and an evolving right cerebellar infarct. Hemorrhagic material around the ventriculostomy shunt catheter was unchanged and there was a slight interval increase in intraventricular blood. The subject remained sedated and ventilated.

Laboratory tests on [redacted]-2007 showed a low density lipoprotein of 154; Zocor for hyperlipidemia **(AE #901)** was initiated.

On [redacted] 2007 (post enrollment day 7), NCT showed interval repositioning of the ventricular catheter with the tip across the midline and left lateral ventricle. An increase in intra-ventricular blood and hemorrhage along the shunt catheter with surrounding edema somewhat increased. The ventricular catheter clotted off and was replaced on [redacted] 2007 **(update to SAE #014).**

The subject was noted on [redacted]-2007 to have hiccups **(AE #016)**; Thorazine and Reglan were given. The hiccups continued until [redacted]-2007.

On [redacted]-2007 the subject extubated himself after freeing his arms from wrist restraints. He remained off the ventilator until [redacted]-2009, when he was re-intubated for respiratory distress. On [redacted] 2007 he again extubated himself and a tracheostomy as well as percutaneous endoscopic gastrostomy (PEG) tube placement was performed.

On [redacted] 2007 (post enrollment day 13), the subject was hypertensive **(AE #018)**; Clonidine was initiated.

On [redacted]-2007 (post enrollment day 15) NCT showed a hemorrhagic transformation **(AE #013)** within the right cerebellar infarct. The ventricular catheter was removed.

On [redacted]-2007 the subject complained of chest pain and shortness of breath. No tests or changes in medication occurred. On [redacted]-2007 the subject complained of abdominal discomfort and his abdominal binder (worn due to PEG tube) was loosened. On [redacted] 2007 tracheitis was suspected, no treatment was given.

The subject was transferred to an in-patient rehabilitation facility on [redacted]-2007.

On [redacted] 2007 (post enrollment day 26) the subject complained of intermittent headaches **(AE #008).** The headaches resolved by [redacted]-2007.

The 30 day follow-up visit was done on [redacted]-2007. The subject's NIHSS was 13, mRS was 04, Barthel Index was 30 and Glascow Outcome Scale was 3.

From [redacted] 2007 to [redacted]-2007 the subject complained of a sore throat, general aches and malaise, left hand and shoulder tingling, and right joint pain **(update to AE #003).**

The subject was discharged from the hospital on [redacted]-2007 to home without assistance.

At the 90 day follow-up visit on [redacted]-2007, the subject's NIHSS was 3, mRS was 4, Barthel Index was 75 and Glascow Outcome Scale was 3.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
13-Nov- 2008	000	003	503 - Nausea/ Vomiting	Likely not related	Likely not related
13-Nov- 2008	000	002	403 - Cerebral edema	Likely not related	Unknown
Unk-Nov-2008		901	303 - Urinary Tract Infection	Likely not related	Likely not related
19-Dec- 2008	**036**	**001**	**899 - Other: Right ankle fracture**	**Likely not related**	**Likely not related**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
29-Jan-2009	077	004	899 - Other: Lip laceration	Likely not related	Likely not related
06-Feb-2009	085	005	414 - Neurological worsening	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 61-year-old Caucasian female with a past medical history of diabetes, hypertension, hyperlipidemia, coronary artery disease, peripheral vascular disease, fibromyalgia, osteoarthritis, depression, and left subclavian steal syndrome with in-stent restenosis. A carotid ultrasound done two months prior to the index admission showed >80% stenosis. Her surgical history includes back surgeries in 2006 and 2007, a gall bladder resection and tonsillectomy. Medications at admission included: Carvedilol, Lotrel, Neurontin, Lipitor, Metformin, Aspirin and Cymbalta.

Current Stroke Onset and SENTIS Enrollment: The subject was scheduled for an elective left carotid endarterectomy on the day of her enrollment, [redacted] 2008, but awoke at 05:30 with the stroke symptoms. She was last known normal at 21:00, [redacted] -2008. Symptoms at presentation included aphasia, dysarthria, a fixed left gaze deviation, right facial weakness and right arm weakness. NIHSS was 19 on admission but improved to 15 at baseline. CT scan at admission revealed left MCA infarct with clot in the left MCA artery. The subject was randomized to the treatment arm of the SENTIS trial at 08:45, [redacted] -2008, 11.8 hours from last known normal.

The subject was participating in another clinical trial with Cymbalta, and a waiver was granted for enrollment into SENTIS since the drug in the Cymbalta trial was already approved by the FDA with known side effects.

NeuroFlo Procedure: NeuroFlo procedure was initiated on [redacted] -2008 at 09:45. Treatment was unremarkable.

Post Enrollment Course: A carotid duplex study showed 40-60% stenosis of right internal carotid artery (ICA) and mild to severe stenosis of left ICA with no Doppler signal beyond stenosis.

On [redacted] 2008 (day of enrollment) the subject complained of nausea **(AE #003)** and was treated with Reglan and Zofran. A follow-up MRI on [redacted] -2008 showed developing edema in the left temporal lobe and basal ganglia **(AE #002).** CT scan the next day showed some mass effect with mild (3mm) midline shift. The 24 hour NIHSS increased to 18.

On [redacted] -2008 (post enrollment day 3), the subject's pupils were unequal. CT scan showed an increase in midline shift to 6-7mm, and more mass effect on the left lateral and third ventricles **(update to AE #002).** The 4 day NIHSS on [redacted] 2008 remained at 18.

During her index hospitalization, the subject was treated with Amoxicillin for a urinary tract infection **(AE #901).** The subject was discharged from the hospital on [redacted] 2008 to a rehabilitation facility.

At the 30 day follow-up visit on [redacted] 2008 the subject's NIHSS was 18, mRS was 5, Barthel Index was 45 and Glasgow Outcome Scale was 3.

On [redacted]-2008 (post enrollment day 36), while being transferred from the rehabilitation center to a skilled nursing facility, the subject fractured her right ankle **(SAE #001).** She was admitted to the hospital and underwent an open reduction of the fracture on [redacted] 2008.

The subject was discharged to a skilled nursing facility on [redacted]-2008; however, family did not like the facility, so the subject returned to the hospital on that same day for re-admission until an alternative placement was found. There were no changes in medical status and the subject was discharged to a different skilled nursing facility on [redacted] 2009.

On [redacted]-2009 (post enrollment day 77), the subject fell from her wheelchair and was treated in the emergency department for a lower lip laceration and moderate ecchymosis of the lower jaw **(AE #004).** CT scan of the head was negative for acute abnormalities.

The 90 day visit was completed on [redacted]-2009. The subject's NIHSS was reported as 22, mRS was 4, Barthel Index was 60 and Glasgow Outcome Scale was 3. The assessments were not done by her primary physician, but based upon the NIHSS worsening of 4 points, an adverse event of neurological worsening was reported **(AE #005).**

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
22-Dec-2009	000	002	603 - Electrolyte imbalance	Likely not related	Likely not related
23-Dec-2009	001	001	108 - Congestive heart failure	Likely not related	Likely not related
24-Dec-2009	**002**	**004**	**414 - Neurological worsening**	**Unknown**	**Unknown**
27-Dec-2009	005	007	806 - Agitation/Excitation	Likely not related	Likely not related
31-Dec-2009	009	006	818 - Pain	Likely not related	Likely not related
05-Jan-2010	014	008	599 - GI Other: Hiatal hernia	Likely not related	Likely not related

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Jan-2010	014	005	115 - Patent foramen ovale (PFO)	Likely not related	Likely not related
09-Jan-2010	018	009	504 - GI Motility Disorders	Likely not related	Likely not related
19-Jan-2010	028	901	899 - Other: Allergies	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 59-year-old African American female with a past medical history of a right basal ganglion stroke (mRS=1), seizures, hyperlipidemia, and hypertension. Medications at admission included: Aspirin, Hyzaar, Keppra, Fosinopril and Vytorin. The subject smokes a half pack per day and denies alcohol use.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 02:00 on [redacted]-2009. Symptoms at presentation included aphasia, hemianopsia, right tongue deviation, facial palsy, right-sided weakness and neglect. CT scan at admission revealed no acute abnormalities. CT perfusion scan revealed significantly increased time to peak diffusion in the left MCA distribution suspicious of high-grade proximal occlusion. Baseline NIHSS was 14. The subject was randomized to the treatment arm of the SENTIS trial at 11:35, [redacted] 2009, 9.6 hours from last known normal.

The subject's family denied a recent myocardial infarction and Principal Investigator did not delay randomization and randomized the subject into the trial prior to reviewing cardiac enzyme results. Lab results revealed elevated cardiac enzymes (creatinine kinase of 5.9 and troponin of 0.27). The subject had fluctuating periods of apnea in the emergency department, but her oxygen saturations remained at 100%.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 13:00 on [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment), the subject's serum potassium was low **(AE #002)**, so an IV replacement was given. Serial troponin levels were as follows: 1.20; 1.17; and 1.03. A cardiology consult was obtained.

An echocardiogram showed an ejection fraction of 15-20% with right and left ventricular dysfunction and severe diffuse left ventricular hypokinesis. In addition, there was a minimal pericardial effusion and a moderate sized left pleural effusion noted. The subject's brain naturetic peptide level was 3200. The subject was noted to be tachypneic, so a heparin drip and lasix were initiated **(AE #001).** A diagnosis of non-ST elevation myocardial infarction vs Tako-tsubo cardiomyopathy was suggested. The subject was started on Coreg and lisinopril to treat her cardiomyopathy. A cardiology note on [redacted]-2009 stated that the subject may not have had a myocardial infarction, but rather a troponin leak not necessarily indicative of myocardial necrosis. However, the rest of the notes that followed in the chart continued to question myocardial infarction vs troponin

leak. The subject's telemetry was discontinued. The subject's brain naturetic peptide level decreased to 150.

On [redacted]-2009 (post enrollment day 2) CT scan showed evolution of the index stroke **(SAE #004).** The 4 day NIHSS on [redacted]-2009 increased to 18 from 14 at 24 hours due to decrease of right-sided weakness, dysarthria and neglect.

On [redacted]-2009 (post enrollment day 5), the subject was noted to have a serum potassium of 2.9 that was treated with IV potassium replacements **(cont. of AE #002).** She was also given Haldol for agitation **(AE #007).**

On [redacted] 2009 the subject complained of left arm pain **(AE #006)** and was treated with Percocet and arm elevation.

On [redacted] 2010 (post enrollment day 14), a percutaneous endoscopic gastrostomy (PEG) tube was placed due to the subject's inability to swallow. A small hiatal hernia was noted during the procedure **(AE #008).** A transesophageal echocardiogram was also performed that showed a small to moderate size patent foramen ovale **(AE #005)** with right to left shunting**.**

On [redacted]-2009 (post enrollment day 19), the subject was constipated **(AE #009)** and was treated with Colace and Dulcolax. On [redacted]-2010 (post enrollment day 21), the subject's hemoglobin was 9.6. It was thought to be due to excessive blood draws; no treatment was given.

The subject was transferred to a skilled nursing facility on [redacted]-2010; her hemoglobin was 9.8.

At the 30 day follow-up visit on [redacted]-2010, the subject's NIHSS was 19, mRS was 4, Barthel Index was 10 and Glascow Outcome Scale was 3. She was noted to be taking an antihistamine (Claritin) for allergy symptoms **(AE #901).**

The subject was discharged from the skilled nursing facility on [redacted]-2010 to home with assistance.

At the 90 day follow-up visit on [redacted]-2010, the subject's NIHSS was 16, mRS was 5, Barthel Index was 10 and Glascow Outcome Scale was 3. She complained of a painful right arm with diminished range of motion in the right shoulder **(cont. of AE #006).**

[redacted] enrolled 1[redacted]-2010

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
18-Jan-2010	000	002	503 - Nausea/ Vomiting	Likely not related	Likely not related
20-Jan-2010	002	003	603 - Electrolyte imbalance	Likely not related	Likely not related
28-Jan-2010	**010**	**001**	**499 - Neuro Other: Altered mental status**	**Likely not related**	**Likely not related**
28-Jan-2010	010	004	205 - Infectious pneumonia	Likely not related	Likely not related
28-Jan-2010	010	901	699 - Lab/electrolyte Other: Elevated BNP	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is an 82 year-old Caucasian female with a past medical history of hypertension, hypothyroidism, chronic atrial fibrillation, and cholecystectomy. Medications at admission included: Aspirin and Synthroid. The subject had refused to take Coumadin for stroke prophylaxis. She denied alcohol and tobacco use.

Current Stroke Onset and SENTIS Enrollment: The subject was found by a neighbor outside lying on the road in front of her house at 07:30 on [redacted] 2010. She was last seen normal at 21:00 on [redacted] 2010. The subject usually gets up at 7:00 to her morning routines; therefore, it was assumed that since she was dressed and found outside, the symptoms occurred between 07:00 and 07:30. Symptoms at presentation included decreased level of consciousness, aphasia, and right leg weakness. The subject was in atrial fibrillation. NCT scan at admission revealed chronic ischemic changes and atrophy but no acute abnormalities. In addition, heterogeneous material partially opacifying the left sphenoid sinus was observed and determined to likely represent sinusitis. A subsequent CT cerebral perfusion scan revealed a large area of hypoperfusion involving the left MCA distribution. A major MCA trunk occlusion or multiple branch occlusions was suspected. Baseline NIHSS was 7. The subject was randomized to the treatment arm of the SENTIS trial at 13:30 on 1[redacted] 2010, 6.0 hours from assumed symptom onset.

NeuroFlo Procedure: The NeuroFlo procedure was initiated at 15:05 on [redacted] 2010. Treatment was unremarkable.

Post-Enrollment Course: Post procedure, the subject complained of nausea and vomiting **(AE #002)**; Zofran was given.

On [redacted]-2010 (post enrollment day 1), the subject was prescribed Augmentin for the pre-existing left sphenoid sinusitis that was observed on the admission CT scan. The subject continued to refuse Coumadin, so she was treated with aspirin and Plavix. NCT scan revealed a developing cortical infarct in the posterior left temporal and parietal lobes without hemorrhage or mass effect. Extensive periventricular subcortical white matter

hypoattenuation was also noted which likely reflected sequela of chronic microvascular ischemia. The 24 hour NIHSS was 7.

On [redacted] 2010 the subject's serum potassium was 3.2 **(AE #003)**; replacements were given and the hypokalemia resolved by the next day.

The subject was discharged from the hospital on [redacted] 2010 to home to the care of her family.

On [redacted] 2009 (post enrollment day 9), the subject complained of a mild headache, and her family noted that she was more confused than the previous day, so she was taken to the emergency room **(SAE #001)**. She also had chills, but no fever. NCT scan revealed mild swelling of the previously infarcted brain which was considered insignificant. There was no significant mass effect, midline shift or hemorrhage, and no evidence of any new infarctions. Blood and urine cultures were negative, but based upon urinalysis findings of white blood cells and rare bacteria in the urine; Moxifloxacin, Vancomycin and Zosyn were started. Treating physicians attributed the subject's altered mental status to a probable urinary tract infection.

A chest x-ray revealed cardiomegaly with moderate pulmonary vascular congestion and a probable small left pleural effusion. A repeat chest x-ray on [redacted] 2010 (post enrollment day 10) demonstrated an enlarging left pleural effusion and an associated left basilar opacity which was interpreted as probable atelectasis. The subject was started on Levaquin for possible pneumonia **(AE #004)**. Laboratory results on [redacted]-2009 revealed marked elevation of serum brain naturetic peptide (BNP) at 417 **(AE #901).**

The subject was discharged to home on [redacted] 2010.

At the 30 day follow-up visit on [redacted] 2010, the subject's NIHSS was 0, mRS was 1, Barthel Index was 100 and Glascow Outcome Scale was 5.

At the 90 day follow-up visit on [redacted]-2010, the subject's NIHSS increased to 2, mRS was 1, Barthel Index was 100 and Glascow Outcome Scale was 5.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
03-Jun-2009	002	001	407 - Seizure	Likely not related	Likely not related
15-Jun-2009	**014**	**002**	**404 - HT, likely contributing to mass effect**	**Likely not related**	**Likely not related**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
15-Jun-2009	014	903	503 - Nausea/ Vomiting	Likely not related	Likely not related
15-Jun-2009	014	902	116 - Bradycardia	Likely not related	Likely not related
22-Jun-2009	021	901	305 - Urinary retention	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 58-year-old Caucasian male with past medical history of myocardial infarction in 2005, coronary artery disease status post stent x 2, hypertension, dyslipidemia, diabetes mellitus, and urethral cancer. Surgical history includes left nephrectomy and urethrectomy. Medications at admission included: Aspirin, Colace, Simivastin, Lisionopril, Novolog, and Lantus Insulin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 10:30, [redacted] 2009. Symptoms at presentation included decreased level of consciousness, right-sided weakness with facial palsy, aphasia, and dysarthria. CT scan at admission revealed a large area of hypoattenuation in the left parietotemporal region that was indicative of a large posterior middle cerebral artery (MCA) infarct. CT perfusion showed decreased cerebral blood volume confirming large left MCA infarct. Baseline NIHSS was 12. The subject was randomized to the treatment arm of the SENTIS trial at 15:40, [redacted] 2009, 5.2 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 16:[redacted] 2009. Treatment was unremarkable.

Post-Enrollment Course: The 24 hour MR of the brain on [redacted]-2009, showed a large well-defined infarct in the left parieto-occipital, posterior division of the MCA distribution. No hemorrhage or new infarct was identified.

On [redacted] 2009 (post enrollment day 2) the subject had two brief episodes of shaking **(AE #001)**. Partial seizure secondary to stroke was considered by the neurologist. Infection was ruled out. The subject was treated with Keppra, and no further shaking episodes were documented.

The subject was discharged from the hospital on [redacted] 2009 to home with NIHSS of 4.

On [redacted] 009 (post enrollment day 14), the subject presented to the emergency room with complaints of a severe headache started on the previous night. Emergent NCT of the brain showed acute parenchymal hemorrhage **(SAE #002)** involving left parietal and temporal lobes associated with edema, mass effect, and approximately 10mm left to right midline shift. Probable mild hydrocephalus and possible early or impending herniation were also suggested. The subject was transferred to the index hospital, where his NIHSS was ranked as 13 upon arrival. A repeat NCT confirmed initial findings.

The subject was admitted to the intensive care unit (ICU) for neurological monitoring. While in the ICU, the subject was treated with hydrocodone-APAP for complaints of a headache. Nausea **(AE #903)** was also reported that was treated with Zofran.

Aspirin was withheld and IV Mannitol was started. Repeat NCTs revealed an increasing midline shift measuring 11mm and increasing edema around the acute intraparenchymal hematoma which may have also increased in size **(cont. of SAE #002)**. NCT on [redacted]-2009 showed stable hemorrhagic transformation with mildly improving surrounding edema. The subject was clinically stable and Mannitol was discontinued.

The subject's heart rates had been documented in the 40s and 50s **(AE #902)** without any symptoms during his second hospitalization. Bradycardia continued despite withholding of Metoprolol. Review of telemetry showed predominately sinus bradycardia with occasional episodes of junctional escape waves and one episode of a short run of accelerated ventricular rhythm. Echocardiogram showed ejection fraction of 53-58% with inferior and inferolateral akinesis consistent with previous left circumflex coronary artery territory infarct. This bradycardia was thought to be most likely secondary to the increased intracranial pressure and withholding of beta blockers was the treatment; no further interventions were required.

On 2[redacted]2009, urinary retention **(AE #901)** was noted and an indwelling foley catheter was placed**.**

The subject was discharged from the hospital on [redacted]2009 to a rehabilitation facility.

Subject [redacted], enrolled [redacted]-2010

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
06-Jan-2010	**000**	**002**	**118 - Atrial Fibrillation with pacemaker placement**	**Likely not related**	**Likely not related**
06-Jan-2010	000	006	809 - Diabetes mellitus	Likely not related	Likely not related
06-Jan-2010	000	003	201 - Atelectasis	Likely not related	Likely not related
07-Jan-2010	001	004	603 - Electrolyte imbalance	Likely not related	Likely not related
07-Jan-2010	**001**	**005**	**414 - Neurological worsening**	**Unknown**	**Unknown**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
Unk-Jan-2010		901	303 - Urinary Tract Infection	Likely not related	Likely not related
03-Feb-2010	**028**	**001**	**412 - HT, no concomitant mass effect**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 74-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, and anxiety disorder. Medications at admission included: Aspirin, Cardizem CD, Doxazosin, Dyazide, hydralazine, Lorazepam, Tekturna, and Zocor.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 05:00, [redacted] 2010. Symptoms at presentation included right gaze preference and left-sided weakness, facial palsy, dysarthria, and neglect. CT scan at admission revealed an acute to subacute ischemic infarction in the anterior right frontal lobe of the right middle cerebral artery (MCA) and mild chronic small vessel ischemic disease. CTA revealed thrombus in the right MCA M1 segment, with evidence of subacute stroke in right MCA anterior division. The subject was in atrial fibrillation. Baseline NIHSS was 11. The subject was randomized to the treatment arm of the SENTIS trial at 10:00, [redacted]-2010, 5.0 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 10:55 on [redacted] 2010. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 010 (the day of enrollment), the subject's atrial fibrillation found at admission was thought to be due to severe biatrial dilatation with a left ventricular index of 41ml/m^2. Coumadin was started on [redacted]-2010. Continued monitoring showed paroxysmal atrial fibrillation **(SAE #002)** with a rapid ventricular response with conversion pauses greater than 4 seconds. A pacemaker was successfully placed on [redacted] 010.

Admission laboratory results showed an elevated glucose level with an A1C of 5.8% **(AE #006)**. The subject was started on an insulin sliding scale that was stopped upon discharge. Type II diabetes was eventually diagnosed and Metformin was started.

During the evening of [redacted] 2010 the subject was febrile and Tylenol was given. The temperature remained elevated and peaked at 102°F. Chest x-ray and urine cultures were initially negative but a repeat chest x-ray on [redacted] 2010 showed bibasilar subsegmental atelectasis **(AE #003)**. The subject was started on incentive spirometry and Vancomycin. On 11-Jan-2010 the subject was afebrile.

NCT showed an evolving right MCA stroke with new peripheral hyperattenuation, likely representing contrast from previous angiography versus hemorrhage. The 12 hour MRI revealed large right MCA infarct and minimal petechial hemorrhage in the anterior aspect

of infarct, much smaller than the area seen on prior NCT. This suggested the majority of high attenuation seen on the prior NCT scan represented contrast rather than true hemorrhagic conversion. The 24 hour NCT showed resolution of hyperattenuation at the right frontal gray-white interface, representing contrast from recent angiography.

On [redacted] 2010 (post enrollment day 1) the subject's potassium level was 3.2 **(AE #004)** and potassium supplements were given. The 24 hour NIHSS increased to 18 from 10 at 6 hour **(SAE #005)** due to the increase of left-sided weakness. NCT revealed an evolving right MCA territory stroke that involved the ipsilateral frontal and parietal lobes; no hemorrhagic conversion was seen. Resolution of hyperattenuation at the right frontal gray-white interface from contrast was shown.

The 4 day NCT on [redacted] 2010 confirmed evolution of the right MCA territory infarct without hemorrhagic conversion.

The subject was discharged from the hospital on [redacted] 2010 to a rehabilitation facility.

In Jan-2010, the subject developed a urinary tract infection **(AE #901).** A course of antibiotic therapy was initiated, ending just before the [redacted] 2010 admission. On 05-Feb-2010 the subject's urine was positive for coagulase-negative Staphylococcus and no further antibiotic treatment was given.

On [redacted] -2010 (post enrollment day 28), the physical therapist noticed that the subject was sluggish and drifting when using a walker. The subject was readmitted to the index hospital. NCT showed hemorrhagic conversion **(SAE #001)** of the right MCA territory infarct. The subject's INR was 1.9 and Coumadin was held for one week. NCT on 04-Feb-2010 showed an unchanged large right MCA infarct with patchy areas of petechial hemorrhage/laminar necrosis. The 30 day NIHSS on [redacted] 010 decreased to 7. The subject remained neurologically stable throughout her re-hospitalization and was discharged back to the rehabilitation facility on the following day.

At the 90-day follow-up visit on [redacted] 2010, the subject's NIHSS decreased to 5 with mRS of 4.

Subject [redacted] enrolled [redacted] -2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
23-Dec-2007	002	002	817 - Chest pain	Likely not related	Likely not related
23-Dec-2007	002	904	605 - Hypercholesterolemia	Likely not related	Likely not related
25-Dec-2007	004	001	818 - Pain	Likely not related	Likely not related

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
26-Dec-2007	005	003	412 - HT, no concomitant mass effect	Likely not related	Likely not related
30-Dec-2007	009	014	699 - Lab/electrolyte Other: Increased LFT's	Likely not related	Likely not related
02-Jan-2008	012	005	811 - Depression	Likely not related	Likely not related
02-Jan-2008	012	008	599 - GI Other: GERD	Likely not related	Likely not related
04-Jan-2008	014	013	115 - Patent foramen ovale (PFO)	Likely not related	Likely not related
05-Jan-2008	015	901	899 - Other: Equinovarus posturing of right ankle	Likely not related	Likely not related
06-Jan-2008	016	006	815 - Skin irritation	Likely not related	Likely not related
09-Jan-2008	019	007	818 - Pain	Likely not related	Likely not related
12-Jan-2008	022	902	813 - Fall	Likely not related	Likely not related
19-Jan-2008	029	905	413 - Headache	Likely not related	Likely not related
23-Jan-2008	033	009	899 - Other: L3 fracture	Likely not related	Likely not related
23-Jan-2008	033	903	814 - Sleeping Disturbance/ Disorder	Likely not related	Likely not related
28-Jan-2008	038	010	504 - GI Motility Disorders	Likely not related	Likely not related
30-Jan-2008	**040**	**011**	**207 - Pulmonary embolism**	**Likely not related**	**Likely not related**
07-Mar-2008	**077**	**004**	**899 - Neuro Other: Altered level of consciousness**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 33-year-old Caucasian male with past medical history of hypertension, morbid obesity, and two packs per day smoking. The subject was not taking any medication at the time of admission.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 13:00, [redacted]-2007. Symptoms at presentation included decreased level of consciousness, right-sided weakness, facial palsy, expressive-receptive aphasia, dysarthria and left gaze preference. CT scan at admission revealed occlusion of the M1 segment of the left MCA. An MRI of the brain revealed a left-sided subcortical infarct with patchy areas of infarct in the left insular cortex and dots of infarction in the left frontal and parietal gray-white junction. There was no associated hemorrhage or mass effect. Baseline NIHSS was 17. The subject was randomized to the treatment arm of the SENTIS trial at 21:45, [redacted]-2007, 8.8 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 22:20, [redacted]-2007. Treatment was unremarkable.

Post-Enrollment Course: The 24 hour NIHSS on [redacted]-2007 decreased to 15.

On [redacted] 2007 (post enrollment day 2), the subject complained of midsternal chest pressure **(AE #002)**. He was treated with morphine, nitroglycerin and oxygen (2 liters by nasal cannula). A chest x-ray, cardiac enzymes and an ECG were negative. The subject was also diagnosed with hypercholesterolemia **(AE #904)** and started on medication.

On [redacted] 2007 (post enrollment day 4), the subject complained of lower extremity and shoulder pain **(AE #001)**; Tylenol and Motrin were administered. The 4 day NIHSS was 13.

On the following day, [redacted] 2007, the subject's NIHSS had worsened to 16. Level of consciousness (LOC) questions and commands had worsened by one point and right lower extremity score had worsened from 3 to 4. The neurologist's note stated that the subject's neurological condition is "somewhat worse". MRI revealed no significant change in the areas of restricted diffusion, but the T1 series showed "faint high signal intensity in the left basal ganglia" **(AE #003)**. Mass effect on the left frontal horn was also noted; no midline shift. Medical management was unchanged.

On [redacted] 007 (post enrollment day 9) the subject experienced an elevation of liver function tests (LTFs) with an aspartate transaminase (AST) of 38 (norm: 5-45 IU/L) and an alanine transaminase (ALT) of 71 (norm: 5-60 IU/L) **(AE #014)**. Both values continued to rise until they reached a peak on [redacted] 2008 with AST of 103 and ALT of 339; Zanaflex and statin were held. The LFTs came back into a normal range. There was no further mentioning of liver issues during the remainder of the subject's study participation.

The subject was discharged from the hospital on [redacted]-2008 to rehab in stable medical/neurological condition.

On [redacted]-2008 (post enrollment day 12), Celexa was started for depression and mood swings **(AE #005)** and Seroquel for agitation. Psychiatry consult on [redacted] 2008 suggested continuing treatment with Celexa. Diagnosis of adjustment disorder with depressed mood related to major medical illness was made. The subject's mood was improving at the time of acute rehab discharge on [redacted] 2008. Also on [redacted]-2008 the subject complained of heartburn **(AE #008)**. Cardiac work-up ruled out a cardiac cause for the discomfort. He was successfully treated with Maalox and Nexium.

A transesophageal echocardiography on [redacted]-2008 revealed patent foramen ovale **(AE #013)**; no intervention was planned.

On [redacted]-2008 (post enrollment day 15) the subject was noted to develop some equinovarus posturing of his right ankle **(AE #901)**; an ankle-foot orthotic was prescribed.

On [redacted] 2008 a red facial rash **(AE #006)** was noted. Triamcinolone cream was applied and the condition had improved, although not completely resolved at the time of acute rehab discharge.

Beginning of [redacted] 2008 and continuing through acute rehab discharge on [redacted] 008, the subject complained of multiple body aches and pains **(AE #007)**. Specifically, he complained of pain in his shoulder, arms, leg, knee, head and back. He was treated with analgesics and narcotics - most relief was coming from Oxycodone administration. He was also treated with hot and cold packs, massage and an arm sling. X-rays of the arm, knee and leg did not reveal abnormal findings.

The subject fell **(AE #902)** on [redacted]-2008. X-rays did not reveal any fractures of his right ankle or knee.

On [redacted] 2008 (post enrollment day 29) the subject complained of headache **(AE #905)** and was treated medically.

The 30 day NIHSS on [redacted] 2008 was ranked as 8 with mRS of 4.

The subject continuously complained of lower back pain and was treated with medication. Lumbar spine x-ray on [redacted] 2008 (post enrollment day 33) showed L3 fracture of undetermined age **(AE #009)**. CT scan of the lumbar spine did not confirm acute fracture. No neurosurgical intervention was recommended by the consulting physician. Continued pain control and a corset as needed was ordered. The subject's pain had improved but continued at the time of discharge from acute rehab. The subject was also started on Klonopin for his insomnia issues **(AE #903)**.

The subject was on a standard rehab bowel regimen of Colace and Senna. By [redacted] 2008, the subject had not had a bowel movement in 4 days and complained of constipation **(AE #010)**. Lactulose and Fleets enema were administered. By the time of acute rehab discharge, his constipation had resolved.

On [redacted]-2008 (post enrollment day 40), the subject complained of chest pain and shortness of breath and dyspnea. Cardiac work-up was negative. Ventilation/Perfusion scan showed high probability for pulmonary embolism **(SAE #011)**. While conducting the pulmonary embolus consultation, the physician noted that the right leg was larger than the left leg. The subject had also complained of pain in the right leg and knee area. A duplex ultrasound was completed on the following day revealed an occlusive deep vein thrombosis at the right popliteal vein extending into the posterior and perineal vein **(part of SAE #011)**. The subject was treated with heparin and Coumadin.

The subject was discharged from acute rehab on [redacted]-2008 to home.

On [redacted] 2008 (post enrollment day 77), while at home, the subject experienced a syncopal episode and fell **(SAE #004)**. According to his mother, the subject was confused and speaking inappropriately after the episode. He was taken to the emergency department where he returned to his baseline status. The subject was re-admitted to the hospital for further work-up. No new stroke, cardiac event or other significant changes were identified. The subject was discharged to home on [redacted] 2008 without any change in his care plan.

At the time of the 90 day follow-up visit on [redacted] 2008, the subject's NIHSS was ranked as 7; mRS was 3.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Jan-2009	000	004	503 - Nausea/Vomiting	Likely not related	Likely not related
05-Jan-2009	000	005	701 - Hematoma	Unknown	Likely related
06-Jan-2009	001	007	603 - Electrolyte imbalance	Likely not related	Likely not related
07-Jan-2009	**002**	**001**	**899 - Other: Right hilar/left atrial mass**	**Likely not related**	**Likely not related**
07-Jan-2009	002	002	413 - Headache	Likely not related	Likely not related
08-Jan-2009	003	003	899 - Other: Bleeding in both ears - tympanic membrane perforated	Likely not related	Likely not related
13-Jan-2009	008	006	109 - Arrhythmia: Patient had 5 PVC's in a row	Likely not related	Likely not related
13-Jan-2009	008	008	205 - Infectious pneumonia	Likely not related	Likely not related
13-Jan-2009	008	009	303 - Urinary Tract Infection	Likely not related	Likely not related
16-Feb-2009	042	010	199 - Cardiac Other: Presyncopal episode with orthostatic event	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 49-year-old Caucasian female without signigicant past medical history except for smoking for 30 years. Medications at admission included Motrin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 06:00, [redacted]-2009. Symptoms at presentation included decreased level of consciousness, global aphasia, right-sided weakness, and facial palsy. CT scan at admission revealed no

evidence of hemorrhage. CTA revealed an acute thrombus in the first segment of the left MCA. Troponin was elevated at 0.14 but the electrocardiogram was normal. The study team did not believe the subject was having an acute cardiac event and proceeded with enrollment. Baseline NIHSS was 10. The subject was randomized to the treatment arm of the SENTIS trial at 13:15, [redacted] 2009, 7.3 hours from last known normal.

NeuroFlo Treatment: At 13:45 the subject experienced nausea and vomiting and Zofran was given **(AE #004)**. Treatment was initiated on at 14:55 on [redacted] 009. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2009, post treatment, a small groin access hematoma without bleeding was noted **(AE #005)**. Hematoma resolved by the 24 hour assessment.

On [redacted] 2009 (post enrollment day 1) the subject had low potassium, calcium, and magnesium **(AE #007)**. This was treated with replacements and lab values normalized by [redacted] -2009.

On [redacted] 2009 an echocardiogram showed left atrial mass and thrombus and a chest CT scan revealed a right hilar mediastinal mass invading the left atrium and right pulmonary vein **(SAE #001)**. A brochoscopy with biopsy on [redacted] 2009 was positive for adenocarcinoma. No treatment was initiated during the index hospitalization.

The subject also complained of headache **(AE #002)** and was treated with analgesics. The headache continued intermittently until discharge.

On [redacted] 2009 (post enrollment day 3) the subject suffered bilateral tympanic membrane rupture with bleeding **(AE #003)**, which was thought to be related to her brochoscopy. Antibiotic drops were ordered.

On [redacted] -2009 (post enrollment day 8) the subject had an asymptomatic 5 beat run of ventricular tachycardia **(AE #006)** and a blood pressure of 100/55. No treatment was given. The subject also developed right lower lobe pneumonia **(AE #008)** and antibiotics were started. The next day the subject had a positive urinalysis **(AE #009)**; no additional antibiotics were ordered.

The subject was discharged from the hospital on [redacted] 2009 to home in stable neurological condition. She started chemotherapy on [redacted] 2009.

On [redacted] -2009 (post enrollment day 42) the subject had a pre-syncopal episode, thought to be related to poor oral intake and fatigue **(AE #010)**. No treatment was given and she quickly recovered.

During the 90 day follow-up exam on [redacted] 2009 the subject's mental changes were noted. MRI revealed metastatic foci in hemispheres, cerebellum and brain stem **(update to SAE #001)**.

Subject [redacted], enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
15-Aug-2008	**000**	**001**	**414 - Neurological worsening**	**Likely not related**	**Unknown**
16-Aug-2008	001	010	412 - HT, no concomitant mass effect	Likely not related	Unknown
16-Aug-2008	001	006	606 - Hyperglycemia	Likely not related	Likely not related
16-Aug-2008	001	007	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
18-Aug-2008	003	002	603 - Electrolyte imbalance	Likely not related	Likely not related
23-Aug-2008	008	903	201 - Atelectasis	Likely not related	Likely not related
26-Aug-2008	011	003	816 - Oral thrush	Likely not related	Likely not related
Unk-Aug-2008		901	504 - GI Motility Disorder	Likely not related	Likely not related
02-Sep-2008	018	005	811 - Depression	Likely not related	Likely not related
03-Sep-2008	019	008	818 - Pain	Likely not related	Likely not related
04-Sep-2008	020	004	814 - Sleeping Disturbance/ Disorder	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 53-year-old Caucasian female with past medical history of self-reported hepatitis A, several hernia repairs, and hysterectomy. Medications at admission included Lamisil for a fungal infection and Ibuprofen.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 15:30, [redacted] 2008. Symptoms at presentation included complete hemianopsia, facial palsy, left-sided weakness, dysarthria, sensory loss, and neglect. CT scan at admission revealed a large acute infarct in the right middle cerebral artery (MCA) but no hemorrhage. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 19:30, [redacted]-2008, 4.0 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 19:59, [redacted] 2008. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour NIHSS on 15-Aug-2008 at 23:45 increased to 22 **(SAE #001)** due to the decreased level of consciousness and increase of limb ataxia. MRI the next morning (approximately 11 hours post-NeuroFlo procedure) showed acute infarct involving the entire right MCA territory. The report stated "there is a small focus of different diffusion and T2 weighted signal… which may indicate an early small amount of hemorrhage" **(AE #010)**. It also showed absence of normal flow-void in the right ICA and right MCA. NCT at 17:08 on [redacted] 2008 revealed that the right ICA and MCA were hyperdense suggestive of thrombosis within them. A 5mm midline shift with

effacement of the ipsilateral ventricle was also noted. Effacement of sulci was observed in bilateral cerebral hemipheres. Minimal retained attenuation was noted in parts of the striatum which could be due to small petechial hemorrhages. The subject was stable but became more sedated and drowsy overnight. She was found to be hyperglycemic **(AE #006)**, and her insulin doses were adjusted. Hyperlipidemia **(AE #007)** was also diagnosed.

In the early morning of [redacted]-2008 (post enrollment day 2), the subject had stentorous breathing and one 10-second episode of apnea. She was emergently intubated due to concerns about her increasing edema and mass effect **(cont. of SAE #001).** The subject failed to open her eyes on verbal or painful stimuli but followed commands. NCT of the head at 03:14 showed an increase in midline shift to 7.34mm. With concerns for worsening edema, a right hemicraniectomy was performed later that morning. Mannitol and hypertonic saline were commenced. Hypernatremia was induced with Na+ goals between 145-155mEq/L and hypervolemia was monitored. NCT of the head immediately after hemicraniectomy at 11:41 showed an increase in the midline shift to 11.2mm with postoperative changes but no hemorrhage. The subject was stable postoperatively and was able to follow simple commands. A physician note from this date noted "wound infection, no fever, started on Ancef (prophylaxis) for bolt and hemicraniectomy".

On [redacted] 2008 (post enrollment day 3), the subject had a potassium level of 3.3mmol/L **(AE #002)** and was treated with potassium supplements. The subject's hypokalemia was considered resolved on the following day.

On [redacted] 2008 (post enrollment day 4), the NIHSS was 17. The following day the subject's hemoglobin (Hgb) and hematocrit (Hct) dropped to 9.3 and 27, respectively. No treatment was given, and Hgb/Hct had increased to 10.3/30 by [redacted]-2008.

On [redacted]-2008 (post enrollment day 6), NCT of the head showed persistent swelling of the infarcted brain parenchyma with increased herniation through the craniectomy defect. Mild reduction of the midline shift, uncal herniation, and mass effect on the ventricular system were shown **(cont. of SAE #001)** compared to the NCT on [redacted]-2008.

On [redacted] 2008 (post enrollment day 8), signs of left lower lobe atelectasis **(AE #903)** were noted which was treated with intermittent positive pressure breathing (IPPB) and Albuterol. The subject was extubated the next day.

On [redacted]-2008 (post enrollment day 11), the subject had oral thrush **(AE #003)** and was treated with oral Nystatin. Her thrush resolved on [redacted]008.

On [redacted] 2008 (post enrollment day 19), NCT showed significantly less central mass effect with near resolution of the midline shift and improved effacement of the right lateral ventricle with continued herniation through the craniectomy **(cont. of SAE #001)**. It also noted fogging and/or petechial hemorrhagic transformation of the cortical region of the right MCA infarct with deeper focal hemorrhagic conversion within the basal

ganglia. In reference to this scan, the discharge summary stated: ”we felt that collectively that this represented arterial evolution of the right MCA infarct”.

During the index hospitalization the subject received Dulcolax, Senokot, and Milk of Magnesia for constipation **(AE #901).** Administration of Dulcolax and Milk of Magnesia continued through the 90 day follow-up visit.

The subject was discharged from the hospital on [redacted]-2008 to an in-patient rehabilitation unit. She was noted to be treated with Paxil for depression **(AE #005),** Tylenol for chronic neck pain and arthralgias **(AE #008),** and Ambien for insomnia **(AE #004).**

On [redacted]-2008 (post enrollment day 24), NCT of the head showed decreased right hemisphere mass effect and decrease in the small areas of hemorrhage.

The NIHSS at 30 and 90 day follow-up visits were ranked as 14 and 13, respectively; mRS was 4.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
29-Jun-2009	000	001	603 - Electrolyte imbalance	Likely not related	Likely not related
30-Jun-2009	001	002	115 - Patent foramen ovale (PFO)	Likely not related	Likely not related
30-Jun-2009	**001**	**003**	**403 - Cerebral edema**	**Unknown**	**Unknown**
03-Jul-2009	004	005	109 - Arrhythmia	Likely not related	Likely not related
03-Jul-2009	004	901	405 - HT, probably not contributing to mass effect	Likely not related	Likely not related
05-Jul-2009	006	007	103 - Hypertension	Likely not related	Likely not related
07-Jul-2009	008	004	504 - GI Motility Disorders	Likely not related	Likely not related
08-Jul-2009	009	008	806 - Agitation/Excitation	Likely not related	Likely not related
08-Jul-2009	009	009	299 - Pulmonary Other: Nonspecific lung opacity	Likely not related	Likely not related

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
09-Jul-2009	010	010	602 - Thrombocytopenia	Likely not related	Likely not related
12-Jul-2009	013	011	818 - Pain	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 59-year-old Caucasian male with past medical history of hypertension and hyperlipidemia. He was smoking and drinking occasionally. Medications at admission included: Amlodipine, Benazepril, and Atenolol.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:30, [redacted] 2009. Symptoms at presentation included left-sided weakness, facial palsy, hemianopsia, neglect, and dysarthria. CT scan at admission revealed hyperdense right middle cerebral artery (MCA) and no definite evidence of acute infarct or hemorrhage. CT perfusion revealed subtle hypodensity involving the majority of the right MCA territory. No evidence of intracranial hemorrhage or significant mass effect was identified. A clot was noted in the right carotid terminus, M1 and M2 branches. Baseline NIHSS was 16. The subject was randomized to the treatment arm of the SENTIS trial at 11:00, [redacted] 2009, 11.5 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 11:37, [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2009 (the day of enrollment), elevated glucose was noted that was managed with sliding scale insulin. Various electrolytes were imbalanced **(AE #001)** and electrolyte replacements were given. The imbalance resolved on [redacted] 2009.

On [redacted] 2009 (post enrollment day 1) a transesophageal (TEE) revealed a very small patent foramen ovale **(AE #002)**. NCT noted interval progression of mass effect and low attenuation in the large right MCA infarct with slight 3mm midline shift **(SAE #003).** NIHSS decreased to 11.

On [redacted]-2009 (post enrollment day 2), the subject experienced headache, nausea, vomiting and lethargy **(cont. of SAE #003).** NCT demonstrated a maturing MCA infarct with increased mass effect, midline shift of 7mm, and uncal herniation. There was no evidence of hemorrhagic conversion or new infarcts. Mannitol was started. On the next day the midline shift had increased to 10mm with increased uncal herniation as well as near-complete effacement of the right lateral ventricle. NIHSS was 12.

On [redacted] 2009 normal sinus rhythm with occasional premature ventricular complexes (PVC's) was noted. Bradycardia (43bpm) with a rapid return to 90-100bpm **(AE #005)** was recorded on the following day. On [redacted] 2009 tachycardia with PVC's was again noted and continued to be managed medically. Arrhythmia resolved on [redacted] 2009.

On [redacted] 009 NCT identified interval significant increase in edema, increased mass effect and associated cerebral herniation. A few focal densities were seen in the superior aspect likely representing petechial hemorrhage **(AE #901)**. The subject became obtunded with rapid shallow respirations. He was returned to intensive care and intubated (extubated [redacted] -20) **(part of SAE #003).** A right frontal external ventricular drain (EVD) was placed. Post placement the intracranial pressure (ICP) was 12. The subject's mental status did not change and follow-up CT demonstrated no significant changes.

On [redacted] 2009 (post enrollment day 5), the subject's ICP increased to 27 and the EVD was noted to have stopped draining cerebrospinal fluid (CSF). New bloody CSF and brain matter was noted in the tubing, cultures were sent. NCT findings did not indicate any changes. At 21:39 the subject had acute deterioration and was taken for emergent decompressive hemi-crainectomy, duraplasty, and left frontal bolt placement for intracranial pressure monitoring. Follow-up NCT at 23:58 showed significant improvement in overall mass effect and cerebral herniation. New hemorrhage **(part of AE #901)** was observed in the right frontal horn and adjacent brain parenchyma, along the prior ventricular catheter tract. Hemorrhage in the infarcted tissue had also increased.

On [redacted] 2009, the subject's systolic blood pressure increased to the 200's **(AE #007)**. He has been on Labetalol and further antihypertensive medications were added.

The subject's CSF cultures (taken on [redacted] -2009) showed leukocytosis. The subject was afebrile and no treatment was initiated. Final report on [redacted] 2009 was positive for propionibacterium acnes and on [redacted] -2009 bone was positive for Staphylococcus **(part of SAE #003)**; Vancomycin was started. A synthetic flap was recommended and the subject was ordered to wear a helmet until that time.

The subject initially complained of constipation on [redacted] 2009 and was given Senna. On [redacted] -2009 constipation continued **(AE #004)** and Miralax, Dulcolax, and Colace were added.

On [redacted] 2009 (post enrollment day 9), the subject exhibited significant agitation **(AE #008)** and mitts and restraints were applied. Lexapro was started with good effect. The subject failed a swallow study and a percutaneous endoscopic gastrostomy (PEG) tube was ordered. A chest x-ray demonstrates non-specific left lung opacity **(AE #009)**. There was no definitive diagnosis; however, the subject was treated with EzPaP, Mucomyst, Atrovent and Albuterol as though he had pneumonia. Follow-up chest x-ray on [redacted] 2009 showed clear lungs and EzPap was discontinued.

On [redacted] 2009 thrombocytopenia **(AE #010)** was noted and heparin was held. The subject's platelet count returned to normal by [redacted] -2009. A new allergy to heparin was documented.

On [redacted] 2009 (post enrollment day 13), the subject reported 10/10 pain at his PEG site **(AE #011)**. Intermittent pain continued for several days and was treated with Fentanyl and tPA was given to clear the occluded red port. The pain resolved by [redacted] 2009.

The subject was discharged to from the hospital on [redacted] 2009 to an inpatient rehabilitation unit.

On [redacted]-2009, the subject was re-admitted for scheduled right fronto-temporo-parietal cranioplasty with Porex implant **(cont. of SAE #003)**. The procedure was unremarkable and the subject was discharged to home two days later.

At the 90 day follow-up visit on [redacted] 2009, the subject's NIHSS and mRS were both ranked as 3.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
29-Jan-2008	**022**	**001**	**301 - Renal dysfunction**	**Likely not related**	**Likely not related**
06-Feb-2008	030	002	504 - GI Motility Disorders	Likely not related	Likely not related
09-Feb-2008	**033**	**003**	**599 - GI Other: Rectal bleeding**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is an 83-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, osteoarthritis, glaucoma, osteopenia, pacemaker placement for sick sinus syndrome four days prior to the index stroke, and previous smoking. Medications at admission included: Celebrex, Detrol, Hydrochlorothiazide, Lisinopril, Fosamax, Aleve, Aspirin, and Pravachol.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke onset at 13:45, [redacted] 2008. Symptoms at presentation included complete hamianopsia, left-sided weakness, sensory loss and neglect. CT scan at admission revealed no acute findings. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 17:40, [redacted] 2008, 3.9 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 19:00, [redacted]-2008. Treatment was unremarkable.

Post-Enrollment Course: During the index hospitalization, the subject had no adverse events reported. The subject was discharged from the hospital on [redacted]-2008 to a skilled nursing facility.

On [redacted]-2008 (post enrollment day 22) the subject was re-admitted to the hospital after onset of lethargy and mental status changes. Her poor oral intake resulted in hypernatremia and acute renal failure (pre-renal azotemia with blood urea nitrogen (BUN) of 108 and creatinine of 3.5) **(SAE #001).** Intravenous fluids and tube feeding were initiated. Creatinine returned to normal two days later. The BUN returned to normal range on [redacted]-2008. A feeding tube was successfully placed on [redacted] 2008.

At the time of the 30 day follow-up assessment on [redacted]-2008 the subject's NIHSS increased to 16 from 12 at discharge due to lethargy and mental status changes. CT scan of the brain revealed no new infarct. It did show improvement in the appearance of the previous infarct in the right superior parietal lobe with decreased edema and mass effect. Lethargy and mental status changes improved with hydration and by withholding Percocet. Both the admitting physician and the study principal investigator felt that mental status changes were secondary to the subject's failure to thrive resulting in acute renal failure with hypernatremia.

On [redacted]-2008 (post enrollment day 30), the subject had vomiting and diffuse abdominal pain **(AE #002)**. The subject's feeding tube was put to gravity and drained fecal matter. An abdominal CT scan revealed constipation, which was successfully treated with a laxative and a tap water enema. Subsequently, the subject's bowel movements became more soft and regular and she reported relief from the abdominal pain.

On [redacted] 2008 the subject had 2-3 frank red bloody stools from her rectum **(SAE #003)**. Aspirin and Heparin were withheld. Hemoglobin and hematocrit were recorded as 24 and 7.9, respectively. This was treated with 3 transfusions of packed red blood cells and the hemoglobin and hematocrit returned to normal by discharge. A colonoscopy on [redacted]-2008 demonstrated pandiverticulosis and rectal ulcers that were considered to be the source of the bleeding. The subject had no further episodes of rectal bleeding during the remainder of her hospitalization.

The subject was discharged from the hospital on [redacted]-2008 and transferred to the same skilled nursing facility.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
09-Feb-2009	**000**	**001**	**414 - Neurological worsening**	**Unknown**	**Unknown**
11-Feb-2009	**002**	**003**	**899 - Other: Reoccurring/ chronic hidradenitis suppurativa in perianal area**	**Likely not related**	**Likely not related**
24-Mar-2009	043	005	103 - Hypertension	Likely not related	Likely not related
30-Apr-2009	080	004	811 - Depression	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 50-year-old Caucasian male who reported no significant medical history at the time of enrollment except that he was a current smoker. Admission note documents alcohol use (4-5 beers/day) and occasional marijuana use (quantity unknown). Following enrollment, the family reported that the subject uses/used cocaine and marijuana for several years and drinks 5-7 alcoholic beverages a day. Medications at admission: none.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 08:00, [redacted]-2009. Symptoms at presentation included right facial droop, right arm weakness and aphasia. CT scan at admission revealed left MCA infarction with a small region of nonreversible infarction (left insula and inferior surface of operculum) with larger regions of cerebral ischemia in the left hemisphere; no hemorrhage. Baseline NIHSS was 11. The subject was randomized to the treatment arm of the SENTIS trial at 15:01, [redacted]-2009, 7.0 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 15:52, [redacted]-2009. Versed and Fentanyl were given for conscious sedation. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour NIHSS on [redacted]-2009 increased to 16 **(SAE #001).** The subject's level of consciousness had decreased and right-sided weakness increased. MRI on [redacted] 2009 at 03:20 revealed increased signal intensity of the left basal ganglia and frontal and parietal lobes with some mild mass effect without hemorrhage.

On [redacted] 2009 (post enrollment day 2) the subject was found to have hidradenitis suppurativa in the perianal area (5 buttock abscesses) with associated leukocytosis **(SAE #003)**. Antibiotics were started and pain and fever were medically managed. This condition was not reported at the time of enrollment but it was determined that the subject had multiple incisions and drainages in the past. On 1[redacted]-2008 incision and drainage of the 5 buttock abscesses was performed.

The subject was discharged on [redacted]-2009 to a rehabilitation unit with NIHSS of 16.

On [redacted] 2009 (post enrollment day 43) the subject was hypertensive **(AE #005)** and begun on anti-hypertensive medications.

On [redacted]-2009 (post enrollment day 80) the subject underwent surgical incision and drainage of a right perirectal anal abscess **(cont. of SAE #003)**. He had been admitted the previous day and started on antibiotics. The subject was also noted to be depressed **(AE #004)** and was started on anti-depressants.

At the 90 day follow-up visit on [redacted]-2009 the subject's NIHSS was ranked as 10 and mRS was 4.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
07-Jun-2009	000	002	809 - Diabetes Mellitus	Likely not related	Likely not related
10-Jun-2009	003	901	413 - Headache	Likely not related	Likely not related
10-Jun-2009	**003**	**001**	**414 - Neurological worsening**	**Likely not related**	**Likely not related**
15-Jul-2009	038	005	899 - Other: LLE peripheral edema	Likely not related	Likely not related
15-Jul-2009	038	003	103 - Hypertension	Likely not related	Likely not related
15-Jul-2009	038	004	811 - Depression	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 65-year-old Caucasian male with a past medical history of hypertension, hyperlipidemia, sleep apnea, chronic back pain, hernia, cholecystomy, and obesity. The subject also reported a recent diagnosis of phlebitis (no diagnosis via ultrasound). He was smoking 1-2 packs a day and reported consuming up to 6-10 beers a day. (Alcohol use, but not abuse of, was documented and prophylaxis Ativan was ordered but never administered due to absence of withdrawal symptoms). Medications at admission included: Aspirin and fish oil capsules.

Current Stroke Onset and SENTIS Enrollment: The subject experienced symptoms of left-sided weakness, difficulty seeing in the left visual fields, and pain in the right eye at 05:30 on [redacted] 2009; symptoms completely resolved soon after. At 07:00 on [redacted] 2009 the left-sided weakness and left field cut returned. CT scan at admission revealed no obvious acute infarction but indicated partially occlusive thrombus in the right internal carotid artery (ICA). Mild ischemic changes were noted in the right periatrial white matter. A small left caudate head lacune was noted. Baseline NIHSS was 7. The subject

was randomized to the treatment arm of the SENTIS trial at 17:35, [redacted]-2009; 10.6 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:50. The subject received Fentanyl and Versed for sedation. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2009 (day of enrollment) the subject's glucose levels were elevated at 118 **(AE #002)** and reached a high of 176 on the following day. Hemoglobin A1C was 6.3 and the subject was diagnosed with non-insulin dependent diabetes mellitus.

The 6 hour NIHSS on [redacted]-2009 decreased to 5 at 19:50. Two hours later the subject was seen for medical management after developing increased weakness in his left arm and leg. He was awake and alert with no confusion or aphasia. NCT revealed a mild volume loss and chronic ischemic changes without interval development; no hemorrhage. The 24 hour NCT noted some subtle ischemic change of the superior right fronto-parietal subcortical white matter; no hemorrhage or mass effect. The 24 hour NIHSS was 4.

On [redacted] 2009 (post enrollment day 3) the subject complained of a headache **(AE # 901)** and Tylenol and morphine were given. At 16:00 the subject was unable to close his left fist and had increased left hand weakness. An hour later he reported visual disturbances (left field cut), headache, and increased left-sided weakness **(SAE #001)**. Decreasing blood pressures preceding changes were recorded. NCT revealed evolving non-hemorrhagic ischemic insults in the periphery of the right frontal and parietal lobes. A few new lacunar infarcts were present throughout the MCA vascular territory. There was no hemorrhage or midline shift. NIHSS on [redacted] 2009 increased to 10. NCT on [redacted] 2009 did not indicate any changes.

The subject was discharged from hospital on [redacted]-2009 to a rehabilitation center.

On [redacted]-2009 (post enrollment day 38) the subject complained of intermittent episodes of left lower leg swelling (leg affected by stroke); 1-2+ non-pitting edema **(AE #005)** was observed and diuretics were started. Lisinopril was also started for blood pressures ranging from 110/70 to 132/80 **(AE #003)**. The subject had expressed feelings of regret, depression, and aggravation **(AE #004)**; antidepressants were initiated with some improvement.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Nov-2009	**000**	**002**	**799 - Vascular Other: Cervical artery dissection**	**Likely not related**	**Likely not related**
04-Nov-2009	000	003	303 - Urinary Tract Infection	Likely not related	Likely not related
05-Nov-2009	001	001	403 - Cerebral edema	Unknown	Unknown

Serious events are in bold, shaded text.

Demographics and History: The subject is a 28-year-old African American female with past medical history of insulin-dependent diabetes, hypertension, hyperlipidemia, morbid obesity, and headache. She also vomited several times the night before the stroke onset. Medications at admission included: Insulin, birth control, Tramadol as needed, Metformin, and Lipitor.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 09:30, [redacted]-2009. The subject was transferred to the index hospital. Symptoms at presentation included partial hemianopsia, slurred speech, left-sided weakness, facial palsy, and sensory loss. The subject was complaining of a headache and Tramadol was given. Baseline CT revealed very minimal decreased attenuation in the head of the right caudate; no mass effect or hemorrhage. Baseline NIHSS was 15. The subject was randomized to the treatment arm of the SENTIS trial at 16:45, [redacted]-2009, 7.3 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:35, [redacted] 2009. The subject had conscious sedation. During the treatment, difficulties were encountered with the monitoring equipment, but the appropriate pressure differential was achieved at 19:07 after which the procedure proceeded without incident.

Post-Enrollment Course: Upon review of the CT/CTA obtained prior to admission, a small focal filling defect in the proximal right internal carotid artery (ICA) was discovered by the radiologist at the site. Repeated cerebral arteriograms confirmed that the intraluminal smooth defect in the proximal cervical right ICA was likely related to arterial dissection **(SAE #002).** An intraluminal stent was implanted on [redacted]-2009.

The urinalysis collected on [redacted] 2009 at the referring hospital was positive for bacteria **(AE #003)** but the urine culture collected after index hospital admission did not confirm growth within 48 hours. Rocephin was started prophylactically. On 05-Nov-2009 the subject's temperature was 100.2º F. It increased up to 102º F on the following day and returned to normal on [redacted]-2009. Chest x-ray was negative. The subject also complained of sore throat and was treated with Chloroseptic spray.

The 24 hour CT on [redacted]-2009 revealed a progression of edema **(AE #001)** around infarctions in the right frontal and parietal lobes with a 2mm midline shift, and no

hemorrhagic transformation. The 24 hour NIHSS was 16. CT scans were repeated every day for the following 6 days without significant changes, except for an increased to 5mm midline shift on [redacted] 2009. The 4 day NIHSS on [redacted] -2009 was 14. The subject continued to complain of headache, but no clinical deterioration was noted during that time.

The subject was discharged from the hospital on [redacted] -2009 to a rehabilitation center.

Her 30 and 90 day NIHSS were ranked as 4 and 1, respectively.

Subject [redacted], enrolled [redacted] 2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Aug-2006	**032**	**001**	**407 - Seizure**	**Likely not related**	**Likely not related**
10-Sep-2006	**056**	**002**	**207 - Pulmonary Embolism**	**Likely not related**	**Likely not related**
10-Sep-2006	056	901	703 - Venous Thrombosis (DVT)	Likely not related	Likely not related
17-Sep-2006	**063**	**003**	**499 - Neuro Other: Brain tumor**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is an 81-year-old Caucasian male with past medical history of hypertension, hyperlipidemia, and asthma. Medications at admission included: Prednisone, K-dur, hydrochlorothiazide, Lipitor, Lisinopril, Aspirin, and Cardia XT.

Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 08:45, [redacted] 2006. Symptoms at presentation included decreased level of consciousness and global aphasia. CT scan at admission revealed acute infarcts in left anterior temporal and posterior temporo-parietal lobes. Baseline NIHSS was 6. The subject was randomized to the treatment arm of the SENTIS trial at 14:25, [redacted] 2006, 5.7 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 15:15, [redacted] -2006. Erroneously, the infrarenal transducer was initially connected to the balloon rather than to the sheath. The balloons were deflated, connection was corrected, and the procedure restarted 40 min later without complications.

Post-Enrollment Course: The subject's hospital course was unremarkable and the subject was discharged to home on [redacted] -2006. The subject was seen at the 30-day evaluation on [redacted] -2006 and was back to baseline, with a complete return to normal on all 4 assessments' scales.

On [redacted]-2006 (post enrollment day 32), the subject experienced similar symptoms as his recent stroke, speaking nonsensically and not appropriately following directions. CT revealed no evidence of a new stroke; diagnosis was a seizure activity **(SAE #001)**. The subject was admitted and started on anti-convulsant medications. On [redacted]-2006 the subject was discharged from the hospital to home with no further seizure activity.

During the index hospitalization in July, a transthoracic echocardiogram was done that suggested possible vegetation. Due to the possible valve vegetation, an elevated sedementation rate (46) and some unexplained weight loss, a malignancy workup was recommended, and a whole body Positron Emission Tomography CT was ordered. Imaging on [redacted] 2006 suggested possibility of a brain tumor due to abnormal enhancement in the left temporal lobe.

On [redacted]-2006 (post enrollment day 56) the subject was admitted to an outside facility due to a severe pain in his chest. A chest CT revealed a pulmonary embolus **(SAE #002)**. A Doppler of the lower extremities also showed a clot in the left leg **(AE #901).** The subject was treated and discharged on [redacted]-2006.

On [redacted]-2007, the subject was again admitted with signs of additional seizure activity or possible stroke. Electroencephalogram and CT confirmed seizure activity and anti-convulsant medications were again adjusted. MRI revealed a lesion within the posterosuperior temporal lobe and the parietal lobe. A primary malignant lesion was suspected. A left temporal craniotomy revealed a glioblastoma multiforme **(SAE #003).** A Greenfield Filter was implanted on [redacted] 2006. The subject refused any further aggressive treatment and was discharged to home with family on [redacted] 2006 with comfort measures.

On [redacted]-2006, he was re-admitted for increased agitation likely caused by the tumor **(cont. of SAE #003)**. Anti-convulsive and sedative medications were adjusted during his hospitalization. The subject was discharged on [redacted]-2006. At the time of his 90 day follow-up visit on [redacted] 006, the subject's NIHSS was ranked as 8 with mRS of 5.

Subject [redacted], enrolled [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
18-Sep-2007	001	005	603 - Electrolyte imbalance	Likely not related	Likely not related
21-Sep-2007	**004**	**001**	**204 - Aspiration pneumonia**	**Likely not related**	**Likely not related**
22-Sep-2007	005	003	813 - Fall	Likely not related	Likely not related

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
24-Sep-2007	007	004	303 - Urinary Tract Infection	Likely not related	Likely not related
02-Oct-2007	015	002	405 - HT, probably not contributing to mass effect	Likely not related	Likely not related
15-Oct-2007	028	901	301 - Renal dysfunction	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 74-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, non-insulin dependent diabetes, atrial fibrillation, left MCA stroke in 2006 (mRS=1), depression, chronic obstructive pulmonary disease (COPD) and smoking. Medications at admission included: Lipitor, Digoxin, Coumadin, Toprol -XL, Hydrochlorothiazide, Amlodipine, Metformin, Lexapro, and Singulair.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 12:00, [redacted] 2007. Symptoms at presentation included decreased level of consciousness, right facial droop, dysarthria, global aphasia and slight left gaze preference. CT scan at admission revealed an old left MCA territory infarct and no signs of acute infarct/hemorrhage. Baseline NIHSS was 13. The subject was randomized to the treatment arm of the SENTIS trial at 17:30, [redacted]-2007, 5.5 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 18:50, [redacted] 2007. Treatment was unremarkable.

Post-Enrollment Course: The 24 hour follow-up NCT on [redacted] 2007 showed an expected evolution of anterior left MCA infarct with decreased attenuation and a mild mass effect. No acute hemorrhage was seen. The 24 hour NIHSS improved to 11.

The subject's low potassium values **(AE #005)** were noted on [redacted] 2007 and continued through [redacted] 2007. It was treated with oral potassium replacements.

The subject was transferred from the hospital on [redacted] 2007 to a rehabilitation facility. At 20:00 on that date, the subject was noted to have a temperature of 39.2ºC and a mild drop in oxygen saturation from 99% to 95%; oxygen and Tylenol were given. The following day, the subject's chest x-ray showed increased opacity in right lung. Pneumonia **(SAE #001)** was suspected and the subject was transferred back to index hospital. Antibiotics (aztreonam and azithromycin) were initiated and aspiration pneumonia resolved on [redacted] 2007.

On [redacted]-2007 the subject fell to the floor **(AE #003)**. Some hip and buttock pain was reported along with some bruising. An x-ray was negative for fractures.

On [redacted] 2007 (post enrollment day 7), a urinary tract infection was diagnosed **(AE #004).** The subject's temperature spiked and returned to normal within a few hours. Antibiotics were given and by [redacted] 2007 the infection was resolved.

The subject was discharged back to rehab on [redacted] 007.

On [redacted] -2007 (post enrollment day 15) a follow-up scan revealed a hemorrhagic transformation not contributing to mass effect **(AE #002)**. Aspirin and Lovenox were stopped (anticoagulation held) until after follow-up CT scans on [redacted] -2007 and [redacted] -2007 showed no new bleeding. The subject had no clinical symptoms. Her NIHSS on [redacted] -2007 was ranked as 10.

On [redacted] 2007 (post enrollment day 28), while in rehab, the subject was diagnosed with acute renal failure with a creatinine increase from baseline of 0.9 to 1.5 **(AE #901)**. The subject was treated with IV hydration and discontinuation of the angiotensin-converting enzyme (ACE) inhibitor medication. The creatinine returned to normal on [redacted] 2007 and the subject was discharged to home on the following day.

At the 90 day follow-up visit on [redacted] -2007 the subject's NIHSS decreased to 4 with mRS of 2.

Subject [redacted], enrolled [redacted] -2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
02-Sep-2009	**001**	**001**	**403 - Cerebral edema**	**Unknown**	**Unknown**
03-Sep-2009	002	003	602 - Thrombocytopenia	Likely not related	Likely not related
04-Sep-2009	003	006	204 - Aspiration pneumonia and ARDS	Likely not related	Likely not related
05-Sep-2009	004	008	504 - GI Motility Disorders	Likely not related	Likely not related
11-Sep-2009	**010**	**002**	**299 - Pulmonary Other: Tension pneumothorax**	**Likely not related**	**Likely not related**
13-Sep-2009	012	004	601 - Anemia	Likely not related	Likely not related
14-Sep-2009	013	005	711 - Pseudoaneurysm	Unknown	Unknown
24-Sep-2009	023	009	412 - HT, no concomitant mass effect	Likely not related	Likely not related
24-Sep-2009	**023**	**901**	**414 - Neurological worsening**	**Likely not related**	**Likely not related**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
24-Sep-2009	023	902	409 - New ischemic stroke	Likely not related	Likely not related
25-Sep-2009	024	007	816 - Oral thrush	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 43-year-old Caucasian man with a past medical history of a cerebellar stroke in 1997 (mRS=0) secondary to a vertebral artery dissection after chiropractic manipulation. Medication at admission included: fish oil, potassium and Vitamin C supplements.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 12:00 on [redacted] 2009. Symptoms at presentation included decreased level of consciousness, right-sided field cut, facial palsy, right upper extremity drift, and global aphasia. MRI of the brain at admission revealed a recent complete infarct involving the anterior portion of left-MCA territory, including the left basal ganglia, left perisylvian cortex, and anterior portions of the left temporal lobe. There was mild mass effect on the left lateral ventricle without significant midline shift and no evidence of acute hemorrhage. Baseline NIHSS was 13. The subject was randomized to the treatment arm of the SENTIS trial at 21:45, [redacted] 2009, 9.8 hours from last known normal.

NeuroFlo Treatment: NeuroFlo procedure was initiated at 23:07 on [redacted] 2009 via right femoral artery. The subject was sedated for the procedure. Treatment was unremarkable.

Post-Enrollment Course: Because of the size of his stroke and possible needs for neurosurgical intervention, the subject was subsequently transferred to another hospital for further care.

On [redacted] 2009 (post enrollment day 1), the subject's status worsened in the morning with increased right-sided weakness and global aphasia. MRI of the brain at 13:46 showed a large left evolving infarct with mild increase in mass effect and 4mm midline shift **(SAE #001)**. The subject was sedated, intubated and started on hypertonic saline and hypothermia therapy. He was also given Pancuronium, Morphine, and Midazolam.

On [redacted] 2009 (post enrollment day 2), platelet account dropped to 99x10E3/µL from 127 on admission and fluctuated between 75 and the low 100s through [redacted]-2009. On [redacted]-2009, partial thromboplastin time (PTT) was elevated at 34.2 seconds (norm 24.5-31.0) with a maximum value of 51.1 seconds seen on [redacted]-2009. It was diagnosed as heparin-induced thrombocytopenia **(AE #003)**. Sub-Q heparin was discontinued. Protamine and fresh frozen plasma were given.

On [redacted]-2009, the subject had green colored sputum and it cultured positive for Staphylococcus aureus. Chest x-rays showed airspace consolidation in bilateral lower

lobes consistent with aspiration pneumonia **(AE #006)**. Follow-up chest x-rays showed worsening opacification consistent with bronchopneumonia and pulmonary edema. The subject was on a ventilator at that time and was started on multiple antibiotics. Sputum culture was negative on [redacted] 2009.

On [redacted] -2009 (post enrollment day 4), the subject was prescribed Bisacodyl, milk of magnesium, and fleet enema for constipation **(AE #008)**.

On [redacted] 2009 (post enrollment day 9), the subject underwent a tracheostomy for long term airway management and ventilator weaning. On the next day blood clots were suctioned out of his trach tube. A bronchoscopy was performed to clean out the lower airway. The subject's heart rate dropped during the procedure and brief periods of asystole were noted on the monitor. Cardiopulmonary resuscitation, atropine and epinephrine were administered with good response. The subject was then found to have a tension pneumothorax **(SAE #002)** and bilateral chest tubes were inserted. The tracheostomy tube was removed and the bronchoscopy was done through the endotracheal tube. The subject's saturation improved. Elevated troponin levels of up to 1.5ng/ml were noted immediately after this event.

NCT of the brain on [redacted] -2009 showed that the mass effect with midline shift had increased slightly to 6.8mm.

On [redacted] 2009 (post enrollment day 12), the subject's hematocrit was low at 26.1% and hemoglobin was 8.5g/dl **(AE #004)**. Platelet count was also low. He received one unit of packed red blood cells and platelets infusion, and was started on erythropoietin. Starting on [redacted] -2009, the subject's hematocrit level was above 30%.

An arterial line was placed in the right groin on [redacted] -2009. On [redacted] -2009 a pseudoaneurysm at the arterial line entry site **(AE #005)** measuring approximately 2.2cm was noted. A follow-up Doppler study on [redacted] -2009 revealed an increase in the pseudoaneurysm size to 5.2cm and the subject underwent an ultrasound guided compression of the pseudoaneurysm on [redacted] 2009. It was resolved after 15 minutes of treatment.

MRI of the brain on [redacted] -2009 (post enrollment day 23), revealed a small area of hemorrhagic transformation **(AE #009)** was seen in the left posterior putamen; progression of the left MCA infarcts "now involves essentially the entire L-MCA territory" **(SAE #901)**, and also "new infarcts in the left cerebral peduncle, left midbrain, and right posterior putamen, and small focus in the right thalamus and nearly the entire the left thalamus **(AE #902).** Multiple vascular territories suggest an embolic etiology". There was resolution of the midline shift and no hydrocephalus was noted.

On [redacted] -2009, subject was started on Nystatin for thrush **(AE #007)**.

The subject was discharged from the hospital with NIHSS of 19 on [redacted] 2009 to an inpatient rehab facility. He was then discharged to home on [redacted] -2009.

At the 90 day follow-up visit on [redacted]-2009, the subject's NIHSS and mRS improved to 10 and 3, respectively.

Subject [redacted], enrolled [redacted] 2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
25-Oct-2006	**001**	**001**	**413 - Headache**	**Likely not related**	**Likely not related**
25-Oct-2006	**001**	**002**	**818 - Pain**	**Likely not related**	**Likely not related**
25-Oct-2006	**001**	**901**	**603 - Electrolyte Imbalance**	**Likely not related**	**Likely not related**
27-Oct-2006	**003**	**005**	**818 - Pain**	**Likely not related**	**Unknown**
27-Oct-2006	**003**	**013**	**504 - GI Motility Disorders**	**Likely not related**	**Likely not related**
30-Oct-2006	**006**	**006**	**303 - Urinary Tract Infection**	**Likely not related**	**Likely not related**
01-Nov-2006	008	009	115 - Patent foramen ovale (PFO) with closure	Likely not related	Likely not related
02-Nov-2006	**009**	**011**	**817 - Chest Pain**	**Likely not related**	**Likely not related**
07-Nov-2006	014	012	817 - Chest Pain	Likely not related	Likely not related
19-Nov-2006	**026**	**015**	**818 - Pain**	**Likely not related**	**Likely not related**
12-Jan-2007	**080**	**016**	**299 - Pulmonary Other: Bronchitis**	**Likely not related**	**Likely not related**
10-Feb-2007	109	017	411 - Transient ischemic attack (TIA)	Likely not related	Likely not related
10-Feb-2007	**109**	**019**	**817- Chest Pain**	**Likely not related**	**Likely not related**
11-Feb-2007	**110**	**020**	**899 - Other: Sinusitis**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: This subject is a 46-year-old African American male with past medical history of mild hypertension. Medications at admission: none.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 14:00, [redacted] 2006. Symptoms at presentation included partial hemianopsia, right-sided weakness, sensory loss and neglect. CT scan at admission was unremarkable.

Baseline NIHSS was 10. The subject was randomized to the treatment arm of the SENTIS trial at 19:00, [redacted] 2006, 5.0 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated on [redacted] 2006 at 20:15 via right arterial groin puncture. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2006 (post enrollment day 1), the subject complained of headache **(AE #001)** and of bilateral leg pain and back pain **(AE #002)**. The subject's index hospitalization was significant for complaints of pain for which he received at various times, Tylenol, Morphine, Vicodin, Dilaudid, and Darvocet. All of these episodes of pain resolved before discharge. The subject's potassium level decreased to 3.3 **(AE #901)** on [redacted] 2006 and supplemental potassium was given.

On [redacted]-2006 (post enrollment day 3), the subject complained of right groin tenderness **(AE #005)**. The ultrasound report stated that there was an enlarged nodal mass; no abscess. The subject also complained of abdominal pain and had intermittent diarrhea **(AE #013)**; medication was given. The 4 day NIHSS was 7.

On [redacted]-2006 (post enrollment day 6), the subject had a fever and complained of dysuria. He was started on IV antibiotics. Urine culture showed Enterobacter **(AE #006)**. Oral antibiotics were to be continued at the time of discharge.

On [redacted]-2006 (post enrollment day 8), the subject underwent percutaneous closure of patent foramen ovale **(SAE #009)** which was detected by a transthoracic echocardiogram. On the same day, the subject complained of nausea and was started on Protonix.

On [redacted] 2006 the subject complained of sharp, left-sided chest pain **(AE #011)**. He was medicated with Morphine for the pain, Indocin was ordered. An electrocardiogram (ECG) showed sinus bradycardia. Echocardiogram showed "ventricular function in the 60% range, atrial septal occluder device well positioned and no pericardial effusion". The next day, cardiology documented that the chest pain was resolved. The discharge summary attributes the chest pain to pericarditis and notes that the Indocin resolved the symptoms.

The subject was discharged from the hospital on [redacted]-2010 to a hotel.

On [redacted] 2006 (post enrollment day 16), the subject returned to the emergency department (ED) complaining of sharp left-sided chest pain, which started two days prior **(SAE #012)**. He also reported shortness of breath, shakiness and nausea at the time. Work up including ECG, labs, and chest x-rays, was unremarkable. Myocardial infarction was excluded. Nuclear stress test conclusion was "left ventricular enlargement and mild global hypokinesis with slight depression of the ejection fraction at 0.47." The subject's chest pain was described to have "some dyspeptic features" and "musculoskeletal features.

On [redacted] 2006, the subject had a one-time complaint of indigestion **(part of AE #013)** treated with medication. The subject was discharged on the following day.

On [redacted] -2006 and [redacted] 2006, the subject returned to the ED complaining of pain and swelling of the left testicle **(AE #015)**. Ultrasounds of the left testicle were performed. The conclusion was left epididymitis and the subject was discharged with prescriptions for Cipro and an analgesic and a referral to urologist for follow-up.

On [redacted] -2007 (post enrollment day 80), the subject was seen in the ED with complaints of cough, fever, and sharp, non-radiating left-sided chest pain **(AE #016)**. A thorough work-up of the chest pain resulted in no indication that it was cardiac in nature, nor was a pulmonary embolism found. A chest pain was attributed to the bronchitis. Routine labs during the ED visit also indicated a low potassium level of 3.2 **(cont. of AE #901)**. No potassium was given at that time.

On [redacted] -2007 (post enrollment day 109), the subject presented to the ED with new onset (at about 12:30) of disequilibrium, and complaints of right-sided weakness and numbness of the face **(SAE #017)**. CTA and NCT were both negative. MRI on [redacted] 2007 indicated "no acute intracranial abnormality. Specifically, no evidence of recent infarct. No focal abnormalities in the brain parenchyma. Opacified right maxillary sinus **(AE #020)**."

During this hospitalization, the subject was having a productive cough, which was diagnosed as bronchitis **(update to AE #016)** and sharp non-radiating left-sided chest pain **(AE #019)**. Complete work-up, including chest x-ray, labs, ECG, cardiac enzymes, and echo, revealed a toxicology screen positive for cocaine. All other work-up was negative for disease. The subject was treated medically for bronchitis and sinusitis, and discharged on [redacted] -2007. Discharge summary stated that transient ischemic attack and cardiac pain were most likely related to cocaine use.

At the 90 day follow-up visit on [redacted] 2007, the subject's NIHSS was ranked as 8 with mRS of 1.

Subject [redacted], enrolled [redacted] 2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
02-Feb-2007	000	002	806 - Agitation/Excitation	Likely not related	Likely not related
02-Feb-2007	000	001	701 - Hematoma	Likely not related	Likely related
02-Feb-2007	000	902	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
02-Feb-2007	000	901	814 - Sleeping Disturbance/ Disorder	Likely not related	Likely not related

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
21-Apr-2007	**078**	**003**	**299 - Pulmonary Other: Worsening of COPD**	**Likely not related**	**Likely not related**
29-Apr-2007	**086**	**004**	**205 - Infectious pneumonia**	**Likely not related**	**Likely not related**
04-May-2007	091	005	811- Depression	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 68-year-old Caucasian male with past medical history of hypertension, multiple transient ischemic attacks (TIAs), coronary artery disease with coronary artery bypass surgery, gastro-esophageal reflux disease, anxiety, throat cancer, chronic obstructive pulmonary disease (COPD), hypothyroidism, Crohn's disease, peripheral vascular disease including left renal stenosis (received stents), left common carotid artery (CCA) occlusion and high grade right CCA stenosis. His recent history included episodes of dizziness/presyncope. Medications at admission included: Norvasc, Bumex, Synthroid, Coreg, Quinapril, Flomax, Prednisone, Seroquel, Xanax, Colace, and potassium supplement.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 17:00 on [redacted]-2007, following angioplasty of the right CCA at 16:30. The subject was transferred to the study center. Symptoms at presentation included left-sided weakness, mild dysarthria, some neglect of his left arm, and mild left-sided facial droop. CT scan at admission revealed low density areas in the right posterior parietal and right frontal lobe consistent with a stroke in the posterior portion of the right MCA. Baseline NIHSS was 5. The subject was randomized to the treatment arm of the SENTIS trial at 00:50, [redacted]-2007, 7.8 hours from symptom onset.

NeuroFlo Procedure: The NeuroFlo procedure was initiated on [redacted]-2007 at 01:30 via right groin arterial puncture. The site team reported being unable to read the mean arterial pressures using the IR and SR transducers after the initial pressures were recorded (pressure monitoring failure). Both balloons were reported to appear deflated at the end of the 45 min procedure. A malfunction report was received.

Post-Enrollment Course: On [redacted] 2007 (the day of enrollment), the subject was noted to be a little agitated **(AE #002)** and was given Ativan. No additional episodes occurred. On [redacted] 2007 at about 12 hours post-angioplasty and 1 hour post-NeuroFlo treatment, a hematoma was observed around the right groin access site **(AE #001)**. The subject also was noted to be non-compliant about keeping his right leg straight. However, at the 4 hour follow-up assessment, hematoma was not present.

Initial lab testing on [redacted] 2007 indicated elevated triglycerides **(AE #902);** Pravachol was initiated and switched to Mevacor by the 90 day follow-up visit. The subject was also treated for insomnia **(AE #901)** from the beginning of the index hospitalization through the 90 day follow-up visit.

The subject was transferred from the hospital on [redacted] 2007 to an inpatient rehab. On [redacted]-2007 he was discharged to home.

On [redacted] 2007 (post enrollment day 78), the subject was readmitted to the hospital with weakness and worsening symptoms of COPD, including mild bronchitis and bronchospasm **(SAE #003).** He had difficulty with ambulation and was shaking when walking. The subject completed a course of Levaquin (he had already been taking Prednisone for the COPD) and was discharged on [redacted] 2007.

On [redacted] 2007 (post enrollment day 86), the subject had been experiencing increased wheezing and had developed a chronic cough, which was diagnosed as pneumonia [redacted]). He was readmitted to the hospital on [redacted] 2007 and was discharged on the following day.

At the time of the 90 day follow-up visit on [redacted]-2007, the subject reported taking Cymbalta for depression **(AE #005)**.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
08-Jun-2009	**000**	**001**	**199 - Cardiac Other: Endocarditis leading to mitral valve repair**	**Likely not related**	**Likely not related**
08-Jun-2009	000	002	701 - Hematoma: Small hematoma on right side	Unknown	Likely related
09-Jun-2009	001	004	102 - Hypotension	Likely not related	Likely not related
11-Jun-2009	003	005	413 - Headache	Likely not related	Likely not related
13-Jun-2009	005	009	414 - Neurological worsening	Likely not related	Likely not related
13-Jun-2009	005	901	412 - HT, no concomitant mass effect	Likely not related	Likely not related
13-Jun-2009	005	010	409 - New ischemic stroke	Likely not related	Likely not related
14-Jun-2009	006	007	504 - GI Motility Disorders	Likely not related	Likely not related
20-Jun-2009	012	014	503 - Nausea/Vomiting	Likely not related	Likely not related
21-Jun-2009	013	008	816 - Oral thrush	Likely not related	Likely not related
23-Jun-2009	015	903	499 - Neuro Other: Increased spasticity	Likely not related	Likely not related

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
23-Jun-2009	015	011	899 - Other: Drug overdose - somnolence, difficulty arousal, hypotension	Likely not related	Likely not related
24-Jun-2009	016	012	811 - Depression	Likely not related	Likely not related
30-Jun-2009	022	904	411 - Transient ischemic attack	Likely not related	Likely not related
02-Sep-2009	**086**	**902**	**118 - Atrial Fibrillation**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 51-year-old Caucasian female with past medical history of mitral valve prolapse and mild tricuspid regurgitation (2008) and paroxysmal supra-ventricular tachycardia (SVT). Medications at admission included Aspirin and Atenolol.

In May-2009, the subject started to have fevers up to 101°F with chills about every 3 days. Her blood cultures drawn at her local clinic were positive for Viridans Streptococcus. The subject presented at the emergency department with fever and was admitted on [redacted]-2008 for antibiotic treatment. Subacute bacterial endocarditis **(SAE #001)** was suspected and mitral valve repair was planned. The subject also reported a left hip tick bite one week prior to the stroke onset.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at about 09:45, [redacted] 2009, while still in the hospital. Symptoms at presentation included aphasia, right facial droop, right arm paralysis, and right leg weakness. CTA revealed a left MCA occlusion. Baseline NIHSS was 12. The subject was randomized to the treatment arm of the SENTIS trial at 18:15, [redacted] 2009, 8.5 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated on [redacted] 2009, at 20:31, via right groin arterial puncture. Treatment was unremarkable.

Post-Enrollment Course: The subject's pre-existing intermittent SVT continued throughout her hospital stay and was managed with Metoprolol.

On [redacted]-2008 (day of enrollment) a small (2-3cm) right groin hematoma **(AE #002)** was noted post procedure. The next day it had improved.

On [redacted] 009 (post enrollment day 1) transesophageal echocardiogram (TEE) showed no frank vegetation. The 24 hour NIHSS was ranked as 24 due to the subject being sedated for the TEE. Also on [redacted] 2009 the subject had a hypotensive episode **(AE #004)** and Atenolol was stopped.

On [redacted]-2009 at 09:10 the subject's NIHSS was 16. Later that day decline in her neurologic status was observed; alertness was waxing and waning (at 17:30 NIHSS was 13). The investigator determined that this was due to sleep cycle disturbance as the subject was used to being alert at night. Consistent comments in the medical record concur that the subject was lethargic and sleepy during the day and more alert and interactive in the evening and at night. CT on [redacted]-2009 did not show any changes.

On [redacted]-2009 (post enrollment day 3), the subject complained of a headache **(AE #005)** and received medication. The headache worsened and would not be relieved with pain medication.

On [redacted]-2009 (post enrollment day 5), MRI demonstrated interval extension of the infarct **(AE #009)** to involve the temporal lobe, with focal areas of increased T1 signal, suggestive of hemorrhage **(AE #901)**. There was a mismatched ischemic penumbra involving the left frontal and temporal lobes. There was a new small left occipital focal infarct **(AE #010)**; presumed septic emboli. Planned mitral valve repair was postponed and antibiotic coverage was extended.

On [redacted]-2009 (post enrollment day 6), the subject was treated for constipation **(AE #007)**; likely caused by the narcotics she was receiving. Abdominal pain resolved following several bowel movements on [redacted]-2009.

On [redacted]-2009 (post enrollment day 12), the subject complained of nausea **(AE #014)** which was relieved with medication. The following day Nystatin was initiated for an oral yeast infection **(AE #008)** which was likely due to the long course of antibiotic treatment.

On [redacted] 2009 (post enrollment day 15) the subject was started on Baclofen for increased right-sided spasticity **(AE #903)**. The subject became somnolent, hypotensive, and was difficult to arouse **(AE #011)**. Narcan was given and her mental status improved; Morphine and Baclofen were discontinued.

On [redacted] 009, the subject was started on medication for depression **(AE #012)**.

The subject was discharged from the hospital on [redacted] 2009 to an inpatient rehab unit.

On [redacted] 2009 (post enrollment day 22), a brief episode of slurred speech and vision deficit **(AE #904)**, lasting about 5 seconds was observed. When the rapid response team arrived, the subject had returned to her previous state. No change in medical treatment was needed.

The subject was discharged from rehab on [redacted] 2009 to home.

On [redacted]-2009 (post enrollment day 70), the subject underwent a successful minimally invasive mitral valve repair **(cont. of SAE #001)**. Post-operatively she had two short runs of SVT that were controlled with Metoprolol. She was discharged to home on [redacted] 2009.

On [redacted]-2009 (post enrollment day 86), the subject reported feeling intermittent heart palpitations at home and was found to be in atrial fibrillation. She was admitted for rate control **(SAE #902)** and discharged to home on [redacted]-2009. The investigator thought this was related to the mitral valve repair in August.

The 90 day NIHSS on [redacted] 2009 was ranked as 5 with mRS of 3.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
21-Feb-2009	**019**	**001**	**499 - Neuro Other: Transient right hemiparesis**	**Likely not related**	**Likely not related**
21-Feb-2009	**019**	**003**	**199 - Cardiac Other: Staph haemolyticus endocarditis of the aortic valve**	**Likely not related**	**Likely not related**
04-Mar-2009	**030**	**002**	**499 - Neuro Other: Confusion**	**Likely not related**	**Likely not related**
04-Mar-2009	030	004	103 - Hypertension	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: This subject is a 78-year-old Caucasian male with a past medical history of hypertension, hyperlipidemia, insomnia, depression, and a left orchiectomy. His liver enzymes were recently found to be elevated, but the workup was negative, except for dilation of the common bile duct. The subject also had 11 teeth extracted on [redacted] 2009, and has complained of headache intermittently since then. His wife states that he has been confused over the last few months; worse over the past several weeks. Medications at admission included: simvastatin, Lisinopril, Aspirin, Trazodone, and Clonidine.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 09:00 on [redacted]-2009. Symptoms at presentation included confusion, left-sided weakness, and dysarthria. CT scan at admission revealed only mild atrophy; no signs of infarct or hemorrhage. Perfusion images revealed abnormalities in the bilateral temporal regions. Electrocardiogram (ECG) showed sinus rhythm with first degree atrial/ventricular block. Baseline NIHSS was 8. The subject was randomized to the treatment arm of the SENTIS trial at 16:50, [redacted] 2009, 7.8 hours from last known normal.

NeuroFlo Procedure: The NeuroFlo procedure was initiated at 18:50 on [redacted] 009. Treatment was unremarkable.

Post-Enrollment Course: The subject had an uneventful hospital course with good recovery. Upon discharge from the hospital on [redacted]-2009 to home his NIHSS was 0.

On [redacted] 2009 (post enrollment day 19), the subject was re-admitted to the hospital with confusion, aphasia, and right upper extremity weakness **(SAE #001)**. NCT revealed no evidence of acute or subacute infarct, but there was subtle hyperdense sign in left MCA. An electroencephalogram supported the diagnosis of mildly diffuse encephalopathy. A transesophageal echocardiogram showed a Lambl's filament in the aortic valve, mild mitral regurgitation and mild tricuspid insufficiency. Blood cultures were positive for gram-positive cocci, with an eventual diagnosis of Staphylococcus haemolyticus endocarditis of the aortic valve **(SAE #003)**. An infectious disease consult was obtained and Vancomycin and Rocephin were initiated. The subject was discharged to home on [redacted]-2009.

At the 30 day follow-up visit on [redacted]009, the subject's NIHSS and mRS were 0, Glascow Outcome Scale was 5 and Barthel Index was 100.

On [redacted] 2009 (post enrollment day 30), the subject was again admitted to the hospital with confusion and speech difficulty **(SAE #002)**. He presented with hypertension (207/107) **(AE #004)**, frontal headache and slight nausea. NCT scan showed no evidence of hemorrhage or infarct. ECG demonstrated mostly sinus rhythm, but showed some transient episodes of 2-1 atrial/ventricular block and T-wave changes. Cardiac consultation noted that the conduction abnormality in the setting of infective endocarditis involving the aortic valve may indicate an abscess formation on the valve, although, no abscess could be seen on echocardiogram. Telemetry was continued, and no additional episodes of heart block were noted during the remainder of the subject's hospitalization. An electroencephalogram conducted on [redacted] 2009 suggested mild nonspecific encephalopathy. On [redacted]-2009 the subject was noted to be clinically stable and was discharged to home.

At the 90 day follow-up visit on [redacted]009, the subject's NIHSS was 0, mRS was 3, Glascow Outcome Scale was 5 and Barthel Index was 100.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
10-Mar-2008	000	901	116 - Bradycardia	Likely not related	Likely not related
10-Mar-2008	000	001	503 - Nausea/Vomiting	Likely not related	Likely not related
11-Mar-2008	**001**	**002**	**414 - Neurological worsening**	**Likely not related**	**Likely not related**
11-Mar-2008	001	003	818 - Pain	Likely not related	Likely not related

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
13-Mar-2008	003	902	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
14-Mar-2008	004	004	413 - Headache	Likely not related	Likely not related
15-Mar-2008	005	007	504 - GI Motility Disorders	Likely not related	Likely not related
15-Mar-2008	005	012	814 - Sleeping Disturbance/ Disorder	Likely not related	Likely not related
17-Mar-2008	007	005	818 - Pain	Likely not related	Likely not related
27-Mar-2008	017	006	599 - GI Other: Indigestion	Likely not related	Likely not related
21-Apr-2008	042	008	599 - GI Other: Epigastric pain	Likely not related	Likely not related
19-May-2008	**070**	**009**	**413 - Headache**	**Likely not related**	**Likely not related**
19-May-2008	070	011	811 - Depression	Likely not related	Likely not related
19-May-2008	070	903	809 - Diabetes Mellitus	Likely not related	Likely not related
20-May-2008	071	904	397 - Genital Other: Vaginal candidiasis	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 66-year-old Caucasian female with no remarkable past medical history except for degenerative arthritis. She had not had regular medical care. Medications at admission included aspirin and vitamins.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 06:00 on [redacted]-2008. Symptoms at presentation included left facial droop, sensory loss, and visual disturbance. CT scan at admission revealed no abnormality. Baseline NIHSS was 8. The subject was randomized to the treatment arm of the SENTIS trial at 13:15, [redacted] 2008, 7.3 hours from last known normal.

NeuroFlo Treatment: NeuroFlo procedure was initiated at 14:13 on [redacted]008. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2008 (the day of admission), the subject's heart rate was in the range of 52-58 per minute for about 4 hours **(AE #901)**. No medical intervention was initiated. In the evening the subject had nausea and vomiting **(AE #001)**. She was medicated with Zofran, with no further occurrence.

On [redacted]-2008 (post enrollment day 1) at about 06:00, the nursing staff noted that the subject had increasing left-sided weakness, visual loss, and was drowsy **(SAE #002)**. NIHSS increased to 16. CT scan showed expected evolution of the right MCA infarct with no evidence of hemorrhage or significant mass effect. Hydration was increased. The subject was kept on bed rest and blood pressure was carefully monitored.

Also on [redacted] 2008, the subject complained of right shoulder pain **(AE #003)**. Apparently, she fell at home following her index stroke onset on 10-Mar-2008. An x-ray of the shoulder was negative for fracture or dislocation. Pain resolved at the time of the 30 day follow-up visit.

Mild hypercholesterolemia **(AE #902)** was diagnosed on [redacted] -2008 and was treated with simvastatin through the 90 day follow-up visit.

The subject was discharged from the hospital on [redacted] -2008 to an inpatient rehab facility with NIHSS of 14.

While in rehabilitation facility, the subject complained of headache **(AE #004)** on [redacted] -2008, constipation **(AE #007)** and insomnia **(AE #012)** on [redacted] 2008, leg cramps **(AE #005)** on 17-Mar-2008, and indigestion **(AE #006)** on 27-Mar-2008. These were all treated with medication and have resolved.

At the time of the 30 day follow-up visit on [redacted] 2008, the subject NIHSS was ranked as 13 with mRS of 4.

On [redacted] 2008 (post enrollment day 42), the subject presented to the hospital emergency department (ED) complaining of epigastric pain **(AE #008)**. Laboratory results showed a slightly elevated white blood cell count (WBC) of 11.3, glucose of 154, and normal levels of liver function tests (LFTs). A gallbladder ultrasound revealed an essentially normal gallbladder. The physician's impression was gastritis versus ulcer. The subject was advised to double up on Nexium and was discharged from the ED to home.

On [redacted] -2008 (post enrollment day 70), the subject returned to the ED with a three-day history of headache **(SAE #009)**. Prior to the admission, she was given Tylenol PM by her daughter who later found the subject very confused. A head CT revealed no acute changes. The subject was admitted. It was determined that the confusion was related to the diphenhydramine in the Tylenol PM. The subject returned back to her baseline mental status the next morning. She also reported to have depression **(AE #011)** and was treated with Celexa. Probable type II diabetes mellitus **(AE #903)** was diagnosed based on the laboratory results. On [redacted] -2008 vaginal candidiasis **(AE #904)** was diagnosed and treated with Diflucan. The subject was discharged to home on the same day with the 90 day NIHSS of 12 and mRS of 4.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
30-May-2008	042	001	899 - Other: Bilateral lower extremity edema	Likely not related	Likely not related
16-Jul-2008	**089**	**002**	**301 - Renal dysfunction**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is an 84-year-old Caucasian female with a history of paroxysmal atrial fibrillation, hypertension, hyperlipidemia, chronic obstructive pulmonary disease (COPD), irritable bowel syndrome, cholecystectomy and right total knee arthroplasty. Medications at admission included: Coumadin, Digoxin, Metoprolol, Diovan/hydrochlorothiazide, simvastatin, Spiriva, Premarin, Proventil, and Azmacort.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:00, [redacted]-2008. Symptoms at presentation included left-sided weakness with facial droop, visual field loss, left sensory deficit, and neglect. CT scan at admission revealed no abnormality. Baseline NIHSS was 15. The subject was randomized to the treatment arm of the SENTIS trial at 10:20, [redacted] 2008, 11.3 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 10:49, [redacted] 2008. Treatment was unremarkable.

Post-Enrollment Course: The subject's neurological condition improved during the hospitalization. She was discharged from the hospital on [redacted]-2008 to a rehabilitation facility with an NIHSS of 6.

On [redacted] 2008 (post enrollment day 42), the subject complained of bilateral lower extremity edema **(AE #001)** during an outpatient cardiology exam; Lasix was initiated.

The edema was unchanged, and on [redacted]-2008, the subject presented at the emergency department (ED) with slight weeping and redness of her left leg **(cont. of AE #001)**. The Lasix was stopped and the subject was placed on Demadex and potassium chloride, with Keflex for prophylaxis. She was not admitted.

During a home health nurse visit on [redacted] 2008 (post enrollment day 89), the subject exhibited low blood pressure of 80/40 and a brief syncopal episode. She also reported previous lightheadedness along with "not feeling well for several days". The subject presented to the ED and was admitted. Per ED note, the subject's extremities showed "no rash or edema" **(update to AE #001).** Laboratory results showed elevated creatinine level of 2.2 **(SAE #002)**. Demadex was stopped and saline was administered, and by the following day the subject's creatinine had returned to 1.0. The treating physicians felt that the syncope, hypotension and elevated creatinine were all due to the subject's

decreased intake of food and fluids over the past few days. The subject's medications were adjusted and she was discharged to home on [redacted] 2008.

At the 90 day follow-up visit on [redacted] 2008 the subject's NIHSS was ranked as 0 with mRS of 1.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
30-May-2008	001	001	413 - Headache	Likely not related	Likely not related
30-May-2008	001	003	199 - Cardiac Other: Cardiomyopathy	Likely not related	Likely not related
30-Jun-2008	**032**	**002**	**799 - Vascular Other: Right groin abscess**	**Likely not related**	**Likely related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 61-year-old Caucasian male with past medical history of hypertension, hyperlipidemia, coronary artery disease status post coronary artery bypass graft (1989), myocardial infarction (1992), rheumatoid arthritis, gastroesophageal reflux disease, pulmonary nodule, and a retinal bleed in the left eye status post laser surgery (2008). Medications at admission included: Metoprolol, Vytorin, Prednisone, Arava, Enbrel, Prilosec, and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 09:30, [redacted] 2008. Symptoms at presentation included confusion and Wernicke's aphasia. CT scan at admission revealed mild lucency of the periventricular deep white matter suggestive of microischemic changes. Baseline NIHSS was 6. The subject was randomized to the treatment arm of the SENTIS trial at 12:45, [redacted]-2008, 3.3 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 14:07 on [redacted]-2008, via right groin arterial puncture. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2008 (post enrollment day 1), the subject complained of headache **(AE #001).** His wife stated that the subject had a history of headache due to arthritis of neck. This headache was not any "different" from previous ones. Tylenol was given.

An echocardiogram on [redacted]-2008 showed cardiomyopathy with ejection fraction of 20-30% **(AE #003)** without any definite shunts or thrombus. The subject did not show any evidence of cardiac overload or significant heart failure

symptoms. The subject was placed on Coumadin and followed up with cardiology and rheumatology after discharge.

The subject was discharged from the index hospital on [redacted]-2008 to home.

At the 30 day follow-up visit on [redacted]-2008, the subject's NIHSS and mRS were both ranked as 1. The subject did not complain of any pain, redness, swelling, or drainage from right groin.

However, three days later, on [redacted] 2008, the subject was admitted with significant erythema of the right lower leg **(SAE #002)**. The subject reported taking oral Doxycyline as an outpatient due to the right leg pain for unknown duration. Right leg groin abscess with cellulitis was diagnosed. Antibiotics were changed to Vancomycin and Unasyn; Coumadin, Arava, and Enbrel were withheld. The subject responded well to the new regimen of antibiotics and did not require a surgical incision and drainage. He was discharged on [redacted] 2008 to home with significantly decreased edema and erythema.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Jul-2008	000	003	817 - Chest pain	Likely not related	Likely not related
18-Jul-2008	**001**	**001**	**199 - Cardiac Other: Cardiac tamponade**	**Likely not related**	**Unknown**
18-Jul-2008	001	002	299: Pulmonary Other: Pleural effusion	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 55-year-old Caucasian male with past medical history of hyperlipidemia, atrial fibrillation, bradycardia, and left bundle branch block (LBBB). Medications at admission included: Zocor, Furosemide, Albuterol, Ciprofloxacin, Vancomycin, Nexium, Toradol, Morphine, Heparin, and Lortab.

On [redacted] 2008 (2 days prior to enrollment) the subject underwent a pre-scheduled ablation of his atrial flutter, as well as a dual chamber pacemaker placement. Following pacemaker insertion, the subject was admitted to the telemetry unit. The subject complained of left-sided chest pain that was thought to be due to migration of the pacer leads. Ectopic beats, AV block, chest wall pain, and negative cardiac enzymes were exhibited. Pericarditis was ruled out by 2D echocardiogram. Pain was partially relieved by non-steroidal anti-inflammatories, Tordol, and Naprosyn. A transthoracic echocardiogram (TTE) on [redacted] 2008 did not indicate pericardial effusion.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 22:00 on [redacted]-2008, while in-patient. Symptoms at presentation included left-sided hemiparesis with facial weakness, neglect, and left-sided chest pain. CT scan revealed no abnormality. Baseline NIHSS was 10. The subject was randomized to the treatment arm of the SENTIS trial at 08:17, [redacted] 2008, 10.3 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 10:42, [redacted]-2008. During the procedure, the subject complained of chest pain **(AE #003)** when taking a deep breath. This was treated with 4mg of Morphine.

Post-Enrollment Course: On [redacted] 2009 (post enrollment day 1), due to his ongoing complaint of chest pain, the subject underwent an elective repositioning of cardiac lead wires on his pacemaker. His chest pain continued on the right side with shortness of breath. Chest x-ray revealed right pleural effusion **(AE #002)** and pulmonary edema **(SAE #001)**. The subject was treated with 60% oxygen by face mask with moderate relief. The subject improved by [redacted]-2008 and was discharged from the hospital on [redacted]-2008 to home.

On [redacted]-2008 (post enrollment day 15) the subject was readmitted to the hospital with dyspnea, cough, and lower extremity edema **(cont. of SAE #001)**. A chest x-ray showed cardiomegaly with a small effusion. NCT showed a large pericardial effusion. Laboratory results indicated elevated liver enzyme, hematocrit of 33.6, and supratherapeutic INR of 4.5 with brain natriuretic peptide (BNP) elevated to 250. The subject was diagnosed with dyspnea, pericardial effusion, probable early tamponade, and coagulopathy. Coumadin was held; 8 units of fresh frozen plasma were given. Reported as part of [redacted] were incidental findings of hypoalbuminemia and hypokalemia that were treated with fresh frozen plasma and potassium replacement, respectively.

On [redacted]-2008, a TTE had been done to evaluate for tamponade. Pleural effusion was not evident, but there was a moderate to large circumferential pericardial effusion. The subject underwent pericardiocentesis on [redacted] 2008 for tamponade relief. Two days later on [redacted] 2008, a second TTE demonstrated trivial pericardial effusion.

A cardiology consult on [redacted] 2008 diagnosed the subject with acute decompensated congestive heart failure due to systolic dysfunction; IV Lasix was administered for fluid overload **(cont. of SAE #001)**. Additional potassium supplement was given for anticipated increased diuresis. On [redacted]-2008 the subject's potassium was 4.6.

Due to the interval changes in the lungs evident on chest x-rays since [redacted] 2008, the subject underwent bilateral thoracentesis on [redacted] 2008 to relieve pleural effusion **(cont. of AE #002)**. 1000cc of fluid was removed from the right side and 600cc was removed from the left. A chest x-ray done 5 hours later demonstrated residual blunting.

On [redacted] 2008, the subject's INR improved to 1.98. Heparin was discontinued. The subject had no further complaints of chest pain or dyspnea and was discharged from the hospital to home.

Subject [redacted] enrolled 20-May-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
20-May-2009	000	002	102 - Hypotension	Unknown	Unknown
21-May-2009	**001**	**001**	**414 - Neurological worsening**	**Unknown**	**Unknown**
22-May-2009	002	003	118 - Atrial Fibrillation	Likely not related	Likely not related
22-Jul-2009	063	901	811 - Depression	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 70-year-old Caucasian male with past medical history of hyperlipidemia, hypertension (non-compliant with medication), chronic headache, peptic ulcer disease status post partial gastrectomy in 1995, lung cancer status post pneumonectomy, radiation and chemotherapy in 1995, and coronary artery disease status post coronary artery bypass graft (CABG) in 2000. He also had a pre-existing lower leg lesion of basal cell carcinoma that was later removed after 90-day study period. Medications at admission included: Tylenol and Rolaids as needed. The subject stopped taking anticoagulants due to epistaxis. He also reported to have a prescription for Lipitor, but had stopped taking it "a long time ago."

Current Stroke Onset and SENTIS Enrollment: The subject was estimated to be normal at 05:30, [redacted] 2009. Symptoms at presentation included decreased level of consciousness, aphasia, right-sided weakness, facial droop, dysarthria and sensory loss. CT scan at admission revealed no abnormality. Baseline NIHSS was 15. The subject was randomized to the treatment arm of the SENTIS trial at 11:45, [redacted] 2009, 6.3 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 12:35, [redacted] 2009. Treatment was unremarkable.

Post-Enrollment Course: The subject's blood pressure was 127/56 at admission and was mostly in the range of 100-120/50-60 in the evening of [redacted]-2009 and through the night **(AE #002)**. Dextran was started following normal saline bolus. Hypotension resolved on [redacted]-2009.

The 24 hour NIHSS on [redacted]-2009 progressed to 22 from 17 at 6 hours **(SAE #001)** due to increase of the right arm weakness and increased aphasia. NCT showed interval development of decreased attenuation within the left caudate head, portion of the left lantiform nucleus and left internal capsule consistent with acute infarct. No hemorrhage,

mass effect, or midline shift was observed. The subject failed the swallow test, and a percutaneous endoscopic gastrostomy (PEG) tube was placed.

Transthoracic echocardiogram (TTE) on [redacted] 2009 revealed sinus bradycardia but no significant cardiac dysfunction; ejection fraction was 55%. Cardiac source of embolus was ruled out. On the morning of [redacted] 2009, the subject developed tachycardia then atrial fibrillation/ flutter **(AE #003).** This continued intermittently until approximately 13:50. Cardiac enzymes were within the normal range. Brain natriuretic peptide (BNP) was in 300s. Chest x-ray was negative and there was no indication of any concern for congestive heart failure (CHF). Digoxin and Coumadin were prescribed but the latter was held until [redacted] 2009 due to a PEG tube placement.

The subject was discharged from the index hospital on [redacted] 2009 to a skilled nursing facility. Per discharge summary, in-patient rehabilitation was recommended but was declined by the family. The subject was discharged from the skilled nursing facility on [redacted] -2009 to an in-patient rehabilitation facility.

At the time of the 30 day follow-up visit on [redacted] 2009, Proxetine was reportedly prescribed for depression **(AE #901)** and continued through the 90 day follow-up visit. The 30 day NIHSS was ranked as 18 with mRS of 5.

The 90 day NIHSS on [redacted] -2009 was ranked as 8 with mRS of 4.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
13-Nov-2009	001	002	818 - Pain	Likely not related	Likely not related
14-Nov-2009	**002**	**001**	**601 - Anemia**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 90-year-old Caucasian female with past medical history of osteoarthritis, esophageal stricture, and remote hip surgeries. Medications at admission included: Mylanta, Ducolax, and “cranberry” pills.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 12:30, [redacted] 2009. Symptoms at presentation included left-sided weakness, facial palsy, sensory loss, dysarthria, and neglect. The subject was initially taken to a local emergency room. Her blood pressure (BP) was elevated to 202/73 and was treated with Labetalol and nitroglycerin patch. BP decreased to 171/85 and the subject was subsequently transferred to the index hospital. CT scan at admission revealed only mild chronic small vessel ischemic changes and no acute findings. Baseline NIHSS was 15.

The subject was randomized to the treatment arm of the SENTIS trial at16:50, [redacted] 2009, 4.3 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:43, [redacted] 2009. Treatment was unremarkable.

Post-Enrollment Course: The subject had chronic neck and back pain prior to the stroke onset, per her daughter. She was treated with Tylenol as needed during hospitalization and later with Tramadol **(AE #002)**.

On 1[redacted]-2009 (post enrollment day 2), the subject had oliguria and received an IV bolus of normal saline. Her hematocrit (Hct) and hemoglobin (Hgb) decreased to 28.8% and 9.3 g/dl, respectively **(SAE #001)** from admission Hct/Hgb of 33.1/11. On the following day, the subject was hypotensive (BP of 97-123/36-40) and IV hydration was given. Her Hct/Hgb dropped to 22.1/7.3. On [redacted]-2009, two units of packed red blood cells (PRBCs) were administered. Hct/Hgb improved to 32.5/11.2 on the next day. The subject's anemia was thought to be related to hemodilution.

The subject was discharged from the hospital on [redacted]-2009 to a skilled nursing facility.

Subject [redacted], enrolled [redacted] 2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
13-Nov-2007	000	001	899 - Other: Right hand white, cold to touch	Likely not related	Likely not related
13-Nov-2007	**000**	**002**	**716 - Carotid stenosis with endarterectomy**	**Likely not related**	**Likely not related**
13-Nov-2007	000	004	412 - HT, no concomitant mass effect	Likely not related	Unknown
13-Nov-2007	000	005	199 - Cardiac Other: Occasional PVC's	Likely not related	Likely not related
16-Nov-2006	003	901	601 - Anemia	Likely not related	Likely not related
20-Nov-2007	007	003	699 - Lab/electrolyte Other: Diagnosis of MRSA	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 69-year-old Caucasian male with past medical history of hypertension, hyperlipidemia, premature ventricular complexes, anxiety, depression, chronic renal insufficiency, peripheral vascular disease, hearing loss, vitamin B12 deficiency, and gout. Medications at admission included: Sular, Colchicine, Diltiazem, Xanax, Elavil, and vitamin B12.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at about 09:00 on [redacted]-2007. Symptoms at presentation included expressive aphasia and some right-sided neglect. CT scan at admission revealed an early acute infarct within the posterior division of the left MCA; no evidence of hemorrhage was seen. Baseline NIHSS was 7. The subject was randomized to the treatment arm of the SENTIS trial on 16:47, [redacted]-2007, 7.3 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 18:14 on [redacted]-2007. Treatment was unremarkable.

Post-Enrollment Course: Following the procedure on [redacted] 2007, the subject's right hand was noted to be white and cold to touch **(AE #001)**, while the remainder of his arm was pale and warm. This resolved spontaneously by the next day. The subject's body temperature was 98.4ºF at admission. At the 6 hours post enrollment, the subject's body temperature dropped to 96.2ºF and to 96.0ºF at the 24 hours post enrollment.

An MR angiography on [redacted] 2007 revealed an 80% occlusion of the left internal carotid artery **(**[redacted] A left carotid endarterectomy was performed on [redacted]-2007.

The 6 hour follow-up CT perfusion scan confirmed posterior left MCA territory infarct with evidence of a small amount of interval hemorrhage without significant mass effect **(AE #004)**. The 24 hour CT did not mention hemorrhagic conversion and specifically noted "no new focus of hemorrhage or ischemia by CT criteria." There was no change in neurological status (the 24 hour NIHSS remained at 7).

Electrocardiogram on [redacted] 2007 showed new onset of occasional premature ventricular complexes (PVCs) **(AE #005)**; no treatment was given and no more PVCs were noted.

On [redacted]-2007 (post enrollment day 3), the subject's hemoglobin decreased to 10.1 from baseline of 13.8 and hematocrit decreased to 29.0 from baseline of 40.5 **(AE #901)**. Ferrous sulfate 300mg daily was initiated and continued through the 90 day follow-up visit. The subject was transferred from the hospital to a rehabilitation facility on [redacted] 2007.

On [redacted]-2007 (post enrollment day 7), a nasal swab taken at index hospital was positive for Methicillin-resistant Staphylococcus aureus **(AE #003)**. No action was taken according to the discharge notes from the rehabilitation facility. The subject was discharged to home on [redacted]-2007.

Subject [redacted], enrolled [redacted] 2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-Nov-2007	000	001	503 - Nausea/Vomiting	Likely not related	Likely not related
17-Nov-2007	003	002	414 - Neurological worsening	Likely not related	Likely not related
Unk-Nov-2007		903	814 - Sleeping Disturbance/ Disorder	Likely not related	Likely not related
14-Dec-2007	030	901	811 - Depression	Likely not related	Likely not related
14-Dec-2007	030	902	819 - Infection	Likely not related	Likely not related
Unk-Dec-2007		904	899 - Other: Vertigo	Likely not related	Likely not related
09-Jan-2008	**056**	**003**	**499 - Neuro Other: Complicated migraine**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 52-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, and migraines. Medications at admission included: Aspirin, Lipitor, Plavix, Pepcid, Levaquin, Norvasc, and Naproxyn.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 05:30, [redacted] 2007. Symptoms at presentation included right-sided weakness, facial palsy, sensory loss, dysarthria and slurred speech. CT scan at admission revealed no acute findings. Baseline NIHSS was 12. The subject was randomized to the treatment arm of the SENTIS trial at 13:00, [redacted]-2007, 7.5 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 14:08, [redacted] 007. Treatment was unremarkable.

Post-Enrollment Course: Immediately following the procedure, the subject complained of nausea **(AE #001)**; IV Phenergan and Zofran were administered. Symptoms quickly resolved and there were no further complaints of nausea during the hospitalization.

On [redacted] 2007 (post enrollment day 3) the subject was undergoing physical therapy when she experienced a new onset right facial numbness and tingling **(AE #002)**. CT showed no acute changes and the symptoms resolved. No changes to the subject's treatment regimen were made. The 4 day NIHSS on [redacted] 007 was 2.

During the index hospitalization the subject was prescribed Restoril for sleep disturbance **(AE #903)**. She was discharged from the hospital on [redacted]-2007 to an acute rehabilitation facility.

On [redacted] 2007 (post enrollment day 11), during strenuous physical therapy, the subject had a reoccurrence of the same right-sided facial numbness and tingling **(update to AE #002)** that she had previously experienced during the physical therapy. By the time the subject presented to the emergency department (ED) most of the symptoms had resolved. CT and electrocardiogram (ECG) were both normal. The subject was released from ED back to the rehabilitation facility with no changes to her treatment regimen except for temporary discontinuation of the physical therapy.

Medication log indicates that at the time of the 30 day follow-up visit on [redacted] 2007 the subject was prescribed Zoloft for depression **(AE #901)**, Macrobid for an unspecified infection **(AE #902);** and Antivert for vertigo **(AE #904)**.

On [redacted] 2008 (post enrollment day 56) the subject was re-admitted to the hospital for an episode involving loss of consciousness with dense hemiplegia and aphasia **(SAE #003)**, apparently triggered by looking into the sun. Symptoms began resolving within hours and by the following day the subject returned to her baseline status.

During the hospitalization the subject also complained of throbbing occipital headache with nausea and photophobia. A full work-up (CT, MRI, ECG, electroencephalogram (EEG), cerebral angiography and transthroacic echocardiogram) was negative. A follow-up sleep deprived EEG showed mild suppression and some paroxysmal slowing in the left hemisphere. The subject was diagnosed with probable complicated hemiplegic migraine and started on Verapamil for migraine prophylaxis. Migraine was considered to be a chronic condition that would not have a resolution. The subject was discharged to home on [redacted]-2008.

Subject [redacted] enrolled [redacted] 2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
15-Nov-2006	000	002	806 - Agitation/Excitation	Likely not related	Likely not related
16-Nov-2006	**001**	**001**	**404 - HT, likely contributing to mass effect**	**Likely not related**	**Unknown**
17-Nov-2006	002	003	413 - Headache	Likely not related	Likely not related
17-Nov-2006	002	004	817 - Chest Pain	Likely not related	Likely not related
02-Dec-2006	017	005	102 - Hypotension	Likely not related	Likely not related
11-Dec-2006	026	006	503 - Nausea/Vomiting	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: This subject is a 72-year-old Caucasian female with past medical history of hypertension and cholecystectomy. The subject was a previous smoker. Medications at admission included: Amlodipine, Trandolapril, and Atenolol.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 12:35, [redacted]-2006. Symptoms at presentation included left-sided numbness and slurred speech. CT scan at admission revealed signs of underlying microvascular disease and no definite acute abnormalities. Baseline NIHSS was 6. The subject was randomized to treatment arm of the SENTIS trial at 14:50, [redacted] 2006, 4.3 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 18:21, [redacted] 2006. The supra-renal aortic diameter was 26mm, 2mm over the suggested upper limit of 24mm. A waiver was received from sponsor to enroll the subject. The procedure was remarkable for device instability reported due to the difference in supra-renal and infra-renal diameters. The subject tolerated the procedure well.

Post-Enrollment Course: On [redacted]-2006 the subject was agitated during the follow-up MR scan and was treated with Ativan and later with Haldol and Lorazepam **(AE #002)**.

On [redacted] 2006 (post enrollment day 1), the subject remained agitated. A repeat CT scan revealed hemorrhagic transformation of the right parietal MCA (with some mass effect) and mild compression of the ipsilateral ventricle **(SAE #001)**. The 4 hour and 24 hour follow-up NIHSS were deemed invalid due to the subject's continued sedation. It was also suggested that the subject's agitation may have been secondary to the hemorrhagic transformation.

On [redacted] 2006 (post enrollment day 2), left hemianopia was noted. The subject complained of a mild headache **(AE #003)** that occurred intermittently over two days and resolved with administration of Acetaminophen. The subject also reported one event of sharp chest pain **(AE #004)** associated with agitation. Elecrtocardiogram showed no acute changes. Chest pain resolved untreated. The 4 day NIHSS on [redacted] 2006 NIHSS was 10.

On [redacted]-2006 (post enrollment day 6), CT scan confirmed existing hemorrhagic transformation with mild regional mass effect without significant brain herniation. The subject was doing well. Her neurological status was gradually improving.

The subject was transferred on [redacted]-2006 in stable condition to an outlying hospital for rehabilitation closer to home. Upon discharge, there was no indication of an embolic condition. Stroke etiology was unknown.

On [redacted] 2006 (post enrollment day 17), the subject had a period of hypotension **(AE #005)** that resolved with decrease of antihypertensive medication dosage.

On [redacted]-2006 (post enrollment day 26), the subject had one episode of "lightheadedness" with nausea and vomiting **(AE #006)** during physical therapy. This was felt to be due to hypotension. Antihypertensive medication dosage was again adjusted.

The 30 day NIHSS on [redacted] 2006 decreased to 6; mRS was 4.

The 90 day NIHSS on [redacted] 2007 decreased further to 3; mRS was 2.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
16-Mar-2008	003	001	414 - Neurological worsening	N/A	N/A
06-Apr-2008	**024**	**003**	**409 - New ischemic stroke**	**N/A**	**N/A**
14-May-2008	**062**	**002**	**303 - Urinary Tract Infection**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is an 81-year-old Caucasian male with past medical history of hypertension, hyperlipidemia, coronary artery disease, myocardial infarction in 1973, atrial fibrillation, hypothyroidism, gout, chronic obstructive pulmonary disease (COPD), peptic ulcer, adrenal failure secondary to non-Hodgkin's lymphoma of the right adrenal gland, status post chemotherapy and radiation, and giant cell arteritis. He also had a mild cognitive impairment, likely on the basis of vascular dementia. Medications at admission included: Synthroid, Lipitor, Metoprolol, Pantoloc, Cozaar, Lasix, and Allopurinol.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 13:30, [redacted]-2008. Symptoms at presentation included right-sided weakness, complete hemianopsia, facial palsy, sensory loss, and dysarthria. Presentation NIHSS was 12. CT scan at admission revealed left MCA changes with no reference to the right hemisphere. The subject's right-sided weakness improved in the emergency department and his condition stabilized. Baseline NIHSS was 6. The subject was randomized to the treatment arm of the SENTIS trial at 19:10, [redacted]-2008, 5.7 hours from symptom onset. However, due to issues with nursing, radiology, and interventional staff, the subject did not receive the NeuroFlo treatment.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject's fluctuation of neurological symptoms continued. The 6 hour NIHSS remained at 6 and increased to 9 at 24 hours. The 24 hour CT scan on [redacted]-2008 showed evolution of the left MCA infarction.

On [redacted]-2008 (post enrollment day 3), the subject had a brief episode of disorientation **(AE #001).** No treatment was given, and the event spontaneously resolved on the same day.

The subject was noted to have a new onset of decreased level of consciousness with worsening aphasia, slurred speech, and mild left hemiparesis. MRI on [redacted]-2008 showed multiple acute infarcts in the right hemisphere ([redacted] and a large MCA infarct on the left side. MRI on [redacted]-2008 showed that there were at least 8 foci of abnormal T2 signal present throughout the right cerebral hemisphere. The 30 day NIHSS on [redacted]-2008 was 7.

The subject was discharged from the hospital on [redacted] 2008 to home.

On [redacted]-2008 (post enrollment day 62), the subject was re-admitted to the hospital with a urinary tract infection **(SAE #002)** and was found to have multifactorial acute urinary retention. A cystoscopy was performed and antibiotics were initiated. Surgery was not an option due to co-morbidities. The subject was discharged to home with a permanent Foley catheter.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
20-Jan-2009	000	002	701 - Groin hematoma	Unknown	Likely related
20-Jan-2009	000	001	603 - Electrolyte Imbalance	Likely not related	Likely not related
21-Jan-2009	001	005	899 - Other: Alcohol withdrawal	Likely not related	Likely not related
21-Jan-2009	001	006	108 - Congestive heart failure	Likely not related	Likely not related
23-Jan-2009	003	003	303 - Urinary tract Infection	Likely not related	Likely not related
05-Feb-2009	016	004	204 - Aspiration pneumonia	Likely not related	Likely not related
29-Mar-2009	**068**	**007**	**304 - Hematuria**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 73-year-old Caucasian male with past medical history of obesity, diabetes, hypertension, hyperlipidemia, coronary artery disease, myocardial infarction with percutaneous transluminal coronary angioplasty (PTCA) in 1998, and prostate adenocarcinoma with resection in 2004. Post PTCA the subject was on Coumadin and had a mild intraventricular hemorrhage which was evacuated. Medications at admission included: Aspirin, Fosenopril, Metoprolol, Metformin, Simvastatin, and Ezetrol.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 02:30, [redacted]-2009. Symptoms at presentation included decreased level of consciousness,

global aphasia, right hemiplegia with facial palsy, and dysarthria. CT scan at admission revealed a hypodensity of the left middle cerebral artery just proximal to its main branch and suggestion of some early loss of definition of gray-white matter interface. Baseline NIHSS was 16. The subject was randomized to the treatment arm of the SENTIS trial at 10:20, [redacted] 2009, 7.8 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 11:05, [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2009 (day of enrollment) at 18:35 the subject had blood oozing at the groin access site with development of a 6x6 inches hematoma **(AE #002)**. Manual compression was applied and cessation of bleeding was achieved. The hematoma gradually resolved.

Also on [redacted]-2009 hypomagnesemia **(AE #001)** was discovered and treated with supplements intermittently throughout hospitalization.

On [redacted]-2009 (post enrollment day 1) the family reported that the subject was a "heavy drinker" and he was started on medication to prevent active alcohol withdrawal **(AE #005)**. That same day the subject complained of shortness of breath and had wheezing with crackles at the bases. Troponins were negative and the subject was in normal sinus rhythm. A transesophageal echo showed severe global left ventricular systolic dysfunction with an ejection fraction of 10-15%. A congestive heart failure **(AE #006)** was diagnosed. Lasix was administered and symptoms improved over 3 days and resolved.

On [redacted] 2009 (post enrollment day 3) the subject complained of burning and frequency of urination. A urine culture showed Enterococcal species **(AE #003)** and antibiotics were started.

On [redacted] 2009 (post enrollment day 16) the subject was diagnosed with bilateral aspiration pneumonia **(AE #004)** after some shortness of breath. Levaquin was started and the symptoms resolved quickly.

On [redacted]-2009 (post enrollment day 68) the subject developed a significant hematuria **(SAE #007)** with a severe hemoglobin drop that required transfusions. Cystoscopy was unremarkable and the subject was taken off Coumadin and kept on Aspirin only.

The subject was medically stable and was slowly improving. He was found to be unsuitable for rehabilitation. He remained on a transitional unit until [redacted] 2009 when he was discharged home to his family and a private caregiver.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
06-Mar-2009	002	001	205 - Infectious pneumonia	Likely not related	Likely not related
06-Mar-2009	002	006	199 - Cardiac Other: Volume overload	Likely not related	Likely not related
06-Mar-2009	002	003	119 - Elevated cardiac enzymes	Likely not related	Likely not related
10-Mar-2009	006	002	601 - Anemia	Likely not related	Likely not related
13-Mar-2009	009	904	603 - Electrolyte imbalance	Likely not related	Likely not related
16-Mar-2009	**012**	**901**	**118 - Atrial Fibrillation with pacemaker placement**	**Likely not related**	**Likely not related**
17-Mar-2009	013	902	504 - GI Motility Disorders	Likely not related	Likely not related
19-Mar-2009	015	005	699 - Lab/electrolyte Other: Leukocytosis	Likely not related	Likely not related
19-May-2009	076	903	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 61-year-old Caucasian male with past medical history of hypertension, coronary artery disease, atrial fibrillation/flutter with transthoracic electrical shock, chronic obstructive pulmonary disease, and depression. The subject underwent cardioversion for atrial fibrillation and atrial flutter ablation in Nov-2008. Medication at admission included: Diphenhydramine, Warfarin, Vicodin, Lexapro, Propafenone, Cardizem, Phenegran, and Spiriva.

Current Stroke Onset and SENTIS Enrollment: On [redacted]-2009, the subject underwent pulmonary vein ablation. He was last known normal at 03:00 on [redacted]-2009, while in-patient. Symptoms at presentation included slurred speech and right-sided weakness. CT scan at admission revealed a small hypodensity in the left internal capsule of corona radiata. Baseline NIHSS was 6. The subject was randomized to the treatment arm of the SENTIS trial at 13:30, [redacted] 2009, 10.5 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 13:55, [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: The subject experienced frequent episodes of shortness of breath and pulmonary edema/pleural effusion throughout the course of his hospitalization. On [redacted]-2009 (post enrollment day 2) he woke up complaining of chest pain and shortness of breath with oxygen saturation in high 80's. White blood cells (WBC) count was elevated at 12.2 and a chest x-ray demonstrated bilateral pleural

effusions, bibasilar atelectasis, and changes at the right base, suspicious for pneumonia **(AE #001)**. Sputum culture was positive for heavy growth of upper respiratory bacteria. Antibiotics were initiated and pneumonia resolved by [redacted]-2009.

CTA of the chest, abdomen and pelvis on [redacted]-2009 revealed presence of mild pericardial fluid or thickening **(AE #006);** mild periportal edema and fluid around the gallbladder and in the pelvis were also noted. Due to the fluid overload and associated hyponatremia, Lasix and hypotonic fluids as carriers for various medications/antibiotics were given. The subject was also started on Prednisone, Albuterol, Imipenem-Cilastatin, Oxymetatozine, Levaquin, Gentamicin, and incentive spirometry.

On [redacted]-2009 cardiac enzymes were drawn due to the subject's chest pain. Creatine phosphokinase (CPK) was within normal range and troponin-I level was elevated to 1.00 (the specimen was possibly tainted). Repeat troponin-I was 0.67 **(AE #003)** which normalized on [redacted]-2009. Troponin elevation was attributed to the subject's pre-stroke pulmonary vein isolation procedure. There was no suggestion of a myocardial infarction.

On [redacted] 2009 (post enrollment day 6) the subject's hemoglobin (Hgb) and hematocrit (Hct) dropped to 10.2 and 29, respectively **(AE #002)**. Ferrous sulfate was ordered and on [redacted]-2009 Hgb/Hct was 10.2/31.

The subject's potassium levels ranged from 3.1 to 5.0 **(AE #904)**, Calcium Citrate-Vitamin D2 was started on [redacted]-2009.

On [redacted]009 (post enrollment day 12), the subject had several runs of atrial tachycardia **(SAE #901)**. On the following day the subject had tachycardia with rate up to 200's with associated hypotension and mild chest pain. The subject was admitted to the Cardiovascular intensive care unit. Medical management included Sotalol, Esmolol, Cardizem, Metropolol, Furosemide, Nitroglycerin, Amiodarone, Ativan, and supplemental oxygen. Pacemaker placement was planned.

On [redacted] 2009 (post enrollment day 13), the subject was constipated **(AE #902)** and treated with Miralax, Lactulose, Docusate, and Milk of Magnesia.

On [redacted]-2009 (post enrollment day 15), the subject's WBC was 18.7 **(AE #005)** and Vancomycin was started. Chest x-ray identified basilar atelectasis; pan cultures and urinary analysis were negative. With negative cultures, Vancomycin was discontinued on [redacted]-2009 and leukocytosis was diagnosed. WBC normalized by [redacted] 2009.

On [redacted] 2009, atrioventricular (AV) node ablation and placement of a dual chamber pacemaker was performed **(cont. of SAE #901)**. No dysrhythmia was noted post procedure, however shortness of breath continued, although it was reported as improved. Interrogation of the subject's pacemaker on [redacted] 2009 revealed atrial fibrillation and atrial tachycardia with frequent rapid ventricular response. Ventricular rates were in the range of 160-200s**.**

The subject was discharged from the hospital on [redacted]-2009 to a rehabilitation facility.

On [redacted]009, the subject was admitted for less than 24 hours with complaints of dyspnea and palpitations **(cont. of SAE [redacted]).** Electrolyte imbalances, myocardial ischemia, and thyroid dysfunction were all ruled out and an AV node radiofrequency ablation was planned. Admission summary also indicated that Simvastatin was started for hyperlipidemia **(AE #903)**.

On [redacted]2009 the subject was admitted for less than 24 hours for the planned ablation **(SAE #901, update)**. There were no complications and the subject's condition was considered improved.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
09-Apr-2008	**000**	**001**	**601 - Anemia**	**Likely not related**	**Likely not related**
15-Apr-2008	006	002	699 - Lab/electrolyte Other: Hyperhomocysteinemia	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 65-year-old Caucasian male with past medical history of cervical stenosis with central cord syndrome treated with anterior cervical discectomy and fusion at C3-C4 level (2007). Two weeks prior to the admission, the subject had been complaining of some left lower extremity paresthesias and some difficulty walking, which family attributed to the back surgery in 2007. Since that surgery, he has also had some swallowing difficulties resulting in decreased appetite and weight loss. Prior to the study enrolment, the subject's prostate-specific antigen (PSA) was noted to be elevated. Medications at admission included: multivitamins, Aleve, and Pepcid.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 05:30, [redacted]-2008. Symptoms at presentation included aphasia, dysarthria, and complete visual field hemianopsia. CT scan at admission revealed no acute infarction. MR perfusion scan showed an area of restricted diffusion within the anterior MCA territory in the posterior left frontal lobe. Baseline NIHSS was 6. The subject was randomized to the treatment arm of the SENTIS trial 14:03, [redacted]2008, 8.6 hours from symptom onset.

NeuroFlo Procedure: The NeuroFlo procedure was initiated at 14:50, [redacted]-2008. Treatment was unremarkable.

Post-Enrollment Course: The subject's labs results upon admission indicated hemoglobin of 7.8 and hematocrit of 25 **(SAE #001)**; 2 units of red blood cells were administered. Iron studies showed ferritin of 15.2, iron saturation of 1, iron level of 400, and total iron-binding capacity (TIBC) level of 289. A Hemoccult test was negative. The subject was started on ferrous sulfate for iron supplementation that continued through the 90 day follow-up visit.

During the index hospitalization a mild hyperhomocysteinemia with a homocysteine level of 12.3 **(AE #002)** was diagnosed, which thought to be due to a gene defect. Hyperhomocysteinemia was treated with vitamins.

The subject was discharged from the hospital on [redacted] 2008 to home with outpatient speech therapy. Follow-up for pre-existing elevated PSA showed no changes requiring treatment.

Subject [redacted], enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
16-May-2008	000	904	503 - Nausea/Vomiting	Likely not related	Likely not related
18-May-2008	002	001	413 - Headache	Likely not related	Likely not related
19-May-2008	**003**	**002**	**207 - Pulmonary embolism**	**Likely not related**	**Likely not related**
Unk-May-2008		902	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
Unk-May-2008		903	603 - Electrolyte imbalance	Likely not related	Likely not related
22-Jul-2008	067	901	811 - Depression	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 69-year-old Caucasian male with past medical history of umbilical hernia with associated abdominal mass, hiatal hernia, appendectomy, and cholecystectomy. He was not taking medications.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 12:10, [redacted] 2008. Symptoms at presentation included left-sided weakness, facial palsy, right gaze preference, neglect of visual stimulation on the left side, and sensory loss. CT scan at admission revealed no evidence of acute ischemia. Baseline NIHSS was 17. The subject was randomized to the treatment arm of the SENTIS trial at 15:35, [redacted]-2008, 3.4 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 16:13, [redacted] 2008. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2008 (the day of enrollment) the subject received Zofran for nausea **(AE #904)**. On the following day, he received another dose of Zofran.

On the morning of [redacted] 2008 (post enrollment day 2) the subject complained of headache **(AE #001)** which was treated with one dose of Morphine with relief.

A spiral CT of the chest on [redacted] 008 revealed a pulmonary embolus **(SAE #002)**. The subject remained free of pulmonary or cardiac symptoms throughout the hospitalization and was anticoagulated with Fragmin.

During the index hospitalization the subject was started on Simvastatin and continued through the 90 day follow-up **(AE #902).** He also required electrolyte (potassium, phosphorus, magnesium) replacements **(AE #903)** during the index hospitalization.

The subject was discharged from the hospital on [redacted] -2008 to an in-patient rehabilitation facility.

At the 90 day follow-up visit on [redacted] -2008 the subject was taking Zoloft for depression **(AE #901)**.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
31-Jul-2009	000	004	201 - Atelectasis	Likely not related	Likely not related
31-Jul-2009	**000**	**001**	**110 - Cardiogenic shock**	**Likely not related**	**Likely not related**
01-Aug-2009	**001**	**002**	**414 - Neurological worsening**	**Unknown**	**Unknown**
01-Aug-2009	001	007	504 - GI Motility Disorders	Likely not related	Likely not related
02-Aug-2009	002	003	399 - Renal Other: Renal calculi	Likely not related	Likely not related
04-Aug-2009	004	901	603 - Electrolyte imbalance	Likely not related	Likely not related
27-Aug-2009	027	902	817 - Chest pain	Likely not related	Likely not related
11-Sep-2009	**042**	**005**	**205 - Infectious pneumonia**	**Likely not related**	**Likely not related**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
22-Oct-2009	**083**	**006**	**205 - Infectious pneumonia**	**Likely not related**	**Likely not related**
22-Oct-2009	083	903	599 - GI Other: C-difficile	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 77-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, coronary artery disease (status post angioplasty and stenting of circumflex in 2002), retroperitoneal hemorrhage secondary to Coumadin for cardiomyopathy in 2005, chronic left bundle branch block (status post pacemaker and defibrillator placement in 2007), congestive heart failure (CHF), severe ischemic dilated cardiomyopathy with ejection fraction (EF) of 20% in June 2009, breast cancer (left lumpectomy), osteoporosis, compression fracture T9 vertebra with kyphoplasty (2008), transient ischemic attack (2008), bilateral cataract surgery, and possible emphysema. Medications at admission included: Advair, Aggrenox, albuterol, Aldactone, Ambien, Amiodarone, Combivent, Coreg, Cozaar, Fosamax, Digoxin, K-Dur, Lasix, and Vytorin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:00, [redacted] 2009. Symptoms at presentation included left-sided weakness, left facial droop and slurred speech. The family provided the subject's medical history verbally for SENTIS screening purposes, and stated there was no history of MI, CHF, or heart surgery. They knew of the pacer/defibrillator and the stent placement, but stated there were no other cardiac issues. Physical exam did not cause suspicion of cardiac issues. CT scan at admission revealed right MCA dense vessel sign over M2 and M3 branches with right insular acute infarct and no signs of hemorrhage. Baseline NIHSS was 10. The subject was randomized to the treatment arm of the SENTIS trial at 09:45, [redacted] 2009, 10.8 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 10:25, [redacted]-2009. Treatment was unremarkable. A slight change in the neurological condition of the subject was noted in that her speech was not as good at the end of the procedure, so the subject was sent for repeat CT from the angio suite. NCT, CTA and CT perfusion done at 12:45 showed right MCA occlusion at distal M1/M2 segment with subsequent large right MCA infarct. There was matched perfusion deficit without significant penumbra; no hemorrhage or mass effect.

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) routine chest x-ray showed an enlarged cardiac silhouette, pacemaker in appropriate position and elevation of the right hemidiaphragm with mild right basilar atelectasis **(AE #004)**. Diuretics and pulmonary toileting were increased. The subject continued to have bibasilar and dependent atelectasis in addition to emphysematic changes, without acute process identified, noted on subsequent CT and x-rays during her admission. Echocardiogram on that day found a mildly dilated left ventricle with EF of 25%, mild concentric left

ventricular hypertrophy and multiple regional wall motion abnormalities. The subject had onset of chest pain, hypotension and dyspnea **(SAE #001)**. An intra-aortic balloon pump (IAPB) was placed for perfusion augmentation. Amiodarone was started for control of intermittent ventricular tachycardia.

On [redacted] 2009 (post enrollment day 1) the subject had increased left-sided weakness that progressed to the loss of movement on the left side **(SAE #002)**. Possible NIHSS was 18 to 20. NCT showed progression of right MCA infarct involving M1 to M3 segments and increasing surrounding edema causing mass effect on the lentiform nucleus.

Also on [redacted] 009 the subject reported an abdominal discomfort. A keofeed tube was placed and a follow-up abdominal x-ray noted stool in the rectum **(AE #007)**. One dose of Lactulose was given to help the subject pass the stool with less effort.

By [redacted] -2009 (post enrollment day 2) there was no indication of an acute cardiac process (ECG and cardiac enzymes had remained stable) and the IAPB was removed. A small hematoma resulted from the IAPB removal had resolved without treatment. The subject complained of abdominal and back pain post IABP removal. A CT of the abdomen and pelvis showed a 3mm non-obstructing calculus in the middle calyx of the left kidney **(AE #003)** and bilateral 1cm hypodense lesions, as well as a 4.1x2.9 simple cyst in the right hepatic lobe. Pain medication was given as needed and no other treatment was instituted. The symptoms disappeared.

The 4 day NIHSS on [redacted] 2009 was 8. The subject's blood pressure remained low (100-150/40-70) and her skin was significant for tenting. On the following day the subject remained hypotensive secondary to dehydration and a normal saline bolus was given as well as potassium phosphate for the subject's low level of phosphate (2.4) and potassium (3.3) **(AE #901)**.

The subject was discharged from the hospital on [redacted] -2009 to a rehabilitation facility.

On [redacted] 2009 (post enrollment day 27) the subject presented to the emergency department (ED) following an episode of chest pain that was relieved with nitroglycerin **(AE #902)**. The subject's work-up was negative and she was transferred to a different rehabilitation facility within 24 hours.

On [redacted] -2009 (post enrollment day 42) the subject was admitted to an outside hospital with infectious pneumonia **(SAE #005)**. She was treated and discharged to the nursing home on [redacted] -2009. Medical records from the outside hospital are not available, information regarding this hospitalization was provided verbally by the nursing home staff.

The 30 day NIHSS on [redacted] 2009 was ranked as 13, which was deferred due to the subject being weak from her recent bout of pneumonia and lack of activity.

On [redacted]-2009 (post enrollment day 83) the subject was re-hospitalized with infectious pneumonia **(SAE #006)**. During this hospitalization she also contracted C. difficile **(AE #903)**, which was treated with antibiotics. The subject was discharged back to the nursing home on [redacted]-2009 following resolution of acute pneumonia.

At the time of the 90 day follow-up visit on [redacted]-2009, the subject's NIHSS was ranked as 14; mRS was 5. The subject remained mildly dyspneic and was on 2L oxygen via nasal cannula.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
21-Dec-2009	000	001	603 - Electrolyte imbalance	Likely not related	Likely not related
22-Dec-2009	**001**	**002**	**404 - HT, likely contributing to mass effect**	**Unknown**	**Unknown**
22-Dec-2009	**001**	**003**	**202 - Respiratory failure**	**Likely not related**	**Likely not related**
22-Dec-2009	**001**	**005**	**805 - Sepsis**	**Likely not related**	**Likely not related**
22-Dec-2009	001	004	407 - Seizure	Likely not related	Likely not related
03-Jan-2010	**013**	**007**	**207 - Pulmonary Embolism**	**Likely not related**	**Likely not related**
06-Jan-2010	016	901	503 - Nausea / Vomiting	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 75-year-old Caucasian male with past medical history of mitral regurgitation, atrial fibrillation, diabetes mellitus, coronary artery disease, hypertension, hyperlipidemia, benign prostatic hypertrophy and mild mental impairment related to head trauma suffered as a child. The subject lived in a nursing home prior to stroke onset, but was able to care for himself. Medications at admission included: Aspirin, Enalapril, Lantus, Lipitor, Metoprolol, Novalin, Pericolace, and Verapamil.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 08:50, [redacted] 2009. Symptoms at presentation included garbled speech, left hemiparesis, facial palsy, sensory loss and neglect. CT scan at admission revealed subtle hypodensity and minimal effacement of the sulci within the right sylvian fissure involving the subinsular cortex and right temporal operculum. No hemorrhage was identified. CT perfusion showed perfusion deficit along the right frontoparietal region with a small posterior penumbra along the anterior parietal region. CTA was normal. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 16:34, [redacted]-2009, 7.7 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:52, [redacted] 2009. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment), the subject's electrolytes (sodium, potassium, calcium) were noted to be low **(AE #001)**. They were replaced as necessary throughout the index hospitalization. The 6 hour NIHSS assessed at 22:00 was 20.

In the early hours of [redacted]-2009 (post enrollment day 1), the subject's mental status changed and his blood pressure increased, requiring Labetolol. A follow-up CT at 03:08 showed interval evolution of the right MCA territory infarct with increasing hypodensity and hemorrhagic conversion **(SAE #002)**. At 05:00 the subject was only responsive to pain stimuli. NCT at 06:22 showed continued evolution of the right MCA infarct, stable intraparenchymal hemorrhage in this region, and surrounding edema resulting in mild mass effect.

Later on the morning of [redacted]-2009 the subject was intubated for airway protection **(SAE #003)**. Chest x-ray later that day showed atelectasis and a left pleural effusion. Fentanyl and Versed drips for sedation were started. CT scan at 10:00 confirmed continued evolution of the infarct and mass effect, although the hemorrhage was stable.

Later that same morning, the subject's blood pressure became more labile with periods of hypotension requiring fluid boluses, Neosynephrine and eventually a Vasopressin drip. The subject's heart rate simultaneously increased and an Esmolol drip, and later, a Diltiazem drip, was started. His white blood cell count increased to 17.3 from baseline of 8.0. The subject was also febrile. He was pan-cultured and antibiotics were started. Positive E. Coli growth in urine and blood confirmed sepsis **(SAE #005)**.

At about 15:00 on [redacted] 2009 the subject had a seizure **(AE #004)**. He was given a Midazolam bolus and loaded with anti-seizure medications. Electroencephalogram was abnormal with bilateral diffuse cerebral slowing and suppressed background consistent with severe diffuse encephalopathy. No epileptiform discharges or electrographic seizures were seen. A few additional small seizures were noted throughout the index hospitalization. The 24 hour NIHSS was not completed due to the subject's sedation. In the early hours of [redacted] 2009 the subject's pupils were unequal and non-reactive and he was not responding even to pain stimuli. Fentanyl and Versed were discontinued.

On [redacted] 2010 the subject had both a percutaneous endoscopic gastrostomy (PEG) tube and tracheostomy tube placed.

On [redacted]-2010 (post enrollment day 13) the subject had a small amount of bleeding from his tracheostomy site so a chest CT was done to determine the cause. Pulmonary emboli and small bilateral pleural effusions were found on the exam **(SAE #007)**. Heparin was started; however, worsening of the hemorrhagic conversion was seen on CT

on [redacted]010 so heparin was discontinued. An inferior vena cava filter was placed on [redacted]-2010.

On 0[redacted]-2010 (post enrollment day 16) the subject had nausea and vomited twice **(AE #901)**. Each time he was treated with Zofran.

The subject was discharged (on ventilator) to a long-term care facility on [redacted]-2010. His 30 day and 90 day NIHSS was ranked as 37 with mRS of 5.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
26-Jul-2008	**000**	**002**	**711 - Pseudoaneurysm with surgical repair**	**Unknown**	**Likely related**
27-Jul-2008	001	007	809 - Diabetes mellitus	Likely not related	Likely not related
28-Jul-2008	002	003	414 - Neurological worsening	Likely not related	Unknown
30-Jul-2008	004	005	603 - Electrolyte imbalance	Likely not related	Likely not related
02-Aug-2008	007	006	405 - HT, probably not contributing to mass effect	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 67 year-old Caucasian female with past medical history of hypertension, type II diabetes, hypothyroidism, dyslipidemia and a recent breast biopsy (normal). Medications at admission included: Simvastatin, Darvocet, Oxycodone, Singulair, Avandia, Micardis and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 09:00, [redacted]2008. Symptoms at presentation included right-sided weakness with facial droop and dysarthria. CT scan at admission revealed cerebral atrophy and no acute findings. Baseline NIHSS was 9. The subject was randomized to the treatment arm of the SENTIS trial at 16:25, on [redacted]-2008, 7.4 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:28, [redacted]2008. At the end of the procedure, an attempt was made to close the subject's right groin with Perclose. This was not successful, so manual pressure was applied. When manual pressure was released, a large hematoma was noted. An immediate ultrasound of the right lower extremity revealed a 1.4 x 1.2 x 3.2 cm pseudoaneurysm **(SAE #002)**. The subject had been stabilized and observed by Vascular neurology and Vascular surgery.

Post-Enrollment Course: The 6 hour NIHSS at 21:30 decreased to 4, and the subject was able to move her right arm and leg, and her facial droop was gone.

On [redacted] 2008 (post enrollment day 1) the subject's groin pseudoaneurysm was described by Vascular surgeon as "stable", but ultrasound on [redacted]-2008 and [redacted] 2008 reported enlarging hypoechoic area within the right groin consistent with hematoma and/or thrombosed pseudoaneurysm **(SAE #002, update)**. The subject's pseudoaneurysm was re-assested on [redacted]-2008 and a surgical repair was planned but delayed due to anemia **(part of SAE #002).** The subject's Hemoglobin decreased to 8.8 from 13.4 at the time of admission. There were no signs of bleed except for hematoma. Oral ferrous sulfate was administered and the subject's Hemoglobin increased to 9.1 on [redacted]-2008.

On [redacted]-2008 the subject's blood glucose level was high enough to require treatment with insulin **(AE #007).** The 24 hour CT showed acute infarct in left basal ganglia adjacent to the left lateral ventricle. Carotid duplex indicated complete occlusion of right ICA.

On [redacted] 2008 the subject's NIHSS increased to 8 and she was unable to move her right leg **(AE #003)**. CT scan on the following day demonstrated evolution of the left basal ganglia and left centrum semiovale infarction without evidence of hemorrhagic conversion.

On [redacted]-2008 (post enrollment day 4), the subject's serum potassium was low at 2.8 **(AE #005)** and supplemental replacement was given**.**

On [redacted]-2008 (post enrollment day 7), MRI of the head showed hemorrhagic transformation of the left basal ganglia infarct with mild mass effect over the left lateral ventricle **(AE #006).** The subject's neurological status remained stable.

On [redacted]-2008 the subject underwent surgical repair of the pseudoaneurysm **(update to SAE #002)**. She was discharged from the hospital on [redacted] 2008 to an inpatient rehabilitation.

At the 30 day follow-up visit on [redacted]-2008, the subject's NIHSS was 5 and mRS was 4.

The 90 day NIHSS on [redacted]-2008 was ranked as 2 with mRS of 4.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
29-Sep-2009	000	001	799 - Vascular Other: Limb ischemia	Likely not related	Unknown
30-Sep-2009	001	002	603 - Electrolyte imbalance	Likely not related	Likely not related
02-Oct-2009	003	003	103 - Hypertension	Likely not related	Likely not related
05-Oct-2009	006	004	499 - Neuro Other: Lethargy	Likely not related	Likely not related
06-Oct-2009	007	005	303 - Urinary Tract Infection	Likely not related	Likely not related
11-Oct-2009	012	006	399 - Renal Other: Pre-renal azotemia	Likely not related	Likely not related
15-Oct-2009	016	007	899 - Other: Decubitus ulcer	Likely not related	Likely not related
06-Dec-2009	**068**	**008**	**104 - Unstable angina**	**Likely not related**	**Likely not related**
25-Dec-2009	087	009	299 - Pulmonary Other: Upper respiratory infection	Likely not related	Likely not related
04-Jan-2010	**097**	**901**	**414 - Neurological worsening**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 78-year-old Hispanic female with past medical history of congestive heart failure, coronary artery disease with stent placement, 3 myocardial infarctions, supraventricular tachycardia and paroxysmal atrial fibrillation (permanent pacemaker implanted), hypertension, dyslipidemia, right carotid occlusion and a recently diagnosed left atrial thrombus. The subject had a transient ischemic attack 6 months prior to enrollment. There is also a questionable history of diabetes. Medications at admission included: Coumadin, Lasix, Lisinopril, Coreg, Amlodipine and Xanax.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 09:10 on [redacted]-2009. Symptoms at presentation included a left-sided weakness, facial palsy, forced right gaze deviation, a moderate to severe dysarthria, complete sensory loss and neglect. CT scan at admission revealed an increased density to the distal right MCA, hypodensities in the right thalamus, left internal capsule and bilateral subinsular regions; no hemorrhage. CTA showed right deep femoral artery occlusion. Baseline NIHSS was 19 (a protocol deviation was received for not meeting enrollment criterion). The subject was randomized to the treatment arm of the SENTIS trial at 17:06, [redacted]-2009, 7.9 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated on [redacted]-2009 at 18:00 via right arterial groin puncture. Treatment was remarkable for the over-inflation of the infrarenal balloon by 2.25 ml. This resulted in a pressure gradient of 15, but as the case

progressed, the differential reached 40, so 2 ml of fluid was removed from the infrarenal balloon. The subject was sedated and tolerated the procedure well.

Post-Enrollment Course: At 20:45 following the NeuroFlo procedure, no palpable pulse in the subject's right foot was noted **(AE #001)**. Her right foot was cold, but the subject denied any pain and was able to move her foot. A vascular surgery consult determined that it was most likely due to the chronic right femoral occlusion that was noted during angiography. Doppler pulses were present during the exam.

The 24 hour CT scan on [redacted]-2009, showed a stable right MCA infarct without hemorrhage. Serum potassium was 3.2 **(AE #002)** and supplemental replacement was given. Hypokalemia persisted intermittently throughout the index hospitalization.

On [redacted] 2009 (post enrollment day 3), the subject's blood pressure was poorly controlled, so Lisinopril was added to her regimen **(AE #003)**. Over the next several days, Metoprolol, HCTZ, and an increased dose of Coreg were also added.

CT scan on [redacted] 2009 showed an evolving right MCA infarct without hemorrhagic transformation and mildly increased minimal mass effect on the right lateral ventricle without midline shift.

On [redacted]-2009 (post enrollment day 6), the subject became hypotensive, and was lethargic with dilated pupils **(AE #004)**. She normalized quickly, but remained minimally responsive for 2 minutes. CT scan did not demonstrate any significant changes from the previous study. Electroencephalogram showed a possible structural lesion in the right hemisphere as well as a lesion in the left central region.

On [redacted]-2009, the subject had positive urine culture **(AE #005)** that was treated with Levaquin.

On [redacted]-2009 (post enrollment day 12), a lower extremity ultrasound ruled out deep vein thrombosis. Doppler ultrasound showed occlusion of the bilateral superficial femoral arteries proximally to the distal portion and bilateral posterior tibial arteries **(cont. of AE #001)**. Lab work revealed a decreased glomerular filtration rate (GFR) of 37, increased blood urea nitrogen (BUN) of 27 and creatinine of 1.38. The subject's pre-renal azotemia **(AE #006)** improved with increased fluid intake.

On [redacted]-2009 (post enrollment day 16), the subject was noted to have a stage II decubitus ulcer **(AE #007)**. A wound care consult was obtained and the subject was treated with Duoderm. On the following day the subject was discharged from the hospital to a skilled nursing facility.

At the 30 day visit on [redacted]-2009, the subject's NIHSS was 14 with mRS of 4.

On [redacted]-2009 (post enrollment day 68), the subject was admitted to the hospital with a chest pain **(SAE #008).** The workup was negative for acute cardiac events and the subject returned to the skilled nursing facility on [redacted] 2009.

On 25[redacted] 2009 (post enrollment day 87), the subject developed a productive cough, a chest x-ray and sputum culture were obtained. Sputum was positive for Candida albicans, so Cipro for 10 days was started **(AE #009)**.

At the 90 day visit on [redacted]-2010, the subject's NIHSS increased to 18 **(SAE #901)** due to the increase of the left-sided weakness and facial palsy. According to a family member, the subject's condition slightly worsened when the nursing facility withdrew physical/ occupational therapy following the 30 day follow-up visit. The investigator believed that the worsening was related to the stroke.

Subject [redacted], enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
11-May-2008	000	901	412 - HT, no concomitant mass effect	Likely not related	Likely not related
12-May-2008	**001**	**002**	**411 - Transient ischemic attack**	**Likely not related**	**Likely not related**
15-May-2008	004	001	603 - Electrolyte imbalance	Likely not related	Likely not related
18-May-2008	007	003	407 - Seizure	Likely not related	Likely not related
22-May-2008	011	004	503 - Nausea/Vomiting	Likely not related	Likely not related
25-May-2008	014	005	806 - Agitation/Excitation	Likely not related	Likely not related
03-Jun-2008	023	006	303 - Urinary Tract Infection	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is an 82-year-old Caucasian male with past medical history including hypertension, hyperlipidemia and myocardial infarction in 1970. Medications at admission included: Lisinopril, Hydrochlorothiazide, Pravastatin, and Nitroglycerin as needed for chest pain.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 06:30, [redacted]-2008. Symptoms at presentation included decreased level of consciousness, hemianopsia, right-sided weakness with facial palsy, sensory loss and aphasia. CT scan at admission revealed left ICA occlusion with partial occlusion of the left MCA; no hemorrhage. Baseline NIHSS was 13. The subject was randomized to the

treatment arm of the SENTIS trial at 14:55, [redacted]-2008, 8.4 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 16:30, [redacted]-2008. The pre-treatment aortogram showed a supra-renal aortic diameter of 25.8mm, 1.8mm larger than protocol-specified limit. CoAxia gave the site a pre-approved protocol exemption. NeuroFlo treatment proceeded and was unremarkable.

Post-Enrollment Course: The 6 hour follow-up CT indicated acute infarct involving portions of the left MCA including left basal ganglia and caudate head with hemorrhagic transformation (HI-1) without concomitant mass effect **(AE #901)**.

Beginning of [redacted] 2008 (post enrollment day 1) the subject began having daily events of left hemispheric transient ischemic attacks related to the left ICA occlusion **(SAE #002)**. He was dependent on pressors to maintain neuologic stability (continuous infusion on Neosynephrine)**.**

On [redacted]-2008 (post enrollment day 4) the subject's potassium was 2.7 **(AE #001)**, and potassium supplements were given. By [redacted]-2008 the potassium was stable and within normal limits at 3.6.

On [redacted] 2008 (post enrollment day 7) the subject developed an acute seizure **(AE #003)**, starting with eyes deviation to the left, and right-sided tonic clonic activity; Phenytoin and Keppra were administered. CT scan showed subacute infarct with a slight increase in cross sectional area of abnormality but no hemorrhage. Electroencephalogram (EEG) showed diffuse slowing of the EEG background and non-reactive stage II sleep consistent with severe diffuse nonspecific cerebellar dysfunction. The subject had no additional seizures through discharge.

The subject's continuing fluctuating neurological status and seizure led the treating physician to revascularize the carotid artery via stent and angioplasty on [redacted]-2008 **(update to SAE #002)**. The subject tolerated the procedure well. CT scan performed post-carotid stenting on [redacted]-2008 reported "progression of hemorrhage", but the site's principal investigator argued that that was a contrast staining.

On [redacted] 2008 (post enrollment day 11) the subject complained of abdominal pain and vomited multiple times **(AE #004)** after his feeding tube was removed. Zofran was given with resolution of the vomiting and pain.

On [redacted]-2008 (post enrollment day 16) the subject was agitated and combative **(AE #005).** Restraints were applied and Risperidol was administered. The subject's agitation subsided and he was calm and cooperative at discharge to an acute rehabilitation facility on the same day. His 30 day NIHSS on [redacted]-2008 was ranked as 6.

While in the acute rehabilitation facility, the subject developed a urinary tract infection **(AE #006)** which resolved after the treatment with a five day course of Levaquin.

The 90 day NIHSS on [redacted]-2008 was ranked as 4 with mRS of 2.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
20-Aug-2008	001	002	413 - Headache	Likely not related	Likely not related
21-Aug-2008	002	001	102 - Hypotension	Likely not related	Likely not related
23-Aug-2008	004	003	603 - Electrolyte imbalance	Likely not related	Likely not related
Unk-Aug-2008		902	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
05-Sep-2008	**017**	**004**	**411 - Transient Ischemic Attack**	**Likely not related**	**Likely not related**
Unk-Sep-2008		901	299 - Pulmonary Other: Cough	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 37-year-old Asian-American male with past medical history of hyperlipidemia. Medications at admission included Claritin and Lipitor.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 06:30, [redacted] 2008. Symptoms at presentation included right-sided weakness, sensory loss and slurred speech. CT scan at admission revealed hypodensity in the left parieto-occipital lobe; no hemorrhage. Baseline NIHSS was 11. The subject was randomized to the treatment arm of the SENTIS trial at 14:10, [redacted]-2008, 7.7 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 14:40 on [redacted]-2008. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour NIHSS decreased to 10. On [redacted] 2008 (post enrollment day 1) the subject complained of a headache **(AE #002)**. Tylenol was administered with good relief.

On [redacted]-2008 (post enrollment day 2) the subject had hypotension with blood pressure of 45/25 **(AE #001)** and a brief syncopal episode. The subject was recently weaned off from a Neo-synephrine drip which was started for permissive hypertension to maintain his cerebral perfusion. Pressors were restarted and an IV fluid bolus was given. The subject was neurologically stable throughout the rest of the hospitalization. He was started on Florinef.

On [redacted]-2008 (post enrollment day 3) the subject's potassium was 3.1 **(AE #003)** and potassium chloride replacement was given. By [redacted]-2008 his potassium level had normalized to 3.9.

During the index hospitalization, the subject's fasting lipid profile showed triglycerides of 166, cholesterol of 234, high density lipoprotein 45 and low density lipoprotein of 163 **(AE #902)**. His dose of Lipitor was increased from 10mg to 80mg.

The 4 day NIHSS on [redacted]-2008 decreased to 6. The subject was discharged from the hospital on [redacted]-2008 to a rehabilitation facility in stable condition.

On [redacted]-2008, while in physical therapy, the subject had a 30 minute episode of slurred speech and right facial numbness **(SAE #004)**. By the time he arrived at the emergency room his symptoms had resolved. He was admitted to the hospital for evaluation. CTA and MRI showed no acute changes from the previous exams. His Plavix dose was increased and Aspirin was added to his treatment regimen. The subject was discharged to home on [redacted]-2008 (discharge was slightly delayed because his stay was over the weekend). Discharge summary report indicates that the subject was discharged on Guaifenesin for cough **(AE #901)**.

The 30 day and 90 day NIHSS were both ranked as 4.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
27-Apr-2009	**000**	**001**	**116 - Bradycardia with pacemaker placement**	**Likely not related**	**Unknown**
04-May-2009	007	002	811 - Depression	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 72-year-old African-American female with past medical history of hypertension, diabetes mellitus, hyperlipidemia, obesity, cholecystectomy, and seasonal allergies. Medications at admission included: Lovothyroxine, Combivent inhaler, Advair, and Fluticosone.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 07:00, [redacted] Symptoms at presentation included weakness in her right hand, facial droop and dysarthria. CT scan at admission revealed an acute ischemia within the left middle cerebral artery territory. Baseline NIHSS was 8. The subject was randomized to the treatment arm of the SENTIS trial at 15:15, [redacted]-2009, 8.3 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:30, [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: Following the NeuroFlo procedure the subject's heart rate dropped to the 30-40 beats per minute (bpm) **(SAE #001)** from 47-79 bpm at admission. Overnight it dropped into the 20's and a temporary transvenous pacemaker was inserted on [redacted]-2009 to correct the subject's junctional heart rhythm. A permanent pacemaker was inserted on [redacted] 2009.

On [redacted]-2009 (post enrollment day 7) the subject was diagnosed with depression **(AE #002)** and started on medication. She was discharged to an in-hospital rehabilitation facility on [redacted]-2009.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
08-Jul-2009	000	008	603 - Electrolyte imbalance	Likely not related	Likely not related
08-Jul-2009	000	007	102 - Hypotension	Likely not related	Unknown
08-Jul-2009	**000**	**001**	**113 - MI, non-Q wave; Non ST elevated MI**	**Likely not related**	**Unknown**
08-Jul-2009	**000**	**005**	**202 - Respiratory failure**	**Likely not related**	**Likely not related**
09-Jul-2009	**001**	**002**	**207 - Pulmonary embolism**	**Likely not related**	**Likely not related**
09-Jul-2009	**001**	**901**	**414 - Neurological worsening**	**Unknown**	**Unknown**
09-Jul-2009	001	902	606 - Hyperglycemia	Likely not related	Likely not related
14-Jul-2009	006	004	601 - Anemia	Likely not related	Likely not related
19-Jul-2009	011	003	811 - Depression	Likely not related	Likely not related
20-Jul-2009	012	006	818 - Pain	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 57-year-old Caucasian male with past medical history of stroke (mRS=0), hypertension, hyperlipidemia, and glaucoma. Approximately one month prior to index stroke onset the subject had 30 min of slurred speech for which he did not seek medical care. Medications at admission included: Aspirin, Lipitor, and Xalatan eye drops.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 05:30, [redacted] 2009. Symptoms at presentation included left-sided weakness with facial droop, sensory deficit, dysarthria and hemianopsia. He also complained of headache. The subject was bradycardic at the time of admission, and was in atrial fibrillation prior to enrollment. CT scan at admission revealed dense vessel sign involving distal right M-1 segment and proximal right M-2 segment with hypodensity concerning for developing infarct in the right insula. Baseline NIHSS was 12. The subject was randomized to the treatment arm of the SENTIS trial at 16:40, [redacted]-2009, 11.2 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:13, [redacted] 009. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2009 (the day of enrollment) the subject developed an electrolyte imbalance **(AE #008)**. Potassium, calcium, sodium and phosphate levels fell below normal limits and supplements were provided throughout the index hospitalization. Lab values had not fully normalized at the time of discharge and the subject remained on oral supplements through the 90 day follow-up visit.

Also on [redacted] 2009 the subject was hypotensive **(AE #007).** At the time of admission his blood pressure (BP) was 96/56. Dopamine drip was initiated. At baseline BP was 120/89 and increased to 148/70 at 6 hour post treatment. It fluctuated between 94-192/52-94 in the first 24 hours. The subject was switched to Levophed on [redacted] 2009. The 6 hour NIHSS remained stable at 12, although, some neurological changes were noted. The subject continued to have hypotension with pharmacological blood pressure support. Levophed was finally weaned on [redacted] 2009.

On [redacted] 2009 at 20:25 the subject's troponin was elevated to 0.085 (norm 0-0.034). He had nausea, vomiting and a headache above the left eye over night (this was not reported as an AE because the same headache was described by the subject prior to enrollment). On the following day he became diaphoretic and tachycardic with heart rate in the 120s. Digoxin was ordered. An electrocardiogram showed anterolateral infarct **(SAE #001).** Transesophageal echocardiogram showed severe global hypokinesis of the left ventricle with ejection fraction of 25-30%. Total creatine kinase (CK) elevated to 203 (norm 55-170) around noon. By 18:00, the subject's troponin level peaked at 4.51 with total creatine kinase myoglobin (CKMB) of 22.6 (norm 0-3.2).

On [redacted]-2009 (post enrollment day 1) the subject had decreased oxygen saturation (88%), became drowsy and had difficulty breathing **(SAE #005)**. Chest x-ray showed bilateral diffuse interstitial and airspace opacities that could be due to atypical pneumonia or noncardiogenic pulmonary edema. Given the subject's low grade fever and elevated white blood cell (WBC) count of 20-28, infectious pneumonia was reported. Antibiotics were initiated. Blood and sputum cultures were later reported as negative.

Ultrasound of the lower extremities ruled out deep vein thrombosis (DVT). A chest CT on the following day showed a tiny pulmonary embolism **(SAE #002)** in the segmental

pulmonary artery to the right lower lobe, and "small bilateral pleural effusion …that might represent pulmonary edema versus atypical pneumonia". The subject was put on 100% oxygen but continued to be in distress so was sedated and intubated. Heparin drip was initiated. Furosemide, Diamox and Xopenex were prescribed. Chest x-rays continued to worsen through 15-Jul-2009 until the respiratory failure began resolving and the subject was extubated. Fever was listed as unknown origin in the chart. It resolved by [redacted]-2009. WBC count normalized by [redacted] 2009.

The subject's 24 hour NIHSS on [redacted] 2009 progressed to 18 from 12 at 6 hours **(SAE #901)**. The subject's left-sided weakness and dysarthria had increased. The 24 hour CT of the head showed interval evolution of right MCA infarct with dense MCA sign anterior to an area of encephalomalacia and associated local mass effect; no hemorrhagic transformation was noted.

Also on [redacted]-2009 the subject's blood glucose elevated from 97 to 130s, and peaked at 185 **(AE #902)**. Insulin was given during the index hospitalization.

On [redacted]-2009 (post enrollment day 3) the subject's platelet level fell to 119. Heparin was discontinued and Argatroban was started. Heparin-induced thrombocytopenia (HIT) antibody was reported positive on [redacted] 2009 **(cont. of SAE #002)**. Platelet level normalized by [redacted]-2009. The subject was eventually bridged to Coumadin and remained on that at the 90 day follow-up visit. The subject also complained of throat pain following extubation on [redacted]-2009 **(cont. of SAE #005)**, which continued through [redacted] 2009.

On [redacted] 2009 (post enrollment day 6) the iron and total iron binding capacity (TIBC) levels were low and hemoglobin dropped to 9.4 **(AE #004)**. CT of the abdomen and pelvis and ultrasound of the spleen were negative for source of bleeding. Hematology consult suggested the anemia was likely secondary to chronic inflammation. By [redacted] 2009 the hemoglobin had rebounded above 10 and remained so through hospital discharge. The subject continued on iron supplements through the 90 day follow-up visit.

The 4 day NIHSS on [redacted] 2009 decreased to 12.

On [redacted]-2009 (post enrollment day 11) the subject was felt to be depressed **(AE #003)** and Effexor was initiated. Psychiatry consult recommended continuation of the medication.

On [redacted]-2009 (post enrollment day 12) the subject complained of left shoulder pain **(AE #006)**. Pain was thought to be related to subluxation of the left arm. Arm support and medication were provided for pain management. Left shoulder pain was still present at the time of the 90 day follow-up visit.

The subject was discharged to a rehabilitation facility on [redacted] 2009, and then to home on [redacted]-2009. His 30 and 90 day NIHSS were ranked as 8 and 4, respectively.

Subject [redacted] enrolled [redacted]-2010

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
23-Jan-2010	001	001	404 - HT, likely contributing to mass effect	Unknown	Unknown
23-Jan-2010	001	008	603 - Electrolyte imbalance	Likely not related	Likely not related
23-Jan-2010	001	901	812 - Fever	Likely not related	Likely not related
25-Jan-2010	003	903	809 - Diabetes Mellitus: worsening	Likely not related	Likely not related
28-Jan-2010	006	003	504 - GI Motility Disorders	Likely not related	Likely not related
29-Jan-2010	007	002	407 - Seizure	Likely not related	Likely not related
30-Jan-2010	008	006	299 - Pulmonary Other: Pulmonary infiltrates	Likely not related	Likely not related
31-Jan-2010	009	005	303 - Urinary Tract Infection	Likely not related	Likely not related
Unk-Jan-2010		902	103 - Hypertension: worsening	Likely not related	Likely not related
Unk-Jan-2010		904	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
08-Feb-2010	**017**	**007**	**899 - Other: Failure to thrive**	**Likely not related**	**Likely not related**
Unk-Feb-2010		**905**	**414 - Neurological worsening**	**Likely not related**	**Likely not related**
03-May-2010	101	009	899 - Other: Shingles	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is an 89-year-old Caucasian female with past medical history of hypertension, non-insulin dependent diabetes and hypothyroidism. Medications at admission included: Lisinopril, Diltiazem, Synthroid, Omeprazole, and Celexa.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 07:00 on [redacted]-2010. Symptoms at presentation included decreased level of consciousness, aphasia, right-sided weakness and left gaze preference. CT scan at admission revealed loss of grey-white matter differentiation involving the posterior left insula and adjacent left superior temporal gyrus concerning for infarct with no hemorrhage noted. CT perfusion showed ischemia in the left MCA territory with mildly decreased cerebral blood volume but not quite reaching the criteria for infarct at the time of imaging. CTA showed left MCA occlusion. Baseline NIHSS was 15. The subject was randomized to the treatment arm of the SENTIS trial at 20:07, [redacted]-2010, 13.1 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 21:00 on [redacted]-2010. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour NIHSS remained at 15.

On [redacted] 2010 (post enrollment day 1) the subject had increased lethargy and decreased right extremity strength. The 24 hour NIHSS increased to 17. MRI revealed a petechial hemorrhage with mild mass effect and 1-2mm midline shift to the right. CT done 8 hours later showed hemorrhagic conversion **(AE #001)** involving the left middle and superior temporal gyri, the left posterior insula and the left inferior parietal lobe with 3mm midline shift and effacement of the left lateral ventricle and the adjacent sulci. Core Lab confirmed a large hemorrhagic transformation at 29 hours. Midline shift worsened by the next day, but by day 4 ([redacted]-2010) her NIHSS improved to 11. CT on [redacted]-2010 revealed a large left posterior parietal ischemia with intraparenchymal hemorrhage, extensive vasogenic edema with 7.5mm midline shift, which decreased from before measured 10mm. No intervention was indicated.

On [redacted] 2010, the subject also had an electrolyte imbalance (low potassium, calcium and phosphorus) **(AE #008)**. She was treated successfully with potassium replacement.

Also on [redacted]-2010 the subject's body temperature increased to 101.1ºF **(AE #901)** from baseline of 97.7 ºF. Tylenol was given. The subject's white blood cell (WBC) count was 13.25 (norm is 4.10 -10.80) and reached 17.53 on the following day. A routine nasal swab came back positive for Methicillin-resistant Staphylococcus aureus (MRSA), which was not treated.

On [redacted]-2010 (post enrollment day 3) the subject's blood glucose increased to 255 **(AE #903)** from baseline of 150; regular insulin was started. Lantus and Glipizide were added later.

On [redacted]-2010 (post enrollment day 6) the subject complained of abdominal discomfort and constipation **(AE #003)**. Two enemas were given with good results. The subject started having regular bowel movements on [redacted]-2010.

On [redacted]-2010 the subject had nystagmus, was unresponsive and was diagnosed with a seizure **(AE #002)**. Ativan was administered and the subject began to awaken and respond. Head CT showed no changes and electroencephalogram (EEG) showed some left temporal slowing with some rare left temporal sharp waves. Keppra was prescribed. At the time of the 90 day follow-up visit no new seizures had been reported and the subject remained on Keppra.

On [redacted]-2010 (post enrollment day 8) the subject had a cough, rhonchi, elevated WBC count and a chest x-ray positive for infiltrates **(AE #006)**. Chest x-ray showed bilateral lung opacities consistent with increased bilateral pleural effusions with atelectasis and/or pneumonia and increased pulmonary edema. Follow-up chest x-ray on [redacted] 2010 revealed improvement with only left pleural effusions with underlying atelectasis and/or pneumonia. At the time of the 90 day follow-up visit this condition was noted as ongoing, improved.

On [redacted] 2010 the subject had a positive urinalysis and was treated with Levaquin for urinary tract infection (UTI) **(AE #005)**. When she was re-admitted on [redacted]-2010 UTI was ongoing and antibiotics were continued.

During the index hospitalization, the subject's blood pressure was initially kept between 160 and 200. The subject was then placed on several blood pressure medications to maintain adequate blood pressure control. The medication log indicates that Cardene, metoprolol, labetalol, amlodipine and hydralazine were added to the subject's regimen during the index hospitalization to control her hypertension **(AE #902)**.

During the index hospitalization, the subject's low density lipoprotein (LDL) was 122 **(AE #904)** and Lipitor 40mg was initiated. On [redacted]-2010 the dose of Lipitor was increased to 80mg. On the same day the subject was discharged in good condition from the hospital to a skilled nursing facility.

On [redacted] 2010 (post enrollment day 17) the subject was re-hospitalized for failure to thrive **(SAE #007)**. While in the skilled nursing facility the subject refused to take anything by mouth (pills, fluids, nutrition). She became dehydrated and lethargic. IV fluids were initiated and a percutaneous endoscopic gastrostomy (PEG) tube was placed during this hospital admission. The subject was discharged back to nursing home on [redacted] 2010 in stable condition.

The 30 day NIHSS on [redacted]-2010 increased to 18 **(SAE #905)** from 11 at 4 day and mRS was 5. The subject had significant increase of the right-sided weakness. The increase in NIHSS score was thought to be related to the failure to thrive and not related to a progression of the index stroke.

On [redacted] 2010 (post enrollment day 101) a nurse noted a rash on the subject's back and Acyclovir was prescribed for a diagnosis of shingles **(AE #009)**.

The 90 day NIHSS on [redacted]010 decreased to 11; mRS was 4. The subject remained in a skilled nursing facility at that time.

Subject [redacted], enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
30-May-2006	**000**	**001**	**204 - Aspiration pneumonia**	**Likely not related**	**Unknown**
31-May-2006	001	901	603 - Electrolyte imbalance	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is an 80-year-old Caucasian female with past medical history of hypothyrodisim, borderline diabetes, and a recent diagnosis of atrial fibrillation with rapid ventricular response. She was recently hospitalized for an episode of atrial fibrillation. Echocardiogram was negative for any evidence of congestive heart failure (CHF); an ejection fraction was 65%. Medications at admission included: Cardizem, Coumadin, Prevacid, Toprol, Levoxyl, and Cartia.

Current Stroke Onset and SENTIS Enrollment: The subject presented to the emergency room (ER) at 09:07 with shortness of breath and not feeling well. She was slurring her speech in the morning but upon presenting to the ER no neurological symptoms were noted. The subject had an elevated heart rate in the 120 and a Cardizem drip was administered at 09:14. The subject began slurring her speech around 09:20. Following CT scan at 09:27, the subject was speaking clearly. A second dose of Cardizem was administered at 09:54. At 10:00 the subject was noted by the neurologist to have a significant neurological change and a stroke code was called. Symptoms included right-sided weakness with facial palsy, dysarthria, sensory loss, and neglect. CT scan at admission revealed no evidence of acute intracranial process. Baseline NIHSS was 10. The subject was randomized to the treatment arm of the SENTIS trial at 12:30, [redacted] 2006, 3.3 hours from last known "neurologically" normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 13:07, [redacted] 2006. Treatment was unremarkable. The subject was intubated due to the general anesthesia. Prior to intubation, the subject had nausea and vomiting.

Post-Enrollment Course: On [redacted] -2006, following the NeuroFlo procedure the subject was extubated and awakened from anesthesia. She remained on a Cardizem drip for her atrial fibrillation. Upon transferring to the intensive care unit (ICU), the subject experienced multiple episodes of emesis. A decision was made to electively intubate the subject for airway protection. Conscious sedation was used with Versed and Fentanyl. The subject was extubated on [redacted] 2006.

A chest x-ray dated [redacted] -2006 suggested mild pulmonary congestion and possible mild congestive heart failure. Chest x-ray on the following day revealed "borderline cardiomegaly, pulmonary vascular congestion with bilateral interstitial infiltrates or edema and a left pleural effusion." Aspiration pneumonia **(SAE #001)** was later diagnosed; IV antibiotics were started and switched to oral Augmentin. This event was documented as resolved after a course of antibiotics. Follow-up chest x-ray done around the time of the 30 day follow-up visit was normal.

During the index hospitalization, the subject's serum potassium decreased to 3.2 **(AE #901)** and she was treated with potassium supplements. Potassium level improved to 3.6 on [redacted] -2006.

The subject was discharged from the hospital on [redacted] 2006 to home with NIHSS of 0.

Subject [redacted], enrolled [redacted] 2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
02-Nov-2006	000	003	799 - Vascular Other: Right groin discomfort	Likely not related	Unknown
05-Nov-2006	003	001	303 - Urinary Tract Infection	Likely not related	Likely not related
07-Nov-2006	**005**	**002**	**102 - Hypotension**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 69-year-old African American female with past medical history of hypertension, type I diabetes, hyperlipidemia, hypothyroidism, and previous right MCA infarct in 2005 (mRS=1). Medications at admission included: Lotrel, Clonidine, Metoprolol, Metformin, and Levothyroxine.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 10:00, [redacted]-2006. Symptoms at presentation included slurred speech, left-sided weakness, and slight worsening of her per-existing left facial droop. MRI and MRA at admission revealed right periventricular white matter acute infarct, penumbra at risk for additional ischemia, and stenosis of the M2 segment of the right MCA. Baseline NIHSS was 5. The subject was randomized to the treatment arm of the SENTIS trial at 15:30, [redacted] 2006, 5.5 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:00, [redacted]-2006 via right arterial groin puncture. Treatment was unremarkable.

Post-Enrollment Course: The subject indicated experiencing discomfort in right groin, leg and back **(AE #003)** following aortogram and NeuroFlo procedure. She continued complaining of discomfort at the time of the 90 day follow-up visit on [redacted] 2007, which she described as "sensitivity". No treatment or medication was required.

On [redacted]-2006 (post enrollment day 3), the subject complained of frequent urination and had a positive urinary culture for bacteria **(AE #001)**. This infection was treated with Bactrim DS and symptoms resolved.

The 4 day NIHSS on [redacted] 2006 decreased to 3. On the following day, worsening of neurologic symptoms, including increased weakness of the subject's left arm, facial drooping and increased slurring of her speech was noted. NIHSS increased to 5. The subject's blood pressure dropped to 106/68 **(SAE #002)**. The neurologic symptoms were transient in nature and were determined to be associated with the decrease in blood pressure. The subject received IV Albumin in addition to normal saline. Her anti-hypertensive medications were discontinued with a new blood pressure goal of 140/90.

The subject showed increased mobility and a stronger voice by 21:00 on [redacted]-2006. However, she was not discharged to the rehab facility on that day as planned because of the above described episode. Therefore, the site categorized this event as serious. The subject was discharged to the rehab facility on the following day, [redacted]-2006. Her blood pressure at the time of discharge was 131/75.

The 30 day NIHSS on [redacted]-2006 was ranked as 2.

Subject 0125-1202-008, enrolled 02-Feb-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
02-Feb-2009	000	001	118 - Atrial Fibrillation	Likely not related	Likely not related
02-Feb-2009	000	005	606 - Hyperglycemia	Likely not related	Likely not related
02-Feb-2009	000	002	818 - Pain	Likely not related	Likely not related
02-Feb-2009	000	008	701 - Hematoma	Unknown	Likely related
03-Feb-2009	001	902	299 - Pulmonary Other: Pulmonary congestion	Likely not related	Likely not related
03-Feb-2009	001	010	699 - Lab/electrolyte Other: Abnormal UA	Likely not related	Likely not related
03-Feb-2009	**001**	**003**	**414 - Neurological worsening**	**Likely not related**	**Unknown**
03-Feb-2009	001	901	115 - Patent foramen ovale (PFO)	Likely not related	Likely not related
03-Feb-2009	001	006	603 - Electrolyte imbalance	Likely not related	Likely not related
07-Feb-2009	005	009	899 - Other: Abdominal wall hematoma	Likely not related	Likely not related
08-Feb-2009	006	004	818 - Pain	Likely not related	Likely not related
11-Feb-2009	009	007	699 - Lab/electrolyte Other: Increased INR	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is an 85-year-old Caucasian female with past history of hypertension, hyperlipidemia, coronary artery disease, myocardial infarction, and a cardiac stent placement. Medications at admission included Aspirin and Lopressor.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 13:00, [redacted]-2009. Symptoms at presentation included hemianopsia, slurred speech, left sided weakness with facial palsy, and neglect. CT scan at admission revealed no abnormality. ECG at admission showed atrial fibrillation. Baseline NIHSS was 13.

The subject was randomized to the treatment arm of the SENTIS trial at 19:15, 02-Feb-2009, 6.3 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 21:37, [redacted] 2009 via right arterial groin puncture. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment), the subject continued to have atrial fibrillation with rapid ventricular response **(AE #001)**. Heparin was started on [redacted] 2009 and later changed to Coumadin.

Initial blood glucose level was 159 and increased up to 201 during her hospitalization **(AE #005)**. Regular insulin at sliding scale was started. She did not require insulin after discharge. This event was resolved on [redacted]-2009.

The subject also complained of right knee pain **(AE #002)** due to a fall at the time of the stroke onset. There was no apparent injury to the right knee and the pain was treated with Tylenol and resolved on 1[redacted]-2009.

Also on [redacted]-2009, following the NeuroFlo procedure, a large hematoma **(AE #008)** was noted at the right groin. Right pedal pulse was +1 and a dry dressing was applied. No treatment was given and the hematoma resolved on [redacted] 2009.

On [redacted]-2009 (post enrollment day 1), chest x-ray showed cardiomegaly and pulmonary vascular congestion. Echocardiogram revealed mild pulmonary hypertension and normal left ventricular systolic function with ejection fraction of 60%. Systemic inflammation response syndrome (SIRS) and pulmonary toilet was documented. Chest x-ray on the following day showed bilateral basilar atelectasis/infiltrate with possible pleural effusion **(AE #902).** Urinalysis on the same date showed cloudy and bloody urine with many bacteria **(AE #010)**. A subsequent urine culture was negative and the subject's urine was clear in appearance on the following day.

On [redacted] 2009, the subject was noted as "drowsy but easily awakens" **(SAE #003)**. The 24 hour NIHSS increased to 17. NCT of the brain showed no abnormality. CT perfusion on [redacted] 2009 showed increased time to peak in the right frontoparietal lobe and middle cerebral artery (MCA) distribution. It also showed decreased blood volume and flow that was consistent with completed infarct. The subject's neurological condition gradually improved by [redacted]-2009.

Two dimensional echocardiogram on [redacted]-2009 revealed biatrial enlargement and evidence of right to left intracardiac shunt suggestive of a patent foramen ovale **(AE #901)**.

Also [redacted]-2009, the subject started having hypokalemia with potassium of 3.0 **(AE #006)**. Hypokalemia was treated with potassium supplements until the 30 day follow-up visit.

The 4 day NIHSS on [redacted]-2009 was 16.

On [redacted]-2009 (post enrollment day 5), a nurse noted a golf ball sized hematoma in the subject's supra-pubic area **(AE #009)**. The affected area was dark purple in color and was hard to the touch. The hematoma resolved on its own on [redacted]-2009.

On [redacted]-2009, the subject complained of back pain **(AE #004)** and received Tylenol and Ultram as needed**.**

The subject was discharged from the hospital on [redacted]-2009 to a skilled nursing facility.

On [redacted]-2009 (post enrollment day 9), the subject's INR level was 6.69 (therapeutic range 2.0-3.0) **(AE #007)** and Coumadin was held. One dose of vitamin K was given on [redacted]-2009 and her INR decreased to 2.06 on [redacted]-2009.

The 30 day NIHSS on [redacted]-2009 was ranked as 14, mRS was 4.

At 90 day follow-up visit on [redacted]-2009, the subject remained in a skilled nursing facility. Her 90 day NIHSS was ranked as 12 with mRS of 4. The subject remained on Coumadin for atrial fibrillation and Tylenol for back pain.

Subject [redacted] enrolled [redacted]-2010

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Jan-2010	**000**	**002**	**404 - HT, likely contributing to mass effect**	**Unknown**	**Unknown**
06-Jan-2010	001	001	603 - Electrolyte imbalance	Likely not related	Likely not related
06-Jan-2010	**001**	**003**	**202 - Respiratory failure**	**Likely not related**	**Likely not related**
11-Jan-2010	**006**	**005**	**703 - Venous thrombosis (DVT)**	**Likely not related**	**Likely not related**
11-Jan-2010	006	007	809 - Diabetes Mellitus	Likely not related	Likely not related
11-Jan-2010	006	006	815 - Skin irritation	Likely not related	Likely not related
16-Jan-2010	**011**	**008**	**805 - Sepsis**	**Likely not related**	**Likely not related**
19-Jan-2010	014	901	899 - Other: Decubitus ulcer	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 56-year-old Caucasian male with past medical history of obesity, hypertension, hyperlipidemia, gastroesophageal reflux disease (GERD), arthritis, diabetes mellitus and right knee surgery. Medications at admission included: Mobic, Omeprazole, Simvastatin, Quinapril, Avandia, Glyburide, Hydrocholorothiazide, Metoprolol, and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 00:30, [redacted]-2010. Symptoms at presentation included decreased level of consciousness, global aphasia, complete right-sided hemiparesis with facial palsy, and severe dysarthria. CT scan at admission revealed hypodensity within the left middle cerebral artery (MCA) territory suggestive of a left MCA infarct. A CTA of the head revealed complete occlusion of the M1 segment of the left MCA without evidence of ischemic penumbra. Baseline NIHSS was 17. The subject was randomized to the treatment arm of the SENTIS trial at 07:40, [redacted]-2010, 7.2 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 08:50, [redacted] 2010. Treatment was unremarkable.

Post-Enrollment Course: NCT of the brain performed at 12:42, 0.5 hour post NeuroFlo procedure revealed an evolving left MCA infarct with acute hemorrhage and contrast within the left lenticular striate distribution **(SAE #002)**. This resulted in mass effect on the left lateral ventricle and a 6mm left-to-right midline shift. The 6 hour NIHSS was invalid due to sedation.

On [redacted]-2010 (post enrollment day 1), the subject was hypokalemic with a potassium level of 3.3 (norm 3.5-5.5) **(AE #001)** and was treated with potassium supplements.

The 24 hour NCT scan on [redacted] 2010 showed an evolving left MCA infarct with hemorrhage, mass effect and left cerebral edema with 11mm midline shift **(cont. of SAE #002)**. MRI, MRA, and MR perfusion of the head performed on the same day noted an increased midline shift to 13mm. The 24 hour NIHSS was 16. Mannitol IV was started and Labetalol IV was also given per intracerebral hemorrhage protocol.

The subject was given IV sedation in preparation for a Codman catheter for intracranial pressure (ICP) measurement on [redacted]-2010. He subsequently developed dyspnea and was intubated on the same day for mechanical ventilation support **(SAE #003)**. The subject's arterial blood gas (ABG) was abnormal. Eventually, a tracheostomy tube was placed on [redacted] 2010. The subject was weaned off of mechanical ventilation on [redacted]-2010.

Additionally, the subject had intermittent fever beginning in the evening of 0[redacted]-2010 and a chest x-ray during the emergency room admission revealed interstitial edema. A series of chest x-rays showed mild pulmonary congestion and bilateral infiltrations. On [redacted]-2010 the subject was diagnosed with pneumonia **(part of SAE #003)** and received a series of IV antibiotics. Chest x-ray on [redacted]-2010 showed clear lungs. However, the

subject remained febrile despite administration of IV antibiotics and resolution of the pneumonia.

On 11-Jan-2010 (post enrollment day 5), the blood level of D-dimer was elevated to >20 mcg/mL. A venous Doppler demonstrated deep vein thrombosis (DVT) bilaterally in the lower extremities **(SAE #005)**. An inferior vena cava filter was placed on [redacted]-2010.

The subject's blood glucose at admission was 261 **(AE #007).** The subject remained hyperglycemic subsequent to admission and was placed on an insulin sliding scale, then insulin drip, per stroke protocol, and was later treated with oral medications.

Also during [redacted] 2010, the subject developed a rash involving his arms (posterior surface), axilla, back, buttocks and thighs **(AE #006)** which was treated with hydrocortisone cream and resolved by [redacted]-2010.

NCT scan on [redacted]-2010 showed continued evolution of a large left MCA infarct with a midline shift of 19mm **(cont. of SAE #002)**. The subject's ICP was stable and ICP monitoring was discontinued on [redacted]-2010.

A blood culture on [redacted]-2010 tested positive for gram-positive cocci and the subject had episodes of hypotension and tachycardia. On the following day, the subject's pupils were reactive to light but he was found comatose. He was diagnosed with sepsis **(SAE #008)** and started on IV Cefepime and Vancomycin. On [redacted]-2010, the subject was more alert and looked around spontaneously but was unable to follow any commands. On the following day, the subject opened his eyes to voice and was awake and alert on [redacted]-[redacted]-2010. Per attending neurologist's progress note, sepsis resolved on [redacted] 2010.

On [redacted]-2010, stage I decubitus ulcer **(AE #901)** was found on the subject's right thigh and a dry dressing was applied.

The subject was discharged from the hospital on [redacted]-2010 to a rehabilitation facility.

At the 90 day follow-up visit on [redacted]-2010, the subject's NIHSS was ranked as 17 with mRS of 4. He remained taking oral potassium supplements and daily oral medication for blood glucose control. No further signs or symptoms of DVT were noted.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
02-Apr-2008	000	902	414 - Neurological worsening	Unknown	Unknown
03-Apr-2008	001	001	601 - Anemia	Likely not related	Unknown

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Apr-2008	032	002	603 - Electrolyte imbalance	Likely not related	Likely not related
Unk-Apr-2008		901	811 - Depression	Likely not related	Likely not related
31-May-2008	**059**	**003**	**599 - GI Other: Pancreatitis secondary to biliary sludge**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is an 89-year-old African American female with a past medical history of hypertension, hyperlipidemia, atrial fibrillation, congestive heart failure, coronary artery disease, previous stroke (mRS=0), deep vein thrombosis, diabetes, osteoarthritis, pneumonia, hypothyroidism, gastroesophageal reflux disease, glaucoma, cataracts and senile dementia. Medications at admission included: Metoprolol, Timolol, Travatan, Levothyroxine, Protonix, Glipizide and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 09:30 on [redacted]-2008. Symptoms at presentation included decreased level of consciousness, right arm weakness, facial palsy, sensory loss, severe aphasia, dysarthria, right-sided neglect, hemianopsia and left gaze preference. CT scan at admission revealed no evidence of a new infarct; however, it did show an area of decreased attenuation in the left occipital lobe consistent with an old infarct. A CTA revealed distal occlusion of the left vertebral artery. Baseline NIHSS was 17. The subject was randomized to the treatment arm of the SENTIS trial at 17:00, [redacted] 2008, 7.5 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:25 on [redacted]-2008. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour NIHSS was ranked as 20 due to the increased weakness of the left and right extremities **(AE #902)**.

The 24 hour NIHSS on 0[redacted] 2008 was 18. The 24 hour MRI revealed an acute/subacute infarct of the left medial temporal and occipital lobes which was interpreted as an extension of a prior infarct. These findings were consistent with infarct within the left PCA territory. In addition, four small acute/subacute lacunar infarcts within the bilateral high frontal, parietal and occipital lobes were observed.

The subject's hemoglobin (Hgb) decreased to 8.8 **(AE #001)** from 10.0 at admission. Her Hgb remained low throughout the index hospitalization with no evidence of hematoma or active bleeding. On [redacted] 2008, one unit of packed red blood cells was administered and the subject's Hgb elevated to 9.3 gm/dl.

On [redacted] 2008 (post enrollment day 2), the subject's potassium had dropped to 3.3

(AE #002). Potassium replacement was given per standard protocol and potassium level normalized to 4.4 on the same day. It remained within normal range until discharge.

During the index hospitalization the subject was prescribed Prozac for depression **(AE #901).** The subject continued taking antidepressants through the 90 day follow-up visit.

The subject was discharged from the hospital on [redacted] 2008 to a skilled nursing facility with NIHSS of 12. Since the subject was at risk for future cardioembolic stroke, she was started on Coumadin at the time of discharge.

On [redacted]-2008 (post enrollment day 59), the subject was readmitted to the hospital from home following an episode of nausea, vomiting and altered mental status. She was diagnosed with acute pancreatitis **(SAE #003)** with elevated lipase and liver function tests, secondary to biliary sludge which subsequently resolved. During this admission the subject's Hgb was 11.8. The subject was discharged to home in stable condition on [redacted] 2008.

The 30 day NIHSS on [redacted] 2008 was ranked as 6 with mRS of 4.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
27-Feb-2008	**001**	**001**	**702 - Femoral artery occlusion/ thrombosis**	**Unknown**	**Likely related**
29-Feb-2008	003	002	603 - Electrolyte imbalance	Likely not related	Likely not related
07-Mar-2008	010	003	398 - Urinary Other: Urinary incontinence	Likely not related	Likely not related
05-May-2008	069	004	413 - Headache	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 61-year-old Caucasian female with past medical history of smoking. Medications at admission included Biaxin for pneumonia diagnosed on [redacted] 2008.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 10:30, [redacted]-2008. Symptoms at presentation included decreased level of consciousness, global aphasia, hemianopsia, and right-sided weakness with facial palsy. CT at admission revealed an acute left MCA infarction with no evidence of hemorrhage. Baseline NIHSS was 15. The subject was randomized to the treatment arm of the SENTIS trial at 15:50, [redacted]-2006, 5.3 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:10, [redacted]-2006 via right arterial groin puncture. Treatment was unremarkable. Two thousand units of heparin were administered during the procedure. Limb perfusion was noted to be adequate at the end of the procedure. As per institution standard practice, the sheath was removed 24 hours later, at 10:30 on [redacted] 2008 and hemostasis was achieved with manual compression.

Post-Enrollment Course: On [redacted]-2008 (post enrollment day 1) two hours after sheath removal the right pedal pulses were not palpable or present via Doppler and the extremity was cool to touch **(SAE #001)**, but the subject did not complain of pain. Vascular surgery was consulted and a CTA showed non-occlusive thrombus in the right common femoral artery causing severe stenosis. A repeat NCT ensured there was no bleeding in the brain that would be exacerbated by intra-operative heparin administration and the subject underwent right femoral thrombectomy and arterial repair. Post-operatively the right pedal pulses were palpable and the extremity was warm to touch. The subject's neurologic status remained unchanged after the thrombectomy.

On [redacted]-2008 (post enrollment day 3) the subject's serum potassium level was 2.9 **(AE #002)**. The subject was treated with oral potassium replacement (K-dur) and by [redacted] 2008 her potassium level had normalized.

During the hospitalization the subject was incontinent of urine **(AE #003)**. On 0[redacted]r-2008 the subject's peri-anal area was found to be excoriated from the incontinence and Zinc oxide cream was applied.

The subject was discharged from the hospital on [redacted]-2008.

On[redacted]-2008 (post enrollment day 69) the subject developed a frontal headache with accompanying diplopia **(AE #004)**. The subject took Tylenol 3 and went to the emergency room (ER). By the time she got to the ER, her headache was almost gone. Headache was rated as 7/10 and lasted approximately 2 hours. The subject did not report any additional episodes of headache or diplopia.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Nov-2008	000	002	699 - Lab/electrolyte Other: Euthyroid sick syndrome	Likely not related	Likely not related
05-Nov-2008	**001**	**001**	**118 - Atrial fibrillation with cardioversion**	**Likely not related**	**Likely not related**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Nov-2008	001	003	818 - Pain	Likely not related	Likely not related
05-Nov-2008	001	004	412 - HT, no concomitant mass effect	Likely not related	Unknown

Serious events are in bold, shaded text.

Demographics and History: The subject is a 79-year-old Caucasian female with a past medical history of atrial fibrillation, hyperlipidemia and intraocular lens replacements with chronic dry eyes. She also had a fractured right tibia many years ago. Medications at admission included: Tambocor, Fosamax, Zocor, and eye drops.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:30 on [redacted]-2008. Symptoms at presentation included left-sided weakness with facial droop, severe left neglect, and dysarthria. CT scan at admission revealed no evidence of acute ischemic change. However, CT perfusion suggested an acute infarct in the right hemisphere. Baseline NIHSS was 17. The subject was randomized to the treatment arm of the SENTIS trial at 12:00, [redacted] 2008, 12.5 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 12:44 on [redacted] 008. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour NIHSS decreased to 13. The subject's initial lab work revealed that she had Euthyroid Sick Syndrome **(AE #002)**. An endocrinology consult was obtained but no treatment was given.

On [redacted] 2008 (post enrollment day 1), the subject's electrocardiogram (ECG) showed atrial fibrillation with rapid ventricular response **(SAE #001)**. Cardizem IV and Flecainide were not effective. Amiodarone was begun without improvement. After the transesophageal echocardiogram (TEE) was performed, the decision was made to cardiovert the subject. Cardioversion on [redacted]-2008 was successful and the sinus rhythm went back to normal. Amiodarone continued after discharge from the hospital.

On [redacted]-2008 the subject complained of headache, as well as of bruising and pain of the left and right side **(AE #003)**. She was treated with Tylenol. X-rays of ribs were negative.

NCT and MR scans on [redacted] 2008 revealed petechial hemorrhage **(AE #004)**. No change in the subject's neurological status was observed. Her 24 hour NIHSS remained at 13.

At the 30 day follow-up visit on [redacted]-2008, the subject's NIHSS was 6 with mRS of 4.

The 90 day NIHSS on [redacted]-2009 was 4 and mRS was 3.

Subject [redacted] enrolled [redacted] 2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
27-May-2007	000	901	503 - Nausea/Vomiting	Likely not related	Likely not related
27-May-2007	**000**	**001**	**414 - Neurological worsening**	**Unknown**	**Unknown**
28-May-2007	001	902	204 - Aspiration pneumonia	Likely not related	Likely not related
28-May-2007	001	903	603 - Electrolyte imbalance	Likely not related	Likely not related
Unk-May-2007		904	818 - Pain	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is an 83-year-old African American female with past medical history of hypertension, hyperlipidemia, breast cancer (right mastectomy), and back surgery (lumbar laminectomy). Medications at admission included: Detrol, Cilostazol, Simvastatin and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 02:15, [redacted] 2007. Symptoms at presentation included left arm weakness with facial palsy, sensory loss, gaze palsy, and neglect. CT and CT perfusion scan at admission revealed infarct in the region of right MCA with a penumbra. Baseline NIHSS was 9, although presenting NIHSS on 07:30 was 14. The subject was randomized to the treatment arm of the SENTIS trial at 09:15, [redacted] 2007, 7.0 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 10:35, [redacted] 2007. The subject was sedated with Versed and Fentanyl. The site misinterpreted the treatment time requirements and the balloons were deflated after 36 minutes as the site thought the balloons needed to be completely deflated 45 minutes after initiation of treatment. Zofran was given during and post procedure for complaint of nausea **(AE #901)**.

Post-Enrollment Course: Immediately post NeuroFlo treatment the subject's neurological status remained similar to her pre-treatment neurological status. She was awake but was a bit drowsy secondary to the sedation for the procedure. Prior to her admission to the neuroscience intensive care unit, the subject's neurological status worsened; NIHSS increased to 18 **(SAE #001)**. At 12:25 CT showed an increase in the overall size of the right MCA infarct. Edema was also seen in the infarct on the conventional CT. At 14:15 the NIHSS was 20. The subject's left arm weakness progressed to no movement on the left side.

On [redacted]-2007 (post enrollment day 1) five-day coverage with Rocephin, Clindamycin and Zithromax was started after witnessed aspiration **(AE #902)**. The 24 hour NIHSS was

17 and NCT confirmed acute infarct in the distribution of the right MCA with no evidence of hemorrhage.

During the index hospitalization the subject received potassium chloride, calcium-gluconate, phosphorus, and magnesium sulfate supplements **(AE #903)**. The subject was given Baclofen and Naproxen for her leg pain **(AE #904)**.

The 4 day NIHSS on [redacted]-2007 was ranked as 19. The subject was discharged from the hospital on [redacted]-2007 to an inpatient rehabilitation unit.

No further information is available for this subject. The subject was considered lost to follow-up on [redacted] 2007 after the family requested that no further contact by the site be made.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
18-Dec-2008	**000**	**001**	**414 - Neurological worsening**	**Likely not related**	**Unknown**
18-Dec-2008	000	004	601 - Anemia	Likely not related	Likely not related
19-Dec-2008	001	003	603 - Electrolyte imbalance	Likely not related	Likely not related
22-Dec-2008	004	002	303 - Urinary Tract Infection	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 30-year-old African American female with past medical history of lupus. The subject had a positive cannabis level at admission and reported using cannabis approximately twice a week. Medications at admission included Prednisone.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 01:00, [redacted] 2008. Upon arrival to the emergency room she became confused and agitated. Haldol, Ativan, and a stress dose of steroids were given. Symptoms at presentation included decreased level of consciousness, severe aphasia, sensory loss, slurred speech, partial gaze palsy, left and right-sided drift, facial asymmetry, severe dysarthria and neglect. CT scan at admission revealed an acute left MCA infarct, no hemorrhage. CTA showed left internal carotid artery (ICA) dissection with extensive thromboembolic event to the paraclinoid left ICA as well as left MCA. Baseline NIHSS was 17. The subject was randomized to the treatment arm of the SENTIS trial at 12:25, [redacted] 2008, 11.4 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure with general anesthesia was initiated at 13:25, [redacted]-2008. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour NIHSS at 18:45 worsened to 34 **(SAE #001)** due to the progression of left and right-sided weakness and worsening of aphasia and neglect. The subject's neurological worsening was attributed to the carotid dissection and progression of the left MCA infarct.

The subject's hemoglobin on [redacted]-2008 was 9.7 **(AE #004)**. Oral ferrous sulfate was started on [redacted]-2008; no blood products were given. The subject was asymptomatic and her hemoglobin remained stable. Anemia was attributed to her lupus and steroid use.

On [redacted]-2009 (post enrollment day 1) the subject's magnesium, calcium, phosphorus and potassium values were low **(AE #003)** and were treated with replacements through [redacted] 2008. All electrolytes were within normal limits at discharge.

The 24 hour NIHSS on [redacted]-2009 was 32. NCT showed extensive left hemispheric edema related to the ischemic infarction, left lateral ventricular effacement and mild midline shift; no hemorrhage. On the following day NCT showed increased edema and midline shift **(cont. of SAE #001)** with possible early brainstem compression; no hemorrhage. The 4 day NIHSS on [redacted]-2008 decreased to 10.

On [redacted]-2008 the subject was positive for urinary tract infection **(AE #002)** and a seven-day course of Ciprofloxacin was started.

The subject was discharged from the hospital on [redacted] 2008 to home.

The 30 day NIHSS on 1[redacted] 2009 was ranked as 7 with mRS of 3.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Sep-2009	000	002	809 - Diabetes Mellitus	Likely not related	Likely not related
06-Sep-2009	001	001	118 - Atrial Fibrillation	Likely not related	Likely not related
06-Sep-2009	001	006	108 - Congestive Heart Failure	Likely not related	Likely not related
08-Sep-2009	003	003	603 - Electrolyte imbalance	Likely not related	Likely not related
08-Sep-2009	**003**	**004**	**414 - Neurological worsening**	**Unknown**	**Unknown**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
09-Sep-209	004	011	116 - Bradycardia	Likely not related	Likely not related
16-Sep-2009	011	901	399 - Renal Other: Adrenal mass	Likely not related	Likely not related
16-Sep-2009	011	007	599 - GI Other: Bleeding post PEG tube insertion	Likely not related	Likely not related
19-Sep-2009	014	012	814 - Sleeping Disturbance/ Disorder	Likely not related	Likely not related
20-Sep-2009	**015**	**008**	**805 - Sepsis**	**Likely not related**	**Likely not related**
20-Sep-2009	015	013	811 - Depression	Likely not related	Likely not related
21-Sep-2009	016	009	601 - Anemia	Likely not related	Likely not related
21-Sep-2009	**016**	**902**	**799 - Vascular Other: Phlebitis**	**Likely not related**	**Likely not related**
29-Sep-2009	**024**	**010**	**599 - GI Other: Abscess at the PEG site**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 68-year-old African American female with past medical history of hypertension, hyperlipidemia, hypothyroidism, atrial fibrillation, heart failure, non-insulin dependent diabetes, and obesity. She had a hysterectomy, hemicolectomy related to rectal fistula occurred after hysterectomy, and a colostomy with reversal. Medications at admission included: Synthroid, Carvedilol, Metformin, Aldactone and Novolin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 13:30 on [redacted]-2009. Symptoms at presentation included decreased sensation on the left side, partial hemianopsia, slurred speech, left-sided facial droop and neglect. Bilateral crackles in the lungs were noted. In the emergency department the subject was treated with Albuterol and Atrovent inhalation and later IV Solumedrol for recurrent shortness of breath and dyspnea. CT scan at admission revealed hyperdense sign in right MCA without acute findings. Baseline NIHSS was 7. The subject was randomized to the treatment arm of the SENTIS trial at 22:09, [redacted] 2009, 8.7 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated on [redacted]-2009, at 00:15 with the 7 French catheter but the instructions for the 9 French catheter were used to determine the target volume calculations. The subject's blood pressure (BP) was 187/130 at the time of admission. It remained elevated despite multiple doses of IV Labetalol. Fifteen minutes into the NeuroFlo procedure, miscalculation of the target values was realized and in conjunction with the subject's elevated systemic BP, the NeuroFlo procedure was aborted.

Post-Enrollment Course: The 6 hour NIHSS decreased to 4.

The subject was noted to have fluctuations of elevated blood glucose **(AE #002)** and a medical consult was called for diabetes management. A new medication and a sliding scale insulin therapy were initiated**.**

On [redacted]009 (post enrollment day 1), the subject developed an episode of atrial fibrillation **(AE #001)** that required significant medication changes. The subject also had an acute episode of congestive heart failure **(AE #006)**. A chest x-ray demonstrated moderate pulmonary vascular congestion with a superimposed right basilar infiltrate. The subject's brain natriuretic peptide (BNP) was elevated at 395.37 (norm 0-100). Echocardiogram revealed an enlarged left atrium with reduced left ventricular function. Left ventricular ejection fraction was estimated at 40-50% and a moderate pulmonary hypertension was also noted. Antibiotics, inhalers and steroids were administered with an improvement.

The 24 hours NIHSS on [redacted]2009 was 3. The 24 hour MRI of the brain revealed small acute multifocal infarcts in the upper MCA territory. MRA noted sclerotic right ICA and probable occluded right MCA. The subject failed several swallowing tests and a naso-gastric (NG) tube was placed for medication administration and feeding.

On [redacted]-2009 (post enrollment day 3), the subject's potassium level dropped to 3.4 **(AE #003)** from 3.8 at baseline. Following a supplement administration, potassium level returned to baseline and remained stable with the supplements.

On [redacted]-2009 the subject had an increased left-sided weakness **(SAE #004)**. The 4 day NIHSS on [redacted]-2009 increased to 8. CTA demonstrated occluded mid to distal M1 segment of the right MCA. The repeat CT revealed "no acute hemorrhage or mass effect." Also on [redacted]2009, subject complained of increased shortness of breath and a non-productive cough. Chest x-ray showed cardiomegaly with resolution of prior right lower lobe infiltrate. Also noted was obscured left costophrenic angle due to pleural effusion and/or the enlarged left ventricle.

On the same day, the subject was noted to be bradycardic **(AE #011).** Her bradycardia was thought to be related to obstructive sleep apnea. The subject was treated with medication and with continuous positive airway pressure (CPAP), which was later discontinued. The subject's bradycardia improved but continued intermittently.

On [redacted]-2009, there was a suspicion of the subject's continued decline in mental status and function **(cont. of SAE #004)**. A head CT revealed "increased low density involving right MCA territory infarcts and no acute intracranial hemorrhage, edema or mass-effect".

On [redacted]-2009 (post enrollment day 11), a CT of the abdomen and pelvis was done prior to the percutaneous endoscopic gastrostomy (PEG) tube placement. A large left lower quadrant ventral hernia (most likely related to the subject's past abdominal surgical procedures) containing most of the hemicolon was observed. An incidental finding was a

2 cm left adrenal mass **(AE #901)**. The radiologist indicated that the mass "did not characterize as benign" but a follow-up to determine etiology was recommended. No further evaluation of adrenal mass was documented.

Following the PEG tube placement on [redacted]009, a bleeding **(AE #007)** was noted from the tube insertion site and a D-stat patch was placed for hemostasis.

The subject was discharged from the hospital on [redacted]-2009 to the acute rehabilitation unit with prescription of Zolpidem for insomnia **(AE #012)**.

On [redacted]-2009 (post enrollment day 15) the subject was re-admitted to the intensive care unit with hypotension, atrial fibrillation, fever, urosepsis and possible pneumonia. The chest x-ray showed an infiltrate and the urinalysis showed "too many white cells to count". Urine culture was positive for Klebsiella Pneumoniae. Diagnosis of sepsis **(SAE #008)** was made. Treatment included multiple antibiotics and adjustment of antihypertensive medications.

On [redacted]2009 the subject was prescribed Trazadone for depression **(AE #013).**

On [redacted]-2009, the subject's hemoglobin and hematocrit were 9.3 and 28.4, respectively **(AE #009),** and iron supplementation was initiated.

On [redacted]2009, the subject developed tenderness in her left calf. A Duplex scan revealed left calf vein phlebitis **(SAE #902)** that required placement of an inferior vena cava (IVC) filter on [redacted]2009. A follow-up Duplex scan on [redacted]2009 showed no evidence of thrombus or phlebitis.

On [redacted]-2009, more bleeding was noted from the PEG insertion site **(cont of AE #007).** The subject was discharged back to the acute rehabilitation unit on [redacted]-2009.

On [redacted]2009, the infectious disease physician noted an induration and brown drainage from the PEG site. An abdominal CT scan showed that the PEG tube was malpositioned in the abdominal soft tissue and there was an abscess at the site **(SAE #010)**. Because of the elevated INR, the PEG tube removal was postponed until [redacted]2009. Drainage cultures revealed Klebsiella pseudomonas and Enterococcus. A fistulogram on [redacted] 2009 demonstrated a gastrocutaneous fistula, which was most likely related to the subject's past abdominal surgical procedures.

At the 30 day follow-up on [redacted]-2009, the subject's NIHSS was 8 and mRS was 5. On the following day, a new gastrostomy tube was placed in the stomach through the existing fistula tract. The subject was discharged from acute rehab on [redacted]-2009 to a subacute facility.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
15-Feb-2008	004	001	813 - Fall	Likely not related	Likely not related
17-Feb-2008	006	901	405 - HT, probably not contributing to mass effect	Likely not related	Likely not related
17-Mar-2008	**035**	**002**	**205 - Infectious pneumonia**	**Likely not related**	**Likely not related**
28-Mar-2008	**046**	**003**	**108 - Congestive Heart Failure**	**Likely not related**	**Likely not related**
Unk-Mar-2008		004	601 - Anemia	Likely not related	Likely not related
Unk-Mar-2008		005	899 - Other: Erythema	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: This subject is a 73-year-old Caucasian male with a past medical history of congestive heart failure, quadruple bypass 17 years ago, two myocardial infarctions, biventricular defibrillator/pacemaker, left carotid endarterectomy, hyperlipidemia, surgical removal of kidney stones and a tendon surgery on the left hand. Medications at admission included: Aspirin, Coreg, Ensure, Amiodarone, Colace, Lasix, potassium and iron supplements.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 13:00 on [redacted] 2008. Symptoms at presentation included hemianopsia, left-sided weakness with facial droop, sensory loss, and neglect. CT scan at admission revealed focal hypodensity involving the right frontal lobe and basal ganglia. Baseline NIHSS was 12. The subject was randomized to the treatment arm of the SENTIS trial at 20:50, [redacted] 2008, 7.6 hours from last known normal.

At the time of enrollment, the subject was not in heart failure. Previous medical records indicating ejection fraction (EF) of 10-29% became available at the later time. An echocardiogram on [redacted]-2008 demonstrated an EF of 10%.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 21:50 on [redacted]-2008. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour and 24 hour NIHSS were both ranked as 11.

While hospitalized, the subject had an unwitnessed fall **(AE #001).** No injuries resulted from this event.

The 24 hour CT on [redacted]-2008 confirmed a large acute infarct in right MCA territory with mild mass effect and a possible petechial hemorrhage. No hemorrhagic transformation was seen on subsequent NCT scans dated [redacted]-2008 and [redacted]-2008.

Petechial hemorrhage was identified by Core Lab on NCT scan dated [redacted] 2008 **(AE #901)**. The 4 day NIHSS was ranked as 8.

The subject was discharged from the hospital on [redacted] b-2008 to rehab.

At the 30 day follow-up visit on [redacted] -2008, the subject's NIHSS was 6 and mRS was 3.

On [redacted] -2008 (post enrollment day 35), the subject was hospitalized with infectious pneumonia **(SAE #002)**. He was treated with antibiotics, fluids and breathing treatments.

On [redacted] -2008, the subject complained of acute shortness of breath. Chest x-ray showed congestive heart failure **(SAE #003)** and pulmonary edema. The subject was treated with diuretics, Morphine, Dobutamine and his Carvedilol was titrated up.

During that hospitalization, the subject received a transfusion for anemia **(AE #004)**, but the complete records were not made available for the study. The subject was also noted to have a small erythema **(AE #005)** on his buttock at discharge and was given an ointment to treat it. He was discharged in stable condition on [redacted] 2008 to rehab.

The 90 day NIHSS on [redacted] -2008 was ranked as 8 with mRS of 2.

Subject [redacted], enrolled [redacted] -2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
24-Apr-2009	000	901	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
24-Apr-2009	000	005	812 - Fever	Likely not related	Likely not related
25-Apr-2009	**001**	**001**	**414 - Neurological worsening**	**Likely not related**	**Unknown**
27-Apr-2009	003	002	809 - Diabetes Mellitus	Likely not related	Likely not related
27-Apr-2009	003	003	603 - Electrolyte imbalance	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 61-year-old Caucasian female with a past medical history of hypertension, chronic hearing loss, arthritis and a right knee replacement. The subject was not taking medications at the time of admission.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 06:00 on [redacted] -2009. She presented to an outside facility with blood pressure (BP) of 218/130. A Nicardipine drip improved her BP to 175/105 and the subject was transferred

to the index hospital for further treatment. Symptoms at presentation included confusion, severe aphasia, partial hemianopsia, facial palsy and neglect. CTA and CT perfusion scan at admission revealed ischemic penumbra in the left posterior MCA distribution as well as partial occlusion or early recanalization of a left M2 branch. Baseline NIHSS was 7. The subject was randomized to the treatment arm of the SENTIS trial at 17:02, [redacted]-2009, 11.0 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:21, [redacted] 2009. There were no complications during the procedure.

Post-Enrollment Course: On [redacted] 2009 (day of enrollment), the subject's lipid profile was mildly elevated **(AE #901)** and treatment with Atorvastatin was initiated. The subject also had a fever **(AE #005)** and received one dose of Acetaminophen.

On [redacted]-2009 (post enrollment day 1) at 22:30, the subject was weaker on the right side and her aphasia was more prominent than earlier in the day **(SAE #001)**. Her 24 hour NIHSS increased to 13. NCT scan revealed new evidence of a patchy, subcortical area of acute ischemic infarct in the left posterior MCA territory but no hemorrhage. On the following day the subject was not following commands, had global aphasia and left hemiparesis. Her NIHSS was assessed as 20 by a neurology resident. MRA showed a near complete occlusion of a posterior branch of the left MCA. Her NIHSS was later assessed as 15 by the neurologist.

On [redacted]-2009 (post enrollment day 3), the subject's blood glucose level was elevated **(AE #002)**. She had no history of diabetes, so an endocrinology consult was obtained and Metformin was started. The subject's serum potassium was noted to be low **(AE #003)** and was corrected with oral potassium supplements.

The subject was discharged from the hospital to a rehabilitation facility in stable condition on [redacted]-2009.

At the 30 day follow-up visit on [redacted]-2009, the subject's NIHSS was 12 and mRS was 4.

The 90 day NIHSS on [redacted]-2009 was ranked as 9 with mRS of 4.

Subject [redacted] enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Aug-2008	**000**	**001**	**105 - Pulmonary Edema**	**Unknown**	**Likely related**
06-Aug-2008	001	003	503 - Nausea/Vomiting	Likely not related	Likely not related

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
06-Aug-2008	001	004	504 - GI Motility Disorders	Likely not related	Likely not related
08-Aug-2008	003	901	413 - Headache	Likely not related	Likely not related
08-Aug-2008	003	905	403 - Cerebral Edema	Unknown	Unknown
12-Aug-2008	007	002	405 - HT, probably not contributing to mass effect	Likely not related	Likely not related
15-Aug-2008	010	902	603 - Electrolyte imbalance	Likely not related	Likely not related
26-Aug-2008	**021**	**005**	**108 - Congestive Heart Failure**	**Likely not related**	**Likely not related**
Unk-Sep-2008		903	499 - Neuro Other: Spasticity	Likely not related	Likely not related
Unk-Sep-2008		904	811 - Depression	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 52-year-old Caucasian male with a past medical history of insulin dependent diabetes mellitus, hypertension, hyperlipidemia, obesity, severe diffuse small vessel disease (2004) not amenable to revascularization, unstable angina with non-ST-elevation myocardial infarction (MI) (May and Jun-2008), percutaneous transluminal coronary angiogram with stent placement (Jun-2008), peripheral artery occlusive disease with ongoing right lower extremity claudication and lower extremity bypass surgery, rheumatic fever, and left ankle fracture. Medication at admission included: Aspirin, Actos, Atarax, Pletal, Lantus, Lexapro, Lisinopril, Metoprolol, NovoLog, Plavix, Crestor, and Ranexa.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 15:00, [redacted]-2008. Symptoms at presentation included left hemiplegia, slurred speech, drowsiness, and deviated eyes to the right. CT scan at admission revealed hyper-attenuation of the distal branches of the right MCA which suggested acute thrombosis. There was no definite change in brain parenchyma, no mass effect or hemorrhage. MR showed occlusion of the right MCA and stenosis of the proximal right PCA. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 21:10, [redacted]-2008, 6.2 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 22:23, [redacted]2008. Approximately 30 min into the NeuroFlo procedure, the subject developed significant shortness of breath, hypertension, and tachycardia. The NeuroFlo balloons were slowly deflated and the subject's head was elevated. He was given Labetalol and Lasix IV with significant improvement. At that point, the treating physician and the cardiac interventionalist felt that it was safe to continue with the NeuroFlo procedure. However, near completion of the procedure and prior to the device removal, the subject experienced another episode of shortness of breath and tachycardia. Prior to the sheath removal, an

arteriogram revealed a markedly elevated left ventricular and diastolic pressure and a diagnosis of flash pulmonary edema (SAE #001) was made. The subject was placed on bi-level positive airway pressure (Bi-PAP) and given additional Lasix, Labetalol, and Apresoline. During the both episodes the subject had no chest discomfort or electrocardiogram (ECG) changes.

Post-Enrollment Course: Post NeuroFlo procedure serial cardiac enzymes were normal with elevated troponins of 0.77, 0.91, and 0.80 (norm < 0.06). ECG demonstrated normal sinus rhythm with left axis deviation. The subject's diastolic dysfunction was felt to be most likely exacerbated by hypertension and tachycardia from stress of the situation and procedure.

The 24 hour CT scan on [redacted] 2008 revealed acute infarct of the right MCA territory with mild mass effect. Bilateral carotid duplex ultrasound showed significant high grade stenosis of the external carotid arteries. The 24 hour NIHSS was 16.

Echocardiogram on [redacted] 2008 demonstrated severely impaired left ventricular systolic function with ejection fraction of 25-30%. The subject's dyspnea, blood pressure, and heart rate had improved. The Bi-PAP was discontinued and oxygen was given via nasal cannula. The subject complained of nausea **(AE #003)** that resolved with Zofran IV. The subject also complained of constipation **(AE #004)** and was treated with Senekot, Maalox, and lactulose enema as needed.

On [redacted] -2008 (post enrollment day 3), the subject complained of right temple headache and neck pain **(AE #901)** and was treated with Morphine. His headache with occasional neck pain continued until discharge. MRA showed recanalization of the right MCA and stenosis of both major branches of the right MCA distal to the bifurcation. MRI demonstrated 7mm right to left midline shift **(AE #905)** in the right MCA infarcted territory. The 4 day NIHSS on [redacted] -2008 remained at 16.

On [redacted] 2008 (post enrollment day 6), the subject complained of shortness of breath, had a fever of 101°F and elevated white cell count. He received antibiotics IV and was afebrile by the next day. Serial chest x-rays revealed questionable congestive heart failure and a small bilateral pleural effusion. Pulmonary consultation recommended continuing with Lasix.

CT scan on [redacted] 008 showed increased demarcation of the right MCA infarct. Hemorrhagic transformation **(AE #002)** was now present within the infarcted area. Also noted were leftward subfalcine herniation, which was significantly worse than before, and a diffuse right cerebral edema. A probable new area of infarction involving the anterior aspect of the corpus callosum was also documented. CT scan on [redacted] -2008 revealed that the hemorrhagic transformation and herniation was slightly worse (14 mm) than the day before. A repeat CT scan showed further progression of herniation. Subarachnoid blood was noted in the right sylvian fissure and in the cerebral cortical sulci.

Starting on [redacted] 2008 (post enrollment day 10), the subject received intermittent potassium replacements for a borderline potassium level **(AE #902)**. The subject continued on a potassium replacement through the 30 day follow-up visit.

CT scan on [redacted]-2008 suggested new, small, more focal areas of hemorrhage in the right parietal lobe **(cont. of AE #002)**. The left midline shift was less pronounced. CT on [redacted]-2008 showed no significant change.

The subject was discharged from the hospital on [redacted]-2008 to a rehabilitation facility.

On [redacted]-2008 (post enrollment day 21), the subject complained of chest pain and was admitted to the hospital. Cardiac enzymes were negative and a diagnostic cardiac catheterization was performed. A diagnosis of congestive heart failure **(SAE #005)** was made. The subject required intra-arterial pump support from [redacted]-2008 to [redacted] 2008. He was discharged from the hospital on [redacted]-2009 to a rehabilitation facility in stable condition.

On [redacted] 2008 (post enrollment day 30), the subject was readmitted to the hospital with chest pain and shortness of breath. Cardiac enzymes were negative for acute MI and his symptoms were attributed to the congestive heart failure **(cont. of SAE #005)**. The subject was discharged back to the rehabilitation facility on [redacted] 2008.

His 30 day NIHSS on [redacted] 2008 was ranked as 14 with mRS of 5. At the time of the 30 day follow-up visit, the subject was noted to be taking Baclofen for spasticity **(AE #903)** and Seroquel for depression **(AE #904)**.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
02-May-2008	029	901	814 - Sleeping Disturbance/ Disorder	Likely not related	Likely not related
24-Jun-2008	**082**	**001**	**407 - Seizure**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is an 83-year-old Caucasian female with a history of coronary artery disease, heart failure with ejection fraction of 20% (CoAxia waiver obtained), atrial fibrillation, valvular disease, moderate to severe pulmonary hypertension, hyperlipidemia, depression, dementia, and hysterectomy (40 years ago). Medications at admission included: Coumadin, Mirtazapine, Aricept, Digoxin, Lipitor, Lisinopril, Aspirin, Namenda and Ciprofloxin for a recent diagnosis of urinary tract infection.

On [redacted]-2008 (6 days prior to the stroke onset), the subject was admitted to the hospital for severe depression and non-specific chest pain.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 11:00, [redacted] 2008, while inpatient. Symptoms at presentation included confusion, right hemiplegia with facial palsy, sensory loss, severe aphasia and dysarthria. CT scan revealed multiple chronic infarctions in the left cerebellum and left basal ganglia as well as a 1.6 cm calcified right frontal meningioma. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 13:30, [redacted] 2008, 2.5 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 14:12, [redacted] 2008. Treatment was unremarkable with the exception of the difficulty with securing the NeuroFlo catheter during the procedure and the infrarenal balloon rupture (captured as field experience report) while deflating the balloon at the end of the procedure.

Post-Enrollment Course: The subject had an unremarkable hospital course and was discharged to a rehabilitation facility on [redacted]-2008.

At the 30 day follow-up visit on [redacted]-2008 the subject was given a prescription for Restoril for sleep disturbance **(AE #901)**. The subject continued taking Restoril through the 90 day follow-up visit.

On [redacted] 2008 (post enrollment day 82) the subject presented to the emergency room with right-sided focal motor seizures **(SAE #001)** that lasted for five hours and was treated with Ativan and Dilantin. Another seizure occurred after admission. NCT demonstrated prior known infarct and right meningioma, but no acute changes or hemorrhage. Electrocardiogram was negative for any ST-T changes. Routine electroencephalogram did not reveal status epilepticus and the seizure was determined to be caused by residual effects of the stroke.

Subject [redacted], enrolled on [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
31-Dec-2007	**001**	**001**	**414 - Neurological worsening**	**Likely not related**	**Likely not related**
01-Jan-2008	002	002	603 - Electrolyte imbalance	Likely not related	Likely not related
13-Jan-2008	014	003	811 - Depression	Likely not related	Likely not related

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-Jan-2008	015	004	303 - Urinary Tract Infection	Likely not related	Likely not related
23-Jan-2008	024	005	499 - Neuro Other: Muscle spasms	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 74 year-old Caucasian female with a past medical history of esophageal reflux disease and hiatal hernia repair. Medications at admission included Prevacid.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 12:30 on [redacted]-2007. Symptoms at presentation included disorientation, right-sided weakness with facial palsy, severe aphasia and dysarthria. CT scan at admission revealed no acute findings. CTA showed occlusion of the left distal ICA with a left MCA anterior segment occlusion. Baseline NIHSS was 13. The subject was randomized to the treatment arm of the SENTIS trial at 19:10, [redacted]-2007, 6.7 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated on [redacted]-2007 at 19:45. Treatment was unremarkable.

Post-Enrollment Course: The subject's neurological status initially improved, however, at the 6 hour follow-up, his NIHSS was ranked as 20 **(SAE #001)** due to the decreased level of consciousness and increase of the right-sided weakness. CT scans at 17 and 30 hours post-enrollment showed an evolving left MCA infarct without hemorrhagic transformation. The 24 hour NIHSS remained at 20.

On [redacted] 2008 (post enrollment day 2), the subject's serum potassium was low **(AE #002)** and supplemental replacements were given.

The subject's 4 day NIHSS on [redacted]-2009 was ranked as 23. She was transferred from the hospital to a rehabilitation facility on [redacted]-2008.

On [redacted] 2008 (post enrollment day 14), the subject was treated for depression **(AE #003)**. On the following day, a urinary tract infection **(AE #004)** was noted and treated with antibiotics.

On [redacted] 2008 (post enrollment day 24), the subject received treatment for muscle spasms **(AE #005).**

At the 30 day follow-up visit on [redacted]-2008, the subject's NIHSS was 18, and mRS was 4.

The 90 day NIHSS on [redacted] 2008 was ranked as 15 with mRS of 4.

Subject [redacted], enrolled [redacted]009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
01-Dec-2009	000	901	818 - Pain	Likely not related	Likely related
01-Dec-2009	000	902	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
28-Dec-2009	027	001	814 - Sleeping Disturbance/ Disorder	Likely not related	Likely not related
28-Dec-2009	027	002	504 - GI Motility Disorders	Likely not related	Likely not related
03-Jan-2010	033	903	806 - Agitation/Excitation	Likely not related	Likely not related
24-Jan-2010	**054**	**003**	**207 - Pulmonary embolism**	**Unknown**	**Unknown**
24-Jan-2010	054	904	703 - Venous Thrombosis (DVT)	Unknown	Unknown

Serious events are in bold, shaded text.

Demographics and History: The subject is an 80-year-old Caucasian female with past medical history of hypertension, hyperlipidemia and arthritis. Medications at admission included: AsaFlow, Omnibionta, Amlor, Tritace, Fraxiparin, Alvityl and Venoruton.

Current Stroke Onset and SENTIS Enrollment: On [redacted]2009 the subject fell and was admitted to the geriatric unit with dizziness, nausea, vomiting, and general decline. Motilium and Litican were given for vomiting and Augmentin was started for a tentative diagnosis of gastroenteritis. The subject experienced sudden onset of stroke symptom at 22:00 on [redacted]-2009. Stroke symptoms included left hemiplegia with facial palsy, sensory loss and dysarthria. CT scan revealed a few hypodensities in the pons and brainstem (possibly artifact) and old small lacunar infarcts. Baseline NIHSS was 11. The subject was randomized to the treatment arm of the SENTIS trial at 10:50, [redacted]2009, 12.8 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 11:39, [redacted]2009. The site personnel had difficulty placing the 7 Fr NeuroFlo catheter through a 7 Fr sheath and replaced it with a 9 Fr sheath. The treatment was unremarkable except for an accidental detachment of the inflation apparatus right after the suprarenal balloon inflation. The inflation apparatus was corrected and suprarenal balloon was inflated to the correct pressure. Zofran was given for the subject's ongoing nausea during the procedure. Perfusalgan was administered 30 min into the procedure due to orthopedic pain **(AE #901)** caused by the subject lying flat on her back.

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) Lipitor was initiated for the subject's total cholesterol of 227 and low-density lipoprotein of 113 **(AE #902).**

The 24 hour MRI on [redacted]2009 revealed hyperdensity in the right posterior basal ganglia that was compatible with recent ischemia. MRA showed multiple small focal and

elongated occlusions in the posterior cerebral arteries and multiple small occlusions in the distal aspect of the middle cerebral artery.

The subject was discharged from the hospital on [redacted] 2009 to a rehabilitation unit within the same hospital.

On [redacted]-2009 (post enrollment day 27) the subject complained of insomnia **(AE #001)** and Temesta was started. The subject also complained of obstipation **(AE #002)** and was treated with Movicol.

On [redacted] 2010 (post enrollment day 33) Dogmatil was started for agitation **(AE #903)**.

On [redacted]-2010 (post enrollment day 54) the subject complained of sudden dyspnea and was transferred from rehab to the emergency room. Chest x-ray and CT showed multiple lung emboli and retro-obstructive pleuropneumonic density **(SAE #003)**. Duplex of lower extremities showed bilateral deep vein thrombosis **(AE #904)**. Fraxodi and Marevan were initiated. The subject was transferred back to the rehabilitation facility on [redacted]-2010.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Dec-2008	**000**	**904**	**899 - Other: Hip fracture with surgical repair**	**Likely not related**	**Likely not related**
04-Dec-2008	000	003	799 - Vascular Other: Popliteal trifurcation thrombosis	Unknown	Likely related
05-Dec-2008	001	001	701 - Hematoma	Unknown	Likely related
06-Dec-2008	002	901	117 - Tachycardia	Likely not related	Likely not related
09-Dec-2008	**005**	**004**	**601 - Anemia**	**Likely not related**	**Unknown**
15-Dec-2008	015	902	299 - Pulmonary Other: Exacerbation of asthma	Likely not related	Likely not related
Unk-Dec-2008		903	303 - Urinary Tract Infection	Likely not related	Likely not related
07-Feb-2009	065	007	303 - Urinary Tract Infection	Likely not related	Likely not related
12-Mar-2009	**098**	**006**	**299 - Pulmonary Other: COPD exacerbation**	**Likely not related**	**Likely not related**
22-Mar-2009	108	005	117 - Tachycardia	Likely not related	Likely not related

Serious events are in bold, shaded text

Demographics and History: The subject is an 83-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, angina, asthma, resection of benign breast tumor and lip tumor, appendectomy, and cholecystectomy. Medications at

admission included: Aldactezine, Hypan, Omeprazole, Lipanthyl, Betahistine, Coruno, and Lorazepam.

Current Stroke Onset and SENTIS Enrollment: On [redacted] 2008 the subject fell and was admitted to the hospital. She had large hematomas on both thighs. The right leg was visibly shorter and the left leg was found to have decreased pedal pulses. The subject was diagnosed with pertrochanteric fracture of her right hip **(SAE #904)**.

The subject experienced stroke symptom onset at 15:00 on [redacted]-2008. Symptoms at stoke onset included confusion, severe aphasia and dysarthria. CT scan revealed no acute processes or bleeds. MRI demonstrated multiple small vascular lesions and one acute lesion in the left peri-occipital lobe. Baseline NIHSS was 6. The subject was randomized to the treatment arm of the SENTIS trial at 19:30, [redacted]-2008, 4.5 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 20:38, [redacted]-2008 via left groin arterial puncture. The site personnel called CoAxia and received a waiver to include the subject in the study with suprarenal (SR) aortic diameter measuring 28.7mm at 6cm (outside of the inclusion range). The site personnel was advised to lower the position of the SR balloon to where the aortic diameter was approximately 24mm.
As a result, the infrarenal (IR) balloon was positioned lower as well; however, it was above the bifurcation so when both balloons were inflated no vessels were at risk for being occluded.

At the time of the SR balloon inflation, the catheter was kinking between the balloons. The aorta was convexly shaped, causing the balloons to be on the opposite ends of a "C" and "pulsing and coming closer together" with the subject's heart beats. The catheter was found to be very pliable and unstable, hard to keep at the level of the renal arteries, whipping back and forth in the aorta and threatening to kink off. Opting to measure pressure, the treating physician inserted a guide wire and then an Amplatz wire, and reportedly that helped somewhat.

The catheter was also kinking distally and it was difficult to keep in place. The subject was noted to have increase in blood pressures; however, they were within the guidelines throughout the procedure and did not require additional medications. CoAxia personnel was consulted and instructed the treating physician to proceed with the treatment for 40 min, while continuing carefully monitoring the subject's systemic pressures and pedal pulses.

Almost 40 min of treatment was delivered, upon which the SR balloon was deflated without an issue. However, when the IR balloon was deflated, blood in the endoflater was found (possible cause could be balloon rupture). The treating physician was able to remove the device from the introducer without an issue, and performed manual compression for 40 min. Because of the "dancing" of the balloons in the aorta, the treating physician performed another aortogram which was normal.

The subject's pedal pulses were present throughout the procedure. At the end of the procedure, the subject's pedal pulse was absent on the left (NeuroFlo) side. An angiogram revealed an embolus in the trifurcation of the popliteal artery **(AE #003)**. With the first sheath in place, another puncture was performed antegrade through the femoral artery and the embolus was aspirated, after which the pedal pulse returned. When both sheaths were removed, the pedal pulses decreased somewhat but remained clinically acceptable. It was felt that a residual thrombus dislodged and settled between the sheaths. The subject also received a bolus of heparin during the procedure. The extracted thrombus (two bloody pieces of approx. 0.4cm by 1.0 to 1.4cm) was sent to Pathology. The thrombus was determined to be the coagulation type with infiltrations by granulocytes, and with no macrophage invasion and no fibrin formation.

Post-Enrollment Course: On [redacted] 2008 (post enrollment day 1) a hematoma **(AE #001)** was noted at the arterial puncture site. That same day the subject underwent a successful surgical repair of the pertrochanteric fracture of her right hip **(update SAE #904)**.

On [redacted]-2008 slightly irregular tachycardia **(AE #901)** was noted and treated with a beta-blocker.

On [redacted] 2008 (post enrollment day 5) the subject was dyspneic and anemic **(SAE #004)**. Two units of blood were transfused.

On [redacted]-2008 steroids were started due to the poor control of the subject's asthma **(AE #902)**.

The subject was diagnosed with a urinary tract infection (UTI) **(AE #903)** and was treated with antibiotics. Onset date was not identified but the antibiotics were taken until [redacted]-2008.

The subject was discharged from the hospital on [redacted] 2008.

On [redacted]-2009 (post enrollment day 65) the subject developed a UTI **(AE #007)** which was treated with Ciprofloxacin.

On [redacted] 2009 (post enrollment day 98) the subject was admitted with dyspnea, tachycardia, and bilateral chest crepitations and wheezing. Exacerbation of chronic obstructive pulmonary disease **(SAE #006)** was diagnosed and antibiotics were started.

On [redacted] 2009 (post enrollment day 108) tachycardia **(AE #005)** was noted and treated with a beta-blocker.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Apr-2009	**002**	**001**	**414 - Neurological worsening**	**Likely not related**	**Likely not related**
24-Apr-2009	009	901	818 - Pain	Likely not related	Likely not related
27-Apr-2009	012	002	204 - Aspiration pneumonia	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 79-year-old Caucasian male with past medical history of stroke (mRS=1), transient ischemic attack (TIA), carotid endarterectomy (1989 and 1999), peripheral vascular disease, hyperlipidemia, interstitial lung disease, pneumonia (1999), pyelonephritis, prostate cancer status post prostatectomy (1999), and rheumatoid arthritis (2008).

The subject reported a general decline in health (sweating, increased sleepiness and fatigue) since Dec-2008. In Mar-2009 he was admitted for recurrent syncopal episodes of unclear origin. He had fallen 3 times in 3 weeks and had fractured his left clavicle and left 4th rib. Extensive testing was inconclusive, although, an incidental finding of almost total occlusion of the right ICA was made (no plan for treatment was noted). During that admission the subject had increased glucose levels (no diagnosis of diabetes) and increased dyspnea. C-reactive protein (CRP) was elevated at 2.7. CT revealed old focal ischemic injuries.

On [redacted]-2009 the subject was admitted to the hospital with left-sided weakness and vertigo. Bilateral wheezing was noted and a chest x-ray showed bilateral diffuse increased lung trauma. The subject had bilateral malleolar edema and no pedal pulse in his left foot. CT showed subcortical atrophy and chronic vascular changes and no hemorrhage. His neurological exam was essentially normal and a working diagnosis of intermittent paralysis of the left arm (TIA's) and claudication of the left leg was made. Carotid Doppler on [redacted] 2009 showed diffuse plaques and no flow in the right common, internal, and external carotid arteries. Small plaques were noted in the bifurcation of the left ICA with normal flow. Medications at admission included: Plavix, Simvastatin, Methotrexate, and Prednisolone.

Current Stroke Onset and SENTIS Enrollment: The subject experienced sudden stroke symptom onset at 18:00 on [redacted] 2009, while inpatient. Symptoms at onset included left-sided weakness with facial palsy, sensory loss and dysarthria. Baseline CT did not show any acute changes. MRI revealed multiple small acute lesions in the right MCA territory with severe atrophy and periventricular vascular demyelinization. Baseline NIHSS was 7. The subject was randomized to the treatment arm of the SENTIS trial at 19:20, [redacted]-2009, 1.3 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 20:10, [redacted] 2009. Treatment was unremarkable.

Post-Enrollment Course: The subject's 6 hour and 24 hour NIHSS were both ranked as 5. The 16 hour CT on [redacted]-2009 showed known chronic vascular disease in the periventricular white matter with several previous, more focal, ischemic injuries suspected. No evidence of acute infarct and/or hemorrhage was seen.

On [redacted] 2009 (post enrollment day 2) the subject had an acute onset of new left hemiplegia and a deterioration in neurological status **(SAE #001)**. His NIHSS increased to 13. CT did not show any interval changes from [redacted] 009. Increased spasticity was noted in the left paretic limbs and Lioresal was started.

The 4 day NIHSS on [redacted] 2009 was 9. The subject was discharged from the hospital on [redacted] 2009 to a rehabilitation facility.

On [redacted]-2009 an x-ray of the hips was performed due to the subject's complaints of left hip pain **(AE #901)**. Moderate degenerative changes in the sacro-coxofemoral and iliac joints, appropriate for the age, were noted and Paracetamol was given.

While in rehab, the subject's general condition worsened. He had dysphagia, fever, and fatigue. The subject's CRP on [redacted]-2009 was 6.5. A chest x-ray on [redacted] 2009 demonstrated chronic infection or post-infection sequela in bilateral lung fields **(AE #002)**. The subject's pneumonia was treated with Augmentin and resolved by [redacted] 2009.

The 30 day and 90 day NIHSS were ranked as 14 with mRS of 4.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
11-Jun-2009	**000**	**003**	**899 - Other: Wound left leg**	**Likely not related**	**Likely not related**
15-Jun-2009	004	001	299 - Pulmonary Other: COPD exacerbation	Likely not related	Likely not related
24-Sep-2009	105	004	803 - Cellulitis	Likely not related	Likely not related
24-Sep-2009	**105**	**005**	**108 - Congestive Heart Failure**	**Likely not related**	**Likely not related**
24-Sep-2009	105	006	809 - Diabetes Mellitus	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is an 81-year-old obese Caucasian female with past medical history of left MCA stroke in 2006 (mRS=1), insulin-dependent diabetes with kidney disease and polyneuropathy, hypertension, hyperlipidemia, atrial fibrillation, dilated cardiomyopathy with congested heart failure (CHF), brady-tachy syndrome (pacemaker 2004), chronic obstructive pulmonary disease (COPD), obstructive sleep apnea, spinal stenosis, goiter, appendectomy, cholecystectomy, hysterectomy, cataract surgery, constipation with rectal prolapse, depression, and left lung tumor (radiation 2006).

On [redacted] 2009 the subject was admitted to the hospital with significant increase of edema in the lower extremities and a diabetic wound on the left leg that was treated with Augmentin. The subject also reported increased shortness of breath and lethargy over the preceding months. Exacerbation of COPD was diagnosed and the subject responded well to diuretics, inhalers, and oxygen therapy. Intermittent episodes of right facial droop were noted during the hospitalization and attributed to transient ischemic attacks (TIA). CT demonstrated bilateral old ischemic lesions mainly in the right temporal and left frontal, no acute stroke or hemorrhage. ECG showed rate-controlled atrial fibrillation and echocardiogram was mildly abnormal. The subject was discharged to home on [redacted] 2009. Medications at admission included: Lipitor, Lyrica, Lexapro, Lanoxin, Omeprazole, Bumetanide, Mianserini chloridum, NTG patch, Befact Forte, Forlax, Allopurinol, Transtec, Chlortalidone, Magnetop, Chlonazepam, Augmentin, Marevan, Fraxodi, Spiriva, Duovent, Seretide, Novolin insulin and Lantus.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:30 on [redacted] 2009. Her glycemic index was 200 and Actrapid was given. Symptoms at presentation included somnolence, right-sided weakness with facial palsy, dysarthria, amnesia and global aphasia. CT revealed a possible hypodensity in the left cerebellum that was likely an artifact and no hemorrhage or mass effect. Baseline NIHSS was 14. The subject was randomized to the treatment arm of the SENTIS trial at 11:16, 1[redacted] 2009, 12.8 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 12:15, [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2009 (the day of enrollment) the subject's pre-existing left leg diabetic wound **(SAE #003)** and bilateral pitting edema was noted. Augmentin was continued (subject had 7 more days of Augmentin therapy from previous admission).

The 24 hour CT showed no changes from the baseline exam; no evidence of acute infarction. At discharge the site concluded that the subject had a TIA.

On [redacted]-2009 (post enrollment day 4) the subject had an exacerbation of COPD **(AE #001)** manifested by hypoxia, hypercapnia and dyspnea. Seretide was increased and the subject's respiratory status improved.

The subject was discharged from the hospital on [redacted]-2009 to rehab. Her prolonged index stay was due to the left leg wound and dyspnea.

On [redacted]-2009 (post enrollment day 105) the subject was admitted to the geriatric ward with increased bilateral edema and redness and pain in the left lower leg. The subject was diagnosed with exacerbation of congestive heart failure **(SAE #005)** and was successfully treated with high dose of intravenous diuretics. The event resolved on [redacted]-2009. Cellulitis of the left leg **(AE #004)** was also diagnosed and successfully treated with Amoxicillin and chloric acid. The subject's poor metabolic control of her diabetes (hyperglycemia, A1c of 8.4) **(AE #006)** was treated with increased doses of Lantus and Novo norm. The subject was discharged from the hospital on [redacted] 2009.

Subject [redacted], enrolled [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
19-Dec-2007	001	004	699 - Lab/electrolyte Other: Glucose intolerance	Likely not related	Likely not related
19-Dec-2007	001	001	412 - HT, no concomitant mass effect	Likely not related	Unknown
21-Dec-2007	**003**	**002**	**403 - Cerebral edema**	**Likely not related**	**Likely not related**
21-Dec-2007	003	003	103 - Hypertension	Likely not related	Likely not related
19-Mar-2008	092	901	811 - Depression	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 68-year-old Caucasian male with no past medical issues and no medications.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at approximately 11:00 on [redacted] 2007. Symptoms at presentation included severe left hemiplegia with facial palsy, dysarthria and neglect. CT and MRI on admission revealed an acute ICA occlusion. Baseline NIHSS was 14. The subject was randomized to the treatment arm of the SENTIS trial at 18:15, [redacted]-2007, 7.3 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 20:00 on [redacted]-2007 (the cardiology procedure room was busy with an emergency). Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2007 (post enrollment day 1) a diagnosis of glucose intolerance **(AE #004)** was made for which a diabetic diet was initiated.

The 24 hour MR on [redacted]-2007 revealed a new small bleed **(AE #001)** into the basal ganglia area. No clinical symptoms were present. The 24 hour NIHSS remained at 13.

A repeat CT on [redacted]-2007 (post enrollment day 3) revealed moderate cerebral edema **(SAE #002)** which was treated with Mannitol. (The event was adjudicated as serious as it was thought that it prolonged hospitalization.) There was no indication of bleeding on this scan. The 4 day NIHSS on [redacted] 2007 was 13. The cerebral edema was reported as resolved by [redacted]-2007.

The subject was also diagnosed with hypertension **(AE #003)** and treated with Perindopril and Bisoprolol.

The subject was discharged from the hospital on [redacted]-2008 to a rehabilitation facility.

The 30 day NIHSS on [redacted]-2008 was ranked as 12 with mRS of 4.

At the 90 day follow-up visit on [redacted] 2008 the subject was taking Remerjil (Zoloft) for depression **(AE #901)**. The 90 day NIHSS was ranked as 9 with mRS of 4.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
12-Feb-2009	**001**	**901**	**403 - Cerebral edema**	**Unknown**	**Unknown**
13-Feb-2009	**002**	**001**	**702 - Femoral artery occlusion/thrombosis**	**Unknown**	**Likely related**
19-Feb-2009	008	902	413 - Headache	Likely not related	Likely not related
21-Feb-2009	010	002	205 - Infectious pneumonia	Likely not related	Likely not related
25-Mar-2009	042	903	811 - Depression	Likely not related	Likely not related
22-May-2009	**100**	**003**	**899 - Other: Hyperthyroidism**	**Likely not related**	**Likely not related**
06-Jun-2009	**115**	**004**	**205 - Infectious pneumonia**	**Likely not related**	**Likely not related**

Serious events are in bold, shaded text.

Demographics and History: The subject is an 83-year-old Caucasian female with a past medical history of insulin-dependent diabetes, hypertension, and post hepatic liver cirrhosis. Medications at admission included Bisoprolol and Berlinsulin.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at approximately 18:00 on [redacted] 009. Symptoms at presentation included

confusion, global aphasia and right hemiparesis with facial palsy. CT scan on admission revealed a left MCA territory infarct with a total occlusion of the left common carotid and internal carotid artery. Baseline NIHSS was 13. The subject was randomized to the treatment arm of the SENTIS trial at 21:00, [redacted]-2009, 3.0 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 21:58, [redacted]-2009 via right femoral artery. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour NIHSS was 14. The 24 hour NIHSS on [redacted]-2009 was ranked as 17 due to the increase of the right-sided weakness. The 24 hour CT showed increased demarcation of the left fronto-paretal infarct with focal edema **(SAE #901)**.

On [redacted]-2009 (post enrollment day 2) the right lower extremity pulses were not palpable and the leg was cool to touch. Angiogram revealed an occlusion of the proximal right femoral artery (NeuroFlo puncture site) **(SAE #001)** that was attributed to the closure device. Proximal right femoral artery was recanalized with percutaneous transluminal angioplasty. The superficial femoral artery was not amenable to recanalization. Heparin was administered and the subject was placed on Aspirin as secondary prophylaxis. A repeat angiography on 1[redacted]-2009 showed adequate perfusion.

The 4 day NIHSS on [redacted]-2009 was 14.

On [redacted]009 (post enrollment day 8) the subject complained of a headache **(AE #902)** for which Novalgin was given.

On [redacted]-2009 (post enrollment day 10) the subject had rhonchi, dyspnea, and was febrile. Chest x-ray showed infectious pneumonia **(AE #002)**; Novalgin was given for fever and Rocephin was started.

The subject was discharged from the hospital on [redacted]-2009 to rehabilitation. During the rehabilitation, Rocephin was changed to Vancomycin due to the Methicillin-resistant Staphylococcus aureus (MRSA) positive sputum **(AE #002, update)**. The subject remained on Vancomycin at the 30 day follow-up visit on [redacted]-2009.

The 30 day NIHSS on [redacted]2009 was ranked as 8 with mRS of 4.

On [redacted]-2009, while in rehabilitation, the subject was started on Cipralex for depression **(AE #903)**.

On [redacted]2009 (post enrollment day 100) the subject was admitted with tachycardia, fever, and abdominal pain. Investigation ruled out ileus and Carbimazole was started for hyperthyroidism **(SAE #003)**. The subject's tachycardia and temperature normalized.

On [redacted]-2009 (post enrollment day 115) the subject was admitted to the hospital with recurrent pneumonia **(SAE #004)** and was started on antibiotics. She was discharged on [redacted] 2009.

At the 90 day follow-up visit on [redacted]-2009, the subject's NIHSS was ranked as 11 with mRS of 4.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
03-Oct-2008	001	001	701 - Hematoma	Unknown	Likely related
03-Oct-2008	001	010	899 - Other: Edema right leg	Likely not related	Likely not related
03-Oct-2008	001	003	503 - Nausea/Vomiting	Likely not related	Likely not related
05-Oct-2008	003	007	118 - Atrial fibrillation	Likely not related	Likely not related
05-Oct-2008	003	005	699 - Lab/electrolyte Other: Increased C-reactive protein (CRP)	Likely not related	Likely not related
07-Oct-2008	005	009	199 - Cardiac Other: Aneurysm of front heart wall	Likely not related	Likely not related
15-Oct-2008	013	011	413 - Headache	Likely not related	Likely not related
15-Oct-2008	013	012	899 - Other: Intermittent dizziness	Likely not related	Likely not related
24-Oct-2008	**022**	**002**	**711 - Pseudoaneurysm**	**Unknown**	**Likely related**
26-Oct-2008	024	006	899 - Other: Common cold	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is an 80-year-old Caucasian male with a past medical history of ischemic cardiomyopathy and a myocardial infarction with coronary artery bypass surgery, hypertension, hyperlipidemia, diabetes mellitus and hyperuricemia. Medications at admission included: Bisoprolol, Aspirin, Metformin, Nitrolingual, and Simvahexal.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 14:30 on [redacted] 2008. Symptoms at presentation included decreased level of consciousness and severe aphasia. MRI scan revealed a lesion in the left posterior part of the MCA territory with mismatch. One small chronic microbleed was noted. Baseline NIHSS was 5. The subject was randomized to the treatment arm of the SENTIS trial at 22:00, [redacted]-2008, 7.5 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 22:50 on [redacted]-2008 via right femoral artery. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2008 (post enrollment day 1) a hematoma **(AE #001)** was noted in the right groin (NeuroFlo puncture site). The subject developed lymphedema **(AE #010)** which lead to swelling of his right leg. He also complained of nausea and vomiting **(AE #003)** and was treated with Dimenhydrinat.

On [redacted]-2008 (post enrolment day 3), the subject developed atrial fibrillation **(AE #007)** with rapid ventricular response. He was treated with a beta blocker and Digoxin. His C-reactive protein was also elevated **(AE #005)** and the subject was started on antibiotics.

A transthoracic ultrasound on [redacted]-2008 revealed an anterior ventricular aneurysm **(AE #009)**. An oral anticoagulant was started as secondary prophylaxis despite the subject's groin hematoma.

The subject was discharged from the hospital on [redacted] 2008 with only minor symptoms.

On [redacted] 2008 (post enrollment day 13), the subject complained of headache **(AE #011)** and intermittent dizziness **(AE #012).**

On [redacted] 2008 (post enrollment day 22), the subject complained of increasing pain in the right groin and was admitted to the vascular surgery department. Duplex-ultrasound revealed an Aneurysma spurium of the right femoral artery **(SAE #002)**. The subject was advised to discontinue the oral anticoagulation and change to subcutaneous low-molecular-weight heparin. Surgical repair was scheduled on [redacted]-2008, however repeated Duplex-Sonography demonstrated a completely thrombosed aneurysm so no intervention was necessary and the subject was discharged.

At the 30 day follow-up visit on [redacted]-2008, the subject reported an episode of a common cold from [redacted]-2008 to [redacted]-2008 **(AE #006).** His 30 day NIHSS was 1 and mRS was 2.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
18-Jun-2009	001	001	412 - HT, no concomitant mass effect	Unknown	Unknown
19-Jun-2009	**002**	**003**	**716 - Carotid stenosis with stent placement**	**Likely not related**	**Likely not related**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
19-Jun-2009	002	004	701 - Hematoma	Likely not related	Likely not related
19-Jun-2009	002	005	812 - Fever	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 71-year-old Caucasian male with a past medical history of hypertension and hyperlipidemia. In May-2009 the subject was hospitalized with ischemia of the right MCA territory, which left no residual symptoms (mRS=0). A 60% stenosis of the right ICA was diagnosed and treated conservatively. Medications at admission included: Aggrenox, Ramiprie, and Simvastatin.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 06:30 on [redacted] 2009. Symptoms at presentation included clumsiness of the left hand and complete left hemianopsia. MRI scan at admission revealed a right-sided MCA infarct and no hemorrhage. Baseline NIHSS was 3. The subject was randomized to the treatment arm of the SENTIS trial at 12:14, [redacted]-2009, 5.7 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 13:15, [redacted] 2009 via right femoral artery. Treatment was remarkable for blood pressure monitoring equipment failure after the infrarenal balloon was inflated. The equipment was quickly replaced and the rest of the treatment was unremarkable.

Post-Enrollment Course: A follow-up CT scan showed bleeding **(AE #001)** into the right-sided infarcted area. This was an asymptomatic bleed. The subject's NIHSS remained at 3.

A carotid ultrasound on [redacted]-2009 revealed 50% stenosis of the left ICA as well as the known right ICA stenosis (increased to 70%). A right ICA stent **(SAE #003)** was placed on [redacted] 2009. Post procedure, a hematoma **(AE #004)** was noted on the right groin that resolved with a bandage compression. (There was no evidence of hematoma present at the NeuroFlo puncture site between completion of the NeuroFlo procedure and prior to the ICA stenting. Therefore, the DSMB adjudicated AE #004 as not related to the NeuroFlo device or procedure.) The subject also had a slightly increased temperature **(AE #005)** which resolved with Paracetamol.

The subject was discharged from the hospital on [redacted]-2009 to home until arrangements for rehabilitation were finalized. The subject was admitted to a rehabilitation hospital from [redacted]-2009 to [redacted]-2009.

At the 30 day follow-up visit on [redacted]-2009, the subject's NIHSS was 1 and mRS was 2.

The 90 day NIHSS on [redacted] 2009 was ranked as 2 with mRS of 1.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
03-Jul-2009	000	006	503 - Nausea/Vomiting	Likely not related	Likely not related
03-Jul-2009	000	001	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
03-Jul-2009	000	007	814 - Sleeping Disturbance/ Disorder	Likely not related	Likely not related
06-Jul-2009	003	009	819 - Infection	Likely not related	Likely not related
06-Jul-2009	003	008	504 - GI Motility Disorders	Likely not related	Likely not related
08-Jul-2009	005	005	603 - Electrolyte imbalance	Likely not related	Likely not related
09-Jul-2009	006	004	817 - Chest pain	Likely not related	Likely not related
24-Aug-2009	052	011	817 - Chest pain	Likely not related	Likely not related
25-Aug-2009	**053**	**010**	**704 - Aortic Injury: Dissection or aorta abdominalis**	**Likely not related**	**Likely not related**
07-Oct-2009	096	012	811 - Depression	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is a 75-year-old Caucasian female with a past medical history of non-insulin dependent diabetes mellitus, hypertension, atrial fibrillation (not on anticoagulation therapy) and a thyroidectomy. Four days prior to the stroke onset the subject had a tick bite and was treated prophylactically with Doxycycline. Medications at admission included: Ramipril, Mobloc, Godamed (Aspirin) and Doxycycline.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:00 on [redacted]-2009. Symptoms at presentation included disorientation, right-sided hemiparesis and global aphasia. CT and CT perfusion scan at admission revealed a disseminated infarction with subacute MCA infarct and deficit of perfusion in the left insula. Baseline NIHSS was 11. The subject was randomized to the treatment arm of the SENTIS trial at 08:35, [redacted] 2009, 10.6 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 09:05, [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) the subject complained of nausea **(AE #006)** and Vomex (Dramamine) was given. The subject's cholesterol was slightly elevated **(AE #001)** and Simvastatin was prescribed. That night the subject had trouble sleeping **(AE #007)** and was given Stienox (Ambien).

On [redacted] 2009 (post enrollment day 3), the subject's C-reactive protein was >150 and temperature was 37.6ºC **(AE #009)**. Doxycycline (started for tick bite) was changed to Augmentin. The subject complained of constipation **(AE #008)** which resolved with Lactulose.

On [redacted] 2009 an echocardiogram showed aortic valve sclerosis and mitral and tricuspid valve insufficiency. Due to these findings and the subject's previous history of atrial fibrillation, the source of the stroke was deemed as cardiac embolism and anticoagulation was initiated.

On [redacted] 2009 (post enrollment day 5), the subject's potassium was low at 3.1 **(AE #005)**. No action was taken other than that the subject's electrolyte balance was continued to be monitored.

On [redacted]-2009 the subject had severe chest pain **(AE #004)**. Myocardial infarction was ruled out with normal electrocardiogram and cardiac enzymes. The chest pain subsided and no treatment was necessary. The subject was transferred from the hospital on the following day to the rehabilitation clinic.

At the 30 day follow-up visit on [redacted]-2009, the subject's NIHSS and mRS were both ranked as 1.

On [redacted] 2009 (post enrollment day 52), the subject was admitted to an outside hospital with severe chest pain **(AE #011)**. A diagnostic cardiac catheterization was attempted but the catheter was unable to be advanced and the procedure was aborted. Follow-up sonography showed a double lumen and aortic dissection was suspected. The outside hospital assumed that the dissection was due to the NeuroFlo procedure and the subject was transferred to the index hospital. A CT angiogram on [redacted] 2009 confirmed a small dissection of the abdominal aorta starting right above the renal arteries and going into the right iliac artery **(SAE #010)**. The dissection and mesenteric inferior artery was supplied by false lumen of dissection and was deemed of no clinical or surgical consequence as the subject was asymptomatic. The site's neurologists and radiologists reviewed this case. They felt that 95% likely the aortic dissection was caused by the cardiac catheter. They did allow, although unlikely, that it could be a spontaneous dissection, or a dissection unnoticed after the NeuroFlo procedure. The subject was transferred back to the outside hospital.

At the 90 day follow-up visit on [redacted] 2009 the subject reported a mild depressive episode **(AE #012)** which was treated with Opipramol. Her 90 day NIHSS was 0 and mRS was 1.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
13-Aug-2009	001	003	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
14-Aug-2009	**002**	**001**	**409 - New ischemic stroke**	**Unknown**	**Unknown**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 61-year-old Caucasian female with a past medical history of hypertension, hysterectomy, and occasional headaches. Medications at admission included Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 01:45, [redacted] 2009. Symptoms at presentation included left hemiparesis, left facial paralysis, slight dysarthria and left sensory and visual neglect. MRI at admission revealed acute ischemia in the right basal ganglia, old bilateral ischemic lesions, and distal right MCA stenosis; no hemorrhage. Baseline NIHSS was 7. The subject was randomized to the treatment arm of the SENTIS trial at 14:30, [redacted] 2009, 12.8 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 14:55, [redacted] 2009. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2009 (post enrollment day 1) the subject's total cholesterol was 207 **(AE #003)** and Atorvastatin was started. The 24 hour MRI on [redacted] -2009 showed no new lesions and no hemorrhage related to acute infarct. The 24 hour NIHSS was 5.

On [redacted] 2009 the subject appeared sleepy and had worsening of neurological symptoms. Her NIHSS increased to 11. MRI revealed a new small hyperacute ischemic lesion **(SAE #001)** in bihemispheral border zone areas with a larger right temporo-occipital lesion in the dorsal MCA territory/MCA-PCA border zone. The MRI report indicated a possible petechial hemorrhage, which was not confirmed by Core Lab (adjudicated as non-event). The 4 day NIHSS on [redacted] 2009 decreased to 6.

NCT on [redacted] -2009 revealed a calcified meningioma associated with the left frontal lobe of the brain. No treatment was initiated and no new ischemic lesions were noted.

The subject was discharged from the hospital on [redacted] -2009 to home. Rehabilitation was planned for [redacted] -2009.

Her 30 day NIHSS on [redacted] 2009 was ranked as 2 with mRS of 3.

At the 90 day follow-up visit on [redacted] -2009 the subject's NIHSS was 2 with mRS of 1.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-May-2009	**014**	**001**	**404 - HT, likely contributing to mass effect**	**Likely not related**	**Likely not related**
21-May-2009	021	901	811 - Depression	Likely not related	Likely not related
21-May-2009	021	902	814 - Sleeping Disturbance/ Disorder	Likely not related	Likely not related
21-May-2009	021	903	103 - Hypertension	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is an 83-year-old Caucasian male with a past medical history of untreated hypertension and dyslipidemia and no medications at admission.

Current Stroke Onset and SENTIS Enrollment: The subject presented at an outside hospital at 16:30 on [redacted] 2009 with dizziness and vomiting. A left extremity dysmetria with recovery was diagnosed and the subject was transferred to the index hospital. Upon arrival, the subject experienced stroke symptom onset at 22:30 on [redacted] 2009. Symptoms at presentation to the index hospital included left homonymous hemianopsia, facial palsy, and right gaze preference. CT scan revealed no acute findings. Baseline NIHSS was 9. The subject was randomized to the treatment arm of the SENTIS trial at 10:15, [redacted] 2009, 11.8 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 12:30, [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: The 24 hour CT on [redacted]-2009 showed a right posterior cerebral artery (PCA) infarct. The 24 hour NIHSS improved to 3.

The subject was discharged to his referral hospital on [redacted]-2009. The etiology of the subject's stroke was considered as cardio embolic and warfarin was initiated on [redacted] 2009.

On [redacted]-2009 (post enrollment day 14) the subject's condition abruptly worsened with increased left hemiparesis, headache, vomiting, and drowsiness. His NIHSS was 13. CT showed hemorrhagic transformation (PH-2) **(SAE #001)** of the right PCA infarction with associated mass effect and 8mm midline shift, as well as incipient hydrocephalus. This was thought to be related to the subject's anticoagulation treatment. Anticoagulation was immediately stopped and Protamine was given.

The subject's 30 day NIHSS on [redacted] 2009 was ranked as 15 with mRS of 5. At the time of the 30 day follow-up visit the subject was taking the following new medications: Paroxetine for depression **(AE #901)**, Lorazepam for insomnia **(AE #902)**, and Enalapril for pre-existing hypertension **(AE #903)**.

The subject's 90 day NIHSS was ranked as 8 and his mRS was 3.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
09-Dec-2009	**028**	**001**	**899 - Other: Femur fracture**	**Likely not related**	**Likely not related**
28-Dec-2009	047	901	806 - Agitation/Excitation	Likely not related	Likely not related
28-Dec-2009	047	902	299 - Pulmonary Other: Bibasilar crackles	Likely not related	Likely not related
03-Feb-2010	084	002	407 - Seizure	Likely not related	Likely not related

Serious events are in bold, shaded text.

Demographics and History: The subject is an 85-year-old Caucasian female with past medical history of atrial fibrillation, non-insulin dependent diabetes, peripheral vertigo, syncope of unknown origin and head trauma (Jul-2006), right lower extremity cellulitis (2005), and confusional syndrome (2007). Medications at admission included: Metformin, Omeprazole, Amiodarone and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 08:00, [redacted] -2009. Symptoms at presentation included confusion, aphasia, right homonymous hemianopsia and right facial paralysis. CT scan at admission revealed hypodensity in the periventricular white matter, no space occupying lesions, and cerebral atrophy with demyelination versus chronic adult hydrocephalus. Baseline NIHSS was 8. The subject was randomized to the treatment arm of the SENTIS trial at 17:05, [redacted] 2009, 9.1 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 18:20, [redacted] -2009. Treatment was unremarkable.

Post-Enrollment Course: The subject's hospital stay was uneventful. Her 4 day NIHSS on [redacted] -2009 improved to 0 and on [redacted] -2009 the subject was discharged to home.

On [redacted]-2009 (post enrollment day 28) the subject fell and was admitted with a left subcapital hip fracture **(SAE #001).** A left hip replacement was performed on [redacted]-2009.

On [redacted]-2009 the subject was admitted for additional rehabilitation following her hip replacement. At that time the subject's disorientation to time-space was noted. Neuropsychology evaluated the subject and determined that she had moderate to severe cognitive impairment. Haldol was required at times for her agitation **(AE #901)**.

Bi-basilar crackles **(AE #902)** were noted on [redacted]-2009 and Budesonide and Ipratropium Bromide were initiated.

On [redacted]-2010 (post enrollment day 84) the subject was seen with generalized tonic-clonic movements and episode of unconsciousness that lasted for about 5 min **(AE #002)**. Physical exam revealed paresis and right gaze deviation. After 30 min the subject became oriented to the surroundings and recovered neurologically. She had no lasting motor or sensory deficits and responded well to Levetiracetam.

Control Arm

Subject[redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-May-2009	001	002	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
29-May-2009	**002**	**003**	**403 - Cerebral edema**	**N/A**	**N/A**
30-May-2009	003	901	814 - Sleeping Disturbance/ Disorder	N/A	N/A
15-Jun-2009	**019**	**001**	**716 - Carotid stenosis with endarterectomy**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 56-year-old Caucasian female who has not seen a doctor in the past 10 years and her twelve-point system review was negative. She was not taking any medications and was smoking 1 pack a day. Prior to the stroke onset the subject reported two days of intermittent word finding difficulty, right hand weakness, and complained of a pressure behind her left eye. The principal investigator and the stroke team felt that the index stroke was discrete from the symptoms the subject experienced in the previous two days as those symptoms had completely resolved.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:00, [redacted] 2009 when she went to bed. Symptoms at presentation included right-sided weakness and inability to express herself. An egg size hematoma from falling on the bathroom floor was noted on her forehead. CT at admission suggested subacute left MCA territory infarct with no evidence of hemorrhage. Baseline NIHSS was 11. The subject was randomized to the control arm of the SENTIS trial at 10:56, [redacted]-2009, 11.9 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 6 hour NIHSS remained at 11.

On [redacted]-2009 (post enrollment day 1) CT demonstrated multifocal left-sided predominantly MCA distribution infarcts. MRI was consistent with extensive left MCA distribution infarct with multiple areas of additional infarcts in left basal ganglia and periventricular white matter. There was perfusion/diffusion mismatch. MRA of the neck showed approximately 90% stenosis of the proximal left ICA.

The subject's triglycerides were elevated on [redacted]-2009 and she was started on Simvastatin **(AE #002)**.

On [redacted]-2009 (post enrollment day 2) the subject continued to be significantly aphasic with a flaccid right upper extremity and minimal right lower extremity withdrawal to noxious stimuli. CT revealed peri-infarct edema **(SAE #003)**. NIHSS increased to 14. Multiple emboli were detected in the left MCA by transcranial Doppler; an endarterectomy was planned.

On [redacted]-2009 (post enrollment day 3) the subject was started on Ambien for insomnia **(AE #901).**

The 4 day NIHSS on [redacted]-2009 was 16. MRI on [redacted]-2009 showed a slight interval increase in edema in the left parietal lobe infarct. No new areas of infarct were identified.

The subject was discharged from the hospital on [redacted]-2009 to a rehabilitation facility.

On 1[redacted] 2009 (post enrollment day 19), after multiple postponements due to peri-infarct edema and concern for bleeding, the subject underwent a successful left carotid endarterectomy **(SAE #001)**.

The 90 day NIHSS on [redacted]-2009 was ranked as 9 with mRS of 4.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
29-Nov-2008	**001**	**001**	**403 - Cerebral Edema**	**N/A**	**N/A**
29-Nov-2008	001	004	809 - Diabetes Mellitus	N/A	N/A
30-Nov-2008	002	901	103 - Hypertension	N/A	N/A
30-Nov-2008	002	902	812 - Fever	N/A	N/A
09-Dec-2008	011	007	118 - Atrial Fibrillation	N/A	N/A
11-Dec-2008	013	005	303 - Urinary Tract Infection	N/A	N/A
13-Dec-2008	**015**	**006**	**404 - HT, likely contributing to mass effect**	**N/A**	**N/A**
13-Dec-2008	**015**	**002**	**202 - Respiratory failure**	**N/A**	**N/A**
14-Dec-2008	016	008	301 - Renal dysfunction	N/A	N/A
15-Dec-2008	017	003	603 - Electrolyte imbalance	N/A	N/A
05-Jan-2009	038	010	899 - Other: Right mastoiditis	N/A	N/A
06-Jan-2009	039	903	303 - Urinary Tract Infection	N/A	N/A
15-Jan-2009	048	011	599 - GI Other: C. difficile	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 58-year-old Caucasian male with a past medical history of atrial fibrillation, diabetes and coronary artery disease. Medications at admission included: Glyburide/Metformin and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:00 on [redacted]-2008. Symptoms at presentation included left-sided weakness, confusion, slurred speech, and a dull headache. CT scan at admission revealed a hyperdensity in the right MCA suggestive of a clot. CT perfusion scan showed a large blood volume perfusion abnormality involving right hemisphere with mild local mass effect. Taking into consideration that the CT scan showed hypodensity being close to 1/3 of the MCA territory, the Principal Investigator was asked to use his medical judgment regarding the subject's enrollment. Baseline NIHSS was 13. The subject was randomized to the control arm of the SENTIS trial at 11:10, [redacted] 2008, 13.2 hours from time last known normal.

NeuroFlo Procedure: N/A

Post Enrollment Course: An MRI done one hour after randomization showed a large right hemispheric infarct with local mass effect and thrombus suspected at the right carotid terminus extending into the MCA and the ACA. Trans-esophageal echocardiogram showed no evidence for a cardiac source of embolus.

On [redacted] 2008 (post enrollment day 1) at 23:00 the subject became somnolent and was not following commands. He was urgently intubated for airway protection. CT scan showed evolutionary changes and extension of a very large right MCA infarct with increasing mass effect, as well as a right to left midline shift and herniation involving the brainstem **(SAE #001)**. Neurosurgery was consulted and the subject underwent a right fronto-temporal-parietal decompressive craniectomy on the following day.

Also on [redacted]-2008 the subject required sliding scale insulin to control his blood glucose **(AE #004)**.

On [redacted] 2008 (post enrollment day 2), the subject's systolic blood pressure was noted to be as high as 169 (at the time of admission it was 139) **(AE #901)**. Lopressor was initiated.

The subject had leukocytosis at admission and it persisted throughout his hospitalization. On [redacted]-2008 the subject was febrile **(AE #902)** and Ancef was started. His temperature continued to fluctuate throughout hospitalization.

NCT scan on [redacted] 2008 showed evolution of the infarct core with possible petechial hemorrhage. No associated changes in neurological status of the subject were noted. The subject was extubated on [redacted]-2008.

On [redacted]-2008 (post enrollment day 11), persistent uncontrolled atrial fibrillation was noted **(AE #007)**. A cardiology consult was obtained and Cardizem, Digoxin and

Lopressor were started. The subject was dysphagic and was potentially aspirating without respiratory distress. Due to the risk of aspiration pneumonia, Zosyn was initiated.

On [redacted]-2008 the subject's urine culture was positive for acinetobacter **(AE #005)**; Flagyl was added, and later antibiotics were changed to Primaxin.

On [redacted] 2008 (post enrollment day 15), the subject's level of consciousness decreased. CT scan of the brain revealed extensive hemorrhagic transformation within right MCA infarction with mass effect and midline shift **(SAE #006)**. The heparin was reversed with Protamine, held for 24 hours, and re-initiated at a lower level. The subject was re-intubated for airway protection and became ventilator-dependent **(SAE #002)**.

On [redacted]-2008 (post enrollment day 16), the subject's blood work reflected acute renal dysfunction **(AE #008)**. A renal consult was obtained; free water was given. Renal function improved by [redacted] 2008 and resolved by [redacted] 2008.

On [redacted]-2008, the subject's serum potassium was low and supplemental replacement was given **(AE #003)**.

On [redacted]-2008 (post enrollment day 24), a bronchoscopy was performed for atelectasis noted on chest x-ray, and a tracheostomy was performed two days later **(cont. of SAE #002)**.

On [redacted]-2008 (post enrollment day 32), the subject underwent a feeding tube placement and was transferred from intensive care to the step down unit.

At the time of his 30 day follow-up visit on [redacted] 2008, the subject's NIHSS was 15, mRS was 5, Glascow Outcome Scale was 3 and Barthel Index was 0.

On [redacted]-2009 (post enrollment day 38), CT of the head revealed a right mastoiditis **(AE #010)** and antibiotics were initiated.

The subject was transferred on [redacted] 2009 to an inpatient rehabilitation facility. Upon admission, his urine culture showed Klebsiella **(AE #903)**, which was treated with Suprax for 7 days. On [redacted] 2009, a repeat urine culture was positive for Enterococcus and Vancomycin was started. The event resolved by [redacted]-2009**.**

On [redacted] 2009 (post enrollment day 48), the subject developed diarrhea. Stool culture was positive for Clostridium difficile **(AE #011)**. The subject was treated with Flagyl for 10 days, and the event resolved by [redacted] 2009.

The subject's tracheostomy tube was removed on [redacted] 2009, and he was transferred to an assisted living facility on [redacted]-2009. The subject remained at the assisted living facility at the 90 day follow-up visit on [redacted]-2009 with NIHSS of 12, mRS of 4, Glascow Outcome Scale of 3 and Barthel Index of 45.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
18-Jun-2009	000	002	899 - Other: Planum sphenoidal meningioma	N/A	N/A
07-Jul-2009	**019**	**901**	**601 - Anemia**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is an 82-year-old Caucasian female with a past medical history of a prior left brain stroke (mRS=0), atrial fibrillation (not on Coumadin), hypertension, chronic obstructive pulmonary disease/asthma, chronic anemia with a B12 deficiency and gastrointestinal bleeding. Medications at admission included: Prevacid, Lisinopril, Cardizem, Singulair, Nasonex, Allegra, Advair and Albuterol inhalers, Humibid as well as iron, vitamin D and B12 supplements.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 19:30 on [redacted]-2009. Symptoms at presentation included Broca's aphasia, a right facial droop and slight weakness in the right hand. CT scan at admission revealed no acute intracranial abnormality. Baseline NIHSS was 9. The subject was randomized to the control arm of the SENTIS trial at 02:50, [redacted]-2009, 7.3 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 6 hour MRI on [redacted]-2009 revealed an acute infarction in the insular region on the left measuring 3cm in size with questionable petechial bleeding (no hemorrhage later confirmed; adjudicated as a non-event). No significant edema or mass effect. Also noted was a planum sphenoidale meningioma **(AE #002)**, which made an impression upon the frontal lobes but was not associated with any vasogenic edema or mass effect. MRA showed both internal carotid arteries to be widely patent, but the subject was missing insular branches of the left middle cerebral artery.

On [redacted]-2009 (post enrollment day 1), follow-up CT scan showed no definitive petechial hemorrhage, nor significant mass effect.

The subject was discharged from hospital to home on [redacted] 2009 with NIHSS of 6.

Following discharge from the hospital, the subject underwent hematology evaluation for her chronic anemia and received a blood transfusion on [redacted]-2009 for reported hemoglobin of 8.2. A second transfusion was documented on [redacted] 2009 **(SAE #901).** The subject was taken off Aspirin and Plavix due to decreasing hemoglobin and placed on Coumadin.

At the 30 day and 90 day follow-up visits, the subject's NIHSS was assessed as 1 and mRS as 3.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Nov-2009	001	901	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
07-Dec-2009	021	902	811 - Depression	N/A	N/A
01-Feb-2010	**077**	**001**	**499 - Neuro Other: Altered mental status**	**N/A**	**N/A**
01-Feb-2010	077	002	201 - Atelectasis	N/A	N/A
01-Feb-2010	077	903	301 - Renal dysfunction	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 79-year-old African American male with a past medical history of hypertension, non-insulin dependent diabetes, benign prostatic hypertrophy, gout, sick sinus syndrome (permanent pacemaker implanted in March of 2008), and hyperlipidemia (untreated). Medications at admission included: Teveten, Flomax, Minoxidil, Torsemide, Lasix, Avodart, and Percocet.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 01:00 on [redacted]-2009. Symptoms at presentation included partial left-sided facial weakness, dense left homonymous hemianopsia and mild left hemiparesis. CT scan at admission revealed no acute changes. Presentation NIHSS was 13, but the baseline NIHSS performed 3 hours later decreased to 8. The subject was randomized to the control arm of the SENTIS trial at 14:10, [redacted]-2009, 13.2 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (post enrollment day 1), the subject's cholesterol values were found to be elevated **(AE #901)**. Zocor was initiated and continued through the 90 day follow-up visit.

The 24 hour CT scan revealed a low density in the right parietal and insular cortex consistent with right MCA branch infarct. Carotid Doppler showed stenosis of the external carotids, and additional studies could not confirm the source of emboli. A possible small intrapulmonary shunt was seen on trans-esophageal echocardiogram.

The subject showed neurological improvement during his hospitalization, and was discharged on [redacted] 2009 to home to the care of his wife. NIHSS was 6.

At the 30 day follow-up visit on [redacted]-2009, the subject's NIHSS had improved to 4. He was noted to be taking Lexapro for depression **(AE #902)**, which continued through the 90 day follow-up visit.

On [redacted] 2010 (post enrollment day 77), the subject awoke with confusion, aphasia and a gait disturbance **(SAE #001)**. The symptoms resolved approximately one hour prior to arrival to the Emergency Department; however, the subject stated that it became harder to "find the words" over the last several days. The subject presented with chronic left-sided deficits consistent with his recent stroke, but no new neurological deficits. Admission CT scan revealed encephalomalacia related to the prior stroke; no new acute changes were seen. An electroencephalogram was essentially normal. Neurology was consulted and the subject was started on Aggrenox.

The subject's chest x-ray on admission showed cardiomegaly with vascular congestion and basilar atelectasis **(AE #002).** Laboratory results revealed a glomerular filtration rate of 33-40ml/min, blood urea nitrogen of 29 and creatinine of 1.98 **(AE #903)**. Trace edema was noted in the ankles bilaterally. The laboratory results improved with IV fluids by the next day. The subject was discharged on [redacted]-2010 to home in stable condition.

At the time of the 90 day follow-up visit on [redacted]-2010, the subject's NIHSS and mRS were both ranked as 3, with a Barthel Index of 85 and a Glascow Outcome Scale of 3.

Subject [redacted] enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
31-Dec-2006	002	001	303 - Urinary Tract Infection	N/A	N/A
02-Jan-2007	**004**	**902**	**414 - Neurological worsening**	**N/A**	**N/A**
09-Jan-2007	011	002	405 - HT, probably not contributing to mass effect	N/A	N/A
12-Jan-2007	014	003	815 - Skin irritation	N/A	N/A
Unk-Jan-2007		901	504 - GI Motility Disorders	N/A	N/A
06-Feb-2007	039	004	813 - Fall	N/A	N/A
13-Feb-2007	046	005	811 - Depression	N/A	N/A
07-May-2007	129	006	303 - Urinary Tract Infection	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 83-year-old Caucasian female with a past medical history of atrial fibrillation (not on Coumadin since gastrointestinal bleeding 2 years ago), hypertension, hyperlipidemia, cholecystectomy, gastro-esophageal reflux disease, angina, myocardial infarction, coronary artery bypass graft (CABG) in 1981 and

repeat CABG in 1991, transient ischemic attack in 2001, and dementia. Medications at admission included: Aricept, Protonex, Primidone, Norvasc, Levothyroxine, Toprol, Mevacor, Indapamide and Isosorbide.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 07:45 on [redacted]-2006. Symptoms at presentation included decreased level of consciousness with global aphasia, right-sided hemiplegia, right facial weakness and left gaze preference. CT scan at admission revealed a large hypodensity within the left middle cerebral artery (MCA) territory. CTA showed acute occlusion of the left internal carotid artery just distal to the bifurcation of the common carotid artery and stenosis of the left MCA. Baseline NIHSS was 16. The subject was randomized to the control arm of the SENTIS trial at 15:10, [redacted] 2006, 7.4 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2006 (post enrollment day 1), both MRI and MRA revealed acute left MCA territory infarct including the basal ganglia and insular region of the temporal lobe.

On [redacted]-2006 (post enrollment day 2), the subject's urinalysis and culture confirmed a urinary tract infection **(AE #001)**. She was treated with a 7-day course of Ampicillin.

On [redacted]-2007 (post enrollment day 4) the subject's neurological status declined; the NIHSS increased to 21 **(SAE #902)**. CT scan revealed larger infarction with increased mass effect and slight compression of the left lateral ventricle, but no midline shift.

On the morning of [redacted] 2007 (post enrollment day 11), the subject's mental status decreased from the baseline for a few hours. A repeat CT scan revealed a large left-sided MCA territory infarction with a collection of blood products in the shape and position of the basal ganglia, without significant mass effect **(AE #002)**.

On [redacted] 2007 (post enrollment day 14), the subject developed a blister on her left calf **(AE #003)**, which was treated with wound gel and a dry sterile dressing.

Medication Log indicates that the subject was prescribed Colace and Senokot for stool softening **(AE #901)** during her index hospitalization. Senokot was continued to be prescribed through the 90 day follow-up visit.

The subject was discharged from the hospital on [redacted]-2007 to a nursing home.

On [redacted] 2007 (post enrollment day 39), the subject fell **(AE #004)**. Her Barthel Index was ranked as 10/100, with the subject being only capable of sitting with significant assistance. She sustained a bruise to the right side of her face which resolved by the follow-up visit on [redacted] 2007. The subject was noted to be depressed and Lexapro was prescribed **(AE #005)**. She was also prescribed Zyprexa for agitation related to her depression.

At the time of the 90 day follow-up visit on [redacted]-2007, the subject's NIHSS was 21. The examining clinician noted that she was diagnosed with a urinary tract infection on [redacted]-2007 **(AE #006)** during her stay in the nursing home. She was treated with a 7-day course of Bactrim with no persistent effects.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
07-Jul-2008	000	003	413 - Headache	N/A	N/A
10-Jul-2008	**003**	**002**	**202 - Respiratory failure**	**N/A**	**N/A**
13-Jul-2008	006	004	303 - Urinary Tract Infection	N/A	N/A
16-Jul-2008	009	005	818 - Pain	N/A	N/A
26-Jul-2008	**019**	**006**	**504 - GI Motility Disorders**	**N/A**	**N/A**
03-Aug-2008	**027**	**007**	**209 - Respiratory dysfunction**	**N/A**	**N/A**
24-Sep-2008	079	009	818 - Pain	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 51-year-old Caucasian female with a recent past medical history of right cerebellar metastatic adenocarcinoma diagnosed in Jan-2008, suspected left lingual lung adenocarcinoma, hypovolemic hypernatremia, and hypertension. She was status post-surgical removal of right cerebellar tumor on [redacted] 2008 and left pneumonectomy on 0[redacted]-2008. The subject smoked one pack per day for 36 years, but quit in May 2008. Medications at admission included: Hydrocodone and Chantix.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 06:45 on [redacted]-2008. Symptoms at presentation included left facial flattening, no sensation or movement in her left arm and left leg, slurred speech, a slowness to answer questions, and headache. MRI at admission revealed abnormal signal on DWI involving the deep aspects of the right MCA territory and some insular cortex. CTA demonstrated complete occlusion of the right MCA-M1. Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 15:20, [redacted] 2008, 8.6 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2008 (the day of enrollment) the subject's headache (7-8/10 point scale) was noted **(AE #003)**. She was given Tylenol and cold packs. The headache pain was reduced to a 2/10. Headache recurred on [redacted]-2008, for which she

was given one dose of Lortab with good relief. Headaches were completely resolved by [redacted] 2008.

Between [redacted] l and [redacted] -2008 the subject had recurring events of rapid atrial fibrillation (rate of 170) **(part of SAE #002)** and developed respiratory distress, leading to ventilatory failure with the need for intubation **(SAE #002)**. Neo-Synephrine was thought to be attributed to her atrial fibrillation. She was placed on Amiodarone. On [redacted] -2008, the subject was weaned off of Neo-Synephrine and Propofol.

On [redacted] -2008 (post enrollment day 6), the subject's urine input/output ratio was noted to be out of balance. A urine culture was positive for Klebsiellla pneumoniae **(AE #004)**. The subject was given Lasix and was started on Bactrim two days later. Her input/output returned to normal prior to hospital discharge. At the same time, the subject's respiratory sputum sample confirmed gram-positive infection, for which Levaquin was started.

On [redacted] -2008, the subject underwent a tracheostomy and percutaneous endoscopic gastrostomy (PEG) tube placement. She tolerated both procedures well, and was weaned off the ventilator **(update to SAE #002)**. The subject remained on Amiodarone and was converted from IV to an oral form. On [redacted] -2008 one incident of superficial bleeding around the tracheostomy tube was observed, which was thought to be suction induced; aspirin was held. The bleeding stopped following packing of the tracheostomy site. The subject' hemoglobin and hematocrit were stable, and she was given 1 unit of packed red blood cells prophylactically.

On [redacted] -2008 (post enrollment day 9) the subject complained of muscle, chest, and neck pain **(AE #005)**. Cardiac work-up was negative. This pain was believed to be due to tracheostomy and PEG tube placement on [redacted] -2008. She was given one dose of Lortab with good relief.

The subject was discharged from the hospital on [redacted] -2008 to the rehabilitation facility on Amiodarone and a 40% tracheostomy collar.

On [redacted] -2008 (post enrollment day 19) the subject passed some maroon-colored stool, with periods of constipation **(SAE #006)**. She was readmitted to an outside hospital. Abdominal CT showed a large left pleural effusion, biliary excretion of contrast versus sludge, and distended rectum. The family refused colonoscopy. The subject was also found to have a urinary tract infection (Coagulase-negative Staph), which was treated with a 10-day course of Zyvox **(cont. of AE #004)**. CT scan revealed some right-sided patchy airspace disease for which she was started on Levaquin. The subject was discharged back to the rehabilitation facility in stable condition on [redacted] -2008.

On [redacted] -2008 (post enrollment day 27) the subject was again readmitted to an outside hospital from the rehab facility due to respiratory distress with a respiratory rate of 81 **(SAE #007)**. Infectious disease work-up found questionable pneumonia on the right side but no microbiological confirmation could be made. Chest x-ray found improvement of

right atelectasis versus infiltrates. The subject was discharged on [redacted]-2008 back to the rehab facility.

At the 30 day follow-up visit on 0[redacted]-2008, the subject's tracheostomy tube was noted to be plugged and she was breathing on her own without difficulty and had no reports of rapid atrial fibrillation **(update to SAE #002)**. A family member reported that the subject had "achey" pain isolated to her left leg, and had been receiving frequent pain medication **(part of AE #005).** The subject reported to be pain free at the time of her 30 day visit. She was discharged from rehab on [redacted]-2008 to home with assistance.

At the time of the 90 day follow-up visit on [redacted]-2008, it was reported that the subject was receiving radiation therapy for her pre-existing cancer that was nearing completion. While undergoing radiation therapy, the subject complained of musculoskeletal pain **(AE #009)** during body movements secondary to radiation, for which she was taking Lortab.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
25-Aug-2009	000	001	806 - Agitation/Excitation	N/A	N/A
26-Aug-2009	001	002	603 - Electrolyte imbalance	N/A	N/A
26-Aug-2009	001	003	102 - Hypotension	N/A	N/A
27-Aug-2009	**002**	**901**	**601 - Anemia**	**N/A**	**N/A**
27-Aug-2009	002	004	303 - Urinary Tract Infection	N/A	N/A
27-Aug-2009	002	006	116 - Bradycardia	N/A	N/A
28-Aug-2009	003	005	299 - Pulmonary Other: Chest congestion/ rhonchi	N/A	N/A
29-Aug-2009	004	007	397 - Genital Other: Penile swelling	N/A	N/A
30-Aug-2009	005	008	504 - GI Motility Disorders	N/A	N/A
01-Oct-2009	037	009	303 - Urinary Tract Infection	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 81-year-old Caucasian male with a past medical history of hypertension, atrial fibrillation (not on Coumadin), bladder cancer with surgical resection (1994), and bilateral macular degeneration rendering him legally blind. Medications at admission included: Toprol and aspirin. The subject was reported to be a social drinker.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 20:00 on [redacted]-2009. Symptoms at presentation included loss of consciousness, dysarthria and right facial droop. CT scan at admission revealed no acute pathology.

Baseline NIHSS was 9. The subject was randomized to the control arm of the SENTIS trial at 09:40, [redacted] 2009, 13.7 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) the subject became very agitated **(AE #001)** requiring Ativan, restraints, and a 24 hour sitter. On [redacted]-2009 the subject continued to be extremely agitated and combative. The nephew reported that his uncle drank 1 bottle of wine/day. Although, the subject's wife maintained that the subject did not have an alcohol addiction the delirium tremens protocol was initiated. The subject remained agitated throughout his stay and his medications were changed accordingly.

On [redacted]-2009 (post enrollment day 1) the subject received potassium and calcium replacements **(AE #002)**. The subject's blood pressure dropped to 95/52 **(AE #003)** and a 250cc fluid bolus was given. No further hypotensive episodes occurred.

On [redacted] 2009**,** while on a heparin drip, the subject developed large intramuscular hematomas on his right quadriceps and anterior thigh; a result of his ongoing agitation and combativeness. Two days later blood was noted on his posterior soft palate and his hemoglobin was 8.4g/dL; heparin was discontinued and 2 units of packed red blood cells were given **(SAE #901)**.

Also on [redacted]-2009 the subject complained of urinary retention. Urinalysis was positive for hemoglobin, leukocytes, and bacteria. A Foley catheter was placed and irrigated and the urinary tract infection was successfully treated with Bactrim **(AE #004)**. Clinically insignificant arrhythmias (PVCs, bigeminy and couplets) were documented that corrected on their own **(AE #006)**; an electrocardiogram was negative.

On [redacted]-2009 audible wet breath sounds and thick secretions were noted **(AE #005).** The subject was unable to clear his lungs and Mucomyst and Albuterol were started. Small pleural effusions were noted and frequent oral suctioning was required. No diagnosis of pneumonia was made.

On [redacted]-2009 (post enrollment day 4) penile swelling was noted; elevation and ice were recommended **(AE #007)**. Two days later the foreskin was adjusted and relief from the swelling was achieved.

On [redacted]-2009 the subject was given milk of magnesia and an enema as he had not had a bowel movement since prior to admission **(AE #008)**. Constipation resolved on [redacted]-2009.

The subject was discharged from hospital on [redacted]-2009 to a rehabilitation facility.

On [redacted]-2009 (post enrollment day 37) the subject's urine was positive for E-coli and he was successfully treated with Bactrim **(AE #009)**.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-Jan-2008	003	001	603 - Electrolyte imbalance	N/A	N/A
14-Jan-2008	003	002	603 - Electrolyte imbalance	N/A	N/A
17-Jan-2008	**006**	**003**	**207 - Pulmonary Embolism**	**N/A**	**N/A**
24-Jan-2008	013	004	303 - Urinary Tract Infection	N/A	N/A
28-Jan-2008	017	005	305 - Urinary retention	N/A	N/A
25-Apr-2008	105	006	899 - Other: Anxiety	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 59-year-old Caucasian male with past medical history of hypertension, cholecystectomy, prostate surgery, and obstructive sleep apnea. Medications at admission included: Amlodipine, Diovan, Flonase, and Lipitor. He is currently smoking and uses continuous positive airway pressure (CPAP) at night.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 12:00, [redacted]-2008. Symptoms at presentation included aphasia, facial palsy, no movement in right arm, dysarthria, and neglect. CT scan at admission revealed no acute abnormality and possible old infarct in the right frontal lobe. CT perfusion of the brain showed marked hypoperfusion of left middle cerebral artery (MCA) region. Baseline NIHSS was 16. The subject was randomized to the control arm of the SENTIS trial at 18:44, [redacted]-2008, 6.7 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2008 (post enrollment day 3), the subject's magnesium level dropped to 1.7mg/dL (norm 1.8 - 2.5) **(AE #001)** and his phosphorus level dropped to 1.7mg/dL (norm 2.4 - 4.5) **(AE #002).** The subject was given IV Magnesium 2g and Neutraphos; both events resolved on the following day.

On [redacted] 2008 (post enrollment day 6) CT of the chest was done to evaluate for pulmonary arteriovenous malformation (AVM). The scan showed occlusive filling defects in the right lower lobe, segmental and subsegmental pulmonary arteries, and a small right basal pleural effusion. A diagnosis of pulmonary embolism **(SAE #003)** was made and warfarin and enoxaparin were started**.**

The subject was discharged from the hospital on [redacted]-2008 to an in-patient rehabilitation unit.

On [redacted]-2008 (post enrollment day 13), the subject's urine culture showed Escherichia coli **(AE #004).** Cipro was initially given but was switched to Bactrim DS. On [redacted] 2008 urinary retention was noted **(AE #005)** and a Foley catheter was placed.

At the time of the 90 day follow-up visit on [redacted]-2008, the subject reported that he had recently been placed on Klonopin for anxiety **(AE #006).**

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-Jan-2009	000	006	413 - Headache	N/A	N/A
14-Jan-2009	000	007	606 - Hyperglycemia	N/A	N/A
15-Jan-2009	001	003	118 - Atrial Fibrillation	N/A	N/A
15-Jan-2009	001	004	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
16-Jan-2009	002	002	499 - Neuro Other: Lethargy	N/A	N/A
28-Feb-2009	**045**	**005**	**499 - Neuro Other: Altered mental status**	**N/A**	**N/A**
06-Mar-2009	051	008	603 - Electrolyte imbalance	N/A	N/A
06-Mar-2009	051	010	817 - Chest pain	N/A	N/A
09-Mar-2009	054	009	818 - Pain	N/A	N/A
12-Apr-2009	088	011	818 - Pain	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 78-year-old Caucasian female with past medical history of Crohn's disease status post ileal bowel resection in 2005, transient ischemic attack in 2007, gastroesophageal reflux disease (GERD), hypertension, macular degeneration, muscle spasms, anxiety, acute bronchitis and sinusitis, vitamin B12 deficiency. Medications at admission included: Atenolol, Tekturna, and monthly Vitamin B12 shots. The subject was told not to take anticoagulatory agents, including aspirin, due to her bowel resection secondary to Crohn's disease.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:00, [redacted]-2009. Symptoms at presentation included left-sided neglect, weakness, and sensory deficit along with slurred speech and left facial palsy. CT scan at admission showed no abnormalities. Baseline NIHSS was 18. The subject was randomized to the control arm of the SENTIS trial at 05:50, [redacted]-2009, 7.8 hours from last known normal.

NeuroFlo Procedure: N/A.

Post-Enrollment Course: The subject complained of a right-sided headache **(AE #006)** since her stroke onset on [redacted]-2009. She was continuously taking Tylenol as needed for general pain. MRI post enrollment revealed large acute infarct involving the right MCA distribution with possible focus of petechial hemorrhage in the lantiform nucleus (DSMB adjudication led to adjudication of non-event).

The subject's glucose level was 118mg/dL at admission **(AE #007)**; sliding scale insulin was initiated per institution stroke protocol and continued through the hospital stay. No treatment was needed following discharge.

On [redacted] 2009 the subject was diagnosed with atrial fibrillation **(AE #003)**. Electrocardiogram (ECG) showed atrial fibrillation and tachycardia. Echocardiogram revealed moderate to severe pulmonary hypertension and severely enlarged left atrium. The subject was treated with Metoprolol and Digoxin. She felt better on [redacted]-2009 and atrial fibrillation was converted to normal sinus rhythm per telemetry.

During the subject's hospitalization lipid study results were within normal limits but Zocor was initiated on [redacted] 2009 and continued through the 90 day follow-up visit **(AE #004)**.

On [redacted]-2009 (post enrollment day 2) the subject appeared to be more lethargic and difficult to arouse **(AE #002)**. CT of the brain was consistent with maturing right MCA territory infarct without hemorrhagic conversion or progression. Lethargy was thought to be the sedating side effect of Flexeril which had been prescribed for her muscle spasm since admission. Flexeril was discontinued and lethargy had improved. The subject was clinically stable and was discharged from hospital on [redacted] 2009 to a rehabilitation facility.

At the time of the 30 day follow-up visit on [redacted]-2009 the subject was started on Coumadin for her atrial fibrillation **(update to AE #003)** and continued on it through the 90 day follow-up visit.

On [redacted]-2009 (post enrollment day 45) the subject was brought to the emergency room (ER) from a nursing home by her family with a complaint of agitation and behavioral changes **(SAE #005)**. The agitation increased even after the subject had been given Ativan by a psychiatrist the day before. The family insisted on having the subject examined further for this issue. A chest x-ray and lab results were all within normal ranges. The subject was discharged back to the nursing home the same day.

Four days later on [redacted] 2009, the family brought the subject back to the ER because of her altered mental status. She became more confused, disoriented, paranoid, and her agitation had worsened since the last ER discharge. The subject's behavior was "uncharacteristic" per family. The family insisted that the subject needed to be hospitalized this time and she was admitted. Infectious cause was ruled out. CT of head did not show any evidence of stroke progression. The subject was diagnosed with delirium/altered mental status secondary to medications **(update to SAE #005)**;

Benzodiazepines, Amiodarone and Ambien were discontinued. Depakote, Seroquel and Melatonin were started.

On [redacted]-2009 the subject's potassium level was 3.2mmol/L **(AE #008)**; a single dose of potassium supplement was administered.

Also on [redacted]2009 the subject had mild chest pain **(AE #010)** with abnormal ECG. A follow-up ECG was normal, except for sinus bradycardia. Cardiac enzyme tests were normal on [redacted]-2009 but elevated on [redacted]-2009 (Creatine Kinase (CK) was 214U/L (24-180), CK-MB was 6.6ng/mL (0.0 - 5.0), and CK-MB Relative Index was 3.1% (<3.0). Troponin I had been < 0.013ng/mL). No follow-up CK/CK-MB were recorded and no treatment was required. This was a single episode of chest pain and the subject had no similar complaints through her 90 day follow-up visit.

On [redacted]-2009 (post enrollment day 54) the subject complained of left shoulder pain **(AE #009)** and was treated with Tylenol. She was discharged back to the nursing home in stable condition on the same day.

On [redacted]-2009 (post enrollment day 88) the subject was brought to the ER due to the right flank pain radiating to the groin **(AE #011)**. Shortness of breath, blood in stool, and rectal/vaginal itching were also reported. External hemorrhoid was noticed upon physical exam. All diagnostic tests were within normal range. The subject was discharged to her home on the same day without any treatment.

At the 90 day follow-up visit on[redacted]-2009 the subject's NIHSS decreased to 10 and mRS remained at 4. The subject no longer complained of headache but continued with Tylenol for her general pain. Her lethargy and agitation were improved but not completely resolved **(update to AE #002 and SAE #005)**.

Subject [redacted], enrolled [redacted]2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
08-Sep-2009	000	001	499 - Neuro Other: Delirium, hallucination, and agitation	N/A	N/A
08-Sep-2009	000	004	398 - Urinary Other: Bladder spasms	N/A	N/A
09-Sep-2009	001	003	115 - Patent foramen ovale (PFO)	N/A	N/A
09-Sep-2009	**001**	**002**	**805 - Sepsis**	**N/A**	**N/A**
09-Sep-2009	001	903	399 - Renal Other: Exophytic cyst of right kidney	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
09-Sep-2009	001	904	599 - GI other: Diverculosis	N/A	N/A
12-Sep-2009	004	005	899 - Other: Nose bleeds	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is 70-year-old Caucasian male with past medical history of hypertension, probable transient ischemic attacks (TIAs), duodenal ulcers, and daily lower abdomen cramping of unknown etiology relieved by the over-the-counter antacid, and a recent cholecystectomy on [redacted]-2009. The surgeon was suspicious of a benign mass near the pancreas. Medications at admission included: aspirin, Lodine, Lisinopril, antiacid, Multivitamin, and Vicodin as needed for post cholecystectomy.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 12:00, [redacted]-2009. Upon admission the subject was experiencing severe delirium/hallucinations/agitation **(AE #001)**. He was combative and restrains were applied and medication administered. Symptoms at presentation included confusion, facial palsy, expressive aphasia and acute delirium with hallucinations. CT scan at admission revealed no abnormality. Baseline NIHSS was 7. The subject was randomized to the control arm of the SENTIS trial at 16:40, [redacted] 2009, 4.7 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment), the subject complained of urinary discomfort due to the foley catheter **(AE #004)**. The foley catheter was removed and Diprovan was given.

NCT on [redacted]-2009 noted ventriculomegaly, right greater than left, without transependymal cerebrospinal fluid (CSF) flow. No acute infarct, midline shift, or hemorrhage was found.

On [redacted]-2009 (post enrollment day 1), the 24 hour NCT noted a new mild right posterior hemisphere sulci effacement without evidence of mass effect, midline shift, or hemorrhage. The subject was hypotensive (lowest 70's/40's); vasoactive agents and IV fluids were given. The subject experienced significantly increased heart rate and intermittent runs of tachycardia. A pulmonary artery catheter was placed to monitor heart status and was removed the next day with normal cardiac function noted. A transesophageal echocardiography (TTE) on [redacted]-2009 suggested presence of a patent foramen ovale **(AE #003).**

On [redacted]-2009 the subject went into cardiogenic vs. septic shock. He experienced circulatory failure, neurologic failure and acute respiratory failure but was afebrile. The subject required ventilation, frequent vasoactive agent adjustments, neurological assessments and constant monitoring. A percutaneous endoscopic gastrostomy (PEG)

tube was placed as part of medical management. Given the subject's white blood cells (WBC) of 14.1 mg/dl, sepsis was suspected **(SAE #002).** The 24 hour NIHSS was not assessed due to the subject being intubated and sedated.

CT scan of the subject's chest, abdomen, and pelvis on [redacted]-2009 revealed a probable 3 mm nodule in right upper lung (visualization was limited by motion artifact), bilateral atelectasis in the lungs, and adjacent trace pleural effusions **(part of SAE #002)**. It also showed a small exophytic cyst in the the right kidney **(AE #903)** and diffuse diverticulosis **(AE #904)** in the left hemicolon. CT scan also revealed free fluid in abdomen and pelvis; a small amount of fluid was identified in the anterior pararenal space and peripancreatic region.

During hospitalization, the work ups conducted to determine the etiology of delirium/hallucinations and sepsis ruled out illicit drug use and heavy metal poisoning (history of lead exposure). Lab tests were significant for elevated CSF protein at 93mg/dl (norm 15 - 45) and CSF glucose at 113mg/dl (norm 60 - 80). Blood and urine culture findings were not clinically significant. The full paraneoplastic panel was negative as well as negative findings were for various viral infections. Cardiac and hepatic enzymes were within normal limits. Electroencephalogram (EEG) ruled out seizure but revealed an indication of encephalopathy. The subject was given broad spectrum antibiotics and antiviral until the results were fully obtained. He remained afebrile throughout his hospitalization.

On [redacted] 2009 the subject was given sliding scale insulin as his glucose level was 237. Additional various electrolyte replacements were given throughout his hospitalization. The subject was also anemic with low hematocrit of 29% and hemoglobin of 10.3g/dl. [Note: After reviewing this information, the DSMB did not consider these findings clinically relevant enough to warrant additional AEs.]

The subject's status gradually improved, with hemodynamic status normalizing and subject becoming conscious and oriented to his surroundings. Hypotension, electrolytes and abnormal lab values improved and normalized. The subject was extubated on [redacted]-2009 and the PEG tube was also removed. His 4 day NIHSS on [redacted]-2009 was ranked as 0. Gradual improvement was noted in delirium/hallucinations. On [redacted] 2009, the delirium was documented as resolved **(update to AE #001)**.

On [redacted]-2009 (post enrollment day 4), the subject woke up with a nose bleed containing clots **(AE #005)**. Heparin was held and dry gauze packing was administered. This resolved on the following day.

The subject was discharged from the hospital on [redacted] 2009 to home. No discharge dictation is available; however, notes indicated a final diagnosis of hallucinations and transient neurological attack with unknown etiology.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
09-Dec-2008	**004**	**001**	**403 - Cerebral edema**	**N/A**	**N/A**
Unk-Dec-2008		**901**	**413 - Headache**	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 79-year-old Caucasian male with a past medical history of myocardial infarction, angina, atrial fibrillation, hypertension, hyperlipidemia and past cerebrovascular accident (CVA) with mild left-sided weakness (mRS=1). Medications at admission included: Coumadin, Lasix, Prednisone, Lovenox, Amoxicillin, and Lortab.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 08:00 on [redacted]-2008. Symptoms at presentations included partial gaze palsy, facial palsy, left-sided weakness, sensory loss, dysarthria and neglect. CT scan at admission revealed a large right ischemic middle cerebral artery stroke without evidence of hemorrhage. Baseline NIHSS was 16. The subject was randomized to the control arm of the SENTIS trial at 16:20, [redacted]-2008, 8.3 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 24 hour MRI on [redacted]-2008 (post enrollment day 1) revealed a possible petechial hemorrhage in portion of the infarct. The 24 hour NIHSS remained at 16. A repeat MRI on [redacted]-2008 indicated minor mass effect and 1-2mm midline shift from right to left **(SAE #001).** The subject's NIHSS increased to 20. CT scan on [redacted]-2008 specifically noted "no hemorrhage", and Core Lab analysis concurs.

The subject was discharged from the hospital on [redacted]-2008 to a rehabilitation facility. While in the hospital, the subject was treated for headache **(AE #901).**

At the 90 day follow-up visit on [redacted]-2009 the subject's NIHSS was ranked as 15 with mRS of 5.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
09-May-2009	000	002	303 - Urinary Tract Infection	N/A	N/A
02-Jun-2009	**024**	**001**	**817 - Chest pain**	**N/A**	**N/A**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
03-Jun-2009	025	004	815 - Skin irritation	N/A	N/A
08-Jun-2009	030	901	811 - Depression	N/A	N/A
16-Jun-2009	**038**	**003**	**109 - Arrhythmia with pacemaker placement**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is an 80-year-old Caucasian female with past medical history of coronary artery disease, congestive heart failure, recurrent urinary tract infections, atrial fibrillation with cardioversion in 2005, hypertension, hyperlipidemia, degenerative joint disease with chronic back pain, chronic renal insufficiency, chronic bronchitis, and obesity. The subject recently started smoking again after quitting in 2007; she smoked a pack a day for more than 50 years. The subject also had a gastrointestinal bleed secondary to Mallory Weis tear and has refused Coumadin since that time. Medications at admission included: Lisinopril, Metropolol, Nifedipine, Pacerone, Plavix, Zocor, Lasix, and aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 17:30, [redacted]-2009. Symptoms at presentation included decreased level of consciousness, aphasia, facial palsy, right-sided weakness and dysarthria. CT scan at admission revealed no evidence of acute infarct or hemorrhage. Electrocardiogram (ECG) showed atrial fibrillation and was consistent with the ECG done in Jan-2007. Baseline NIHSS was 18. The subject was randomized to the control arm of the SENTIS trial at 02:35, [redacted]009, 9.1 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: MRI on [redacted]-2009 (the day of enrollment) at 10:00 showed acute left middle cerebral artery (MCA) territory ischemic insult and a small zone of signal abnormality along the cortical surface or perhaps in the subarachnoid space of the left parietal operculum that may represent early laminar necrosis or minimal hemorrhage. Petechial hemorrhage was not present on 31 hour CT on [redacted]2009.

The subject was noted to have foul smelling urine with a small amount of blood **(AE #002)**. Antibiotics were started and urine cultures were collected. Cultures revealed no growth and the Foley catheter was draining clear yellow urine. Repeat urine cultures on [redacted]-2009 were positive for Staph species.

The subject was discharged from hospital on [redacted]009 to rehab and to home on [redacted]-2009.

On [redacted]2009 (post enrollment day 24) the subject presented to the emergency room and was admitted with complaints of chest pain, tachycardia, and dyspnea **(SAE #001)**. Chest pain upon admission was 2/10. Myocardial infarction and pulmonary embolus were ruled out. An ECG revealed atrial fibrillation and non-specific ST-T wave changes.

Coumadin and Lovenox were started with a goal to discharge once the subject's International Normalized Ratio (INR) stabilized.

On [redacted]-2009 a large weeping fungal rash was noted on the bilateral groin, perianal, medial buttock, and coccyx area **(AE #004)**. Antifiungal and drying agents were initiated. The rash improved but was ongoing at discharge.

NCT on [redacted] 2009 noted continued evolution of the left posterior insular and temporoparietal infarct with encephalomalacia. There was no corresponding decline in neurologic status, and it was determined that this indicated normal evolution, opposed to stroke progression.

At the time of the 30 day follow-up visit on [redacted]-2009 the subject was noted to be taking Sertraline, Provigil, and Trazodone for depression **(AE #901).** The subject continued on antidepressants through the 90 day follow-up visit.

The subject was originally scheduled to be discharged from the hospital on [redacted]-2009 but was retained in order to achieve a steady anticoagulation on warfarin and consistent control of atrial fibrillation rate. On [redacted]-2009 (post enrollment day 38) the subject experienced atrial fibrillation with rapid ventricular response and intermittent episodes of asymptomatic bradycardia with 2-3 seconds pauses **(SAE #003)**. On [redacted]-2009, a single chamber pacemaker was implanted and the subject was discharged to inpatient rehab on [redacted]-2009.

At the 90 day follow-up visit on [redacted] 2009 the subject's NIHSS was ranked as 7 with mRS of 4.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
20-Aug-2009	000	002	301 - Renal dysfunction	N/A	N/A
20-Aug-2009	000	001	602 - Thrombocytopenia	N/A	N/A
20-Aug-2009	000	003	117 - Tachycardia	N/A	N/A
20-Aug-2009	000	004	606 - Hyperglycemia	N/A	N/A
20-Aug-2009	**000**	**006**	**414 - Neurological worsening**	**N/A**	**N/A**
20-Aug-2009	000	901	603 - Electrolyte imbalance	N/A	N/A
22-Aug-2009	002	005	899 - Other: Coccyx redness, Stage 1 decubitus	N/A	N/A
17-Nov-2009	089	902	811 - Depression	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 87-year-old Caucasian male with past medical history of hypertension, glaucoma, spinal stenosis, gait disturbance (uses cane), left eye cataract status post surgery and a past history of acute renal failure. Medications at admission included: Metoprolol, Toprol, Triamterene/hydrochlorothizide, Travatan, Combigan, Celebrex, Meloxicam, and Flomax.

Current Stroke Onset and NeuroFlo Enrollment: The subject was last known normal at 23:00 on [redacted] 2009. Symptoms at presentation included facial palsy, left-sided weakness, dysarthria, and slurred speech. CT scan at admission revealed acute ischemic changes in the right middle cerebral artery (MCA) distribution with no hemorrhage. His creatinine was 2.1, so a waiver was obtained from CoAxia to enroll this subject. Baseline NIHSS was 12. The subject was randomized to the control arm of the SENTIS trial at 11:45, [redacted] -2009, 12.8 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2009 (the day of admission), the subject's creatinine was 2.1 and blood urea nitrogen (BUN) was 29 **(AE #002).** It was felt that the elevated level of creatinine was due to dehydration and mild pre-renal azotemia. The subject received normal saline (IV) hydration. During the hospital stay, the subject's creatinine fluctuated between 1.6 and 1.9. Renal ultrasound revealed a simple appearing 5.2cm cyst within the right kidney inferior pole, otherwise unremarkable. No other intervention was documented.

At the time of admission, the subject's platelet count was low at 128 **(AE #001)**. It fluctuated between 96 and 131 during his index hospitalization. Hematology consultation determined that the subject's thrombocytopenia appeared to be improving as well as his renal insufficiency and no other workup was required.

The subject also developed asymptomatic premature ventricular contractions, bigeminy and occasional short bursts of non-sustained ventricular tachycardia **(AE #003)**. His magnesium and potassium levels were normal at the time. No further cardiac testing was pursued.

The subject's blood glucose was 141 on admission and ran between 117-154. Sliding scale insulin was administered a few times in the hospital **(AE #004).**

A follow-up CT on [redacted] -2009 revealed decreased attenuation in the mid-right frontal lobe compatible with early edema and loss of the gray-white matter junction compatible with evolving infarction **(SAE #006)**; no mass effect or hemorrhage was seen. The 6 hour NIHSS was 10. The 24 hour NIHSS on [redacted] -2009 increased to 14 with deeper hemiplegia of the left arm and leg. The 24 hour CT scan showed "a moderately prominent region of edema in the right MCA distribution, representing subacute infarction". The subject showed clear sign of aspiration and started feeding via Dobbhoff tube. The 4 day NIHSS on [redacted] 2009 increased to 16.

During the index hospitalization the subject had low serum potassium and high sodium and chloride concentration. Potassium supplements were given **(AE #901).**
A reddened area on the subject's buttocks **(AE #005)** was observed on [redacted]-2009. Treatment with Xenaderm ointments was administered.

Medications for diarrhea, cough, and narcolepsy were reported at the 30 and 90 day follow-up visits. Given the subject's stroke progression and tube feedings through hospitalization and into rehab, the above symptoms were not reported as separate adverse events.

The subject was discharged from hospital on [redacted]-2009 to a rehabilitation unit.

At the 90-day follow-up visit on [redacted] 2009, Celexa was prescribed for depression **(AE #902).** The subject's 90 day NIHSS was ranked as 9 with mRS of 5.

Subject [redacted], enrolled [redacted] 2006

Event Onset Date	Days to AE	AE #	Adverse Event Description	Device Related	Procedure Related
11-Apr-2006	000	901	603 - Electrolyte Imbalance	N/A	N/A
18-Apr-2006	**007**	**001**	**118 - Atrial Fibrillation**	**N/A**	**N/A**
26-Apr-2006	**015**	**003**	**716 - Carotid Stenosis with Endarterectomy**	**N/A**	**N/A**
25-Jun-2006	075	002	899 - Other: Epistaxis	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 82-year-old Caucasian male with a past medical history of hypertension, hyperlipidemia, non-insulin dependent diabetes, hypothyroidism, myocardial infarction (1980), percutaneous transluminal coronary angioplasty (1998), and permanent cardiac pacemaker for third degree heart block (2004). Medications at admission included: Norvasc, aspirin, Glyburide, Lipitor, Imdur, Synthroid, Triamterene, hydrochlorthiazide, Paxil, Ativan, and Ambien.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 10:30 on [redacted]-2006. Symptoms at presentation included severe dysarthria with right-sided weakness and right facial droop. CT scan at admission revealed no definite acute stroke. Baseline NIHSS was 5. Cardiac exam was normal. The subject was randomized to the control arm of the SENTIS trial at 15:20, [redacted]-2006, 4.8 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2006 (the day of enrollment) the subject's potassium level was 3.7mEq/L(norm 3.8-4.8) **(AE #901)**. Potassium replacement was given and repeated on [redacted]-2006.

On [redacted] 2006 (post enrollment day 7) the subject's pacemaker was interrogated to determine whether it was functioning adequately. It was determined that the subject had episodes of atrial fibrillation lasting up to 6 hours **(SAE #001)**. The subject was anticoagulated which prolonged his hospitalization.

CTA at admission revealed left internal carotid artery (ICA) stenosis. The subject was transferred to another hospital in the care of his cardiologist for treatment of the carotid stenosis. On [redacted]-2006 the subject underwent left carotid endarterectomy **(SAE #003)** at another hospital, which was followed by rehabilitation. No further details of that hospitalization are available.

On [redacted]-2006 (post enrollment day 75) the subject was seen in the emergency department for a nosebleed **(AE #002)** that had resolved on the way to the hospital. He was not admitted.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
18-Mar-2008	000	901	303 - Urinary Tract Infection	N/A	N/A
18-Mar-2008	000	902	818 - Pain	N/A	N/A
19-Mar-2008	001	002	102 - Hypotension	N/A	N/A
19-Mar-2008	001	007	601 - Anemia	N/A	N/A
24-Mar-2008	006	004	499 - Neuro Other: Vertigo	N/A	N/A
24-Mar-2008	006	006	599 - GI Other: C.difficile/ Colitis	N/A	N/A
25-Mar-2008	007	005	603 - Electrolyte imbalance	N/A	N/A
27-Mar-2008	**009**	**003**	**819 - Infection**	**N/A**	**N/A**
27-Mar-2008	**009**	**903**	**414 - Neurological worsening**	**N/A**	**N/A**
19-May-2008	062	905	118 - Atrial Fibrillation	N/A	N/A
19-May-2008	062	907	303 - Urinary Tract Infection	N/A	N/A
19-May-2008	062	908	818 - Pain	N/A	N/A
19-May-2008	062	909	899 - Other: Decubitus ulcer	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
30-Jun-2008	104	911	303 - Urinary Tract Infection	N/A	N/A
02-Jul-2008	106	912	699 - Lab/electrolyte Other: Positive blood culture	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 87-year-old Caucasian female with past medical history of type II diabetes, hypertension, arthritis, and atrial fibrillation. Medications at admission included: dyrenium, Toprol XL, aspirin, glyburide, and lisinopril.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 03:00, [redacted]-2008. Symptoms at presentation included dysarthric but comprehensible speech, left facial droop, left-sided weakness, and inattention. CT scan at admission revealed right centrum semiovale infarct and lacunar infarcts in the bilateral capsules. Electrocardiogram (ECG) showed atrial fibrillation. Baseline NIHSS was 12. The subject was randomized to the control arm of the SENTIS trial at 12:30, [redacted] 2008, 9.5 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2008 (the day of enrollment), the subject's urinalysis was cloudy and positive for nitrates, leukocytes, and hemoglobin. The subject was asymptomatic with a normal white blood cell count (WBC). Repeat urinalysis was positive for E-coli and the subject was started on Ancef **(AE #901)**. On the same day the subject complained of right hip pain and was given Tylenol #3 **(AE #902)**.

On [redacted] 2008 (post enrollment day 1) the subject was hypotensive with a blood pressure (BP) of 94/63 **(AE #002)**; a normal saline bolus was given. Later the subject again became hypotensive and a second bolus was given along with water via her naso-gastric tube. BP returned to normal limits with regular fluid intake. The subject was also noted to be anemic **(AE #007)** with hemoglobin (Hgb) 10.1 and hematocrit (Hct) 29%; no treatment was given at that time.

On [redacted]-2008 (post enrollment day 6) the subject complained of dizziness, motion sickness, and nausea. Vertigo **(AE #004)** was treated with Reglan and meclizine and all symptoms resolved within two days. The subject also had episodes of loose stools. Clostridium difficile infection was suspected **(AE #006)** and a seven day course of Flagyl was started. WBC was within normal limits at 7.7.

On [redacted]-2008 the subject had a potassium level of 5.1mmol/L (norm 3.8 - 4.8) **(AE #005)**. It was decided to treat this aggressively with Kayexalate and the subject subsequently had two large bowel movements. The event resolved on the following day.

The subject was discharged in stable condition from hospital on [redacted]-2008 to an in-patient rehab center affiliated with another hospital.

On [redacted]-2008 (post enrollment day 9), the subject was admitted to the rehab-affiliated hospital for suspected infection of unknown source **(SAE #003)**. The investigator felt that this admission was for sepsis, based on the subject's history of suspected Clostridium difficile at the time of her discharge to the rehab center (a seven day course of Flagyl was to end on [redacted] 2008). According to a family member, the subject began having significant neurological deterioration **(SAE #903)** on the first day in rehab, [redacted] 2008, with no subsequent change in CT scans. The subject remained in the hospital until [redacted]-[redacted]-2008 when she was discharged to a nursing home. Her NIHSS on [redacted]-2008 was 25.

On [redacted]-2008 (post enrollment day 62), the subject was re-admitted to the index hospital with low oxygen saturation and labored respirations, elevated WBC at 16.2 but was afebrile. The subject had decreased awareness and was anxious. Upon admission it was noted that the subject was taking ciprofloxacin and Flagyl for Clostridium difficile **(cont. of SAE #003, AE #006)**. The subject was tachycardic (pulse 96-150, irregularly irregular). ECG showed rapid atrial fibrillation with rapid ventricular response of 135. Her international normalized ratio (INR) was sub-therapeutic and Coumadin was adjusted for ongoing atrial fibrillation management **(AE #905)**. WBC count increased to 20.9 and her stool was guiac-positive; Vancomycin, Gentamycin, and Piperacillin were initiated. A chest x-ray was clear. Blood cultures revealed coagulase-negative Staphylococcus in 1 of 3 bottles. A colonoscopy was unremarkable. A urine culture was positive for E. coli **(AE #907)**. The subject was treated with Ceftriaxone and Vancomycin IV. During the subject's admission, her Hgb ranged from 8.5 to 11.4; one unit of red blood cells was given on [redacted]-2008 **(cont. of AE #007)**.

Also, on [redacted]-2008, the subject complained of back and left arm pain **(AE #908).** She was given morphine with moderate relief. It was also noted that the subject had a stage II decubitus ulcer **(AE #909).** This was treated with multivitamins, ascorbic acid, zinc and wound care during her hospitalization.

On [redacted] 2008 (post enrollment day 70) the subject had improved clinically and her diarrhea resolved. She was transferred back to the nursing home where she was to complete a seven day course of Vancomycin for Clostridium difficile infection (on [redacted] 2008 the subject was positive for Clostridium difficile). The WBC count was 29.9 on [redacted]-2008 and remained elevated at 15.9 on [redacted]-2008. On [redacted]-2008 the subject was found to be neurologically stable with prognosis for good recovery.

By [redacted]-2008 the subject's Hgb/Hct had again dropped to 9.4/28.1. On [redacted] 2008 Hgb/Hct was 8.8/25.3 and blood was given **(cont. of AE #007)**.

On [redacted]-2008 (post enrollment day 104) the subject was brought to the emergency room (ER) after experiencing multiple episodes of vomiting and diarrhea followed by low oxygen saturation levels (respiratory insufficiency: respiratory rate 35, pulse 100).

The diarrhea was presumably due to continued Clostridium difficile colitis **(cont. of SAE #003, AE #006)**, although, stool cultures were not collected. Vancomycin, Gentamycin, and Cefazolin were given in the ER and the subject was initially admitted to the telemetry unit when she was found to be in rapid atrial fibrillation; INR was 1.8. She was treated with Cardizem. A urine culture was positive for 3+ leukocytes and Enterococcus **(AE #911)**. The subject's 90 day NIHSS on [redacted]-2008 decreased to 14.

The subject remained in the hospital. Her blood culture results from [redacted] 2008 (post enrollment day 106) showed gram-positive cocci and coagulase-negative Staphylococcus in 1 of 3 bottles (anaerobic) **(AE #912)**. The subject continued to be treated with Vancomycin, Piperacillin, and Bentamicin.

Subject [redacted] enrolled [redacted] 2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
01-Aug-2006	001	004	119 - Elevated Cardiac Enzymes	N/A	N/A
01-Aug-2006	001	005	699 - Lab/electrolyte Other: Creatinine elevated	N/A	N/A
02-Aug-2006	**002**	**007**	**502 - Ischemic Bowel Syndrome**	**N/A**	**N/A**
02-Aug-2006	002	001	601 - Anemia	N/A	N/A
05-Aug-2006	005	902	115 - Patent foramen ovale (PFO)	N/A	N/A
08-Aug-2006	008	003	205 - Infectious pneumonia	N/A	N/A
12-Aug-2006	**012**	**002**	**501 - GI Bleed**	**N/A**	**N/A**
12-Aug-2006	012	903	816 - Oral thrush	N/A	N/A
28-Aug-2006	**028**	**008**	**703 - Venous Thrombosis (DVT)**	**N/A**	**N/A**
28-Aug-2006	028	010	815 - Skin irritation	N/A	N/A
20-Sep-2006	**051**	**006**	**409 - New ischemic stroke**	**N/A**	**N/A**
20-Sep-2006	051	009	603 - Electrolyte imbalance	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 72-year-old Caucasian male with past medical history of hypertension, hyperlipidemia, status post skin cancer (squamous cell carcinoma) excision, subdural hematoma evacuation (1995), varicose veins and borderline diabetes. He was initially admitted to the hospital with abdominal pain and a possible small bowel obstruction (SBO) on [redacted]-2006. He was admitted to be evaluated for the surgery and was decompressed with a nasogastric tube. The subject showed signs of thrombocytopenia with a platelet count of 58,000. Medications at admission included:

Lipitor, aspirin 81mg, Lasix, potassium supplement, and an unknown blood pressure medication.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 18:45 on [redacted] 2006, while being worked up for the suspected SBO. Symptoms included slurred speech and right-sided weakness. Baseline MRI/MRA revealed acute infarction without hemorrhage within the territories of the left posterior cerebral artery (PCA) and left posterior inferior cerebellar artery (PICA) involving the left inferomedial cerebellum, left thalamus; left occipital, temporal and posterior parietal lobes. Baseline NIHSS was 8. At the time of enrollment the subject's platelet count was 115,000. The subject was randomized to the control arm of the SENTIS trial at 23:35, [redacted] -2006, 4.8 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2006 (post enrollment day 1), laboratory findings indicated elevation of Troponin **(AE #004)** and creatinine **(AE #005)**. The subject worsened with acute renal dysfunction, respiratory distress, hypotension, tachypnea, fever and increased abdominal pain. He was found to have an ischemic small bowel syndrome involving the distal jejunum and proximal ileum which included ischemic stricture. The subject was taken to the operating room for a bowel resection **(SAE #007)** and transfused with 1 unit of blood (hemoglobin (Hgb)/hematocrit (Hct) was 26.1/ 8.9) **(AE #001)**.

On [redacted] 2006 (post enrollment day 4), NIHSS increased to 7 from 4 at the 24 hour assessment. MRI/MRA revealed evolution of the index stroke which involved the entire left occipital lobe as well as portions of the inferior parietal and posterior temporal lobes, and the left superior medial cerebellum.

On [redacted] -2006, a transesophageal echocardiogram suggested a patent foramen ovale **(AE #902)** within the interatrial septum, an interatrial septal aneurysm, severe atherosclerotic disease, ulceration and associated thrombus within the aortic arch and thoracic aorta. IV heparin was started for anticoagulation.

On [redacted] -2006 (post enrollment day 8), the subject was diagnosed with left lower lobe pneumonia **(AE #003)** which was treated with antibiotics. The subject was relatively stable until 12-Aug-2006, when he developed an upper gastrointestinal (GI) bleed **(SAE #002)** from gastric ulcers. His lowest Hgb/Hct was 8.7/26.6. At the time of the GI bleed the subject had an episode of tachycardia which resolved with blood transfusions. He received a total of 16 units of packed red blood cells over the next two days. By [redacted] 2006, his Hgb/Hct improved to 13.8/42.1.

On [redacted] -2006 (post enrollment day 12) the subject was prescribed Nystatin oral swabs for oral thrush **(AE #903)**.

The subject was discharged from the hospital on [redacted] -2006 to a rehabilitation facility with NIHSS of 9.

Upon the subject's arrival at the rehabilitation facility on [redacted]-2006, a left lower extremity edema was noted. Doppler ultrasound of the left lower extremity revealed deep vein thrombosis (DVT) requiring re-hospitalization **(SAE #008)**. The following day, an inferior vena cava filter was placed to prevent embolization of the thrombus.

Skin ulcerations **(AE #010)** were also noted upon arrival at the rehabilitation facility. Wounds on the back and thigh were treated with dry dressing, and the red excoriated scrotum was treated medically. There was also some dehiscence of the abdominal incision site which was treated with daily wet to dry dressings with good results.

On [redacted]-2006 (post enrollment day 51), the subject was admitted with a new ischemic stroke **(SAE #006)** involving the left parieto-occipital lobes (left PCA territory) and the posterior aspect of the left temporal lobe (left MCA territory). During this admission, the subject experienced significant electrolyte imbalance **(AE #009)**. Potassium, magnesium and calcium levels were low and required replacement. Subsequently, they were stabilized.

The 90 day NIHSS on [redacted] 2006 was assessed as 3 with mRS of 4.

Subject [redacted], enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
11-May-2008	001	002	814 - Sleeping Disturbance/ Disorder	N/A	N/A
11-May-2008	001	003	503 - Nausea/Vomiting	N/A	N/A
13-May-2008	003	004	504 - GI Motility Disorders	N/A	N/A
Unk-May-2008		901	413 - Headache	N/A	N/A
Unk-May-2008		902	603 - Electrolyte imbalance	N/A	N/A
20-May-2008	**010**	**001**	**411 - Transient ischemic attack**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 41-year-old Hispanic female with past medical history of hypertension (not on medication) and gastro-esophageal reflux disease. Medications at admission included: Prevacid, Excedrin, and oral contraceptive.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 09:30, [redacted]-2008, when she developed rather sudden onset of left visual loss which resolved soon after. An expressive aphasia was noted at 11:00, which also resolved. Symptoms at presentation included mild expressive aphasia and mild loss of level of consciousness. Baseline CT was unremarkable. MRI demonstrated a left frontoparietal

infarct with a large territory of perfusion mismatch involving a significant portion of the MCA territory, as well as a likely ICA occlusion. Baseline NIHSS was 2 (1 for aphasia and 1 for stating the wrong month), which did not meet enrollment criteria and a protocol deviation was later received. Although, the subject's NIHSS did not increase, a mild qualitative worsening in her expressive aphasia was observed. The subject was randomized into the control arm of the SENTIS trial at 21:50, [redacted] 2008, 12.3 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2008 (post enrollment day 1) the subject complained of insomnia **(AE #002)** and was given Benadryl with good results. On the same day she also complained of nausea **(AE #003)** and was given Reglan.

On [redacted]-2008 (post enrollment day 3), the subject complained of constipation **(AE #004)** and was given milk of magnesia for two days.

During the index hospitalization, the subject was treated with Morphine sulfate and Acetaminophen for headache **(AE #901)** as well as with magnesium sulfate, potassium chloride, and calcium gluconate for electrolyte imbalance **(AE #902)**.

The subject was discharged from hospital on [redacted] 2008 to home with an NIHSS of 1 for a mild inability to spell multi-syllabic words.

The subject resumed normal activities until [redacted]-2008 (post enrollment day 10) when she was readmitted with blurry patches across her left visual field **(SAE #001)** that she noticed when she awoke at 07:30. The subject denied loss of vision within the blurry areas. The blurry vision began to clear over the next few hours and by the time of discharge, her vision was clear. No new findings were identified on MRI from previous admission. The subject's complaint was thought to be due to a slow-flow state in the ophthalmic artery. The subject was started on oral anticoagulation to prevent further clot formation, and was discharged on [redacted]y-2009.

At the 90 day NIHSS on [redacted]-2008 the subject's was ranked as 0.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
08-May-2008	000	901	103 - Hypertension: worsening	N/A	N/A
11-May-2008	003	002	503 - Nausea/Vomiting	N/A	N/A
11-May-2008	003	003	413 - Headache	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
12-May-2008	**004**	**001**	**118 - Atrial Fibrillation with pacemaker placement**	**N/A**	**N/A**
13-May-2008	005	004	806 - Agitation/Excitation	N/A	N/A
13-May-2008	005	005	303 - Urinary Tract Infection	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 78-year-old Caribbean male from Trinidad with past medical history of hypertension, prostatectomy 10 months prior to admission, occasional headaches, previous infarcts (per MRI of brain) and possible remote myocardial infarction (per ECG). The subject was visiting his daughter. Medications at admission included: Atenolol.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 11:30 on [redacted] 2008. Symptoms at presentation included decreased level of consciousness with moderate aphasia. CT scan at admission revealed no acute changes and no hemorrhage. MR perfusion showed a small perfusion defect corresponding to the area of acute infarction in the left parietal lobe. Baseline NIHSS was 6. The subject was randomized to the control arm of the SENTIS trial at 21:50, [redacted] 2008, 10.3 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject's blood pressure was elevated at 204/100 at the time of admission and remained elevated during the hospital stay **(AE # 901)**. It remained elevated at 194/110 on [redacted]-2008. The subject was started on Benazepril and Metaprolol at index hospitalization and continued on Amlodipine through the 30 day follow-up**.**

On [redacted]-2008 (post enrollment day 3), the subject complained of nausea, vomiting **(AE #002)**, and felt some vertigo. Zofran was given with resolution of symptoms. The subject also complained of headache **(AE #003)** and was treated with Tylenol and morphine sulphate.

On [redacted] 2008 (post enrollment day 4), the subject developed atrial fibrillation with rapid ventricular response **(SAE #001)**; Amiodarone and Digoxin were initiated. On the following day, the subject had sinus pauses, with one longer than 7 seconds, and a brief episode of syncope. Amiodarone was stopped and a dual chamber pacemaker was implanted on [redacted] 2008.

On [redacted] 2008, the subject's daughter reported that the subject became combative at night time **(AE #004)** when nurses attempted to administer care. The subject's wife reported that this would also happen at home during the night. The subject was started on Zyprexa. Also, on [redacted]-2008, the subject's white blood cell count (WBC) was elevated

to 11.50 and a urine culture was positive for E. coli **(AE #005)**. Levaquin for 5 days was initiated with resolution of infection.

The subject was discharged from the hospital on [redacted]-2008 to home with daughter.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
24-Sep-2008	000	001	809 - Diabetes Mellitus	N/A	N/A
27-Sep-2008	003	005	504 - GI Motility Disorders	N/A	N/A
28-Sep-2008	004	002	407 - Seizure	N/A	N/A
28-Sep-2008	004	004	603 - Electrolyte imbalance	N/A	N/A
04-Oct-2008	010	003	603 - Electrolyte imbalance	N/A	N/A
05-Oct-2008	011	007	699 - Lab/electrolyte Other: Hypoglycemia	N/A	N/A
08-Oct-2008	014	006	816 - Oral thrush	N/A	N/A
10-Oct-2008	016	008	303 - Urinary Tract Infection	N/A	N/A
25-Oct-2008	**031**	**009**	**899 - Other: Patient pulled out the feeding tube**	**N/A**	**N/A**
25-Oct-2008	031	010	815 - Skin irritation	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 58-year-old Hispanic female with past medical history of atrial fibrillation, rheumatic heart disease, status post mitral valve replacement 35 years ago. She also had a history of stroke 12 and 5 years ago with no current residual deficits. Medications at admission included: Zetia, Digoxin, Synthroid, Coumadin, Cyclobenzaprine, Quinine sulfate, Mobic.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 10:00 on [redacted] 2008. Symptoms at presentation included aphasia, no movements of right upper extremity, left gaze preference, and right neglect. Baseline CT was negative for any acute process. MRI showed a diffusion positive left MCA stroke. Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 21:30, [redacted] 2008, 11.5 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course**:** On [redacted] 2008 (the day of enrollment) the subject was diagnosed with diabetes mellitus **(AE #001)** and insulin was initiated.
An episode of constipation **(AE #005)** was documented on [redacted]-2008 which was treated with resolution. An electroencephalogram (EEG) performed on the next day

showed abnormal cerebral electrical activity consistent with seizure activity **(AE #002)** and Dilantin and Phenobarbital were started.

During the index hospitalization, the subject also had episodes of electrolyte abnormalities, including hyponatremia **(AE #004),** hypokalemia **(AE #003),** as well as hypoglycemia **(AE #007).** Replacements were given with resolution.

The subject did not pass a swallow study and a percutaneous endoscopic gastrostomy (PEG) tube was placed.

The subject was discharged from the hospital with significant neurological deficits on [redacted] 2008 to an in-house rehabilitation center. She continued to be aphasic, unable to communicate or follow complex commands. She also had an episode of thrush **(AE #006)** that was treated and resolved.

On [redacted] 2008 (post enrollment day 16), while in the rehabilitation unit, the subject was diagnosed with a urinary tract infection **(AE #008)** that was treated with antibiotics.

On [redacted]-2008 (post enrollment day 31), the subject pulled out her gastric feeding tube and was readmitted to the hospital for tube replacement **(SAE #009).** At readmission, she was noted to have a stage II wound to the right axillae area **(AE #010)** which was treated with Duoderm.

At the 90 day follow-up visit on [redacted] 2009, the subject continued to have significant neurological deficits with NIHSS of 11 and a modified Rankin of 4.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-Jan-2009	000	002	806 - Agitation/Excitation	N/A	N/A
28-Jan-2009	000	903	103 - Hypertension: worsening	N/A	N/A
29-Jan-2009	001	901	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
02-Feb-2009	005	001	303 - Urinary Tract Infection	N/A	N/A
07-Feb-2009	010	004	899 - Other: Hypothyroidism	N/A	N/A
25-Feb-2009	**028**	**003**	**303 - Urinary Tract Infection with urinary retention**	**N/A**	**N/A**
10-Mar-2009	041	005	899 - Other: Right heel wound	N/A	N/A
Unk-Apr-2009		902	811 - Depression	N/A	N/A
11-May-2009	103	905	414 - Neurological worsening	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 80-year-old Caucasian male with a past medical history of hypertension, cerebral vascular accident several years ago (mRS=0), transient ischemic attack approximately 1 year ago, and knee pain. Medications at admission included: Captopril, Darvocet, and Cardura.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 11:00, [redacted]-2009. Symptoms at presentation included a complete right-sided paralysis and complete aphasia. CT scan at admission revealed atrophy and multiple small infarcts. MRI/MRA of the brain revealed acute non-hemorrhagic infarct in the left anterior cerebral artery territory. Baseline NIHSS was 11. The subject was randomized to the control arm of the SENTIS trial on 18:02, [redacted]-2009, 7.0 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2009 (the day of enrollment) the subject became agitated **(AE #002)** and was treated with Haldol. Another episode of agitation was noted in the evening of the following day.

During the index hospitalization, the subject's blood pressure was found to be poorly controlled **(AE #903)**. It ranged from 190s to 200s; IV Labetalol was initiated. The subject remained hypertensive and Captopril titrations were started. At the time of discharge on [redacted] 2009, the subject's BP was ranging from 120s to 160s. The plan was to transition to oral Lisinopril as tolerated.

On [redacted]-2009 (post enrollment day 1), the subject had improved right-sided mobility; although he still had weakness bilaterally. The subject began to say yes, no, and his name, however, he still had significant expressive aphasia. The 24 hour NIHSS had slightly improved to 10. The subject's lab results suggested hyperlipidemia **(AE #901)** and Atorvastatin was started.

On [redacted]-2009 (post enrollment day 5), the subject was hemodynamically stable but was somnolent, non-cooperative, nonverbal, and responsive only to painful stimuli. An MRI showed normal evolution of stroke with no acute or new infarct and no hemorrhagic component. The subject was found to have an E. coli urinary tract infection **(AE #001)**. He responded quickly to IV Levaquin and returned to post-stroke baseline.

The subject was discharged from the hospital on [redacted] 2009 to an in-house rehabilitation center.

The family reported that the subject had been started on Synthroid for hypothyroidism **(AE #004)** following discharge. The subject was found to have an elevated thyroid-stimulating hormone (TSH) of 10.1 (norm 0.5 -5.5), considered to be secondary to sick euthyroid due to the fact that thyroxine (T4) was within normal limits and the free triiodothyronine (T3) was only mildly low at 191.

On [redacted]-2009 (post enrollment day 28), the subject experienced urinary retention and was readmitted to the hospital for insertion of a Foley catheter and treatment of Methicillin-resistant Staphylococcus aureus (MRSA) urinary tract infection **(SAE #003)**.

At the 30 day follow-up visit on [redacted] 2009, the subject's NIHSS decreased to 9; mRS was 4.

On [redacted] 2009, while in rehabilitation, the subject developed an ulcer on his right heel **(AE #005)** which was treated with debridement and dressings.

The Medication Log indicated that the subject was started on a new medication, Remeron, for depression **(AE #902)**.

At the 90 day follow-up visit on [redacted]-2009, the subject's NIHSS had increased to 12 (3 points higher than the 30 day NIHSS). The increase consisted of worsening of right-sided motor function, dysarthria and neglect **(AE #905).**

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-Dec-2009	000	901	413 - Headache	N/A	N/A
15-Dec-2009	001	002	403 - Cerebral edema: Mild cerebral edema	N/A	N/A
17-Dec-2009	003	001	398 - Urinary Other: Inability to void	N/A	N/A
22-Dec-2009	008	902	499 - Neuro Other: Spasticity	N/A	N/A
23-Dec-2009	009	003	813 - Fall	N/A	N/A
20-Feb-2010	**068**	**004**	**414 - Neurological worsening**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 25-year-old Hispanic male with no prior medical history and no medications at admission.

Current Stroke Onset and SENTIS Enrollment: The subject had stroke onset at 09:40, [redacted] 2009. Symptoms at presentation included hemianopsia, facial palsy, inability to move his left side, dysarthria, and neglect. CT scan at admission was normal. MRI revealed an acute non-hemorrhagic infarct of the right middle cerebral artery (MCA) territory with a clot in the right MCA and suspected pseudoaneurysm in the right internal carotid artery (ICA). Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 18:45, [redacted]-2009, 9.1 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: Upon admission, the subject complained of headache **(AE #901)**. His headaches occurred 4 to 5 times a day throughout his admission and were thought to be possibly related to the stroke with an element of analgesic overuse. During his admission the headaches were treated with Toradol, Tylenol, Morphine, Vicodin, Dilaudid, Elavil, Naproxen, and Topamax.

The 24 hour CT on [redacted]009 (post enrollment day 1) showed cerebral edema with mild mass effect and midline shift **(AE #002)**. NIHSS remained at 17. Further follow-up scans showed that the mass effect and midline shift remained stable throughout the hospitalization.

On [redacted]-2009 (post enrollment day 3) the subject was unable to void **(AE #001)** following removal of his Foley catheter and a second Foley catheter was placed. The catheter was removed on [redacted]-2009, after which the subject required straight catheterization every six hours. The subject was able to void on his own by discharge.

On [redacted]-2009 (post enrollment day 8) the subject's exam was notable for spasticity in the left upper and lower extremities **(AE #902)**. The left-sided jerking was consistent with clonus and Baclofen was started.

On [redacted]-2009 (post enrollment day 9) the subject requested privacy while attempting to use the urinal when he fell out of bed and hit his head **(AE #003)**. He was bleeding from a left ear wound and complained of head pain. An urgent CT showed no new findings and no neurological changes were noted. His skull was intact; one stitch was placed to the left ear.

The subject was discharged from the hospital on [redacted]2009 to an in-patient rehabilitation center. The 30 day NIHSS on [redacted]2010 was 9 with mRS of 4. The subject was discharged to home on [redacted]-2010.

On [redacted]010 (post enrollment day 68) the subject was admitted after presenting to an outside emergency room with complaint of increased difficulty swallowing and increased slurred speech **(SAE #004)**; he thought he was having a stroke. MRI showed no evidence of new stroke. The subject did have symptoms of a mild upper respiratory infection (sore throat). He was discharged the next day with a diagnosis of possible reactivation of stroke symptoms secondary to mild upper respiratory infection.

At the 90 day follow-up visit on [redacted]-2010 the subject's NIHSS was 9 with mRS of 3.

Subject [redacted] enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-Mar-2006	003	004	899 - Other: Dizziness	N/A	N/A
21-Apr-2006	027	009	811 - Depression	N/A	N/A
24-Apr-2006	**030**	**003**	**809 - Diabetes Mellitus**	**N/A**	**N/A**
24-Apr-2006	030	901	303 - Urinary Tract Infection	N/A	N/A
24-Apr-2006	030	008	699 - Lab/Electrolyte Other: Creatinine elevation	N/A	N/A
24-Apr-2006	030	007	603 - Electrolyte imbalance	N/A	N/A
13-Jun-2006	**080**	**006**	**118 - Atrial Fibrillation**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 78-year-old African American female with past medical history of insulin dependent diabetes, hypertension, hyperlipidemia, atrial fibrillation, osteoarthritis, gastrointestinal (GI) bleed, hysterectomy, cholesystectomy, bilateral cataract surgery, and previous stroke (mRS=1). Medications at admission included: Diltiazem, Colace, Lisinopril, Lasix, Lipitor, Coumadin, and potassium supplement.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 14:30, [redacted]-2006. Symptoms at presentation included disorientation to time and place, aphasia, dysarthria, generalized weakness, right-sided hemiparesis including right-sided facial droop, and diminished bilateral gait. CT scan at admission revealed no hemorrhage, mass effect or midline shift. MRI/MRA revealed a left frontal infarct involving left MCA territory. Baseline NIHSS was 6. The subject was randomized to the control arm of the SENTIS trial at 21:45, [redacted]-2006, 7.3 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2006 (day of admission), the subject's chest x-ray showed marked cardiomegaly with pulmonary vascular congestion and small bilateral pleural effusions. The subject's chest was clear and she was not in respiratory distress; no treatment was given.

On [redacted]-2006 (post enrollment day 2) the subject reported that she felt slightly fatigued and experienced slight shortness of breath (SOB) after ambulating about 25 feet with a wheeled walker. The following day she complained of dizziness after standing for less than two minutes **(AE #004)**. Blood pressure (BP) was 146/98 and no intervention was taken.

The subject was discharged from the hospital on [redacted]-2006 to home.

On [redacted]-2006 (post enrollment day 27), Effexor was started for post stroke depression **(AE #009)**. A family member noted that the subject did not like taking the antidepressant medication.

On [redacted]-2006 the subject was seen by her primary care physician for complaint of SOB and chest pain. Her glucose was found to be in the 600's and she was given 20 units of insulin **(SAE #003)**. The subject was sent to the emergency department where she denied any complaints of SOB or chest pains and received additional 10 units of insulin. Her chest was clear. Altered mental status was observed and the admitting physician thought it was possibly related to her decreased function and depression. Infection was also thought to be a contributing cause as the subject's white blood cell (WBC) count was 16.2 and urine analysis revealed greater than 182 WBC. Levaquin was started for urinary tract infection **(AE #901)**. An elevated creatinine level of 1.5 **(AE #008)** was noted and thought to be likely related to dehydration; IV hydration was initiated. Other electrolyte abnormalities were also noted and magnesium and potassium supplements were given **(AE #007)**. Medication non-compliance was thought to play a role in the cause of this admission.

On [redacted] 2006 (post enrollment day 80), the subject was admitted with some SOB and a heart rate (HR) of 120-130 **(SAE #006)**. The subject was in atrial fibrillation with an INR of 1.7. The SOB resolved after the subject was rate controlled (HR 70-80) with Diltiazem and Atenolol. The subject was discharged to home on the following day. Medication compliance was again questioned. The subject's 90 day NIHSS and mRS on [redacted]-2006 were both ranked as 3.

Subject [redacted], enrolled [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-Jan-2007	001	001	413 - Headache	N/A	N/A
02-Feb-2007	006	002	899 - Other: Choking	N/A	N/A
03-Feb-2007	007	003	813 - Fall	N/A	N/A
03-Feb-2007	007	004	299 - Pulmonary Other: Cough	N/A	N/A
06-Feb-2007	010	005	814 - Sleeping Disturbance/ Disorder: Sleep apnea	N/A	N/A
22-Feb-2007	026	901	814 - Sleeping Disturbance/ Disorder: Insomnia	N/A	N/A
16-Apr-2007	**079**	**007**	**716 - Carotid stenosis with endarterectomy**	**N/A**	**N/A**
16-Apr-2007	079	008	899 - Other: Recurrent laryngeal neuropraxia	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an obese 48-year-old African American male with history of hypertension, hyperlipidemia, 1 pack per day smoking, alcohol and drug abuse. Medications at admission included an unknown blood pressure medication.

Stroke onset and SENTIS Enrollment: The subject was last seen normal at about 19:00, [redacted] 2007. Symptoms at presentation included complete left-sided hemiplegia, dysarthria, right gaze preference, and decreased sensation on the left side of the face and left upper and lower extremities. CT scan at admission revealed some dystrophic calcification in the right internal capsule, but no evidence of hemorrhage or mass effect. The subject was tested positive for cocaine on admission. Baseline NIHSS was 16. The subject was randomized to the control arm of the SENTIS trial at 01:35, [redacted]-2007, 6.6 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2007 (post enrollment day 1) and on [redacted]-2007 the subject complained of headache **(AE #001)**; Toradol was given.

During the index hospitalization, MR revealed an 85% stenosis of the right internal carotid artery. The subject was discharged from the hospital on 01-Feb-2007 to acute rehab.

On [redacted]-2007 (post enrollment day 6), the subject had a choking episode while sipping juice **(AE #002)**. Dysphagia had also been noted on [redacted]-2007, when the subject was observed to sip water with signs and symptoms of aspiration and immediate coughing. Thicker liquids did not cause this. Speech therapy recommended normal consistency diet with thin liquids based on modified barium swallow study results. The subject continued to have difficulty with swallowing thin liquids throughout the course of acute rehabilitation.

On [redacted] 2007 the subject was found lying on the floor after a fall **(AE #003)**. Shortly after admission to rehab, the subject had been noted to have decreased attention and to be highly impulsive, with poor reasoning and poor executive functioning. He repeatedly attempted to get out of bed without assistance, and fell again on the following day. No injuries were incurred with these falls. As his strength and recognition of his deficits improved, he stopped falling. Amantadine was initiated to improve the subject's attention and memory.

The subject also started complaining of cough **(AE #004)** and was treated successfully with Guaifenesin. There was no fever or other evidence of infection.

On [redacted]-2007 (post enrollment day 10), overnight pulse oximetry suggested sleep apnea (AE #005). Many episodes of apnea with oxygen saturation into the 60% range were observed. Continuous positive airway pressure was ordered, but the subject was not

compliant, which resulted in numerous additional episodes of oxygen desaturation and apnea throughout his acute rehab.
On [redacted]-2007 (post enrollment day 20), hypoxia was documented with oxygen saturation dropping during the night to 78%. A chest x-ray revealed an ill defined parenchymal opacity in left upper lobe and an indeterminate nodular density (1.4x0.5cm) in the inferior lingular region. A follow-up CT scan in 6 months was recommended.

On [redacted]-2007 (post enrollment day 27), the subject received Ambien at night for insomnia **(AE #901)**.

The subject was discharged from the rehab unit on [redacted]007 to home.

On [redacted]2007 (post enrollment day 79), the subject underwent elective right carotid endarterectomy **(SAE #007)** to treat the 85% stenosis of the right internal carotid artery. Following the surgery, the subject had a mild hoarseness, which was thought to be related to intubation. The hoarseness was diagnosed as being secondary to recurrent laryngeal nerve neuropraxia **(AE #008)**. No treatment was given, and the hoarseness resolved by [redacted]-2007.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
22-Apr-2009	002	003	814 - Sleeping Disturbance/ Disorder	N/A	N/A
24-Apr-2009	004	001	811- Depression, worsening	N/A	N/A
21-Jun-2009	**062**	**002**	**699 - Lab/electrolyte Other: Bacteremia**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 68-year-old Caucasian male with past medical history of hypertension, hyperlipidemia, diastolic heart failure, coronary artery disease, status post coronary artery bypass graft (CABG) in 2000, peripheral artery disease, chronic obstructive pulmonary disease (COPD), reactive airway disease, insulin-dependent diabetes, probable gastroparesis, and depression. Medications at admission included: Aspirin, Advair, Albuterol, insulin, Chlor-trimeton, Lipitor, Loperamide, Reglan, Nexium, Paxil, Spiriva, Toprol and Wellbutrin. He previously smoked and had a history of heavy alcohol use.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at about 23:00 on [redacted]2009. Symptoms at presentation included right hemiparesis, right facial droop and expressive aphasia. CT scan at admission was unremarkable. MRI later revealed acute infarction in the left MCA territory. Baseline NIHSS was 13. The subject

was randomized to the control arm of the SENTIS trial at 08:35, [redacted]-2009, 9.6 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject's index hospitalization was unremarkable. He was discharged from the hospital on [redacted] 2009 to the inpatient rehab unit with NIHSS of 10.

On [redacted] 2009 (post enrollment day 2), Ambien was prescribed for sleeping disturbance **(AE #003).**

On [redacted]-2009 the subject's pre-existing depression appeared to worsen (the subject was frequently tearful) secondary to stroke and difficult family situation **(AE #001)**; Paxil was continued. The subject was discharged from rehab on [redacted]-2009 to home with his daughter.

On [redacted]-2009 (post enrollment day 62), the subject experienced a feeling of warmth and chest discomfort. He was brought to the emergency department and found to have a fever and a white blood cell count of 16.8. Cardiac source of the discomfort was ruled out. He was started on antibiotics and subsequently admitted to the hospital while blood cultures were pending. A blood culture later revealed Klebsiella bacteremia **(SAE #002)**. The subject was discharged on [redacted]-2009 to a skilled nursing facility for continued antibiotic therapy.

At the 90 days follow-up visit on [redacted]-2009 the subject's NIHSS was ranked as 1 with mRS of 3.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
13-Feb-2009	**001**	**001**	**116 - Bradycardia with pacemaker placement**	**N/A**	**N/A**
17-Feb-2009	005	003	818 - Pain	N/A	N/A
17-Feb-2009	005	002	603 - Electrolyte imbalance	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 61-year-old Caucasian male with a past medical history of hypertension, hyperlipidemia, atrial fibrillation, coronary artery disease, myocardial infarction with coronary artery bypass grafting in 2002 and 2006, congestive heart failure, postcardiotomy syndrome, type II diabetes, chronic neck and back pain, obstructive sleep apnea, chronic obstructive pulmonary disease, a

pseudomonas urinary tract infection and an abscess on his buttock in 2005. Medications at admission included: Metformin, Gemfibrozil, Digoxin, Carvedilol, Amiodarone, Lasix, Coumadin, Sertraline, Plavix, and simvastatin. He quit smoking 6 months prior to admission and denied alcohol use.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at about 11:30 on [redacted]-2009. Symptoms at presentation included right-sided weakness. CT scan on admission revealed no acute intracranial process, but did show a focus of encephalomalacia/hypodensity in the right lateral temporal location; presumed post remote ischemia or trauma. Baseline NIHSS was 7. The subject was in atrial fibrillation on admission, with a heart rate in the 40s-50s. His INR was 1.98, and a waiver was granted for inclusion into SENTIS trial. The subject was randomized to the control arm of the SENTIS trial at 17:50, [redacted]-2009, 6.3 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (post enrollment day 1), the subject became bradycardic with a heart rate in the 30s to 40s **(SAE #001)**. A cardiology consult was obtained and a diagnosis of suspected hypoperfusion related to cerebral ischemia was made. A multiple gated acquisition scan (MUGA) showed an ejection fraction of 57%. The decision was made to treat the subject's bradycardia with a permanent pacemaker and a single chamber pacemaker was implanted on [redacted]-2009.

Also on [redacted]-2009 (post enrollment day 5), the subject complained of bilateral lower extremity pain **(AE #003)** that was treated with Percocet. His serum potassium and magnesium were low **(AE #002)** and were treated with supplements. The subject was discharged from the hospital on [redacted]-2009 to a rehabilitation facility.

The 30 day NIHSS on [redacted]2009 was assessed as 4.

At the 90 day follow-up visit on [redacted]-2009, the subject's NIHSS decreased to 2.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Apr-2009	**001**	**001**	**414 - Neurological worsening**	**N/A**	**N/A**
05-Apr-2009	002	002	603 - Electrolyte imbalance	N/A	N/A
27-Apr-2009	024	003	899 - Other: Weakness	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History**:** The subject is a 65-year-old Caucasian male with a past medical history of hypertension, hyperlipidemia, depression, and a remote appendectomy. He has also had a dry cough for a few months prior to admission, more violent over the last few days. Medications at admission included: Lotrel, simvastatin, Omeprazole, Citalopram, and vitamin E. He quit smoking 16 years ago, and reports 3-4 drinks per day.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal on [redacted] 2009 at 01:00, when he awoke and complained of a headache. Symptoms at presentation included global aphasia, right hemianopsia and mild facial palsy. CT scan at admission was negative, but MRI revealed a moderately large acute stroke involving the medial and posterior left temporal lobe, left caudate and part of the left corona radiata. CT angiography showed thrombus in the left internal carotid artery with complete occlusion at the level of the petrous portion. The investigator felt that the left internal carotid artery was suspicious for dissection based upon the violence of the dry cough. Baseline NIHSS was 8. The subject was randomized to the control arm of the SENTIS trial at 12:52, [redacted]-2009, 11.9 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 24 hour NIHSS on [redacted]-2009 improved to 2. The subject's headache had resolved and he was only mildly confused. Later that afternoon, he deteriorated after a coughing spell and became sleepy **(SAE #001)**. His NIHSS had returned to 8. The subject's severe aphasia and word salad had returned and he had difficulty following commands. CT scan showed an evolving infarct in the left posterior communicating artery territory, but no significant change from previous CT obtained earlier in the day. The subject was transferred to the intensive care unit and treated with a normal saline infusion and a neosynepherine drip to maintain his blood pressure. An electroencephalogram showed a focal structural lesion of the left hemisphere with mild diffuse encephalopathy, but no seizures or epileptiform activity.

On the following day, [redacted]-2009, the subject was mildly hypokalemic **(AE #002)** and potassium supplements were given.

The subject's condition stabilized over the next few days but did not improve. He was weaned off blood pressure support. His dry cough improved with removal of Lotrel from his regimen, but returned when Norvasc was re-introduced. Norvasc was discontinued and he was started on Toprol.

The subject was discharged from the hospital on [redacted]-2009 to a rehabilitation facility.

On [redacted] 2009 (post enrollment day 24), the subject experienced a 10-second episode of shaking and weakness **(AE #003)**. He presented to the emergency room, where lab tests, a CT scan, chest x-ray and echocardiogram were performed. All tests were negative and the subject returned to home without being admitted. His symptoms resolved.

At the 90 day follow-up visit on [redacted]-2009, the subject's NIHSS was 5, mRS was 3, Glascow Outcome Scale was 4 and Barthel Index was 100.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
16-Jan-2009	**001**	**001**	**204 - Aspiration pneumonia**	**N/A**	**N/A**
16-Jan-2009	001	007	603 - Electrolyte imbalance	N/A	N/A
17-Jan-2009	002	009	118 - Atrial Fibrillation	N/A	N/A
21-Jan-2009	006	008	504 - GI Motility Disorders	N/A	N/A
23-Jan-2009	008	006	818 - Pain	N/A	N/A
24-Jan-2009	009	002	413 - Headache	N/A	N/A
09-Feb-2009	025	004	816 - Oral thrush	N/A	N/A
12-Feb-2009	028	003	303 - Urinary Tract Infection	N/A	N/A
16-Feb-2009	**032**	**005**	**699 - Lab/electrolyte Other: Bacteremia**	**N/A**	**N/A**
23-Feb-2009	039	010	503 - Nausea/Vomiting	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 73-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, gastroesophageal reflux disease, osteoporosis, and anxiety. She has a condition of situs inversus. Medications at admission included: Allegra, Cardizem, Fosamax, Imipramine, Nexium, Valium, and Vytorin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 06:30, [redacted]-2009. Symptoms at presentation included left-sided weakness, facial paralysis, and dysarthria. CT scan at admission revealed no abnormality. Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 11:30, [redacted]-2009, 5.0 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2009 (post enrollment day 1), the subject developed a low grade fever, cough, and rhonchi **(SAE #001)**. Chest x-ray showed possible right perihilar mild infiltration; blood culture was negative. Tylenol was given. On [redacted] 2009 aspiration pneumonia was formally diagnosed. The subject's NIHSS increased to 22, which was thought to be related to aspiration pneumonia. IV Zosyn was initiated.

During the index hospitalization, the subject had intermittent hypokalemia **(AE #007)** for which oral potassium supplements were initiated. The subject experienced another episode of hypokalemia on [redacted]-2009 due to diarrhea. Oral potassium supplements were re-started and continued thought the 90 day follow-up visit.

On [redacted]-2009 (post enrollment day 2), telemetry rhythm strips indicated sinus tachycardia and atrial fibrillation **(AE #009).**

On [redacted]-2009 (post enrollment day 6), the subject had diarrhea associated with antibiotic treatments **(AE #008)**. She received Lomotil and later Imodium. A stool culture tested positive for Clostridium difficile on [redacted]-2009. The subject had intermittent diarrhea through out but improved by the 90 day follow-up visit on [redacted]-2009. Diarrhea was thought to be due to the long term antibiotics for her infection.

On [redacted]2009 (post enrollment day 8), the subject complained of back pain **(AE #006)** and received Tylenol and Oxycodone. Back pain resolved by [redacted]-2009.

On [redacted]-2009 the subject complained of headache **(AE #002)**; Tylenol was given.

The subject was discharged from the hospital on [redacted]-2009 to a rehabilitation facility.

On [redacted]2009 (post enrollment day 25), the subject developed oral thrush **(AE #004)**. She was treated with Nystatin for 10 days.

On [redacted]-2009 (post enrollment day 28), the subject developed a urinary tract infection with positive urine culture **(AE #003)**. She was treated with IV antibiotics for 5 days.

On [redacted]-2009 (post enrollment day 32), the subject had fever and positive blood culture for Vancomycin-resistant E. coli (VRE) **(SAE #005)**. She was treated with IV Linezolid and later with oral Zyvox for 14 days. This event resolved by [redacted]-2009.

On [redacted]-2009 (post enrollment day 39), the subject complained of nausea **(AE #010)** after taking Oxycodone. She received Zofran and did not have any further complaints.

The subject was discharged to a skilled nursing facility on [redacted]-2009 and to home on [redacted]009.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
02-Feb-2009	000	001	102 - Hypotension	N/A	N/A
03-Feb-2009	**001**	**004**	**414 - Neurological worsening**	**N/A**	**N/A**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
03-Feb-2009	001	005	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
05-Feb-2009	003	002	303 - Urinary Tract Infection	N/A	N/A
05-Feb-2009	003	003	204 - Aspiration pneumonia	N/A	N/A
20-Feb-2009	018	006	811 - Depression	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 47-year-old Caucasian female with past medical history of prosthetic aortic valve and mitral valve replacement in 2006, chronic pain due to arthritis, rheumatic fever, chronic obstructive pulmonary disorder (COPD), transient ischemic attack in 2008, myocardial infarction in 2006, depression, hepatitis C, and paroxysmal atrial fibrillation. Medications at admission included: Coumadin, Medrol, and Lyrica. The subject has a history of non-compliance with her medications.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:00, [redacted]-2009. Symptoms at presentation included left-sided weakness, facial droop, partial hemianopsia, sensory loss, dizziness and neglect. CT scan at admission revealed no evidence of acute intracranial changes, no hemorrhage. Baseline NIHSS was 12. The subject was randomized to the control arm of the SENTIS trial at 13:35, [redacted] 2009, 15.6 hours from last known normal. The study coordinator miscalculated the relevant timing of events and notified CoAxia of a protocol deviation.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment), the 6 hour NIHSS decreased to 6. The subject experienced hypotension **(AE #001)** starting with systolic pressure below the preferred parameters of 120-130. Dextran IV was administered. Hypotension resolved on [redacted]-2009.

The 24 hour NIHSS on [redacted]-2009 increased to 16 **(SAE #004)** due to the increase of left-sided weakness, visual deficit, and neglect. NCT noted moderate to large right-sided infarct in the posterior basal ganglia region, with involvement of the sylvian cortex. There was no evidence of intracranial hemorrhage, mass effect or midline shift.

A lipid panel on [redacted]-2009 revealed a low-density lipoprotein (LDL) of 114 **(AE #005)**; statin therapy was initiated. It was noted that at the 30 day and 90 day follow-up visits the subject was not taking prescribed Lipitor.

On [redacted]-2009 (post enrollment day 3), the subject experienced hypoxia and fever. A catheter urine culture was positive for Enterococcus **(AE #002)**. The subject was started on IV Vancomycin and eventually transitioned to oral Augmentin. A chest x-ray could not exclude left lower lobe pneumonia and also suggested possible congestive heart failure (CHF). An adverse event form stated that while possible CHF was mentioned in

the chest x-ray report, it could not be confirmed clinically and the subject was not treated for it. The Augmentin was started for aspiration pneumonia symptoms **(AE #003)**.

The subject was discharged from the hospital on [redacted]-2009 to a rehabilitation facility.

On [redacted]-2009 (post enrollment day 18), the subject was noted to be depressed and tearful **(AE #006)**. The subject has a history of depression, but was not compliant with previous medication. Zoloft was prescribed. At the 30 and 90 day follow-up visits, the subject was noted as not taking the prescribed medication.

The subject was discharged from the rehabilitation facility on [redacted] 2009 to home. Her 30 day NIHSS on [redacted]-2009 was ranked as 4 with mRS of 3.

Subject [redacted], enrolled [redacted]-2010

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
19-Jan-2010	000	002	809 - Diabetes Mellitus	N/A	N/A
19-Jan-2010	000	006	601 - Anemia	N/A	N/A
20-Jan-2010	001	001	301 - Renal dysfunction	N/A	N/A
21-Jan-2010	002	003	818 - Pain	N/A	N/A
22-Jan-2010	003	901	108 - Congestive Heart Failure	N/A	N/A
09-Mar-2010	049	902	599 - GI Other: GERD	N/A	N/A
09-Mar-2010	**049**	**004**	**499 - Neuro Other: Encephalopathy**	**N/A**	**N/A**
23-Mar-2010	063	903	603 - Electrolyte imbalance	N/A	N/A
27-Mar-2010	067	905	117 - Tachycardia	N/A	N/A
27-Mar-2010	**067**	**906**	**103 - Hypertension, worsening**	**N/A**	**N/A**
29-Mar-2010	069	907	299 - Pulmonary Other: Respiratory congestion	N/A	N/A
29-Mar-2010	069	908	303 - Urinary Tract Infection	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 84-year-old Caucasian female with past medical history of hypertension, borderline diabetes, hypothyroidism, transient ischemic attack, and a minor stroke in 2003 without any residual effect. The subject had chronic cholecystitis secondary to cholelithiasis for which laparoscopic cholecystectomy was scheduled. Medications at admission included: Diovan, Metoprolol, Plavix,

Levothyroxine, Darvocet as needed, and Protonix for which she was off for 5 days for the procedure.

Current Stroke Onset and SENTIS Enrollment: On the morning of [redacted]-2010, the subject underwent elective laparoscopic cholecystectomy under general anesthesia at an outlying hospital. Pre-operatively, her blood pressure was 200/92 which was managed with Labetalol. Post-operatively, at 11:50 on [redacted]-2010 the subject experienced stroke symptom onset. Symptoms at presentation included receptive aphasia with right visual field cut and right-sided weakness. CT scan at admission revealed only old lacunar infarctions in basal ganglia and no acute abnormality. Baseline NIHSS was 16. The subject was randomized to the control arm of the SENTIS trial at 16:15, [redacted]-2010, 4.4 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject had a history of borderline diabetes without treatment. Her hemoglobin A1C was 8.6 at admission **(AE #002)**. The subject was initially treated with a sliding scale insulin and later with oral medication. However, on [redacted]-2010 the subject experienced hypoglycemia and Glipizide was discontinued.

The subject's pre-operative hematocrit (Hct) and hemoglobin (Hgb) were 36.4 and 12.5, respectively. Post-operatively and at the time of the study enrollment, her Hct/Hgb decreased to 24.2/7.8 **(AE #006)**. Internal and external bleedings were ruled out. No treatment was given during the index hospitalization. Hct/Hgb increased to 30.3/10.2 on the following day.

On [redacted]-2010 (post enrollment day 1), the subject started having oliguria with elevated BUN (baseline was 21), creatinine (baseline was 1.0), and potassium levels **(AE #001)**. Throughout the study follow-up period, the subject's BUN and creatinine were as high as 38 (23-Jan-2010) and 3.6 ([redacted]-2010), respectively. Acute renal impairment was documented. Chronic kidney disease stage IV was documented on [redacted]-2010; renal insufficiency was also noted. A decreased renal perfusion was suspected to be due to some cardiac decompensation (the subject might have had a pre-existing diastolic heart failure). IV Lasix and Kayexalate were administered in addition to gentle hydration. Hyperkalemia was thought to be related to the renal dysfunction. Potassium level normalized on [redacted]-2010. At the time of discharge from the hospital on [redacted]-2010, the subject had good urine output; creatinine level remained elevated but stable.

On [redacted]-2010 (post enrollment day 2), the subject complained of diffuse abdominal pain **(AE #003)**. General surgeon ruled out abnormalities. IV Morphine during the subject's index hospitalization was given for surgical pain.

On [redacted]-2010 (post enrollment day 3), the subject was noted to have tachycardia and edematous hands. Troponin, brain natriuretic peptide (BNP), and haptoglobin were elevated. On the following day, stable diastolic congestive heart failure (CHF) was documented and a β-blocker was prescribed **(AE #901)**.

The subject was discharged from the hospital on [redacted]-2010 to a rehabilitation facility and was eventually discharged to her home on [redacted] 2010. Her 30 day NIHSS on [redacted] 2010 was 2.

On [redacted]-2010 (post enrollment day 49), the subject was noted as "not acting normally" by a home care nurse. She was admitted to a local hospital. Gastroesophageal reflux disease (GERD) **(AE #902)** was documented in the admission exam on [redacted]-2010 and treated with Nexium.

NCT on [redacted]-2010 revealed an infarction in the left parietal region that appeared to possibly be new compared to [redacted]-2010 study. (Multiple acute embolic infarcts were seen in left MCA distribution on the 24 hour follow-up MRI on [redacted] 2010.) Repeated NCT/MRI during this admission showed no evidence of acute abnormalities. Urinalysis was positive for protein and leukocytes of 25. Blood culture was negative. Serum methylmalonic acid was normal. Herpes simplex virus-1 (HSV-1) antibody was positive. Encephalopathy was suspected **(SAE #004).**

An echocardiogram on [redacted]-2010 (post enrollment day 51), showed a mild concentric left ventricular hypertrophy (LVH) with preserved systolic contraction of left ventricle (LV) and evidence of reduced LV compliance. Ejection fraction was 60%. The subject was discharged on the following day from the hospital to home with home health service.

On [redacted] 2010 (post enrollment day 63), the subject's altered mental status had been waxing and waning **(cont. of SAE #004).** She also developed dysphagia. She was readmitted to the same hospital and was diagnosed with herpes encephalitis and was started on IV Acyclovir.

Also on [redacted] 2010, the subject had an electrolyte imbalance **(AE #903).** Potassium was in a range of 2.4-3.3 during this hospitalization and oral potassium supplements were given. Calcium was also low. Sodium was 133-135.

On [redacted]-2010 (post enrollment day 65), the subject became very confused. Dementia with behavioral disturbance was documented in the progress note. Ativan and Haldol were given. Multiple imaging of the brain during this hospitalization showed no acute changes from the previous studies. The subject also received nitroglycerin every 6 hours on the chest wall and IV Labetalol. On [redacted] 2010 she had an episode of hypoglycemia for which sliding-scale insulin was held.

The subject's mental status markedly worsened on [redacted]-2010. She exhibited cardiac arrhythmia with a heart rate of more than 150 **(AE #905)** and uncontrolled hypertension **(SAE #906)**. She had been on Metoprolol 25mg and Amlodipine 5mg. The subject was transferred to the intensive care unit. All oral anti-hypertensives were held due to the subject's renal insufficiency. IV Metoprolol 5mg every 6 hours as needed was prescribed. The subject's blood pressure and heart rate returned to the baseline ranges.

On [redacted]-2010 (post enrollment day 69), the subject remained confused and sometime unresponsive. Diffused expiratory wheeze and scattered rhonchi were noted upon exam **(AE #907).** Urinalysis was positive for protein, white blood cell (WBC) (10-20/hpf), and amorphous 2+ **(AE #908).** Subsequent urine culture showed >100,000 colonies of two colony types - isolating at 24 hours and suggestive contamination at 48 hours; Ceftriaxone was started.

On [redacted]-2010 (post enrollment day 71), electroencephalogram (EEG) showed encephalopathic pattern; no active seizure discharge was noted. The subject's mental status started improving. The subject was discharged from the hospital on [redacted] 2010 to home with home healthcare service.

On [redacted] 2010 (post enrollment day 76), the subject experienced a possible seizure activity and was re-admitted to the local hospital. NCT of the brain showed no interval change. The seizure was thought to be related to the herpes encephalitis **(cont. of SAE #004).** Urinalysis and urine culture were positive **(cont. of AE #905)** and Ceftriaxone was restarted. Chest x-ray indicated an evidence of pneumoperitoneum superior to the liver on the left lateral decubitus view of the abdomen. The subject was discharged from the hospital on [redacted]-2010 to a skilled nursing facility.

At the 90-day follow-up visit on [redacted] 2010, the subject remained in the skilled nursing facility. Her NIHSS was 15 and mRS was 5. Increase in the subject's NIHSS was thought to be due to the protracted illness of herpetic encephalitis that had dramatically debilitated the subject. Per her daughter, the subject had been in about the same condition since the onset of herpes encephalitis and there was no significant change in her care.

Subject [redacted] enrolled [redacted] 2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
23-Aug-2007	000	904	413 - Headache	N/A	N/A
23-Aug-2007	**000**	**001**	**414 - Neurological worsening**	**N/A**	**N/A**
24-Aug-2007	001	903	499 - Neuro Other: Somnolence	N/A	N/A
Unk-Aug-2007		901	603 - Electrolyte imbalance	N/A	N/A
Unk-Aug-2007		902	599 - GI Other: Intestinal discomfort	N/A	N/A
Unk-Oct-2007		905	815 - Skin irritation	N/A	N/A
Unk-Oct-2007		906	299 - Pulmonary Other: Cough	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 77-year-old Caucasian male with a history of hyperlipidemia, hypertension, type II diabetes, and non-Hodgkin's lymphoma. The subject

had surgery on the left ankle, resulting in chronic weakness in that joint. Medications at admission included: Metformin, Glyburide, Lisinopril, Gabapentin, Actos, Simvastatin, and Tamulosin.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 05:55, [redacted] 2007. Symptoms at presentation included left-sided weakness, numbness on the bottoms of his feet secondary to Diabetes mellitus, and a droop of the left side of his mouth; he was not able to move his tongue fully. CT scan at admission revealed increased density in the right MCA, suggestive of acute ischemia. No hemorrhage was seen. Baseline NIHSS was 5. The subject was randomized to the control arm of the SENTIS trial at 11:15, [redacted]-2007, 5.3 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2007 (the day of enrollment) the subject complained of headache **(AE #904)** and was treated with Tylenol. The 4 hour NIHSS increased to 11 **(SAE #001)**. The subject was drowsy and exhibited continued left-sided weakness and facial droop, but responded to voice and correctly answered questions. The 24 hour NIHSS was 13. Methylphenidate was given for somnolence **(AE #903)**. The 24 hour NCT scan showed some edema in the right basal ganglia and right frontal lobe, but no hemorrhage, mass effect or hydrocephalus. No treatment was administered. The 4 day NIHSS on [redacted]007 remained at 13.

During the index hospitalization the subject received magnesium and potassium replacements for low blood levels of these electrolytes **(AE #901)** as well as variety of "intestinal comfort" drugs (Reglan, Maalox, Dulcolax, Milk of Magnesia, Pepcid, Simethicone, Miralax, Metamucil, and Bisacodyl) for nausea, indigestion, constipation, etc. **(AE #902)**.

The subject was discharged from the hospital on [redacted]-2007 to a rehabilitation facility and discharged from there on [redacted]-2007.

The medication log indicates that by later follow-up visits, Bacitracin had been prescribed for abrasion, and Benadryl itch cream for groin rash **(AE #905)**; Robitussin was ordered for cough **(AE #906)**.

The subject's NIHSS was ranked as 12 at both the 30 and 90 day follow-up visits.

Subject [redacted] enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
18-Dec-2006	**000**	**001**	**716 - Carotid stenosis with bypass**	**N/A**	**N/A**
18-Dec-2006	000	901	103 - Hypertension	N/A	N/A
19-Dec-2006	001	902	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 56-year-old Caucasian male with past medical history of hypertension, an old right hemisphere stroke (no deficits), and possible history of prior seizures. The subject was not taking medications at the time of admission.

On [redacted]-2006 the subject collapsed at work and had a seizure. He was taken to the emergency room where he was intubated and sedated in order to obtain CT scan. He was extubated a few hours later. At that time the subject was amnesic regarding events and disoriented to time and place. He was diagnosed with a generalized tonic clonic seizure and recovered over the next few hours with no residual deficits. Admission CT scan showed an old right frontal lobe infarct with no acute findings. A chest x-ray on [redacted] 2006 revealed a possible left clavicle fracture that was later confirmed.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 11:15, [redacted]-2006, while still in the hospital. Symptoms at presentation included aphasia, right facial droop, right-sided weakness, and disorientation. CT scan revealed a new area of acute cerebral ischemia in the left frontal lobe, suggestive of a new left MCA territory infarct. Baseline NIHSS was 12. The subject was randomized to the control arm of the SENTIS trial at 15:35, [redacted]-2006, 4.3 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: During the hospital stay the subject had ongoing difficulty with comprehension, naming, and repetition. His responses to even personal questions were unreliable. The subject's 4 hour and 24 hour NIHSS decreased to 10 and 7, respectively.

On [redacted] 2006 (the day of enrollment), follow-up MR images showed an improvement in perfusion mismatch of the MCA territory infarction. MR and CT imaging indicated bilateral ICA occlusion **(SAE #001)**. Assessment for a possible cerebral artery bypass was planned.

Also on [redacted] 006, the subject's baseline blood pressure (BP) was 151/73. BP remained elevated and Altace was started for hypertension **(AE #901)**. The subject has a previous history of hypertension; although, it is unclear whether or not he was taking medications to control it.

On [redacted] 2006 (post enrollment day 1), the subject was started on Lipitor **(AE #902)**.

A cerebral blood flow study with Diamox challenge on [redacted] 2007 demonstrated an impaired cerebrovascular reserve on the left side in the MCA distribution. The subject was, therefore, considered a candidate for extracranial to intracranial bypass, particularly in view of the fact that he had a good left superficial temporal artery. A left superficial temporal artery to middle cerebral artery bypass was performed on [redacted]-2007 **(update to SAE #001)**. The subject recovered from the surgery with no complications.

The subject remained in the hospital until the [redacted] 007 waiting for a rehab bed. At that time he decided to go home and has been residing at home since.

The 30 day and 90 day follow-up NIHSS were both ranked as 1.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-May-2008	034	001	819 - Infection	N/A	N/A
09-Jul-2008	**076**	**002**	**601 - Anemia**	**N/A**	**N/A**
Unk-Jul-2008		901	811 - Depression	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 61-year-old Caucasian female with past medical history of type II diabetes mellitus, hypertension, hyperlipidemia, obesity, and nephrectomy at age 12 for a congenital condition. The subject underwent coronary artery bypass graft (CABG) x 2 and mitral valve repair on [redacted] 2008 with a post operative ejection fraction of 30%. Medications at admission included: Avapro, Metformin, Aspirin, Pravachol, CoReg, Lasix, potassium choloride, Fluconazole, and insulin per sliding scale.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 04:00, [redacted]-2008, while in-patient. Symptoms at presentation included left-sided hemiparesis with facial palsy and non-reactive right pupil. The subject was intubated. CT scan at admission revealed small focal areas of decreased attenuation in the right posterior parietal lobe. CT perfusion of the head showed delayed mean transit time in the right posterior parietal lobe in the region of the right posterior cerebral artery (PCA). Baseline NIHSS was 11. The subject was randomized to the control arm of the SENTIS trial at 11:55, [redacted]-2008, 7.9 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject's hospital stay was uneventful and she was discharged from the hospital [redacted]-2008 to a rehabilitation facility.

On [redacted]-2008 (post enrollment day 34), while in rehabilitation, the subject's sternal incision site from CABG was noted to be open and draining **(AE #001).** IV antibiotics were administered until [redacted] 2008 with resolution of infection.

On [redacted]-2008 (post enrollment day 76), the subject complained of dyspnea and fatigue and had hemoglobin (Hgb) of 7.8 and hematocrit (Hct) of 23.8 **(AE #002).** She received a blood transfusion of 2 units at an outpatient facility and was started on ferrous sulfate. The subject's Hgb/Hct went back to her baseline level of 10.4/34 by the 90 day follow-up visit.

At the time of the 90 day follow-up visit on [redacted] 2008, the subject was noted to have abnormal affect, sadness **(AE #901)**; Zoloft was initiated.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
27-Jan-2009	001	901	403 - Cerebral edema	N/A	N/A
28-Jan-2009	002	001	818 - Pain	N/A	N/A
29-Jan-2009	003	003	806 - Agitation/Excitation	N/A	N/A
29-Jan-2009	003	004	118 - Atrial Fibrillation	N/A	N/A
01-Feb-2009	006	002	815 - Skin irritation	N/A	N/A
11-Mar-2009	**044**	**005**	**412 - HT, no concomitant mass effect**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 64-year-old Caucasian female with past medical history of hypertension, chronic atrial fibrillation (not treated with Coumadin per subject's decision), Hashimoto's disease, chronic obstructive pulmonary disease, type II diabetes mellitus, and morbid obesity. Medications at admission included: Verapamil, Metoprolol, Aspirin, Flonase, Synthroid, Lantus, Combivent inhaler, Advair, lisinopril, Lipitor, Metformin, and supplements including ginko biloba, calcium, magnesium and zinc.

Current Stroke Onset and SENTIS Enrollment: The subject had a syncopal episode on [redacted]-2009 around 20:20. She fell over to the side of toilet and was wedged between the toilet and the wall causing her to be significantly dysarthric. Emergency medical services extracted the subject and as soon as the pressure was alleviated off from her face, her speech was clear. It is unclear if the subject had left-sided weakness or slurred speech at

the time of the event. These symptoms were absent in the emergency room, although, the subject was confused and disoriented. Head and cervical spine CT was negative for brain ischemia and hemorrhage, but did reveal pulmonary edema. Chest x-ray showed cardiomegaly and pulmonary vascular congestion. A moderate congestive heart failure (CHF) was observed which did not meet the level of SENTIS exclusion criteria. While in the hospital, the subject experienced a new, acute onset of stroke symptoms at 05:24 on [redacted] 2009. Symptoms at onset included partial hemianopsia, left-sided weakness with left facial droop, sensory loss and dysarthria. CT scan revealed ischemia in the anterior right parietal lobe and in the head of the right caudate; no hemorrhage. Follow-up echocardiogram for pre-enrollment diagnosis of CHF showed left ventricular ejection fraction of 65% and Lasix 40 mg IV daily was initiated. Baseline NIHSS was 12. The subject was randomized to the control arm of SENTIS trial at 12:30, [redacted] 2009, 7.1 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 24 hour NCT on [redacted] 009 (post enrollment day 1) revealed vasogenic edema and mass effect with new leftward subfalcine herniation and an approximate 5.5mm midline shift **(AE #901)**. Her 24 hour NIHSS was 10.

Beginning of [redacted] -2009 (post enrollment day 2) the subject complained of intermittent head, neck and back pain **(AE #001)**. She was treated with Ultram.

On [redacted] 2009 (post enrollment day 3) the subject appeared very agitated **(AE #003)**. She was given Ativan and mitten restraints were applied. Agitation subsided by [redacted] 2009. Also starting on [redacted] 2009 the subject had intermittent episodes of atrial fibrillation-related tachycardia **(AE #004).** She received Metoprolol for heart rate control.

On [redacted] 009 (post enrollment day 6) the subject complained of generalized itching **(AE #002)** and received Benadryl. The subject remained neurologically stable and was discharged from the hospital on [redacted] 2009 to a rehabilitation facility.

At the 30 day follow-up visit on [redacted] -2009, the subject's NIHSS was ranked as 3.

During the subject's clinic visit on [redacted] 2009 (post enrollment day 44), she complained of a headache and of numbness in her left foot that started on [redacted] -2009. She was already scheduled for a head CT that day to determine the safety of starting Coumadin (she had been on baby aspirin for stroke prevention). CT showed hemorrhagic conversion in the right parietal infarct **(SAE #005).** Aspirin was stopped and the subject was admitted to the hospital for further monitoring.

Follow-up MRI showed "foci of signal dropout on gradient echo sequence suggestive of blood products versus laminar necrosis in the right frontal and parietal lobes and right caudate nucleus in the regions of the prior infarct. There is mild surrounding edema without significant mass-effect." The subject's neurological status was stable but blood pressure had increased, so Verapmil was started and Metoprolol dose was increased. No

other medication changes or interventions were ordered. The subject was discharged to home in stable condition on [redacted]-2009. Follow-up head CT on [redacted] 2009 showed no interval change.

The 90 day NIHSS on [redacted] 2009 remained at 3.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
07-May-2009	002	001	115 - Patent foramen ovale (PFO), Aneurysm	N/A	N/A
Unk-May-2009		901	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
28-May-2009	**023**	**002**	**299 - Pulmonary Other: Lung cancer**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 61-year-old Caucasian male with past medical history of hypertension, neurogenic bladder, renal insufficiency, hiatal hernia, squamous cell carcinoma of the right tonsil status post chemoradiation and surgery in 2006. The subject has a history of right and left pulmonary nodules that were first noted in 2008 via CT scan. CT scan done on [redacted]-2009 (1 day prior to stroke onset) noted the nodule in the left lung had slightly increased in size. Medications at admission included Toprol.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:00, [redacted]-2009. Symptoms at presentation included right-sided weakness with facial droop, slurred speech, dysarthria, and neglect. CT scan at admission revealed no acute intracranial process. MR angiography revealed significant narrowing of the proximal left MCA. Baseline NIHSS was 11. The subject was randomized to the control arm of the SENTIS trial at 09:45, [redacted]-2009, 10.8 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2009 (the day of enrollment), Oncology consult evaluated the subject for the pre-existing pulmonary nodules. Further diagnostic testing was scheduled after improvement of the acute stroke.

On [redacted]-2009 (post enrollment day 2) transesophageal echocardiogram revealed a small patent foramen ovale and atrial septal aneurysm **(AE #001)**; no treatment was ordered for these findings.

The subject was discharged from the hospital on [redacted]-2009 to inpatient rehabilitation with NIHSS of 5. Per discharge note, diagnosis of hypercholesterolemia was made **(AE #901)**. The subject was on statin during the index hospitalization and through the 90 day follow-up visit.

On [redacted]-2009 (post enrollment day 23) CT-guided fine needle aspiration biopsy identified primary adenocarcinoma of the left lung **(SAE #002)**. The subject was re-admitted to the hospital on [redacted] 2009 for a video-assisted thoracoscopic left upper lobectomy. The procedure was uncomplicated and the hospitalization was uneventful. Pathological exam confirmed the biopsy result. The subject's lung tumor was staged as T1 N0 MX, and measured 1.2cm at its greatest dimension. On [redacted]-2009 the subject was discharged back to home in stable condition. At the time of the 90 day follow-up visit, the subject's oncologist was considering chemotherapy.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
11-Oct-2009	001	001	404 - HT, likely contributing to mass effect	N/A	N/A
12-Oct-2009	002	002	603 - Electrolyte imbalance	N/A	N/A
12-Oct-2009	002	003	115 - Patent foramen ovale (PFO)	N/A	N/A
Unk-Nov-2009		005	103 - Hypertension	N/A	N/A
18-Nov-2009	039	006	899 - Other: Adjustment disorder	N/A	N/A
19-Nov-2009	**040**	**004**	**411 - Transient ischemic attack**	**N/A**	**N/A**
19-Nov-2009	040	901	412 - HT, no concomitant mass effect	N/A	N/A
07-Dec-2009	**058**	**007**	**716 - Carotid Stenosis with endarterectomy**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 62-year-old Caucasian female with past medical history of hyperlipidemia and hypothyroidism secondary to parathyroid resection 3 years ago. The subject was not taking any medications.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:00, [redacted] 2009. Symptoms at presentation included global aphasia, right facial droop and no movement of the right extremities. CT scan at admission revealed evidence of acute infarct in the anterior left MCA territory. CTA showed an ulcerated plaque in the left ICA origin and 40-50% stenosis. Baseline NIHSS was 12. The subject was randomized to the control arm of the SENTIS trial at 11:35, [redacted]-2009, 12.6 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 6 hour NIHSS was 14. The 24 hour NIHSS on [redacted]-2009 increased further to 16. MRI revealed evidence of hemorrhagic conversion of the infarct in the left basal ganglia and cerebral edema **(AE #001)**, as well as occlusion of the distal M1 segment of the left MCA. A follow-up NCT on the following day did not show evidence of the hemorrhage but did show increased cerebral edema with mass effect and 2mm left to right midline shift and hyperdense left MCA. NCT on [redacted]-2009 confirmed slight hyperattenuation corresponding to the hemorrhage seen on [redacted]-2009 MRI and stable, mild mass effect.

On [redacted]009 (post enrollment day 2) the subject began to have electrolyte imbalances **(AE #002)** with hyperkalemia and hypocalcaemia, followed by hypomagnesaemia and hyponatremia. Supplements were given (where applicable) through [redacted]2009 and the event was considered resolved.

An echocardiogram on [redacted]2009 revealed a patent foramen ovale (PFO) **(AE #003)**. At the 90 day follow-up, an investigational chest CT was recommended.

The subject was discharged from the hospital on [redacted]-2009 to acute rehabilitation, and then went home on [redacted]-2009. While in rehab, the subject was started on Lisinopril **(AE #005)** (during the index hospitalization the subject's blood pressure was in a range of 113-152/71-85 without any antihypertensive medication). The subject's blood pressure remained well-controlled through the 90 day follow-up visit.

At the time of 30 day follow-up visit on [redacted]-2009 the subject's NIHSS was 7. The subject was prescribed Lexapro for depression/adjustment disorder **(AE #006)** related to the recent loss of her husband and her recent stroke. Adjustment disorder resolved and the subject was no longer taking Lexapro at her 90 day follow-up visit.

On [redacted]009 (post enrollment day 40) the subject presented to the emergency room for new onset of left-sided weakness and slurred speech with headache and tingling. The symptoms resolved within hours of onset and the subject was admitted and diagnosed with transient ischemic attack **(SAE #004)**. CT and MRI showed no evidence of new infarction. However, NCT on [redacted]-2009 did show a mild hyperdensity within the area of encephalomalacia from the prior left MCA infarct. MRI on [redacted]-2009 confirmed an acute hemorrhage in the area of prior infarct **(AE #901)**. The subject was discharged to home on [redacted]-2009.

On [redacted]2009 (post enrollment day 58) the subject was re-admitted to the hospital for an elective left carotid endarterectomy **(SAE #007).** She was found to have a superficial ulceration of atherosclerotic plaque at the origin of the left ICA that caused a 50% stenosis. Because of deterioration in the subject's right arm and hand function with cross-clamping, a shunt was placed. The subject tolerated the procedure well. Overnight, following the procedure, the subject developed slurred speech and hypotension **(cont. of SAE #007)**. She was given Albumin and started on Neosynephrine to keep mean arterial pressure between 90 and 100. Symptoms improved and the subject returned to her neurological baseline. She was discharged to home on [redacted]-2009.

The 90 day NIHSS on [redacted]-2010 was ranked as 5 with mRS of 4.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
08-Dec-2009	000	005	503 - Nausea/Vomiting	N/A	N/A
09-Dec-2009	**001**	**001**	**403 - Cerebral edema**	**N/A**	**N/A**
09-Dec-2009	001	901	603 - Electrolyte imbalance	N/A	N/A
13-Dec-2009	005	003	102 - Hypotension	N/A	N/A
13-Dec-2009	005	002	601 - Anemia	N/A	N/A
13-Dec-2009	005	004	899 - Other: Anxiety	N/A	N/A
17-Dec-2009	009	006	899 - Other: Pruritis	N/A	N/A
31-Dec-2009	023	008	303 - Urinary Tract Infection	N/A	N/A
Unk-Jan-2010		902	899 - Other: Spasticity	N/A	N/A
16-Jan-2010	**039**	**007**	**899 - Other: Infected cranial wound**	**N/A**	**N/A**
26-Jan-2010	**049**	**009**	**801 - Allergic reaction**	**N/A**	**N/A**
24-Jan-2010	**047**	**010**	**601 - Anemia**	**N/A**	**N/A**
30-Jan-2010	053	903	407 - Seizure: Probable seizure activity	N/A	N/A
Unk-Feb-2010		904	818 - Pain	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 40-year-old Caucasian female with past medical history of episodic migraines, neck discomfort and eczema. Medications at admission included: Aleve, Pamprin, Acetaminophen, Triamcinolone ointment as needed and vitamin/mineral supplements.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 04:20, [redacted]-2009. Symptoms at presentation included complete hemianopsia, left-sided weakness, left facial droop, sensory loss and left-sided neglect. CT scan at admission revealed no acute abnormalities. CTA showed non-visualization of the right MCA distal to the M1/M2 junction and a filling defect within the vessel suggested acute thrombosis. Baseline NIHSS was 14. The subject was randomized to the control arm of the SENTIS trial at 08:42, [redacted]-2009, 4.4 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2009 (the day of enrollment) MRI of the brain at 10:15 revealed a large right MCA infarction without significant mass effect or hemorrhage. The 6 hour NIHSS remained at 14. The subject complained of nausea **(AE #005)**, and was treated with Ondansetron.

The 24 hour NCT on [redacted] 009 revealed a new mass effect on the right lateral ventricle and a 5mm midline shift at the level of the septum pellucidum **(SAE #001)**. The 24 hour NIHSS was 16. A neurosurgery consult was obtained and hemicraniectomy was considered if necessary. NCT on the following day showed right MCA and right ACA infarcts with increasing edema and midline shift of 7.8mm which progressed to 13.3 mm on [redacted] -2009. There was no hemorrhagic transformation and no intraventricular blood present. A hemicraniectomy was performed. The subject was intubated for surgery and placed on ventilator which was removed on the following day.

During the index hospitalization the subject had electrolytes imbalance (potassium 3.4, sodium 133, and calcium 7.5). Potassium supplements were given **(AE #901)** and values normalized by [redacted] -2009.

CT scan on [redacted] -2009 (post enrollment day 4) revealed intraparenchymal and small amount of subarachnoid hyperdense acute blood in the right frontal lobe, likely postoperative; there was also a small amount of post-operative pneumocephalus. Edema and mass effect decreased over time through [redacted] 2009 (the last CT scan obtained).

On [redacted] 2009 the subject had an episode of hypotension where blood pressure dropped to 100-120/50-60 **(AE #003)**. She also became anemic with hemoglobin (Hgb) of 8.9 and hematocrit (Hct) of 26.4 **(AE #002)**. She was transfused with 1 unit of packed red blood cells and received a bolus of Albumin. Hgb/Hct increased to 12.3/35.2 on [redacted] -2009. The subject also had anxiety **(AE #004)**; antidepressant and sleep medication were initiated and continued through the 90 day follow-up visit.

On [redacted] -2009 (post enrollment day 9) the subject had pruritis **(AE #006)** and was treated with Diphenhydramine.

The subject was discharged from the hospital on [redacted] -2009 to an inpatient rehabilitation unit. On the following day she developed a urinary tract infection **(AE #008)** which was treated with antibiotics with good results.

During the index hospitalization the subject had spasticity but it worsened during rehabilitation stay and was treated with Gabapentin, Lyrica or Baclofen through the 90 day follow-up visit **(AE #902)**.

On [redacted] -2010 (post enrollment day 39) the subject started developing fevers and purulent drainage from her craniectomy flap wound. She was readmitted to the hospital for treatment with IV antibiotics and incision/drainage including removal of epidural frank collection of puss and surgical wound closure. Culture from a superficial swab was positive for Methicillin-resistant Staphylococcus aureus and Methicillin-sensitive

Staphylococcus aureus **(SAE #007)**. The subject was discharged back to rehabilitation on [redacted] 2010 on IV Vancomycin.

On [redacted] 2010 (post enrollment day 49) the subject was readmitted to the hospital for fever, rash, lethargy and leukopenia. A lumbar puncture was done with negative cerebrospinal fluid (CSF) study. It was determined that the subject was allergic to Vancomycin **(SAE #009)**. After discontinuation of Vancomycin the symptoms resolved. The subject was started on Daptomycin. While she was in the hospital, her Hgb dropped to the low 7's and Hct was in the 22's; two units of packed red blood cells were given **(SAE #010)**. The subject's anemia was determined to be multifactor (acute infection, menstruation and phlebotomies). The subject was discharged back to rehabilitation on [redacted] -2010.

On [redacted] -2010 (post enrollment day 53) the subject started having intermittent fevers up to 39.2°C. She was noted to be lethargic and poorly responsive. At one point she was noted to be "shaking", primarily the right arm, and possibly in a rhythmic fashion. It was unclear if she was shivering or demonstrating a seizure activity. Neurology consult was obtained. Fever work-ups included a CT of the head that did not show any abnormal enhancement within the brain. Probable seizure was considered **(AE #903)** and the subject was started on Keppra.

The subject also received acetaminophen and morphine for back pain **(AE #904)** while in rehabilitation.

On [redacted] -2010 (post enrollment day 56) the subject was afebrile but was somewhat more lethargic with an episode of vomiting. She was transferred to the hospital for further evaluation. Given that the subject experienced headache and nausea since the lumber puncture was performed, the CSF leakage from the lumbar puncture site was thought to be the cause of her altered mental status. Post-trephine syndrome was considered. Blood patch was performed and the symptoms resolved. The subject was also diagnosed with an epidural empyema for the cranial wound infection and the treatment with antibiotics continued **(cont. of SAE #007)**.

The subject was discharged back to the rehabilitation facility on [redacted] -2010 in a much improved condition. The bone-flap had not yet been replaced at the time of the 90 day follow-up visit, which also took place on [redacted] -2010.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-Apr-2009	000	002	108 - Congestive Heart Failure	N/A	N/A
29-Apr-2009	001	003	603 - Electrolyte imbalance	N/A	N/A
29-Apr-2009	001	004	799 - Vascular Other: Bleeding at PICC site	N/A	N/A
29-Apr-2009	001	005	102 - Hypotension	N/A	N/A
30-Apr-2009	002	006	412 - HT, no concomitant mass effect	N/A	N/A
11-May-2009	**013**	**007**	**499 - Neuro Other: Increased left-sided weakness**	**N/A**	**N/A**
28-May-2009	030	008	899 - Other: Muscle tightness	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 34-year-old Caucasian female with past medical history of stroke, type I diabetes (onset at age 8) with subsequent retinopathy, neuropathy, and stage IV chronic kidney disease, chronic anemia, dyslipidemia, peripheral artery disease, hypertension, asthma, and bronchitis/pneumonia in Apr-2009. The subject also has a history of ischemic cardiomyopathy, angina, and coronary artery disease with an old septal wall myocardial infarction (MI) and a non-Q wave MI 2 weeks prior to enrollment for which she underwent a percutaneous transluminal coronary angioplasty and stent placement to the left anterior descending artery. An ejection fraction improved to 45% from 20s prior to the stent placement. Multiple stents were placed in both right and left coronary arteries between 2002 and 2006. Medications at admission included: Plavix, Toprol, Vytorin, Protonix, Avelox, Iron supplements, Ambien, Xanax, Lasix, potassium supplements, Aspirin, Benazepril, folic acid, sublingual nitroglycerin as needed and Vitamin C.

On [redacted]-2009 the subject presented to an outside facility with complaint of sub-sternal chest pain and right shoulder pain at rest. She was mildly short of breath; lungs were clear. She had a 400cc emesis. At 16:30 creatinine phosphokinase (CPK) was 116, creatinine kinase-myoglobin (CKMB) was 3.7 and troponin level was 0.3. Her hemoglobin was 7.8 and hematocrit 23.3; one unit of leukopor red cells followed by Lasix was administered. Blood urea nitrogen (BUN) was 35, creatinine 2.3, and glomerular filtration rate (GFR) was 26. Chest x-ray showed small to moderate layering pleural effusions with bilateral interstitial and airspace disease. The subject was admitted for observation for suspected pericarditis. At 23:05 CPK was 782, CKMB 49.4, troponin 16.6, BUN 44 and creatinine was 2.6. The subject's admission glucose levels showed extremely poor control, with levels ranging from 50 to >500. The poor control continued throughout both hospitalizations requiring ongoing management in the form of insulin boluses, initiation of Lantus, and insulin pump.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 01:30, [redacted]-2009, while inpatient. Symptoms at presentation included flaccidity on the left side with left facial droop and left tongue deviation. Speech was clear. CT scan at admission to the SENTIS site revealed right basal ganglia and external capsule acute infarct and a previous left basal ganglia lacunar infarct. Baseline NIHSS was 9. The subject was randomized to the control arm of the SENTIS trial at 09:10, [redacted]-2009, 7.7 hours from last known normal.

Note: The site was closed to enrollment by CoAxia after discovery of the multiple protocol violations associated with this enrollment.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) the subject complained of dyspnea upon return from the angio suite. She was administered bronchodilators, Dexamethasone, and Ranitidine for suspected bronchospasm. Chest x-ray showed mild pulmonary edema; Morphine and Lasix were administered. Cardiac consult reported that the subject was diaphoretic, orthopneic, tachycardic, and tachypneic at rest. Lungs had scattered rales throughout. Jugular venous pressure was increased to the angle of the jaw and she had mild ankle edema. She was treated with IV Lasix for congestive heart failure **(AE #002)**; which improved on the following day. Metoprolol was begun. The cardiologist also determined that the subject had a non-ST elevation MI likely due to demand supply ischemia.

Starting on [redacted]-2009 (post enrollment day 1) and continuing through [redacted]-2009 the subject's low magnesium was treated with replacement, Kayexalate was given for potassium 5.2 and creatinine 2.2, as well as calcium acetate for phosphorus 5.5 **(AE #003)**.

Also on [redacted]-2009 the subject's peripherally inserted central catheter (PICC) line site was actively bleeding and dressings were re-applied over a 2 hour period before stasis was obtained **(AE #004)**.

Later that day the subject became hypotensive (systolic blood pressure (BP) of 80) **(AE #005)**. A 300cc saline bolus was given and BP improved to 96/40. Hypotension was thought to be due to the drug regimen. Over the next several days ACE-I and Amlodipine were held to allow Metoprolol dose to be maximized.

On [redacted]-2009 (post enrollment day 2) NCT showed further evolution of the acute infarct involving the right basal ganglia and right external capsule and a probable subtle petechial hemorrhage within the infarct **(AE #006)**. No obvious symptoms were noted.

The subject was transferred from the intensive care unit to the general ward on [redacted] 2009 and to home on the following day with occupational and physical therapy to be done as an outpatient.

On [redacted]-2009 (post enrollment day 13) the subject was admitted after the physical therapist felt that her left-sided upper and lower extremities weakness had increased **(SAE #007)** compared to the strength evaluation done on 0[redacted]-2009. NCT showed evolution of prior infarct involving the right basal ganglia without any new acute intracranial process. The previously noted petechial hemorrhage within the infarct had essentially resolved. Neurology did not identify any new neurological deficits. Cardiac enzymes were within normal limits. Admission was prolonged due to continuing uncontrolled hyperglycemia. Lantus on a sliding scale was initiated. The subject's insulin pump was restarted prior to discharge. The subject was discharged to acute rehabilitation on [redacted]-2009 with decreased motor strength, impaired mobility and self-care.

The 30 day NIHSS on [redacted]-2009 was ranked as 2 with mRS of 2.

On[redacted]-2009 (post enrollment day 30), while in rehabilitation, the subject was noted to have increased tone on the left upper extremity with posturing and muscle tightness **(AE #008)**. Baclofen was initiated and her left arm was casted at night. The subject responded favorably and was discharged to home on[redacted]-2009 on Baclofen.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
25-Apr-2008	000	001	414 - Neurological worsening	N/A	N/A
25-Apr-2008	000	901	103 - Hypertension	N/A	N/A
29-Apr-2008	004	902	603 - Electrolyte imbalance	N/A	N/A
16-Jul-2008	**082**	**002**	**716 - Carotid stenosis with endarterectomy**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 56-year-old Caucasian male with past medical history of hypertension (untreated) and previous stroke "in the left eye" in 2004 (mRS=0). Medications at admission included Aspirin and occasional Benadryl as a sleep aide.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 04:00, [redacted]-2008. Symptoms at presentation included aphasia and right-sided weakness. CT scan at admission revealed a subtle area of low attenuation involving the anterior left insula; no evidence of hemorrhage. CT perfusion analysis demonstrated an area of decreased cerebral blood flow and decreased blood volume with increased transit time within the left frontal lobe and the left basal ganglia. Baseline NIHSS was 9. The

subject was randomized to the control arm of the SENTIS trial at 13:02, [redacted]-2008, 9.0 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: MRI of the brain on [redacted] 2008 at 14:34 showed acute ischemic stroke in the left basal ganglia and left claustrum. The 6 hour NIHSS was 8. Shortly after that assessment, the subject's condition began to deteriorate. NIHSS increased to 11, with worsening of right-sided weakness and sensory dysfunction **(AE #001)**. The investigator verbally stated the subject had deteriorated further (although no other NIHSS from that time is available) when chose to perform a cerebral angiogram and treat the subject with the Penumbra device (Protocol deviation was received). Interventional treatment occurred approximately 17 hours from symptom onset and embolectomy was successful. There were no adverse events associated with intervention. The 24 hour NIHSS was 4.

The subject's blood pressure upon admission was 160/102 **(AE #901)**; a Cardene drip, as well as oral antihypertensives were initiated. At the time of discharge from the hospital the subject was on Metoprolol, Lisinopril, Clonidine, and Hydrochlorothiazide.

On [redacted]-2008 (post enrollment day 4) he subject's potassium was 3.2 **(AE #902)** and potassium supplement was given. The subject was discharged to home with NIHSS of 0 the same day.

On [redacted]-2008 (post enrollment day 82), the subject underwent right carotid endarterectomy **(SAE #002)** to correct the high-grade right ICA stenosis which was noted during the index hospitalization. The procedure was unremarkable. The subject was discharged to home in stable condition on [redacted] 2008.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-May-2009	001	004	115 - Patent foramen ovale (PFO)	N/A	N/A
24-May-2009	**011**	**001**	**205 - Infectious pneumonia**	**N/A**	**N/A**
03-Jun-2009	**021**	**002**	**207 - Pulmonary embolism**	**N/A**	**N/A**
03-Jun-2009	021	902	103 - Hypertension	N/A	N/A
04-Jul-2009	052	901	411 - Transient ischemic attack	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Jul-2009	**052**	**003**	**399 - Renal Other: Retro peritoneal bleed with left renal artery embolization**	**N/A**	**N/A**
04-Jul-2009	052	903	117 - Tachycardia	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 69-year-old Caucasian female with past medical history of hypertension, hyperlipidemia and gastroesophageal reflux disease. Medications at admission included: Triamterene, Hydrochlorothiazide, Simvastatin and Tylenol as needed.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:30, [redacted]-2009. Symptoms at presentation included left-sided weakness, facial droop, slurred speech and anosognosia. CT scan at admission revealed a hypodense right MCA sign as well as a right ACA dot sign; no blood or mass effect. Baseline NIHSS was 5. The subject was randomized to the control arm of the SENTIS trial at 12:05, [redacted] 2009, 12.6 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: Echocardiogram on [redacted] 2009 (post enrollment day 1) revealed a patent foramen ovale (PFO) **(AE #004)** with atrial level shunting and an atrial septum aneurysm. Surgical repair was planned when the subject had completed SENTIS participation.

The subject was discharged from the hospital on [redacted]-2009 to home without services. Her NIHSS was 3.

On [redacted]-2009 (post enrollment day 11) the subject developed a fever, productive cough, shortness of breath and hypoxemia (oxygen saturation on room air 88%) **(SAE #001)**. She was seen in the clinic and started on Azithromycin on [redacted]-2009.

On [redacted]-2009 the subject was admitted following a syncopal episode during the night. She had a temperature of 100.2°F, fatigue and weakness for the past 24 hours. Chest x-ray demonstrated opacity of left lower lobe; pneumonia and sinusitis were confirmed. The subject improved on intravenous antibiotics and was discharged to home on [redacted] 2009 on oral antibiotics. Due to her syncopal episode her antihypertensive medications were held but restarted when her blood pressure trended up.

On [redacted]-2009 (post enrollment day 21) the subject was admitted for continued shortness of breath and worsening hypoxia. Chest CT revealed multiple pulmonary emboli **(SAE #002)** in the right lung and Fragmin and Coumadin were started. The subject remained on antibiotic therapy for her pneumonia. During this admission uncontrolled hypertension **(AE #902)** was documented and Valsartan and

Hydrochlorothiazide were initiated. The subject improved and was discharged to home on [redacted] 2009

On [redacted]-2009 (post enrollment day 52) the subject developed nausea, abdominal pain, lightheadedness, diaphoresis, new left-sided facial droop, slurred speech, and left arm weakness **(AE #901)**. The neurological symptoms lasted approximately 15 to 20 min and the episode was deemed a transient ischemic attack. Upon admission the subject's international normalized ratio (INR) was 2.9 and an abdominal CT showed a large retroperitoneal hemorrhage **(SAE #003)**. The next day a renal angiogram with coil embolization of the small branch of the left renal artery, which was actively bleeding, was performed as well as placement of an inferior vena cava filter for her known pulmonary emboli **(SAE #002, update)**. During that admission the subject was given 15 units of blood and blood products and received medication for complaint of pain and nausea. Several runs of non-sustained ventricular tachycardia **(AE #903)** were also noted and electrolytes were replaced as needed. Blood pressure remained stable and home cardiac medications were restarted. The subject was discharged to home with services on [redacted] 2009.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
01-Aug-2008	001	003	601 - Anemia	N/A	N/A
01-Aug-2008	001	004	603 - Electrolyte imbalance	N/A	N/A
04-Aug-2008	004	005	811 - Depression	N/A	N/A
07-Aug-2008	007	002	303 - Urinary Tract Infection	N/A	N/A
19-Aug-2008	**019**	**001**	**407 - Seizure**	**N/A**	**N/A**
04-Sep-2008	**035**	**006**	**703 - Venous thrombosis (DVT)**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 72-year-old Hispanic female with past medical history of multiple cerebral vascular accidents (CVAs) (mRS=1), mitral stenosis, and atrial fibrillation. She had surgery to remove a left parotid tumor on 24-Jul-2008 and then was re-operated for bleeding. She has ecchymosis on the perioral, periorbital, and upper chest area and a left facial paralysis since the surgery. Her Coumadin was discontinued prior to the surgery. Medications at admission included: Lanoxin, Metoprolol, and Tylenol PM.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:30, [redacted] 2008. Symptoms at presentation included left-sided weakness with facial palsy, sensory loss, neglect and gaze preference to the right side. CT scan at admission revealed thrombus in the right middle cerebral artery without hemorrhage. Cerebral

angiogram revealed complete occlusion of the right common carotid artery. Baseline NIHSS was 13. The subject was randomized to the control arm of the SENTIS trial at 09:27, [redacted]-2008, 10.0 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject had been intubated at the time of enrollment for cerebral angiogram and was extubated on [redacted]-2008. The subject's hematocrit decreased to 27 (from 31.8 prior to enrollment) with a hemoglobin of 9.2 **(AE #003)**. Iron supplement were initiated and continued through the 90 day follow-up visit. A blood work-up on [redacted]2008 showed a potassium level of 3.1 **(AE #004)** and an IV bolus of potassium was administered.

On [redacted]-2008 the subject was diagnosed with depression **(AE #005)** and was treated with antidepressants. Her depression was ongoing but improved at the time of the 90 day follow-up visit.

The subject was discharged from the hospital on [redacted]2008 to a rehabilitation facility on Cipro for a urinary tract infection (UTI) **(AE #002)**.

On [redacted]-2008 (post enrollment day 19), the subject was admitted to the index hospital after she became unresponsive and slumped over to the floor **(SAE #001)**. NCT and MR perfusion confirmed an old right MCA infarct. Electroencephalogram (EEG) was consistent with mild to moderate diffuse encephalopathy. A neurologist felt that the subject possibly had a seizure and Keppra was administered. There was no further seizure activity. A urine culture grew methicillin-resistant staphylococcus aureus (MRSA) **(AE #002, update)**, and the subject was treated with Fluconazole and Bactrim. UTI resolved after the antibiotic regimen. The subject was discharged back to the rehabilitation facility on [redacted]-2008.

On [redacted]-2008 (post enrollment day 35), a venous ultrasound revealed a venous thrombosis (DVT) **(SAE #006)** of the left femoral vein to the proximal popliteal vein, which was treated with permanent placement of a Venatech IVC filter on 0[redacted]2008.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
15-Dec-2008	000	004	103 - Hypertension	N/A	N/A
15-Dec-2008	000	901	606 - Hyperglycemia	N/A	N/A
15-Dec-2008	**000**	**902**	**202 - Respiratory failure**	**N/A**	**N/A**
16-Dec-2008	001	003	204 - Aspiration pneumonia	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
16-Dec-2008	001	002	403 - Cerebral edema	N/A	N/A
16-Dec-2008	001	007	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
17-Dec-2008	002	009	818 - Pain	N/A	N/A
25-Dec-2008	010	008	499 - Neuro Other: Decreased alertness episodes of staring off	N/A	N/A
30-Dec-2008	015	006	303 - Urinary Tract Infection	N/A	N/A
01-Jan-2009	**017**	**001**	**501 - GI bleed**	**N/A**	**N/A**
Unk-Jan-2009		010	811 - Depression	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 71-year-old Caucasian male with past medical history of obesity, obstructive sleep apnea, colon cancer status post colon resection followed by chemotherapy in 2006, vein thrombosis (DVT), and pulmonary embolus in 2007. He was on Coumadin for pulmonary embolus but was taken off approximately 2 or 3 months ago. He is allergic to Aspirin and had no medication prior to the admission.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 01:00, [redacted]-2008. Symptoms at presentation included decreased level of consciousness, left-sided weakness with facial palsy, aphasia and sensory loss. CT scan at admission revealed no abnormality. CTA of the neck and head showed an occlusion at the origin of the right internal carotid artery (ICA) and an occlusion at the mid M1 segment of the right middle cerebral artery (MCA). Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 10:00, [redacted]-2008, 9.0 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]2008 the subject's blood pressure was 187/85 **(AE #004)** and was treated with Nicardipine. Hypertension was later treated with Norvasc.

During the index hospitalization the subject's blood glucose was in the low 100s **(AE #901)** and was treated with insulin.

On [redacted]-2008, the subject developed acute respiratory failure **(SAE #902).** He was sedated and intubated for a diagnostic angiogram prior to enrollment. Weaning of the ventilation started on [redacted]-2008 and the subject was extubated on the following day.

On [redacted]008 (post enrollment day 1), the subject developed a low grade fever **(AE #003).** A series of chest x-rays suggested small pleural effusion, bibasilar atelectasis, and infiltrates. IV Zosyn was started on [redacted]-2008. Aspiration pneumonia was later

diagnosed. The subject completed course of antibiotic and his pneumonia resolved on [redacted] -2008**.**

The 24 hour NCT of the brain on [redacted] 2008 showed sulcal effacement and mass effect **(AE #002)** consistent with evolving ischemia in the right MCA distribution without evidence of significant midline shift or intracranial hemorrhage; IV Mannitol was started. The 24 hour NIHSS was invalid due to sedation. Repeat NCT scans on [redacted] -2008 showed no significant change except for minimal midline shift to the left. On the following day, midline shift measured approximately 6mm, and compression of right lateral ventricle was noted. No cerebral hemorrhage was identified. The 4 day NIHSS on [redacted] -2008 was 20. The mass effect and midline shift was stable on NCT dated [redacted] -2008.

Also on [redacted] -2008, the site reported dyslipidemia **(AE #007)** that was treated with Crestor through the 30 day follow-up, although, the initial lipid panel was within normal range. Elevated lipids were indicated in the daily notes from [redacted] through [redacted] 2008. The subject was no longer on Crestor at his 90 day follow-up visit.

On [redacted] 008 (post enrollment day 2), the subject had generalized pain **(AE #009)**. He was treated with Morphine, Propoxyphe-Acetamin, and Tylenol. The subject continued taking Tylenol every 4 hrs for pain until his 90 day follow-up visit.

On [redacted] 2008 (post enrollment day 9), a percutaneous endoscopic gastrostomy (PEG) tube was placed to replace a feeding tube.

On [redacted] -2008 (post enrollment day 10), the subject seemed to have intermittent decreased alertness with episodes of "staring off" lasting 10-30 seconds **(AE #008)**. Electroencephalogram (EEG) ruled out seizure or epileptic activity. The subject continued to have a few episodes of decreased alertness through the 90 day follow-up visit.

The subject was discharged from the hospital on [redacted] -2008 to a rehabilitation facility.

On [redacted] -2008 (post enrollment day 15), the subject had fever and his urinalysis was positive for nitrite, large leukocyte esterase, and pyuria **(AE #006).** IV Zosyn was started.

On [redacted] -2009 (post enrollment day 17), the subject was admitted to the hospital with blood in PEG tube and at the PEG tube site, elevated white blood cell count and fever. He was diagnosed with an acute gastrointestinal (GI) bleeding **(SAE #001)** related to PEG tube irritation to stomach. Proton pump inhibitors and Carafate were started and anticoagulants were withheld. Urine culture showed growth of Pseudomonas Aeruginosa and IV Ceftazidime and Zosyn were initiated **(update to AE #006)**. The subject's hemoglobin (Hgb) was 12 and hematocrit (Hct) was 35.8; one unit of packed red blood cells was given **(part of SAE #001).** However, the repeat Hgb/Hct on [redacted] -2008 remained low at 9.2/27.5. The subject was discharged back to the rehabilitation facility on the following day.

On [redacted]-2009 (post enrollment day 32), the subject was again hospitalized with a slight bleeding from the PEG tube site **(cont. of SAE #001).** An emergent upper endoscopy revealed superficial ulceration in the area adjacent to the PEG tube. A blood clot was removed from the site. Again, this episode was treated with proton pump inhibitors and Carafate. Arixtra was withheld at the time of admission. During the course of hospitalization the subject received a total of 3 units of packed RBC for his low Hgb/Hct **(part of SAE #001)**. Iron study suggested iron deficiency and ferrous supplements were initiated. The subject was discharged from the hospital on [redacted]-2009 to a rehabilitation facility.

From rehab the subject was discharged on [redacted]-2009 to a skilled nursing facility.

At the 90 day follow-up visit on [redacted]-2009, the subject was taking Celexa and Ritalin for his depression and anxiety **(AE #010)**. His 90 day NIHSS was ranked as 19 with mRS of 5.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
23-Apr-2009	001	001	603 - Electrolyte imbalance	N/A	N/A
23-Apr-2009	**001**	**003**	**102 - Hypotension**	**N/A**	**N/A**
25-Apr-2009	003	002	413 - Headache	N/A	N/A
25-Apr-2009	003	004	814 - Sleeping Disturbance/ Disorder	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 52-year-old Asian male with past medical history of hypertension, hyperlipidemia, coronary artery disease, status post coronary artery bypass graft (CABG) x 7 vessels in 2006, insulin dependent diabetes, and obstructive sleep apnea. Medications at admission included: Imdur, Plavix, Lipitor, Toprol, Niaspan, Aspirin, Humalog and Nitroquick.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 21:00, [redacted]-2009. Symptoms at presentation included left leg weakness, left arm flaccid paresis, and left facial droop. CT scan at admission revealed no abnormality. MRI showed acute infarct involving the dorsal right basal ganglia extending to the periventricular white matter of the right lateral ventricle. Baseline NIHSS was 10. The subject was randomized to the control arm of the SENTIS trial at 09:35, [redacted]-2009, 12.6 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (post enrollment day 1), the subject experienced electrolyte imbalance of hypokalemia and hypomagnesemia **(AE #001)**. The subject was treated with potassium and magnesium IV supplements. The imbalance resolved by [redacted] 2009.

Also on [redacted]-2009, the subject experienced orthostatic hypotension **(SAE #003).** Systolic blood pressure dropped from 170 to 105 and the subject was treated with IV Levophed. The hypotension resolved by [redacted]-2009. The DSMB adjudicated this event as serious due to the extension of the hospital stay (the subject spent 4 days in ICU with Levophed IV).

On [redacted]-2009 (post enrollment day 3), the subject experienced headache **(AE #002)** and was treated with Tylenol, and Tylenol with Butalbital. The headaches resolved by [redacted] 2009.

Also on [redacted]-2009, the subject experienced insomnia **(AE #004)** and was treated with Lunesta. The insomnia resolved by [redacted]-2009.

The subject was discharged from the hospital on [redacted]-2009 to in-patient rehabilitation. On [redacted]-2009 the subject was discharged from rehab to home.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Dec-2009	001	004	499 - Neuro Other: Lethargy, decreased wakefulness	N/A	N/A
17-Dec-2009	001	902	412 - HT, no concomitant mass effect	N/A	N/A
17-Dec-2009	001	002	806 - Agitation/Excitation: Anxiety	N/A	N/A
17-Dec-2009	001	901	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
22-Dec-2009	006	003	504 - GI Motility Disorders	N/A	N/A
08-Jan-2010	023	005	818 - Pain	N/A	N/A
15-Jan-2010	**030**	**006**	**414 - Neurological worsening**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 73-year old African American male with past medical history of hyperlipidemia (untreated), seizures, benign prostatic hypertrophy,

chronic leg pain, and a past gunshot wound with bullet lodged in spine. Medications at admission included: Phenobarbital, omega-3 oil, and occasional multivitamin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 07:30, [redacted]-2009. Symptoms at presentation included left-sided weakness and slurred speech. CT scan at admission revealed no acute abnormality but showed a coarse calcification about 2 cm seen on the left near the tentorium caudal to the left ventricle (unchanged from 2002). CT perfusion revealed an area of acute evolving infarction in the right posterior frontal region. Baseline NIHSS was 8. The subject was randomized to the control arm of the SENTIS trial at 15:20, [redacted]-2009, 7.8 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (post enrollment day 1), the subject was unable to stay awake **(AE #004)** and Provigil was started. The 24 hour NIHSS remained at 8. MRI revealed a large transcortical infarct in the right MCA distribution including the insular cortex and upper basal ganglia as well as questionable 2 or 3 punctuate foci of infarct in the right MCA-ACA watershed zones. Per core lab's further review, the focal low intensity lesion seen in right caudate on MRI was consistent with focal hemorrhage (HI-1) **(AE #902).** CT dated [redacted]009 showed to evidence of hemorrhage.

The subject experienced anxiety **(AE #002),** and Lorazepam was given on 1[redacted]-2009 to facilitate radiology procedures.

Also on [redacted]2009, low-density lipoprotein (LDL) was 111 **(AE #901)** and Simvastatin was initiated and continued through the 90 day follow-up visit.

On [redacted]-2009 (post enrollment day 2), a neurology consult assessed the calcified area of the temporo-occipital lesion. A future MR spectroscopy to evaluate metabolic activity of the lesion was recommended (this was not conducted during the subject's SENTIS participation). No immediate surgical procedure was warranted.

On [redacted]-2009 (post enrollment day 4), NIHSS increased to 11. Due to decreased wakefulness and dysphagia, tube feedings were initiated **(cont. of AE #004).**

The subject did not have a bowel movement and on [redacted]-2009 (post enrollment day 6), constipation was reported **(AE #003)** and Docusate sodium was started. Constipation was noted as resolved on [redacted]-2010.

The subject was discharged from the hospital on [redacted]2009 to in-patient rehabilitation.

On [redacted]2010 (post enrollment day 23), a tooth pain was reported **(AE #005)** and prophylactic Amoxicillin was prescribed. An uneventful tooth extraction was done on [redacted]-2010.

At the time of the 30 day follow-up visit on [redacted]-2010, the subject's NIHSS was ranked as 13 and adjudicated by the DSMB as serious event **(SAE #006)**. However, per site's description the subject was clinically stable and seemed more alert than during the previous NIHSS assessment. No radiologic workup was done.

The 90 day NIHSS on [redacted]-2010 improved to 7.

Subject [redacted] enrolled [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-Jun-2007	000	006	118 - Atrial Fibrillation	N/A	N/A
14-Jun-2007	000	001	503 - Nausea/ Vomiting	N/A	N/A
15-Jun-2007	**001**	**004**	**403 - Cerebral edema**	**N/A**	**N/A**
15-Jun-2007	001	002	603 - Electrolyte imbalance	N/A	N/A
18-Jun-2007	004	005	813 - Fall	N/A	N/A
22-Jun-2007	008	007	399 - Renal Other: Right adrenal mass	N/A	N/A
25-Jun-2007	011	902	412 - HT, no concomitant mass effect	N/A	N/A
Unk-Jul-2007		901	814 - Sleeping Disturbance/ Disorder	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 60-year-old African American male with past medical history of hypertension and gout. Medication at admission included: Indomethacin, Norvasc, Hydrochlorothiazide, potassium chloride, and Nadolol.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 02:00, [redacted]-2007. Symptoms at presentation included left-sided weakness, facial droop, left hemianopsia, and slurred speech. CT scan at admission revealed very subtle effacement of right sylvian fissure; no hemorrhage. MRI showed an acute right temporoparietal infarct with decreased flow in the distal right middle cerebral artery (MCA) branches. Baseline NIHSS was 6. The subject was randomized to the control arm of the SENTIS trial at 09:55, [redacted]-2007, 7.9 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2007 (the date of enrollment), atrial fibrillation **(AE #006)** with rapid ventricular rate was noted. Transesophageal echocardiography (TEE) performed on the following day was negative for a clot but demonstrated ejection fraction of 20% and cardiomyopathy was diagnosed (prior to this finding the subject was able to

do 1 hour of cardio 2x/week without difficulty). Atrial flutter was noted on [redacted]-2007 that required no further intervention. The subject was treated with Carvedilol, Digoxin, and Lisinopril. Anticoagulation therapy except Aspirin was delayed due to the risk of hemorrhagic transformation. The subject also complained of nausea **(AE #001)** that was treated with Phenergan. Nausea resolved on [redacted]-2007.

On [redacted] 2007 (post enrollment day 1), the subject was noted to be more lethargic and complained of headache. The 24 hour NIHSS had slightly increased to 8. NCT showed hypodensity in the right middle artery distribution, consistent with evolving infarct, and effacement of the frontal horn of the right lateral ventricle and minimal right-to-left midline shift **(SAE #004)**. NCT on the following day revealed increased effacement of the right lateral ventricle and increased midline shift (6 mm); no hemorrhage. Mannitol and hypertonic saline was given from [redacted]-2007 to [redacted]-2007 and the headache was treated with Tylenol and Tylenol 3 intermittently through discharge.

The subject's potassium level decreased to 2.5 (norm 3.5-5.5) **(AE #002)** on [redacted]-2007 and his oral KCL was increased to 40 mEq. Hypokalemia resolved on [redacted]-2007.

On [redacted]-2007 (post enrollment day 4), the subject fell out of bed **(AE #005)**. No trauma sign was noted and vital signs were stable. The bed alarm was activated. NCT confirmed increased effacement of the right ventricle and a midline shift of 9 mm **(cont. of SAE #004)**; no hemorrhage. The subject seemed less alert and believed that he was in his house, but had a relatively stable NIHSS of 7**.**

On [redacted] 007 (post enrollment day 8), the subject's blood pressure increased to 182-191 / 94-114. The subject was evaluated for hyperadrenal syndrome due to his hypokalemia with low to normal sodium. MRA of the aorta and renal artery ruled out renal stenosis but did show a right adrenal mass **(AE #007)**, considered as adenoma.

NCT on [redacted]-2007 showed improvement in the effacement of the right lateral ventricle and almost completely resolved midline shift and a small hyperdense focus in the right temporal lobe suggestive of petechial hemorrhage **(AE #902).** The subject had improved strength in his left side but continued to have left hemianopsia. He was discharged from the hospital on [redacted]-2007 to the rehabilitation facility.

At the 30 day follow-up visit on [redacted]-2007, the subject's NIHSS was ranked as 3. He had been started on Zolpidem for insomnia **(AE #901).**

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
22-Jan-2009	000	002	606 - Hyperglycemia	N/A	N/A
22-Jan-2009	000	003	818 - Pain	N/A	N/A
26-Jan-2009	004	902	603 - Electrolyte imbalance	N/A	N/A
04-Mar-2009	**041**	**001**	**415 - Intracerebral hemorrhage**	**N/A**	**N/A**
04-Mar-2009	**041**	**901**	**807 - Coagulopathy**	**N/A**	**N/A**
04-Mar-2009	041	903	815 - Skin irritation	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 81-year-old Caucasian female with past history of mitral valve repair in 1997, coronary artery disease with myocardial infarction in 2006, status post right coronary intervention, atrial fibrillation with implantable cardioverter defibrillator placed in 2006, cardiomyopathy, hypertension, hyperlipidemia, bladder cancer, hysterectomy, chronic back pain, and an occasional left leg pain. She also had a history of falls with a decision made not to restart Coumadin on [redacted]-2008 due to the high risk of bleeding. Medications at admission included: Coreg, Plavix, Lasix, and Lisinopril. Medical records sent by the subject's cardiologist after the enrollment showed ejection fraction of 27.5 % on [redacted]-2008.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 08:00, [redacted]-2009. She had an un-witnessed fall. Symptoms at presentation included altered level of consciousness, slurred speech, and left-sided weakness with facial drooping. CT scan at admission revealed no evidence of acute intracranial hemorrhage or recent cortical ischemia. CT perfusion of the brain showed significant delay in time to peak perfusion in right middle cerebral artery distribution (MCA). Baseline NIHSS was 13. The subject was randomized to the control arm of the SENTIS trial at 15:25, [redacted] 2009, 7.4 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment), the subject's admission glucose level was 167 **(AE #002)** and regular insulin per sliding scale was ordered. No further treatment was required after discharge.

The subject stated that she hit her head on the wall when she fell at the time of stroke onset and complained of a headache, neck, left knee, and left lower extremity pain **(AE #003).** The pain was treated with Tylenol and resolved by the 90 day follow-up visit on [redacted]009.

The 24 hour NCT on [redacted]-2009 showed ill-defined hypodensity in the right MCA territory that was consistent with an evolving acute infarct. The 24 hour NIHSS was 11.

On [redacted] 2009 (post enrollment day 4), the subject's potassium level was low at 3.3 **(AE #902)**. Potassium chloride was administered, and a subsequent potassium level was within the normal range at 4.3. The 4 day NIHSS was 4.

The subject was discharged from the hospital in a stable condition on [redacted]-2009 to a skilled nursing facility.

At the time of the 30 day follow-up visit on [redacted]-2009, the subject's NIHSS was 1 with mRS of 4.

On [redacted] 2009 (post enrollment day 41), the subject indicated that she again felt weakness of the left hand and arm while in physiotherapy and was sent to a hospital for evaluation. NCT of the brain showed a left occipital lobe hematoma measuring 1.1cm in diameter with surrounding edema **(SAE #001).** The subject's clinical stroke symptoms did not match the intra-cranial hemorrhage location; however, she did have a head injury at the time of her index stroke onset. (Note: A repeat NCT report dated 0[redacted]-2009 noted right MCA hypodensity but suggested no evidence of hemorrhage. The Principal Investigator at the site re-read the imaging scan and felt that the intra-cerebral hemorrhage was present in the left occipital lobe.)

The subject's admission lab results revealed pro-time of 26.09 (norm 11.8-15.2) and INR 2.42 (norm 0.81-1.21) **(SAE #901).** Fresh frozen plasma was given and Plavix and Coumadin were held.

Upon admission to the hospital on [redacted]-2009, a lower extremity skin tear was documented **(AE #903)** and a dry dressing was applied. No further documentation of the wound status was noted. The subject was clinically stable and discharged back to the skilled nursing facility on [redacted]-2009.

The 90 day NIHSS on [redacted]-2009 was ranked as 2 with mRS of 4.

Subject [redacted], enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Dec-2008	**000**	**001**	**202 - Respiratory failure**	**N/A**	**N/A**
04-Dec-2008	**000**	**008**	**403 - Cerebral edema**	**N/A**	**N/A**
05-Dec-2008	001	004	102 - Hypotension	N/A	N/A
05-Dec-2008	001	002	304 - Hematuria	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Dec-2008	001	007	899 - Other: Sinusitis and mastoiditis	N/A	N/A
07-Dec-2008	003	901	503 - Nausea/ Vomiting	N/A	N/A
09-Dec-2008	005	005	412 - HT, no concomitant mass effect	N/A	N/A
10-Dec-2008	006	003	603 - Electrolyte imbalance	N/A	N/A
15-Dec-2008	011	009	504 - GI motility disorders	N/A	N/A
20-Dec-2008	016	902	804 - Sleeping Disturbance/ Disorder	N/A	N/A
23-Dec-2008	019	006	599 - GI Other: Erosive gastritis	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 53-year-old Hispanic male with past medical history of hypertension, chronic obstructive pulmonary disease and asthma. He is a current smoker and has a history of alcoholism (not known by the investigator at enrollment). Medications at admission included Clonidine.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:00 on [redacted] 2008. Symptoms at presentation included right gaze deviation and left-sided weakness with left facial asymmetry. CT scan at admission revealed a subtle area of hypodensity at the right frontal lobe with effacement of the gray-white matter differentiation, suggestive of early ischemic infarct in the subsegmental territory of the right MCA. There was no evidence of hemorrhage. Baseline NIHSS was 11. The subject was randomized to the control arm of the SENTIS trial at 04:35, [redacted]-2008, 5.6 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: At 06:30 on [redacted] 2008 (the day of enrollment), the subject was treated with Ativan for agitation. The subject remained agitated, and by 09:30 he was also tachypneic. Albuterol, Solumedrol and oxygen were given. Chest x-ray showed interstitial opacities in the right lung. These were noted as most likely chronic, but pneumonia was not ruled out. Sputum cultures and infectious disease consult were obtained, and the subject was started on Zosyn and Zythromax.

The subject remained in respiratory distress, and during the period from 06:30 to 12:40 on [redacted]-2008, his 6 hour NIHSS increased to 16 due to the worsening of left-sided weakness and pupillary asymmetry **(SAE #008)**. CT scan (quality noted to be poor) showed no significant changes compared to the previous scan. The respiratory distress and agitation continued, and at 14:10 on [redacted] 2008, the subject was intubated and placed on mechanical ventilation **(SAE #001)**. A Propofol drip was initiated.

On [redacted]-2008 (post enrollment day 1), the subject became hypotensive **(AE #004)** from Propofol. His fluid intake was increased and Propofol was discontinued. Hematuria **(AE #002)** was noted in the subject's Foley catheter. Urology was consulted and a new catheter was inserted.

A repeat CT scan on [redacted] 2008 showed that the large hypodense area in the right tempo-parietal region became more conspicuous. According to the Core Lab, the hypodensity had increased to encompass nearly 100% of the MCA territory. The area of edema within the right temporoparietal region created a mass effect on the right lateral ventricle, with minimal right to left midline shift **(SAE #008, update)**. No evidence of hemorrhagic conversion was seen. His 24 hour NIHSS remained at 16.

Bilateral mastoiditis and ethmoidal, sphenoidal sinusitis sphensinusitis/mastoiditis, with associated leukocytosis **(AE #007)** was noted on [redacted] 2008 and Augmentin was initiated.

CT scan on [redacted]-2008 (post enrollment day 2) revealed an interval increase in hypodensity in the right frontal temproroparietal lobe with associated effacement of the sulci, loss of gray-white matter junction differentiation and compression of the right lateral ventricle. Midline shift had increased. No significant neurological change was noted.

On [redacted] 008 the subject had an episode of nausea and vomited dark stomach contents **(AE #901).** The 4 day NIHSS increased to 24, Glasgow coma score was 4 and prognosis was noted to be poor.

CT scan on [redacted]-2008 showed increased mass effect. Right to left midline shift had increased, and the suprasellar cistern was obliterated. There was no evidence of hemorrhagic transformation. Episodic bradycardia was noted. Mannitol was started, and the subject underwent decompressive hemicraniectomy **(SAE #008, update)**.

CT scan on the following day showed various focal hemorrhages **(AE #005)**, with the largest in the right posterior parietotemporal lobe. It was noted that these could be post-surgical in nature, but the possibility of hemorrhagic transformation could not be ruled out.

The subject's neurological improvement after the hemicraniectomy was noted on [redacted] 2008. Glasgow coma score increased from 4 to 8. Hypokalemia was also diagnosed **(AE #003)** and supplemental replacements were administered.

On [redacted] 2008 (post enrollment day 11), the subject had diarrhea **(AE #009)** likely due to the tube feedings. Imodium was given and a nutritionist was consulted. On the following day the subject was transferred from intensive care to a step down unit with NIHSS of 16.

CT scan on [redacted]-2008 showed multiple hemorrhagic foci throughout the right panhemispheric lobe with associated edema consistent with hemorrhagic conversion **(AE #005, update)**. A mild increase in brain herniation through the right parieto-occipital craniectomy was noted. No significant midline shift was found. The subject remained neurologically stable.

On [redacted]-2008 (post enrollment day 16), the subject had insomnia **(AE #902)**, which was treated with Ambien.

On [redacted] 2008 an endoscopic gastrostomy was performed due to the subject's dysphagia, and a gastric feeding tube was placed. Mild erosive gastritis **(AE #006)** was noted and was treated with Zantac.

At the 30 day visit on [redacted]-2008, the subject's NIHSS was 13, mRs was 4, Glascow Outcome Scale was 3 and Barthel Index was 0.

The subject was discharged from the hospital on [redacted] 2008 to an outpatient rehabilitation facility.

At the 90 day visit on [redacted] 2009, the subject's NIHSS was 9, mRS was 4, Glascow Outcome Scale was 3 and Barthel Index was 30.

Subject [redacted], enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
15-Nov-2006	000	001	599 - GI Other: Gastric discomfort	N/A	N/A
15-Nov-2006	000	901	699 - Lab/electrolyte Other: Essential thrombocytosis	N/A	N/A
15-Nov-2006	000	902	814 - Sleeping Disturbance/ Disorder	N/A	N/A
16-Nov-2006	001	002	413 - Headache	N/A	N/A
16-Nov-2006	001	003	818 - Pain	N/A	N/A
17-Nov-2006	002	004	504 - GI Motility Disorders	N/A	N/A
24-Nov-2006	**009**	**005**	**411 - Transient ischemic attack**	**N/A**	**N/A**
28-Nov-2006	013	006	303 - Urinary Tract Infection	N/A	N/A
Unk-Nov-2006		903	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
Unk-Nov-2006		904	811 - Depression	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 65-year-old Caucasian female with past medical history of hypertension, postmenopausal uterine bleeding for the past 3 years, and atrial fibrillation. The subject was not on Coumadin as it caused swelling. Over the last year the subject had fatigue and lost 40 lbs. Medications at admission included: Diltiazem and Nadolol.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 12:30, [redacted]-2006. Symptoms at presentation included decreased level of consciousness, facial droop, right-sided weakness, aphasia and dysarthria. CT scan at admission revealed no acute findings. Baseline NIHSS was 9. The subject was randomized to the control arm of the SENTIS trial at 17:28, [redacted]-2006, 5.0 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]006 (the day of enrollment) the subject complained of epigastric discomfort **(AE #001)** post insertion of a nasogastric tube. The tube was removed and discomfort resolved.

Also on [redacted]-2006 the subject's platelets were elevated at 759 (norm 130- 400x10^9L). It was found that the platelets were as high as 1000 four months prior to the stroke onset. Additional tests confirmed diagnosis of essential thrombocytosis **(AE #901)**. Hydroxyurea was started with the goal platelet count of less than 400. At the time of discharge on [redacted]2006, platelet count decreased to 579. Hematology was scheduled to continue following up with the subject.

The subject complained of a sleep disturbance **(AE #902)** and Ativan was started on [redacted]-2006 and continued through the 90 day follow-up.

On 1[redacted]006 (post enrollment day 1) the subject complained of headache **(AE #002)**. Tylenol administration resulted in complete resolution of symptoms. Although, the subject's 24 hour NIHSS decreased to 0, she remained in the hospital for hematology and rheumatology work-ups as well as waiting for a nursing home.

The subject also complained of right leg pain **(AE #003)**, which started back in January of 2006 when she fell and landed on her right knee. Torodol and Tylenol were given but the subject continued complaining of pain. X-rays of knees revealed bilateral osteoarthritis with the right knee being worse than the left. The right knee injection of 1% Lidocaine and Kenalog 40mg provided the subject with significant relief. The subject had also complained of some pain of hands and feet over the last three months and palindromic arthritis was also diagnosed.

On [redacted]2006 (post enrollment day 2) Lactulose was given for constipation **(AE #004)**. The subject had a bowel movement on [redacted]-2006. The subject continued taking Lactulose through the 90 day follow-up visit and Senokot was also added.

On [redacted]-2006 (post enrollment day 9) the subject had a sudden onset of left gaze deviation, global aphasia, and right hemiparesis **(SAE #005)**. CT angiography revealed a clot in a distal vessel in the left MCA distribution with collateral flow distal to the clot. IV fluids were administered. By the next day, the subject was back to baseline, except that she felt generally weaker and tired. NCT on [redacted]-2006 demonstrated an increase in "lucency" in the infarcted region since the previous exam with mild mass effect. This event was considered to be a transient ischemic attack. No formal NIHSS evaluations were completed between [redacted] 2006 and discharge. Aspirin was started for stroke prevention.

On [redacted]-2006 (post enrollment day 13), the subject was diagnosed with urinary tract infection **(AE #006).** Ciprofloxacin was given and the event resolved by [redacted]-2006.

During the index hospitalization the subject's cholesterol was 4.64, triglycerides 1.6, high density lipoprotein 1.08 (norm 1.30-1.55), low density lipoprotein 2.9 (norm ≤ 2.5) and ratio was 4.3. Pravochol was started and continued through the 90 day follow-up visit. Hypercholesterolemia **(AE #903)** appeared to be pre-existing; however, it was not previously treated.

Also during the index hospitalization Sertraline was started for depression **(AE #904)** and continued through the 90 day follow-up visit.

The subject was discharged from the hospital on [redacted]-2006 to a nursing home with follow-up appointments arranged with a stroke neurologist, rheumatologist, and hematologist.

The 30 day NIHSS on [redacted]-2006 was ranked as 1 with mRS of 3.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
29-Dec-2009	000	901	699 - Lab/electrolyte Other: Elevated anticardiolipin antibody	N/A	N/A
29-Dec-2009	**000**	**001**	**414 - Neurological worsening**	**N/A**	**N/A**
11-Jan-2010	**013**	**002**	**115 - Patent foramen ovale (PFO) with closure**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 46-year-old African American male with past medical history of hernia repair (1980's) and recent diagnosis of duodenal ulcer. The subject was not taking any medications.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:00, [redacted]-2009. Symptoms at presentation included right-sided weakness with facial droop, significant expressive aphasia, some dysarthria, left gaze preference, and possibly right partial homonymous hemianopsia. CT scan at admission revealed signs of ischemic insult involving the left middle cerebral artery (MCA) territory with cortical involvement. Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 09:00, [redacted] 2009, 10.0 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment), anticardiolipin antibody (IgA) was elevated to 42 (norm < 23 GPL U/ml) **(AE #901).** A repeat laboratory test on 15-Jan-2010 demonstrated an IgA level of 9 and the spike of IgA on [redacted]-2009 was considered to be acute rather than chronic.

The 6 hour NIHSS at 16:00 had increased to 23 **(SAE #001)** due to decreased level of consciousness, increased dysarthria and neglect. The 24 hour NIHSS on [redacted]-2009 was 20. NCT revealed an infarct within the left frontal lobe centered at the insula and frontal operculum. The lesion was larger than originally suggested on the prior CT scan. There was mild mass effect but no midline shift, hydrocephalus, or hemorrhage. The 4 day NIHSS assessment conducted on [redacted] 2009 was 18.

The subject was discharged from the hospital on [redacted] 2010 to inpatient rehabilitation.

On [redacted] 2010 (post enrollment day 13), a transesophageal echocardiogram (TEE) revealed a patent foramen ovale (PFO) **(SAE #002)** within the interatrial septum. Percutaneous closure of the PFO with an Amplatzer® Septal Occluder (25 mm) was conducted on [redacted] 2010 without complication. For the following 3 months the subject was placed on Aspirin and Plavix.

The 30 day follow-up visit was conducted on [redacted]-2010 while the subject was still in inpatient rehabilitation. The NIHSS was 13. The subject was discharged from inpatient rehabilitation on [redacted] 2010.

The 90 day NIHSS on [redacted]-2010 was ranked as 10 with mRS of 3.

Subject [redacted], enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
25-Sep-2006	000	901	303 - Urinary Tract Infection	N/A	N/A
27-Sep-2006	002	001	806 - Agitation/Excitation	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Oct-2006	**009**	**003**	**811 - Depression**	**N/A**	**N/A**
12-Oct-2006	017	902	899 - Other: Left chest wound	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 51-year-old Hispanic female with a past medical history of depression, anxiety, hypertension, hypothyroidism, hyperlipidemia, and a seizure several years ago. The subject's single office visit record stated that she had a history of a previous stroke (mRS=0), and Wolff-Parkinson-White syndrome. The subject has an implantable cardioverter-defibrillator. The subject's urine toxicology was positive for cannabis on admission. Medications at admission included: Synthroid, Klonopin, Neurontin, Trazodone, Flexeril, Verapamil, Cogentin, Toprol XL and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 09:00 on [redacted] 2006. Symptoms at presentation included dizziness, right-sided weakness and expressive aphasia. CT scan at admission revealed no acute findings. CT perfusion scan showed a slight deficit in the left hemisphere. Baseline NIHSS was 15. The subject was randomized to the control arm of the SENTIS trial at 13:07, [redacted]-2006, 4.1 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2006 (the day of enrollment), the subject began treatment with Cipro for a urinary tract infection **(AE #901)** that was discovered at the time of admission. .

Starting on [redacted]-2006 (post enrollment day 2), the subject had a few episodes of agitation **(AE #001).** She was anxious and tearful. She also complained of depression, insomnia, decreased motivation, and vague suicidal ideations. The subject had a history of seven prior overdose attempts with the last attempt in 2000. A psychiatry consult was obtained and the subject was started on Lexapro with a slight improvement.

The subject was discharged from the hospital with "no signs of stroke" on [redacted]-2006 to home. Her NIHSS was recorded though as 3. (While the subject was distracted and engaged in activity on the day of discharge, she was observed by the attending physician using her right arm without any difficulty or indication of continued weakness.)

On [redacted]-2006 (post enrollment day 9), the subject was re-admitted to the hospital with depression and suicidal tendencies **(SAE #003)**. The subject stated that she had stabbed herself two days earlier and her left chest wounds were treated with Bactrim cream **(AE #902)**. The subject underwent neuropsychiatric and medical evaluations as well as crisis stabilization and was found to be positive for Cannabis abuse. Eight days later, she had no evidence of agitation, psychosis, or anxiety and denied suicidal or homicidal ideation.

The subject was discharged to home to the care of her family on [redacted]-2006 and was lost to follow-up thereafter.

Subject [redacted] enrolled [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
10-Dec-2007	000	001	899 - Other: Multiple fractures	N/A	N/A
10-Dec-2007	**000**	**004**	**414 - Neurological worsening**	**N/A**	**N/A**
11-Dec-2007	001	006	603 - Electrolyte imbalance	N/A	N/A
24-Dec-2007	014	003	703 - Venous Thrombosis (DVT)	N/A	N/A
Unk-Jan-2008		901	303 - Urinary Tract Infection	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: This subject is a 67-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, right internal carotid artery stenosis, left carotid endarterectomy, transient ischemic attack, migraines, coronary artery disease, peripheral vascular disease, diabetes, hemangioma in the spine, hiatal hernia and cervical cancer. Medications at admission included: Crestor, Benicar, Tricor, Norvasc, Nexium, Aspirin, Nitrostat, and magnesium oxide.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at around 12:00 on [redacted]-2007 while driving a car, which resulted in motor vehicle accident. The subject had abdominal trauma with subcutaneous hemorrhage secondary to the accident. She also had a broken right wrist and four fractured ribs, but this was not discovered for several days **(AE #001).** Symptoms at presentation included right-sided weakness, dysarthria and sensory loss. CT scan at admission revealed no acute findings. Baseline NIHSS was 6. The subject was randomized to the control arm of the SENTIS trial at 17:00, [redacted]-2007, 5.0 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: Soon after randomization, the subject became drowsy. Her NIHSS at 17:30 worsened to 12 **(SAE #004)** due to increase of the right-sided weakness, aphasia, and neglect. The 24 hour NIHSS on [redacted]-2007 remained at 12. CT perfusion scan on [redacted]-2007 revealed a possible new infarct in left paracentral gyrus, but the investigator believed that it was an extension of an existing infarct. Core Lab confirmed an acute infarct in the medial frontal lobe of the left ACA-M3 distribution. No additional follow-up scans were done. The 4 day NIHSS on [redacted]-2007 decreased to 9.

The subject's serum potassium **(AE #006)** fluctuated during the hospitalization. Supplemental replacements were given on [redacted]-2007.

On [redacted]-2007 (post enrollment day 4), the subject complained of a rib pain; x-ray revealed fractures of the left 4-7 ribs, with 2 displaced. The subject complained of right wrist pain on [redacted] 2007. X-ray of the right wrist confirmed a wrist fracture. Both fractures most likely occurred during the motor vehicle accident at the time of stroke onset, but were not diagnosed until later dates **(cont. of AE #001)**.

The subject was discharged from the hospital on [redacted] 2007 to rehab.

On [redacted] 2007 (post enrollment day 14), the subject complained of pain in her right calf. Ultrasound and Doppler imaging demonstrated deep vein thrombosis **(AE #003)**. The subject was already receiving Aspirin and Plavix, so Coumadin was added to her regimen.

The 30 day NIHSS on [redacted]-2008 was ranked as 9 with mRS of 4. The Medication Log indicated that the subject was receiving Cipro for a urinary tract infection **(AE #901).** The subject was discharged from rehab on [redacted] 2008 to home.

At the time of the 90 day follow-up visit on [redacted]-2008, the subject's NIHSS and mRS were both ranked as 4.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
21-May-2008	002	001	108 - Congestive heart Failure	N/A	N/A
23-May-2008	**004**	**002**	**109 - Atrial Fibrillation with pacemaker placement**	**N/A**	**N/A**
31-May-2008	012	901	703 - Venous thrombosis (Deep vein thrombosis)	N/A	N/A
Unk-Jun-2008		902	814 - Sleeping Disturbance/ Disorder	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 78-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, osteoporosis and benign breast cystectomies. Medications at admission included: Lisinopril and Lipitor.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 11:00, [redacted]-2008. Symptoms at presentation included left-sided weakness and numbness. CT scan at admission revealed atrophy with microvascular ischemic changes and old lacunes. CTA of the head and neck revealed a right posterior ACA infarct with possible watershed component. Baseline NIHSS was 6. The subject was

randomized to the control arm of the SENTIS trial at 17:00, [redacted]-2008, 6.0 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2008 (post enrollment day 1), the subject was found to be tachypneic, had low oxygen saturation and bilateral crackles in the lung bases. A chest x-ray revealed mild pulmonary vascular congestion. Pneumonia was suspected and Levaquin was started. However, an echocardiogram on [redacted] 2008 revealed congestive heart failure **(AE #001)**. The subject responded well to treatment with Lasix, oxygen and potassium.

On [redacted]-2008 (post enrollment day 4), the subject complained of palpitations. She was put on a Holter monitor, which showed atrial fibrillation **(SAE #002)**. An electrocardiogram (ECG) also confirmed atrial fibrillation. The subject was given Metoprolol and Digoxin, which controlled the rate and rhythm. She also received heparin for a short period of time and was started on Coumadin for anticoagulation.

The subject was discharged from the hospital on [redacted]-2008 to a rehab facility.

On [redacted]-2008 (post enrollment day 12), a venous duplex ultrasound and color flow study revealed an acute deep venous thrombosis **(AE #901)** of both lower extremities. The subject was already on Coumadin. No other treatment was given.

The subject was discharged from the rehab facility on [redacted] 2008.

On [redacted]-2008, the subject presented to the emergency department with complaints of dizziness. The ECG revealed severe bradycardia. The diagnosis was atrial fibrillation with severe bradycardia. The subject was admitted to hospital and a pacemaker was implanted without complications on [redacted]008 **(cont. of SAE #002)**. There were no other episodes of arrhythmia and the subject discharged to home on 15-Jun-2008.

At the 30 day follow-up visit on [redacted] 2008, the subject was noted to be taking Ambien for insomnia **(AE #902)**.

Subject [redacted], enrolled [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
01-Jan-2008	001	901	303 - Urinary Tract Infection	N/A	N/A
02-Jan-2008	**002**	**003**	**414 - Neurological worsening**	**N/A**	**N/A**
02-Jan-2008	002	001	405 - HT, probably not contributing to mass effect	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Jan-2008	004	902	603 - Electrolyte imbalance	N/A	N/A
04-Jan-2008	004	903	603 - Electrolyte imbalance	N/A	N/A
06-Jan-2008	006	002	407 - Seizure	N/A	N/A
10-Jan-2008	010	905	809 - Diabetes Mellitus	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 67-year-old African American female with a past medical history of paroxysmal atrial fibrillation, hypertension, hyperlipidemia, diabetes mellitus, gastroesophageal reflux disease and possible coronary artery disease. Medications at admission included: Aspirin, Avapro, Atenolol, Prilosec, Lipitor, Lopressor, Lovenox, insulin, vitamin B12 and folate.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 15:00 on [redacted]-2007. Symptoms at presentation included inability to follow command, left gaze preference, aphasia, right-sided drift with facial droop, and dysarthria. CT angiography at admission showed an occlusion of the left ICA and an acute infarct in the left MCA. The baseline NIHSS was 12. The subject was randomized to the control arm of the SENTIS trial at 23:10, [redacted] 2007, 8.2 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2008 (post enrollment day 1), the subject was diagnosed with a urinary tract infection **(AE #901)** and was prescribed Cipro.

The 6 hour NIHSS on [redacted]-2008 at 01:15 was 15. The subject's level of consciousness and right-sided weakness had worsened **(SAE #003)**. Her 24 hour NIHSS at 23:05 was ranked as 17. MRI on 02-Jan-2008 at 00:18 revealed evidence of hemorrhagic conversion **(AE #001)** of the left MCA infarct within the left temporal lobe. A follow-up CT on [redacted] 2008 demonstrated interval evolution of the large left MCA infarct and increased mass effect with a left-to-right midline shift. The 4 day NIHSS on [redacted]-2008 remained at 17.

The subject was hyponatremic and hypokalemic **(AE #902)**, and supplemental replacements were given**.**

On [redacted]-2008 (post enrollment day 6), the subject exhibited uncontrolled lip smacking, indicative of possible seizure activity **(AE #002)**. An electroencephalogram was non-specific, and Lorazepam and Keppra were initiated for prophylaxis.

On [redacted]-2008 (post enrollment day 10), the subject's blood glucose was elevated **(AE #905)**, requiring treatment with additional insulin. The subject was discharged from the hospital on the following day to a rehabilitation facility.

At the 30 day follow-up visit on [redacted]-2008, the subject's NIHSS was 9 and mRS was 4.

The 90 day NIHSS on [redacted]-2008 was ranked as 8 with mRS of 3.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
08-Nov-2008	001	003	109 - Arrhythmia	N/A	N/A
11-Nov-2008	**004**	**001**	**108 - Congestive Heart Failure**	**N/A**	**N/A**
11-Nov-2008	004	004	405 - HT, probably not contributing to mass effect	N/A	N/A
12-Nov-2008	005	005	812 - Fever	N/A	N/A
19-Nov-2008	**012**	**002**	**407 - Seizure**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 56-year-old Caucasian male with a past medical history of coronary artery disease, myocardial infarction, coronary stenting, type II diabetes, hyperlipidemia and hypertension. The subject was prescribed Aspirin, Metformin, and Lasix, but was non-compliant.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 14:00 on [redacted] 2008. Symptoms at presentation included aphasia, hemianopsia, severe dysarthria, right facial droop and right arm weakness. CTA at admission revealed occlusion of M2 branch of the left MCA and bilateral stenosis of ICA. Baseline NIHSS was 13. The subject was randomized to the control arm of the SENTIS trial at 21:40, [redacted]-2008, 7.7 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: Beginning on [redacted]-2008 (post enrollment day 1) and continuing intermittently through [redacted]-2008, the subject had multiple episodes of bradycardia and tachycardia **(AE #003).** No treatment was given. The subject did complain of shortness of breath on [redacted] v-2008. The 24 hour NIHSS was 8.

A chest x-ray on [redacted]-2008 (post enrollment day 4) revealed pulmonary congestion. The subject was treated with Lasix. A Tran esophageal echocardiogram showed severe diastolic dysfunction, global hypokinesis and left ventricular hypertrophy, with an ejection fraction of 25-36% **(SAE #001)**. The subject was transferred to cardiology service for management of his heart failure.

An MRI on [redacted]-2008 demonstrated petechial hemorrhage **(AE #004).** There was minimal mass effect and mild compression of the lateral ventricle without midline shift. The 4 day NIHSS on [redacted]-2008 was 4.

On [redacted]-2008 (post enrollment day 5), the subject had a fever of 100.6ºF **(AE #005)**. Blood and urine cultures were negative. The subject's fever was treated with Tylenol.

The subject was discharged from the hospital on [redacted]-2008 to home.

On [redacted]-2008 (post enrollment day 12), the subject had a seizure **(SAE #002)** and was readmitted to the hospital. An electroencephalogram was performed and anti-seizure medication was initiated. The subject was discharged on [redacted]-2008 back to home.

At the 30 day visit on [redacted]-2008, the subject's NIHSS was 4 and mRS was 2.

The 90 day NIHSS and mRS on [redacted]-2009 were both ranked as 2.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
21-Jun-2009	**000**	**001**	**202 - Respiratory failure**	**N/A**	**N/A**
21-Jun-2009	000	002	603 - Electrolyte imbalance	N/A	N/A
22-Jun-2009	**001**	**004**	**414 - Neurological worsening**	**N/A**	**N/A**
23-Jun-2009	002	003	303 - Urinary Tract Infection	N/A	N/A
23-Jun-2009	002	005	118 - Atrial Fibrillation	N/A	N/A
24-Jun-2009	003	901	806 - Agitation/Excitation	N/A	N/A
27-Jun-2009	006	006	606 - Hyperglycemia	N/A	N/A
29-Jun-2009	008	902	603 - Electrolyte imbalance	N/A	N/A
04-Jul-2009	013	007	816 - Oral thrush	N/A	N/A
05-Jul-2009	014	008	102 - Hypotension	N/A	N/A
10-Jul-2009	019	009	805 - Sepsis	N/A	N/A
02-Sep-2009	073	903	811 - Depression	N/A	N/A
02-Oct-2009	103	012	108 - Congestive Heart Failure	N/A	N/A
02-Oct-2009	**103**	**011**	**205 - Infectious pneumonia**	**N/A**	**N/A**
02-Oct-2009	103	905	399 - Renal Other: Syndrome of inappropriate antidiuretic hormone secretion	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 83-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, palpitations, anemia, osteoarthritis, peripheral neuropathy, vertigo, cataract removal with implant, cholesystectomy, and hysterectomy. She was in atrial fibrillation upon admission to the emergency department, which was new for her. Medications at admission included: Aspirin, calcium, Celebrex, Hydrochlorothiazide, Lyrica, Toprol XL, and Antivert.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 02:00 on [redacted]-2009. Symptoms at presentation included partial hemianopsia, left-sided weakness with left facial droop and mild dysarthria. CTA and CT perfusion scan at admission revealed penumbra in the right MCA territory secondary to occlusion of a right branch and no evidence of intracranial hemorrhage. Baseline NIHSS was 7. The subject was randomized to the control arm of the SENTIS trial at 12:48, [redacted]-2009, 10.8 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: A chest x-ray done at 13:05 on [redacted]-2009 showed an enlarged cardiac silhouette with right basilar atelectasis and right pleural effusion. A chart note indicated pulmonary edema, although, this was not documented in the radiology report. At 14:15, the subject became hypertensive and tachypneic. She was given Lasix with good response, but her oxygen saturation remained in the low 90s on a 100% non-rebreather mask. The subject was having difficulty controlling her oral secretions, so she was intubated and placed on a ventilator **(SAE #001)**. Her serum potassium and magnesium were low **(AE #002)**, and supplemental replacements were given.

On [redacted]-2009 (post enrollment day 1), the subject was noted to be more somnolent. Her systolic blood pressure decreased to 121 from 178 at admission. A Neosynephrine drip was initiated to keep her systolic blood pressure greater than 160. The 24 hour NIHSS increased to 12 **(SAE #004).** Repeat CT scan showed evolution of the infarction in right MCA territory.

On [redacted] 2009 the subject was extubated, but became hypoxic and was re-intubated. Sputum culture was positive, so she was treated with Vancomycin **(SAE #001, update)**. Her urine culture was also positive for staph aureus and treated with Cefipine **(AE #003)**. The subject remained in atrial fibrillation, but her heart rate was in the low 100s so a Cardizem drip was initiated for heart rate control **(AE #005).**

On [redacted]-2009 (post enrollment day 3), the subject was agitated and anxious **(AE #901)**. She was given Ativan.

The 4 day NIHSS on [redacted] 2009 remained at 12. The subject was extubated for a second time. She required nasotracheal suctioning due to secretions. The subject was re-intubated on [redacted]-2009 **(SAE #001, update)** for a hypoxic event secondary to secretions and mucous. She recovered initially with suctioning, but it was thought that

she would benefit from a tracheostomy tube placement, which was placed on [redacted] 2009.

On [redacted]-2009 (post enrollment day 6) the subject's blood sugar was elevated **(AE #006)** and an insulin drip was started for glycemic control. Hyponatremia was noted on [redacted] 2009 **(AE #902)** and was treated with Neutro Phos.

On [redacted]-2009 (post enrollment day 13), the subject's oral thrush **(AE #007)** was treated with Nystatin. On the following day a transient hypotension (76/28) was noted **(AE #008)**. Diltiazem and Lopressor were held and a saline bolus was given with good results.

On [redacted]-2009 (post enrollment day 19) the subject's blood cultures were positive for gram-positive Cocci **(AE #009)**. The subject was treated with Cipro.

The subject's neurological status was noted as slowly improving. She was transferred from the hospital on 15-Jul-2009 to a rehabilitation facility with a tracheostomy and a percutaneous endoscopic gastrostomy (PEG) tubes in place.

At the 30 day follow-up visit on [redacted]-2009, the subject reported that she was taking Celexa for depression **(AE #903)**. Her 30 day NIHSS was ranked as 4 with mRS of 5.

On [redacted]-2009 (post enrollment day 103), the subject presented with a two days history of decreased energy, not feeling well, subjective fevers and chills, shortness of breath, and change in sputum color and production. Oxygen saturation was in the low 80's. A chest x-ray revealed small to moderate bilateral pleural effusions with mild cardiomegaly and mild pulmonary congestion suggestive of a congestive heart failure **(AE #012)** and bibasilar pneumonia **(SAE #011)**. Sputum culture was positive. The subject was admitted to the hospital with infectious pneumonia and treated with antibiotics. Bloodwork indicated syndrome of inappropriate antidiuretic hormone secretion (SIADH) **(AE #905)**, which was treated with Democlocycline. The subject was discharged to the assisted living facility on [redacted]-2009.

The 90 day NIHSS on [redacted]-2009 was ranked as 7 with mRS of 5.

Subject [redacted] enrolled [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
Unk-Dec-2007		901	605 - Dyslipidemia/ Hypercholesteremia	N/A	N/A
Unk-Dec-2007		902	399 - Renal Other: Chronic kidney disease/Azotemia	N/A	N/A
05-Mar-2008	**095**	**001**	**199 - Cardiac Other: Coronary artery disease with stent placement**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 75-year-old Caucasian male with no known past medical history and no medications. He did not see a physician for several years.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 21:30 on [redacted]-2007. Symptoms at presentation included confusion, forced deviation to the left, sensory loss, mild to moderate aphasia and dysarthria. CT scan at admission revealed a 2 mm left basal ganglia lacunar change and mild deep white matter ischemic changes. It was felt that the subject had a cortical stroke as well as there was a suggestion of a possible left MCA thrombus on the CT. The baseline electrocardiogram (ECG) was abnormal and indicated a prior anterior myocardial infarction. Baseline NIHSS was 6. The subject was randomized to the control arm of the SENTIS trial 04:00, [redacted] 2007, 6.5 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 6 hour and 24 hour NIHSS were both ranked as 1. The 24 hour MRI on [redacted]-2007 revealed an acute infarct in the posterior aspect of the left frontal lobe.

During the index hospitalization, the subject was placed on high dose statin therapy **(AE #901)**. Elevated BUN and creatinine levels **(AE #902)** were also noted during the index hospitalization. This condition is referenced as chronic kidney disease stage II, during the index hospitalization, and as azotemia during the subsequent hospitalization. The actual onset date of this condition is unknown.

The subject was discharged from the hospital on [redacted]-2007 to home with NIHSS of 0.

On [redacted] 2008 (post enrollment day 95) the subject was admitted to the hospital to have a diagnostic cardiac catheterization because of the abnormal ECG. A coronary artery disease **(SAE #001)** was diagnosed and a stent was placed in the circumflex artery. The procedure was uneventful and the subject was discharged to home in stable condition on the following day.

Subject [redacted] enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Feb-2008	001	007	115 - Patent foramen ovale (PFO)	N/A	N/A
07-Feb-2008	003	002	405 - HT, probably not contributing to mass effect	N/A	N/A
09-Feb-2008	005	006	819 – Infection (Sputum, urine)	N/A	N/A
09-Feb-2008	005	005	603 - Electrolyte imbalance	N/A	N/A
10-Feb-2008	006	012	117 - Tachycardia	N/A	N/A
11-Feb-2008	**007**	**001**	**899 - Other: Splenic rupture**	**N/A**	**N/A**
14-Feb-2008	**010**	**004**	**202 - Respiratory failure**	**N/A**	**N/A**
16-Feb-2008	012	010	803 - Cellulitis	N/A	N/A
18-Feb-2008	014	013	699 - Lab/electrolyte Other: Thrombocytosis	N/A	N/A
20-Feb-2008	016	009	818 - Pain	N/A	N/A
21-Feb-2008	**017**	**008**	**207 - Pulmonary Embolism**	**N/A**	**N/A**
22-Feb-2008	**018**	**003**	**502 - Ischemic Bowel Syndrome**	**N/A**	**N/A**
23-Feb-2008	019	011	399 - Renal Other: Right cyst - kidney	N/A	N/A
10-Apr-2008	066	014	601 - Anemia	N/A	N/A
13-Apr-2008	069	015	899 - Other: Left sphenoid and posterior right ethmoid sinus disease	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 48-year-old Caucasian female with a past medical history of migraine headaches, chronic obstructive pulmonary disease and anxiety. Medications at admission included Lexapro and "something for her migraines."

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 07:00 on [redacted]-2008. Symptoms at presentation included complete hemianopsia, left-sided weakness with facial palsy and neglect. CT scan at admission revealed occlusions of the right ICA and MCA. Baseline NIHSS was 11. The subject was randomized to the control arm of the SENTIS trial at 14:15, [redacted]-2008, 7.3 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: A transesophageal echocardiogram on [redacted] 2008 (post enrollment day 1) showed a patent foramen ovale **(AE #007)** and Heparin was started.

On [redacted]-2008 (post enrollment day 3), follow-up CT scans revealed progression of the right MCA infarct with effacement of the right ventricle and mild right to left shift, and a petechial hemorrhage **(AE #002)** which deemed not clinically significant by neurology. CT scan on [redacted] 2008 showed continued petechial hemorrhages. The subject's neurological status remained unchanged.

Beginning on [redacted] 2008 (post enrollment day 5), and continuing throughout her hospitalization, the subject had low grade fevers (101-101.6ºF). She had persistent leukocytosis, and had positive urine and sputum cultures **(AE #006)**. She was treated with Levaquin, Vancomycin and Zosyn.

Also beginning on [redacted]-2008, the subject had intermittent electrolyte imbalances (low sodium, potassium, magnesium and calcium) **(AE #005)**. Supplemental replacements were given.

Beginning on [redacted]-2008 (post enrollment day 6) and intermittently throughout her hospitalization, the subject was tachycardic **(AE #012)**. A formal cardiology consult was obtained on [redacted] 2008. The underlying cause was thought to be related to multiple acute events and psychological stress. The subject was treated with Cardizem and a beta blocker, and her rhythm returned to normal by [redacted] 2008.

On [redacted]-2008 (post enrollment day 7), the subject became hypotensive, tachypneic and tachycardic. She was complaining of abdominal pain and distention, and her stools were positive for blood. Her hemoglobin (Hgb) was 6.1 and hematocrit (Hct) was 18.3. She was transfused with 8 units of packed red blood cells, 8 units of fresh frozen plasma and 2 units of platelets. An abdominal CT scan suggested splenic rupture **(SAE #001).** The subject underwent exploratory laporotomy, splenectomy, cholecystectomy, and appendectomy. Two liters of blood were found in the peritoneum. The subject had a fall at the time of the stroke onset that may have contributed to the splenic rupture. Her Hgb/Hct improved to 9.8/29.2 on the following day, and 13.5/36.8 by [redacted]-2008.

The subject was intubated for the surgical procedures. A chest x-ray on [redacted]-2008 (post enrollment day 10) showed worsened pulmonary edema. The subject was extubated on the following day. A chest x-ray on [redacted]-2008 showed bilateral pleural effusions and left lower lobe pneumonia **(SAE #004)**.

On [redacted] 2008 (post enrollment day 12), the subject complained of right flank pain. The site was erythematous. An infectious disease consult was obtained for worsening leukocytosis. A diagnosis of right flank and hip cellulitis **(AE #010)** was made. CT scan of the abdomen and pelvis were not contributory. The subject's cellulitis resolved on [redacted]-2008.

On [redacted]-2008 (post enrollment day 14), the subject's platelet count rose significantly **(AE #013)** and a hematology/oncology consult was obtained. It was thought that the thrombocytosis was a result of the splenectomy and underlying inflammatory condition.

On [redacted]2008 (post enrollment day 16), the subject complained of left knee and back pain **(AE #009)**. Her knee was warm and edematous. An orthopedic consult was obtained. Three days later, the subject complained of right knee pain and was treated with pain medication. X-rays were negative.

On [redacted]-2008 the subject complained of increasing shortness of breath. CTA of the chest showed pulmonary embolism **(SAE #008)** in the right upper lobe of her lung and an inferior vena cava filter was placed. The filter was replaced on [redacted]-2008.

On [redacted]-2008 (post enrollment day 18) the subject complained of abdominal pain. Her abdomen was distended without bowel sounds. An abdominal CT scan on [redacted]-2008 showed occlusion of the superior mesenteric artery and vein **(SAE #003)** and a right renal cyst **(AE #011)**. On [redacted]-2008 the subject underwent a thrombo-endarterectomy of the superior mesenteric artery and embolectomy of the superior mesenteric vein. She returned for an exploratory laporotomy on the following day. The subject's abdomen was left open with a wound vacuum in place, and on [redacted]-2008, eviscerated omentum was noted under the abdominal dressing. The subject returned to surgery for closure of the abdomen. She did not regain bowel function.

The subject was unable to be weaned from the ventilator after her surgery on [redacted]-2008, and was diagnosed with an acute respiratory distress syndrome **(SAE #004, update)**. She underwent a tracheostomy on [redacted]2008. On [redacted]-2008, the subject underwent a left thoracentesis; 600 cc of pleural fluid was removed. Her left lower lobe pneumonia resolved by [redacted]2008. She remained on ventilator until [redacted]-2008, and her tracheostomy tube was removed on [redacted]2008.

At the 30 day follow-up visit on [redacted]2008, the subject's NIHSS was 14 and mRS was 5.

The subject's hemoglobin dropped to 9.5 **(AE #014)** on [redacted]-2008. By [redacted]-2008, it was 8.3. Her vitamin B-12 level was also low. The subject was transfused with 2 unites of packed red blood cells.

CT scan of the head obtained on [redacted]2008 showed an incidental finding of left sphenoid and posterior right ethmoid sinus disease **(AE #015)**. No treatment was initiated.

On [redacted]2008 the subject underwent an exploratory laporotomy which showed multiple strictures of the small bowel with adhesions. She then proceeded to have a small bowel resection and jejuno-ileostomy with an insertion of a gastrostomy tube **(cont. of SAE #003)**.

At the 90 day follow-up visit on [redacted]-2008, the subject's NIHSS was 13 with mRS of 5. Her neurological status was essentially unchanged; however, she could slowly ambulate with an assistance of a walker.

As of [redacted]-2008, the subject remained hospitalized. Symptoms of ischemic bowel syndrome persisted **(SAE #003, update)**. A colonoscopy on [redacted] 2008 revealed erythematous friable mucosa, most noticeable in the right colon. The subject refused further surgery. She was undergoing physical therapy, and was being prepared for discharge.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
18-Jun-2008	000	902	103 - Hypertension	N/A	N/A
19-Jun-2008	001	901	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
19-Jun-2008	001	003	899 - Other: Hypothyreosis	N/A	N/A
21-Jun-2008	003	002	304 - Hematuria	N/A	N/A
25-Jun-2008	007	004	809 - Diabetes Mellitus	N/A	N/A
04-Jul-2008	**016**	**001**	**409 - New ischemic stroke**	**N/A**	**N/A**
05-Aug-2008	048	005	599 - GI Other: Gastric polyp	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 77-year-old Caucasian male with past medical history of hernia, hypertension and benign prostate hypertrophy. Medications at admission included Amlor.

Current Stroke Onset and SENTIS Enrollment: The subject underwent a transurethral resection of the prostate (TURP) surgery on [redacted]-2008. He experienced stroke symptom onset at 13:00 on [redacted]-2008 when he was taken off the surgery table. Symptoms at presentation included complete hemianopsia, left hemiparesis, more in the arm than the leg, left central facial paralysis, sensory loss and moderate dysarthria. MRI at baseline revealed perfusion and diffusion deficit with mismatch in the right posterior MCA territory. Severe intracranial and extracranial carotid stenosis was observed, eliminating intra-arterial (IA) access. Baseline NIHSS was 13. The subject was randomized to the control arm of the SENTIS trial at 16:45, [redacted]-2008, 3.8 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 6 hour NIHSS decreased to 8. Hypertension Blood pressure of 160-180/100-109) **(AE #902)** was noted on the day of enrollment and was controlled with the addition of an ACE-inhibitor.

On [redacted]-2008 (post enrollment day 1) a high dose of statin was started for severe hypercholesterolemia **(AE #901)**. On the same day hypothyroidism **(AE #003)** was discovered and treated with Elthyrone. The 24 hour follow-up NIHSS was 7.

On [redacted] 2008 (post enrollment day 3), low dose low molecular weight heparin was stopped because of persistent urinary tract bleeding **(AE #002).** The surgical wound from TURP surgery was irrigated. There was an evolution from sub-febrile to real fever, presumably of the urinary origin. At the same time a slight increase of the left hemiparesis was noted with an evolution of the NIHSS up to 11. The worsening of the signs and symptoms was attributed to the infectious complication and treated with further bladder irrigation, no antibiotics were given.

On [redacted]-2008 (post enrollment day 4) the bladder irrigation was no longer hemorrhagic and Aspirin was started. A suprapubic catheter was placed.

Diabetes mellitus **(AE #004)** was diagnosed during the index hospitalization and treated with oral medications. Glycemia values normalized.

On [redacted]-2008 (post enrollment day 16) the subject's left hemiparesis evolved into left hemiplegia, with increasing paresis of the left leg. CT of the brain showed a new lesion in the right anterior cerebral artery (ACA) territory not present on earlier imaging **(SAE #001).** Aspirin was changed to Clopidogrel. Perindopril was added and the subject's hemiplegia improved to a NIHSS of 8 on [redacted]-2008.

The subject was discharged to a rehabilitation facility on [redacted]-2008. While in rehab, the subject experienced obstipation. An echo of the abdomen revealed a gastric tumor **(AE #005)**. An abdominal CT scan confirmed the benign, polypomatous nature of the lesion and gastroscopic resection of the polyp was performed. The event resolved on [redacted]-2008.

The 90 day NIHSS on [redacted]-2008 was ranked as 3 with mRS of 4.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-Apr-2008	000	001	899 - Other: Erysipel left lower leg	N/A	N/A
29-April-2008	001	010	412 - HT, no concomitant mass effect	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
01-May-2008	003	007	806 - Agitation/Excitation	N/A	N/A
Unk-May-2008		008	504 - GI Motility Disorders	N/A	N/A
04-May-2008	006	009	606 - Hyperglycemia	N/A	N/A
06-May-2008	008	003	304 - Hematuria	N/A	N/A
16-May-2008	**018**	**002**	**299 - Pulmonary Other: Bronchitis**	**N/A**	**N/A**
16-May-2008	018	011	699 - Lab/electrolyte Other: Liver function test (LFT) elevation, diffuse liver parenchyma damage	N/A	N/A
20-May-2008	022	006	407 - Seizure	N/A	N/A
20-May-2008	022	012	397 - Genital Other: Benign prostatic hypertrophy	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 79-year-old Caucasian male with a past medical history of hypertension and atrial fibrillation.

On [redacted]-2008 the subject was admitted to the hospital for pneumonia (treated with intravenous antibiotics). Medications at this admission included Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 05:00 on [redacted]-2008, while inpatient. Symptoms at baseline included confusion, severe right-sided hemiparesis with facial palsy, severe aphasia and dysarthria. MRI at admission revealed a left MCA territory infarction. Baseline NIHSS was 14. The subject was randomized to the control arm of the SENTIS trial at 10:00, [redacted]008, 5.0 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: Physical examination on [redacted]-2008 revealed erysipelas of the left lower leg **(AE #001)** with elevated C-reactive protein and white blood cell count. It was treated with intravenous antibiotics and resolved as of [redacted]-2008.

The 24 hour CT on [redacted]-2008 demonstrated a petechial hemorrhage **(AE #010)** which was clinically insignificant. The 24 hour NIHSS score improved to 10.

Beginning [redacted]2008 (post enrollment day 3) the subject was intermittently agitated **(AE #007)** and was treated with intravenous Haloperidol. His 4 day NIHSS on [redacted] 2010 was 5.

During the index hospitalization, the subject complained of constipation **(AE #008)** which was treated and resolved.

On [redacted] 2008 (post enrollment day 6), the subject had high serum glucose levels **(AE #009)**, treated with insulin. Further testing for diabetes was negative.

On [redacted]-2008 (post enrollment day 8), the subject pulled out his urinary catheter which resulted in bleeding from his bladder **(AE #003)**. This was treated with bladder lavage and was resolved in two days.

The subject was discharged from the hospital on [redacted]-2008 to the rehabilitation facility on oral anticoagulation.

On [redacted]-2008 (post enrollment day 18) the subject was admitted to the hospital with bronchitis **(SAE #002)**. Antibiotics were initiated and the subject's bronchitis resolved. Lab work revealed an elevation of liver enzymes, and an ultrasound showed diffuse parenchymal damage of the liver **(AE #011)**. No treatment was deemed necessary.

On [redacted]-2008 (post enrollment day 22), the subject suffered an epileptic seizure **(AE #006)**. He was not treated with antiepileptic therapy and had no further seizures.

An ultrasound on [redacted]008 revealed a significantly enlarged prostate and a prostatic hypertrophy was diagnosed **(AE #012)**. The subject also had urinary retention necessitating a permanent suprapubic urinary catheter placement.

At the 30 day follow-up visit on [redacted] 2008, the subject's NIHSS was 5 and mRS was 3. The subject was discharged from the hospital on [redacted]-2008 to home.

The 90 day NIHSS on [redacted] 2008 was ranked as 7 with mRS of 3.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
27-May-2008	001	001	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
27-May-2008	001	002	814 - Sleeping Disturbance/ Disorder	N/A	N/A
27-May-2008	001	003	699 - Lab/electrolyte Other: Glucose intolerance	N/A	N/A
07-Jun-2008	012	004	504 - GI Motility Disorders	N/A	N/A
07-Jun-2008	012	005	413 - Headache	N/A	N/A
22-Jun-2008	027	006	815 - Skin irritation	N/A	N/A
26-Jun-2008	031	012	118 - Atrial Fibrillation	N/A	N/A
04-Jul-2008	**039**	**007**	**409 - New ischemic stroke**	**N/A**	**N/A**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
11-Jul-2008	046	009	413 - Headache	N/A	N/A
11-Jul-2008	**046**	**901**	**405 - HT probably not contributing to mass effect**	**N/A**	**N/A**
12-Jul-2008	047	011	503 - Nausea/Vomiting	N/A	N/A
12-Jul-2008	047	010	812 - Fever	N/A	N/A
12-Jul-2008	047	008	811 - Depression	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 73-year-old Caucasian female with a past medical history of hypertension, polymyalgia rheumatica, depression, pancreatitis and chronic kidney disease with normal kidney function. Medication at admission included: Urbason, Fluctine (Prozac), and Karvezide.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:30 on [redacted]-2008. Symptoms at presentation included drowsiness, left-sided hemiparesis with facial palsy, dysarthria and neglect. MRI at admission revealed an acute/subacute infarct in the right MCA territory. Baseline NIHSS was 10. The subject was randomized to the control arm of the SENTIS trial at 07:10, [redacted]-2010, 8.7 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2008 (post enrollment day 1) Simvahexal was started for hypercholesterolemia **(AE #001)**. The subject complained of insomnia **(AE #002)** and received Stilnox after which she became paradoxically agitated and Stilnox was changed to Stangyl. A blood glucose level of 207 mg/dl **(AE #003)** was noted and the subject received a single dose of insulin.

The 24 hour CT on [redacted]-2008 demonstrated infarction of the right internal capsule and right parietal region; no hemorrhage.

On [redacted]-2008 (post enrollment day 3), the subject was transferred to the general ward. Her neurological status improved to NIHSS of 4, and on [redacted]-2008 the subject was discharged to the rehabilitation hospital.

On [redacted]-2008 (post enrollment day 12) the subject was treated for obstipation **(AE #004)**. She also complained of a headache **(AE #005)**.

On [redacted]-2008 (post enrollment day 27) an eczema of unknown origin **(AE #006)** was treated and resolved with cortisone.

At the 30 day follow-up visit on [redacted]-2008, the subject's NIHSS was 4 and mRS was 2. On the following day the subject was started on oral anticoagulation for a newly discovered paroxysmal atrial fibrillation **(AE #012)**.

On [redacted]-2008 (post enrollment day 39) the subject was discharged from the rehabilitation hospital. She was seen normal at 19:00 that same day and was found by her relatives shortly thereafter with a high grade left-sided hemiparesis. Emergent MRI showed a new lesion in the right MCA territory with occlusion of the MCA and reduced flow in the right ICA **(SAE #007)**. The subject was admitted to the stroke unit and repeated CT scans over the next few days showed demarcation of the new infarction in the right MCA territory.

On [redacted] 2008 (post enrollment day 46) the subject complained of headache **(AE #009)** and became somnolent/soporous. (NIHSS is not provided.) CT scan showed a new hemorrhagic transformation **(SAE #901)** of the infarction and beginning of edema with mild midline shift, which was thought to be the cause of the subject's headache. (Note: Core Lab report indicated index infarct in right basal ganglia and the second new infarct was also seen in the right basal ganglia and parietal lobe. Progressive infarct in the right MCA territory with hematoma in right temporal/parietal lobes, as well as petechial/ confluent hemorrhage in basal ganglia and frontal lobe; a subtle subarachnoid hemorrhage in parietal lobe was also seen by Core Lab on CT scan dated [redacted]-2008.)

On [redacted]-2008 (post enrollment day 47) the subject complained of nausea **(AE #011)** and was treated with Metoclopramide. She also had a fever **(AE #010)** and was treated with Perfalgan and antibiotics. Although the subject had a history of depression treated with Fluctine, on [redacted] 2008 she was diagnosed with post-stroke depression **(AE #008)** and Cipralex was initiated.

The subject was discharged to a rehabilitation facility on [redacted]-2008.

At the 90 day visit on [redacted]-2008, the subject's NIHSS was ranked as 14 with mRS of 4.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
12-Nov-2008	000	902	103 - Hypertension	N/A	N/A
12-Nov-2008	000	901	412 - HT, no concomitant mass effect	N/A	N/A
13-Nov-2008	001	004	809 - Diabetes Mellitus	N/A	N/A
13-Nov-2008	001	003	812 - Fever	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-Nov-2008	002	002	811 - Depression	N/A	N/A
14-Nov-2008	002	005	503 - Nausea/Vomiting	N/A	N/A
16-Nov-2008	**004**	**001**	**409 - New ischemic stroke**	**N/A**	**N/A**
16-Nov-2008	004	008	814 - Sleeping Disturbance/ Disorder	N/A	N/A
17-Nov-2008	005	006	899 - Other: Dizziness	N/A	N/A
18-Nov-2008	006	010	504 - GI Motility Disorders	N/A	N/A
Unk-Nov-2008		903	818 - Pain	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 48-year-old Caucasian female with a past medical history of untreated hypertension, hyperlipidemia, migraines, obesity, and previous thyroid surgery. Medications at admission included: Diclofenac, Pantozol, Norethisterone, Tavor and Tramal. At the time of the enrollment the subject denied alcohol abuse but on [redacted]-2008 she admitted to regular alcohol consumption.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 08:05 on [redacted]-2008. Symptoms at presentation included left arm weakness and facial palsy, sensory loss and dysarthria. MRI scan at admission revealed multiple small acute embolic infarctions in the right MCA territory. Baseline NIHSS was 6. The subject was randomized to the control arm of the SENTIS trial at 14:10, [redacted]-2008, 6.1 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2008 (the day of enrollment), the subject's blood pressure was elevated at 175/120 **(AE #902)**. Delix and hydrochlorothiazide were started for her pre-existing but untreated hypertension. The 24 hour MRI scan showed further demarcation of the right MCA infarcts, with the frontal infarct being slightly larger. A partial hemorrhagic transformation **(AE #901)** was also observed but the subject's neurological status remained unchanged. The 24 hour NIHSS was 5.

On [redacted] 2008 (post enrollment day 1) elevated glucose levels were noted and an oral glucose tolerance test confirmed diabetes mellitus **(AE #004)**. The subject also developed fever **(AE #003)** that was treated with acetaminophen. CT scan demonstrated known right MCA infarcts with no mass effect and no hemorrhage.

On [redacted]-2008 the subject reported being depressed **(AE #002)** and an antidepressant was started. She also complained of nausea **(AE #005)** that was treated with medication. On the following day the subject was transferred to the general ward with NIHSS of 0.

On [redacted] 2008 (post enrollment day 4) at 10:30 the subject complained of nausea and headache, and shortly thereafter developed new left-sided hemiparesis and numbness. Emergent MRI demonstrated new infarctions in the posterior circulation (right thalamus and cerebellum) **(SAE #001)** in addition to the previously known sub-acute infarctions from the index stroke. Her NIHSS was 10. The same day the subject complained of sleeping disturbance **(AE #008)** and was started on medication.

On [redacted] -2008 the subject complained of dizziness **(AE #006)** and was treated with medication.

On [redacted] -2008 (post enrollment day 6), the subject received medication for constipation **(AE #010)**. The medication log also indicates that the subject was given Ibuprofen during her index hospitalization for back pain **(AE #903)** related to her prolapsed disc.

The subject's neurological status once again improved and she was transferred from the stroke unit on [redacted] 2008 to the general ward. On [redacted] -2008 the subject was discharged to the rehabilitation hospital.

Subject [redacted], enrolled [redacted] -2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
22-Nov-2008	000	003	118 - Atrial Fibrillation	N/A	N/A
23-Nov-2008	001	005	303 - Urinary Tract Infection	N/A	N/A
23-Nov-2008	001	004	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
23-Nov-2008	**001**	**901**	**414 - Neurological worsening**	**N/A**	**N/A**
25-Nov-2008	003	006	818 - Pain	N/A	N/A
01-Dec-2008	009	008	504 - GI Motility Disorders	N/A	N/A
05-Dec-2008	013	007	811 - Depression	N/A	N/A
30-Jan-2009	**069**	**009**	**209 - Respiratory dysfunction**	**N/A**	**N/A**
30-Jan-2009	069	010	899 - Other: Tremor and dizziness, nausea due to Theophylline	N/A	N/A
Unk-Jan-2009		902	603 - Electrolyte imbalance	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 69-year-old Caucasian male with a past medical history of severe chronic obstructive pulmonary disease (COPD) requiring intermittent oxygen therapy, hypertension, peripheral artery disease, osteoporosis, and

benign prostatic hypertrophy. Medications at admission included: Actonel, Avodart, Berodual, Spiriva, Ileos, and Urapidil.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:00 on [redacted]-2008. Symptoms at presentation included left-sided weakness with facial palsy, left-sided hemihypoesthesia and dysarthria. Presenting blood pressure was 220/140 and was medically lowered to 117/75. MRI/MRA scan at admission revealed an acute infarction in the right MCA territory and right ICA occlusion. Baseline NIHSS was 9. The subject was randomized to the control arm of the SENTIS trial at 10:40, [redacted]-2008, 11.7 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2008 (the day of enrollment), the subject developed atrial fibrillation **(AE #003)** requiring treatment.

On [redacted]-2008 (post enrollment day 1), the subject had a fever and was diagnosed with a urinary tract infection **(AE #005)** that was treated with intravenous antibiotics. Laboratory results revealed hypercholesterolemia **(AE #004)** and Simvastatin was started.

The 24 hour NIHSS on [redacted] 2008 increased to 10 from 7 at 6 hours due to the worsening of the left-sided weakness **(SAE #901)**. CT scan showed no changes in the size of the infarction and no haemorrhage. On [redacted]-2008 the subject had severe left-sided hemiparesis and his NIHSS increased further to 13. The subject also complained of back pain **(AE #006)** and received medication.

The subject was discharged from the hospital on [redacted]-2008 to rehabilitation.

On [redacted] 2008 (post enrollment day 9) the subject was treated for persistent constipation **(AE #008)**. Cipralex was started on [redacted] 2008 for post-stroke depression **(AE #007)**.

At the 30 day follow-up visit on [redacted]-2008, the subject was still in the rehabilitation facility. He was in poor health condition mainly due to his severe pre-existing COPD. His 30 day NIHSS was 11 and mRS was 5.

On [redacted]-2009 (post enrollment day 69) the subject was admitted to the internal medicine unit with worsening of pulmonary status due to an infectious exacerbation of his severe pulmonary disease **(SAE #009)**. He received antibiotics and did not require ventilation. During this hospitalization the subject was treated with a high dose of Theophylline and developed tremors and nausea **(AE #010).** His daily dose of Theophylline was lowered. The subject's potassium level was 3.3 **(AE #902)** and potassium supplement was initiated by his general practitioner.

The 90 day NIHSS on [redacted]-2009 was ranked as 6 with mRS of 3.

Subject[redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
12-May-2009	000	011	405 - HT, probably not contributing to mass effect	N/A	N/A
12-May-2009	000	002	413 - Headache	N/A	N/A
12-May-2009	000	901	819 - Infection	N/A	N/A
13-May-2009	001	012	409 - New ischemic stroke	N/A	N/A
13-May-2009	001	902	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
14-May-2009	002	010	207 - Pulmonary embolism	N/A	N/A
15-May-2009	**003**	**001**	**107 - Myocardial infarction, Q wave**	**N/A**	**N/A**
16-May-2009	004	004	103 - Hypertension	N/A	N/A
16-May-2009	004	003	115 - Patent foramen ovale (PFO)	N/A	N/A
21-May-2009	009	904	303 - Urinary Tract Infection	N/A	N/A
25-May-2009	013	006	814 - Sleeping Disturbance/ Disorder	N/A	N/A
25-May-2009	013	008	811 - Depression	N/A	N/A
25-May-2009	013	007	503 - Nausea/Vomiting	N/A	N/A
26-May-2009	014	009	407 - Seizure	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 49-year-old Caucasian female with a past medical history of pleuritis, depression disorder (untreated), ovarian cyst and back ache. From [redacted] 2009 to [redacted] 2009 the subject was hospitalized for a recurrent pleuritis of an unknown origin. Medications at admission included Decortin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 11:00 on [redacted]-2009. Symptoms at presentation included drowsiness, partial hemianopsia, left-sided weakness with facial palsy, sensory loss, dysarthria and neglect. CT perfusion scan at admission revealed beginning of the demarcation of an infarcted right fronto-temporal area as well as occlusion of the proximal right ICA with no bleeding or mass effect. Baseline NIHSS was 12. The subject was randomized to the control arm of the SENTIS trial at 16:05, [redacted]-2009, 5.1 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 6 hour MRI on [redacted]-2009 revealed evolution of the acute infarction in the right MCA territory with a petechial haemorrhage **(AE #011)**, no mass effect. The 6 hour NIHSS was 14. The subject complained of headache **(AE #002)**

and Perfalgan was given. The subject had multiple episodes of headache during her admission and responded well to Perfalgan and Novalgin.

The subject's leukocytes and C-reactive protein were elevated on admission **(AE #901)**, and were treated with one dose of Rocephin. Chest x-ray showed scar tissue caused by the recurrent pleuritis and a possible malignancy.

The 24 hour NCT on [redacted] 2009 revealed further demarcation of the known right MCA infarction as well as new infarction areas in the anterior and posterior right MCA territory **(AE #012)**. Increased swelling of infarcted areas without midline shift was also noted. The 24 hour NIHSS remained at 15.

Simvahexal was started on [redacted] 2009 for previously known, but untreated, hyperlipidemia **(AE #902).**

On [redacted]-2009 (post enrollment day 2), chest CT scan showed pulmonary embolism in the left lung lobe **(AE #010)** and the subject was anticoagulated with low-molecular heparin.

On [redacted]-2009 the subject had an episode of left-sided pre-sternal pain and tachycardia. Electrocardiogram showed a ST-elevation. Cardiac enzymes were also elevated. A Q-wave myocardial infarction **(SAE #001)** was diagnosed. Cardiac angiogram revealed a 60-70% stenosis of the left anterior descending (LAD) artery. During the injection of Rheo-Pro, LAD artery was dissected, resulting in three stents being placed with good results.

On [redacted]-2009 (post enrollment day 4), Beloc and Delix were started for hypertension **(AE #004)**. An incidental finding of a patent foramen ovale (PFO) **(AE #003)** was documented.

On [redacted]-2009 (post enrollment day 9), severely concentrated and smelly urine was noted. Urine analysis was positive for nitrates and Ciprobay was started for suspicion of a urinary tract infection **(AE #904).**

On [redacted] 2009 (post enrollment day 13) the subject developed sleeping disturbances **(AE #006)** and Valdispert and Tavor were started. Cipralex was started for worsening of depression **(AE #008)** and was later changed to Mirtazapin. The subject also developed nausea **(AE #007)** which resolved with Metoclopramide.

On [redacted] 2009 the subject had an epileptic seizure (tonic cramp attack with fixed upper left gaze deviation for about 2 min) **(AE #009)**. Keppra was started and Delix was held for associated hypotension. No further epileptic episodes occurred. Delix was restarted on [redacted]-2009.

The subject was transferred from the hospital on [redacted] 2009 to a rehabilitation clinic.

At the 30 day follow-up visit on [redacted]-2009 the subject remained in the rehabilitation clinic. Her NIHSS was 11 and mRS was 4. She was discharged to home on [redacted] 2009.

The 90 day NIHSS on [redacted] 2009 was ranked as 8 with mRS of 4.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
27-Apr-2009	000	001	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
29-Apr-2009	002	002	103 - Hypertension	N/A	N/A
30-Apr-2009	**003**	**003**	**414 - Neurological worsening**	**N/A**	**N/A**
07-May-2009	010	004	303 - Urinary Tract Infection	N/A	N/A
07-May-2009	010	006	818 - Pain	N/A	N/A
13-May-2009	016	007	397 - Genital Other: Genital mycosis	N/A	N/A
26-May-2009	029	005	303 - Urinary Tract Infection	N/A	N/A
04-Jun-2009	038	008	815 - Skin irritation, dermatitis	N/A	N/A
08-Jun-2009	042	009	815 - Skin irritation, eczema	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 87-year-old Caucasian female with a past medical history of transient ischemic attack, congestive heart failure, hypertension, glaucoma and hypothyroidism.

On [redacted]-2009 the subject presented to the hospital with transient left-sided facial paresis in the presence of hypertension. When the hypertension resolved, so did the paresis. No CT scan was performed. The subject was discharged to home upon resolution of symptoms. Medications at admission included: Metoprolol, Ductran for glaucoma, and Thyronajod.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 11:00, [redacted]-2009. Symptoms at presentation included partial gaze palsy, left arm weakness with facial paresis, dysarthria, sensory deficit and hemineglect. MRI and duplex ultrasound at admission revealed acute ischemic infarct in the right caudate and lentiform nuclei, occlusion of both M1 and M2 segments of the right MCA, and stenosis of the proximal and distal right ICA in the absence of hemorrhage. Baseline NIHSS was 7. The subject was randomized to the control arm of the SENTIS trial at 17:50, [redacted] 2009, 6.8 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: Initial lab values revealed significant hypercholesterolemia **(AE #001)** followed by the initiation of Atorvastatin. The subject's NIHSS was stable through 24 hours post-enrollment.

On [redacted]-2009 (post enrollment day 2), the subject's hypertension worsened **(AE #002)** and dosages of anti-hypertensive drugs (Delix and Esidrix) were increased.

The subject's neurological status started to deteriorate on [redacted]-2009 **(SAE #003)**. The 4 day NIHSS increased to 14 due to the worsening of the left-sided weakness. MRI and MRA revealed progressive ischemic expansion of the index stroke within the right basal ganglia, temporal region and centrum semiovale as well as a high grade stenosis of the distal P1 segment of the right posterior cerebral artery (PCA).

On [redacted]-2009 (post enrollment day 10) the subject was diagnosed with a laboratory-positive urinary tract infection (UTI) **(AE #004)** and successfully treated with antibiotics. Concurrently, the subject complained of pain in her left hip **(AE #006)**, likely due to immobilization, and was given an analgesic which subsequently resolved the symptoms.

The subject was moved to the geriatric floor on [redacted]-2009 and subsequently discharged from the hospital to acute rehabilitation.

On [redacted]-2009 (post enrollment day 16), the subject complained of skin inflammation in the genital area **(AE #007)** which was determined to be a mycosis and was treated locally with an anti-mycotic.

At the 30 day follow-up visit on [redacted]009 the subject's NIHSS was 13 with mRS of 5.

On [redacted]2009 (post enrollment day 29) follow-up lab tests indicated a recurrent UTI **(AE #005)** and antibiotic treatment was initiated.

On [redacted]-2009 (post enrollment day 38) the subject was diagnosed with dermatitis medicamentosa **(AE #008)** which was interpreted as being precipitated by antibiotic therapy. The antibiotics were discontinued with resulting diminished symptoms.

On [redacted]-2009 (post enrollment day 40) the subject was diagnosed with dehydration eczema **(AE #009)** and was encouraged to increase oral hydration which eventually resolved the symptoms.

The 90 day NIHSS on [redacted]-2009 was ranked as 10 with mRS of 5.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
23-Jun-2009	001	005	103 - Hypertension	N/A	N/A
25-Jun-2009	003	001	303 - Urinary Tract Infection	N/A	N/A
25-Jun-2009	003	011	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
26-Jun-2009	004	004	899 - Other: Rib fracture	N/A	N/A
27-Jun-2009	005	009	407 - Seizure	N/A	N/A
28-Jun-2009	**006**	**002**	**599 - GI Other: Ileus**	**N/A**	**N/A**
14-Jul-2009	**022**	**003**	**205 - Infectious pneumonia**	**N/A**	**N/A**
15-Jul-2009	**023**	**006**	**113 - Myocardial infarction, non-Q wave**	**N/A**	**N/A**
15-Jul-2009	**023**	**901**	**601 - Anemia**	**N/A**	**N/A**
25-Jul-2009	**033**	**008**	**202 - Respiratory failure**	**N/A**	**N/A**
Unk-Sep-2009		007	811 - Depression	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 78-year-old Caucasian male with a past medical history of prostate cancer with transurethral resection (1998) and ileus with resection (1976). Medication at admission: none.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 08:30, [redacted] 2009. Symptoms at presentation included somnolence, fluctuating left hemiparesis, sensory loss, dysarthria and neglect. CT scan at admission revealed acute ischemia in the right MCA territory. MRI showed M1 occlusion and multiple ischemic lesions in the right MCA territory. Blood pressure (BP) at admission was 193/77. Baseline NIHSS was 15. The subject was randomized to the control arm of the SENTIS trial at 15:57, [redacted] 2009, 7.5 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2009 (post enrollment day 1) the subject remained hypertensive with BP of 170/80 **(AE #005)** and Ramipril was started.

On [redacted] 2009 (post enrollment day 3) the subject was diagnosed with a urinary tract infection **(AE #001)** which resolved with antibiotics. The subject's low-density lipoprotein (LDL) was elevated **(AE #011)** and Pravastatin was initiated.

On [redacted]-2009 the subject fell and fractured his left ribs (5 and 6) **(AE #004)**. Pain medication was given for discomfort and no surgical intervention was required. Suspicion of a small left pneumothorax was noted but it was not present on the chest x-ray obtained on [redacted] 009.

On [redacted]-2009 (post enrollment day 5) the subject experienced transient neurological deterioration (decreased consciousness and aphasia) that was thought to be a seizure **(AE #009)**. Orfiril was started and continued through the discharge.

On [redacted]009 the subject complained of abdominal pain. CT of the abdomen confirmed an ileus **(SAE #002)** with severely distended intestines in the right to middle abdomen. The subject was evaluated by a surgeon and the decision was made to treat the subject's ileus conservatively. Novalgin and Novicol were given.

The subject was discharged from the hospital on [redacted]-2009 to a rehabilitation facility.

On [redacted]2009 (post enrollment day 22) the subject exhibited acute respiratory insufficiency (dyspnea and a rapid respiratory rate) and was admitted to the medical unit for two days with infectious pneumonia **(SAE #003)**. The subject's pneumonia was treated with Tazobac and Clindamycin.

On 15-Jul-2009 the subject's troponin levels had increased to 659 pg/ml. A coronary angiogram demonstrated three vessel disease and a non-ST elevation myocardial infarction **(SAE #006)** was diagnosed. The subject underwent a percutaneous transluminal coronary angioplasty with stenting of the right coronary and left anterior descending arteries on [redacted]-2009.

The subject's hemoglobin on [redacted]2009 was 7.3 **(SAE #901)** and two units of red blood cells were given.

The subject initially improved but on [redacted]-2009 he developed aspiration pneumonia leading to respiratory failure **(SAE #008)** and intubation on [redacted]-2009. Chest x-ray on [redacted]-2009 showed insufficient inspiration, cardiac decompensation with central and tracheal congestion, and a right pleural effusion. A tracheostomy tube was placed on [redacted]-2009.

The subject continued to be febrile with indication for Candida in the trach and positive blood cultures (Staphylococcus epidermidis). Changes to his antibiotics were made **(SAE #003, update)**.

The subject returned to the rehabilitation facility on [redacted]-2009 due to his somnolent state and dysphagia.

The medication log indicates that the subject was taking Cipralex for depression **(AE #007)** at the time of his 90 day follow-up visit on [redacted]-2009.

Subject [redacted] enrolled [redacted] 008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
29-Sep-2008	000	001	103 - Hypertension	N/A	N/A
29-Sep-2008	000	002	806 - Agitation/Excitation	N/A	N/A
01-Oct-2008	002	007	805 - Sepsis	N/A	N/A
05-Oct-2008	006	005	799 - Vascular Other: Thrombophlebitis on right arm	N/A	N/A
05-Oct-2008	006	901	603 - Electrolyte Imbalance	N/A	N/A
07-Oct-2008	008	902	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
08-Oct-2008	009	903	606 - Hyperglycemia	N/A	N/A
12-Oct-2008	013	008	811 - Depression	N/A	N/A
24-Nov-2008	**056**	**010**	**305 - Urinary Retention**	**N/A**	**N/A**
01-Dec-2008	063	011	806 - Agitation/Excitation	N/A	N/A
02-Dec-2008	**064**	**009**	**303 - Urinary Tract Infection**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 75-year-old Caucasian male with a previous medical history of ischemic infarct (left-sided hemiparesis, mRS=1), multiple transient ischemic attacks (TIA), hypertension since 1997, mild dementia related to Parkinson's symptoms (2007), 1st degree atrioventricular block (Mar-2008), and concentric left ventricular hypertrophy with normal left ventricular function. Medications at admission included Ebrantil and Tensiomin.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at approximately 13:15 on [redacted] 2008. Symptoms at presentation included aphasia, right homonymous hemianopsia, right central facial palsy, mild rigor, and moderate right upper and very mild lower extremity paresis. The left dorsal pedal pulse was not palpable. CT scan at admission revealed cerebral and cerebellar atrophy, a "dot" sign in the left angular artery with very subtle low density in the left parietal cortex that indicated new infarct with occlusion of the angular artery branch of the MCA, large confluent hypodensities in the white matter and multiple lacunes in bilateral basal ganglia consistent with significant small vessel disease, and no hemorrhage. Baseline NIHSS was 12. The subject was randomized to the control arm of the SENTIS trial at 18:50 on [redacted]-2008, 5.6 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: Upon admission the subject had uncontrolled hypertension with blood pressure (BP) of 215/93 **(AE #001).** Urapidil was administered twice and switched to Captopril. The subject's BP improved to 164/86, although he experienced a few more episodes of elevated BP when agitated.

On [redacted] 2008 (the day of enrollment) at 22:45 the subject became agitated **(AE#002)** with an increase in BP to 205/111. His agitation resolved with Meprobamat and his BP decreased to 157/80 by midnight. Frustration with his aphasia was considered to be the cause of the subject's agitation.

On [redacted] -2008 (post enrollment day 2) the subject's urinary catheter was removed. Later that day the subject became agitated with an increase in his BP to 225/70 noted. Urinary retention was suspected and the subject was re-catheterized and approximately 200ml of urine was drained; 50mg of Metoprolol was given. A urine culture came back positive for mild pyuria and bacteria, antibiotics were started. Later that night the subject developed shivering, hypotension, tachycardia, fever (41ºC) and vomiting, sepsis was considered **(AE #007)**. Additional antibiotic coverage was added and the subject's intravenous line (IV) and urinary catheter were removed. Lab work revealed urocystitis.

On [redacted] 008 the subject's BP decreased to 80/50 and Voluven was given. The subject was catheterized twice that day due to the low urine output and 60ml and 200ml of urine were drained. On the following day the subject received a saline bolus followed by Lasix, and good urine output was noted. By [redacted] 2008 the subject appeared to be improving (fever free and normalized blood count), although his C-reactive protein (C-RP) was increasing.

Redness and swelling (phlebitis) **(AE #005)** was noted on [redacted] -2008 at the previous IV site. Ointment was applied with good relief.

During the subject's hospitalization, his potassium levels ranged between 3.3 and 4.1 **(AE #901)**. Potassium supplements were given beginning of [redacted] 2008. The subject was also diagnosed with hypercholesterolemia **(AE #902)**; Vasilip and Atoris were initiated.

On [redacted] -2008 (post enrollment day 8) fever, hypotension, shivering, and decreased oxygen saturation were again observed. The urinary catheter was removed and massive pyuria at catheter tip was noted. Lab work showed urosepsis, worsening renal function (elevated creatinine), and thrombocytopenia. The subject's BP decreased to 78/40 and a plasma expander was given. Sepsis was suspected **(AE #007, update)** and Rocephin and Ciprofloxacin were initiated. The urinary catheter was reinserted again because the subject was not passing urine. The subject's fever had resolved on the following day. Urine and urethra pus cultures were positive for Klebsiella pneumoniae and P. Aeruginosa. Rocephin was changed to Meropenem. By [redacted] 2008 the subject's labs, including the elevated creatinine, started to normalize.

On [redacted] -2008 the subject had an elevated blood glucose level of 10 mmol/L **(AE # 903)** and insulin in 5% glucose was ordered.

On [redacted] -2008 (post enrollment day 13) post-stroke depression **(AE #008)** was diagnosed. Citalopram was started with mild improvement. On [redacted] -2008 Levodopa

was started for Parkinson's like symptoms (mild Parkinson's symptoms were present pre-enrollment).

On [redacted]-2008 the subject's urine cultures were negative and the subject was declared healthy with normalized physical condition and lab results. He was discharged on the following day.

On [redacted]-2008 a routine urine culture was positive for Klebsiella pneumoniae. The subject had no symptoms of a urinary tract infection (UTI). Amikacin was recommended but not started by subject's general practitioner. The subject was seen by urology for urinary retention and was admitted on [redacted]-2008 **(SAE #010).** On the following day a permanent bladder catheter was inserted and 200ml of urine was drained.

On [redacted]-2008 (post enrollment day 63) the subject became agitated and complained that his catheter was annoying him very much **(AE #011)**. Levodopa and Piracetam were stopped and Meprobamat was started (agitation was only transiently reduced). A psychiatric consult was suggested.

On [redacted]-2008 the subject was transferred to the internal medicine ward for further evaluation of his low grade fever. A UTI **(SAE #009)** was diagnosed and Ciprofloxacin was initiated. On the following day the subject was discharged to home and instructed to perform regular catheter changes. The subject's catheter was removed mid December and no further episodes of urinary retention was noted. The subject's agitation had also improved.

No further AS was reported through 90 day follow-up on [redacted]-2009. The NIHSS at 90 day was 7

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code and Description	Relation to Device	Relation to Procedure
27-May-2009	000	001	118 - Atrial Fibrillation	N/A	N/A
27-May-2009	000	002	603 - Electrolyte Imbalance	N/A	N/A
27-May-2009	000	003	815 - Skin irritation	N/A	N/A
28-May-2009	001	004	806 - Agitation/Excitation	N/A	N/A
28-May-2009	001	005	699 - Lab/electrolyte Other: Hypoglycemia	N/A	N/A
31-May-2009	004	007	108 - Congestive Heart Failure	N/A	N/A
01-Jun-2009	**005**	**006**	**414 - Neurological worsening**	**N/A**	**N/A**
02-Jun-2009	006	008	305 - Urinary retention	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code and Description	Relation to Device	Relation to Procedure
15-Jun-2009	019	009	398 - Urinary Other: Bleeding via the urethra	N/A	N/A
11-Aug-2009	076	010	303 - Urinary Tract Infection	N/A	N/A
01-Sep-2009	**097**	**011**	**899 - Other: Acute stress reaction and vascular dementia**	**N/A**	**N/A**

Serious events are in bold, shaded text.

Demographics and History: The subject is a 68-year-old Caucasian male with a past medical history of atrial fibrillation, peripheral vascular disease, insulin-dependent diabetes, second toe on the right foot amputated due to gangrene, hypertension, hyperlipidemia, chronic obstructive pulmonary disease (COPD), and prostate cancer. Prostate tumor was determined to be stable via abdominal ultrasound prior to the SENTIS enrollment. Medications at admission included: Tritace, Talliton, Amiloride, Atorva (Lipitor), Syncumar mite (Acenocoumarol), humulin R, humulin N, Zoladex, Bicatlon (Bicalutamide), Altitum uno (Alfuzosin), Atrovent, and Trental.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 12:00 on [redacted]-2009. Symptoms at presentation included left homonymous hemianopsia and left hemiparesis, sensory loss and dysarthria. CT scan at admission revealed cerebral and cerebellar atrophy, vascular encephalopathy, old lacunar lesions in left pons and right basal ganglia, there was no acute infarct or hemorrhage. Baseline NIHSS was 10. The subject was randomized to the control arm of the SENTIS trial at 20:10, [redacted] 2009, 8.2 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) the subject was found to have atrial tachycardia with heart rate of 150-160 beats per minute (bpm) **(AE #001)**. Propafenone was given twice with limited success and Betaxolol and magnesium were administered at 23:00. By the next morning the subject's heart rate had normalized at 90 bpm, although the atrial fibrillation persisted. Betaxolol and magnesium were continued. Upon admission the subject was found to be hyperkalemic with potassium of 6.1 **(AE #002)**. Resonium was administered and diuretics were adjusted. The subject's potassium level returned to normal (3.8) in two days.

At the time of the stroke onset the subject fell and suffered multiple large excoriations **(AE #003)**, which were disinfected and bandaged. Augmentin was given prophylactically for three days and no wound infection occurred.

On [redacted]-2009 (post enrollment day 1) the subject became agitated and disoriented **(AE #004)**. Meprobarate was started and Haldol was given as necessary. The symptoms improved but were not completely resolved.

The subject's blood glucose level dropped to 2.6 mmol/L **(AE #005)** (it had been high upon admission and was managed with increased insulin doses). The glucose level was 4.0 mmol/L following administration of a sucrose solution. Insulin dosage was reduced to approximate pre-stroke level.

The 24 hour CT on [redacted]-2009 showed a 4 cm hypodense area in the right temporal lobe. The 24 hour NIHSS was 9.

On [redacted]-2009 (post enrollment day 4) the subject became hypotensive with his blood pressure fluctuating between 60/40 and 130/80. He remained hypotensive during the night and had apneic episodes while asleep; oxygen saturation decreased to 81-85%. The subject also had intermittent tachycardia, which became constant on [redacted] 2009. The subject's creatine kinase (CK) and cardiac troponin on [redacted] 2009 were at the upper limit of normal. An echocardiogram showed an ejection fraction of 27% with hypokinesis of the left ventricle, tricuspid insufficiency and pericardial fluid at the wall of the left ventricle. A congestive heart failure (CHF) **(AE #007)** was diagnosed. The subject's CHF was aggressively treated and no decompensation was noted on [redacted]-2009. The subject's elevated liver enzymes were attributed to Atorva (Lipitor) administration in the setting of the congestive heart failure. Atorva was discontinued for a few weeks.

On [redacted] 2009 (post enrollment day 5) the subject's stroke symptoms worsened (left hemiplegia, left hemianopsia and somnolence) and his NIHSS increased to 15 from 10 at 4 days **(SAE #006)**. Initially the change in the neurological status was attributed to the hypotension but when the subject did not show any improvement post blood pressure normalization, therefore a CT was ordered. CT scan on [redacted]-2009 revealed the evolving acute infarct in the right temporal lobe.

During the neurological deterioration the subject was also noted to be unable to spontaneously urinate **(AE #008)**. The subject was catheterized on [redacted] 2009 with good effect. The catheter remained in place until [redacted]-2009 when the subject removed it himself. The subject was able to urinate independently at that time.

The subject was discharged from the hospital on [redacted]-2009 to rehab.

On [redacted] 2009 (post enrollment day 19) bleeding from the urethra was noted **(AE #009)**. Ultrasound and catheterization revealed no source of bleeding. Prophylactic antibiotics were started and a catheter was placed for one week after which the subject was able to urinate independently without bleeding.

At the 30 day follow-up visit on [redacted]-2009 the subject's NIHSS was 10 with mRS of 4.

On [redacted]-2009 (post enrollment day 76) the subject experienced frequent and painful urination and antibiotics were initiated for a urinary tract infection (UTI) **(AE #010)**. Urinalysis was still positive on [redacted] 2009 and additional antibiotics were prescribed.

By the end of Aug-2009 the subject became increasingly aggressive, agitated and was having suicidal ideations. He was admitted on [redacted]-2009 (post enrollment day 97) to the psychiatric unit with acute stress reaction and vascular dementia **(SAE #011)**. Meprobamate, Risperidone, and Clonazepam were given. Risperidone was later stopped due to its extrapyrmidal effect (the subject could not walk).

The 90 day NIHSS on [redacted] 2009 improved to 5. The subject's mRS remained at 4.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
16-Oct-2009	000	002	812 - Fever	N/A	N/A
16-Oct-2009	000	004	209 - Respiratory dysfunction	N/A	N/A
16-Oct-2009	000	007	809 - Diabetes mellitus	N/A	N/A
18-Oct-2009	002	003	899 - Other: Maxillar Sinusitis	N/A	N/A
18-Oct-2009	002	006	816 - Oral thrush	N/A	N/A
18-Oct-2009	002	009	599 - GI Other: Malnutrition	N/A	N/A
20-Oct-2009	**004**	**001**	**414 - Neurological worsening**	**N/A**	**N/A**
22-Oct-2009	006	901	303 - Urinary Tract Infection	N/A	N/A
02-Nov-2009	017	005	603 - Electrolyte Imbalance	N/A	N/A
24-Nov-2009	039	008	504 - GI Motility Disorders	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is a 76-year-old Caucasian female with a past medical history of non-insulin dependent diabetes mellitus, hypertension, hyperlipidemia, atrial fibrillation, anemia, and slightly elevated creatinine levels (2008). The subject had been taking Coumadin for atrial fibrillation but had stopped a week prior to the index stroke. Medications at admission included: Aspirin, Omeprazole, Atelolol, Enalapril, and Simvastatin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:00 on [redacted]-2009. Symptoms at presentation included decreased level of consciousness, partial gaze palsy, right-sided weakness, severe dysarthria and global aphasia. CT scan at admission revealed a slightly hypodense area in the left frontal lobe; no hemorrhage or mass effect. Baseline creatinine was 1.13 mg/dl. Baseline NIHSS was 20. The subject was randomized to the control arm of SENTIS at 05:50, [redacted] 2009, 7.8 hours from last known normal.

Note: A protocol deviation was received for enrolling a subject with baseline NIHSS score exceeding the protocol allowed limit.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) at 11:00 the NIHSS slightly increased to 22. The subject had a temperature of 38.2°C **(AE #002)** and Paracetamol was given with partial improvement. Tachypnea **(AE #004)** was also noted and improved with Ipratropium and Salbutamol; chest x-ray was normal.

Admission glucose was 208 mg/dl **(AE #007)** and insulin per sliding scale was initiated. Glucophage was started on [redacted]-2009 and the subject's diabetes stabilized.

On [redacted] 2009 (post enrollment day 2) CT scan showed a large infarct in the left MCA territory with no edema, no midline shift and no intracranial bleeding. An incidental finding of maxillar sinusitis **(AE #003)** was documented. The subject was found to have oral Candidosis **(AE #006)** and was treated with Nystatin.

Also on [redacted] 2009, the subject's serum total protein was 6.0 g/L and albumin was 3.1 g/L, the subject had difficulty swallowing. Malnutrition **(AE #009)** was diagnosed and a feeding tube was placed. EGG-PRO power was started on [redacted]-2009.

The 4 day NIHSS on [redacted]-2009 declined further to 25 **(SAE #001)** and was possibly attributed to the progression of the index stroke, however, no further imaging was done. The subject's fever continued (38.6°C) and some bilateral rhonchi was noted. A chest x-ray on [redacted] 2009 could not rule out infiltrations. The subject's sinusitis was thought to be a possible source of the fever and Augmentin was started **(update AE #003)**. On [redacted] 2009 the subject was afebrile.

On [redacted]-2009 (post enrollment day 6) the subject's urine analysis revealed leukocytes without nitrates and urine cultures were positive for gram-negative bacilli **(AE #901)**. Augmentin was continued and no additional antibiotics were added.

On [redacted] 2009 (post enrollment day 17) the subject's potassium was low at 3.4 **(AE #005)** and replacements were given. The subject was transferred to the rehabilitation facility on the same day.

At the 30 day follow-up visit on [redacted]-2009, the subject's NIHSS was 19 with mRS of 5.

On [redacted] 2009 (post enrollment day 39) the subject complained of constipation **(AE #008)** which resolved with a fleet enema. The subject was discharged to the geriatric department on [redacted]-2009.

The 90 day NIHSS on [redacted] 2010 was ranked as 21 with mRS of 5.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Jun-2009	**001**	**001**	**414 - Neurological worsening**	**N/A**	**N/A**
19-Jun-2009	003	004	413 - Headache	N/A	N/A
12-Jul-2009	026	005	504 - GI Motility Disorders	N/A	N/A
13-Jul-2009	**027**	**002**	**205 - Infectious pneumonia**	**N/A**	**N/A**
13-Jul-2009	027	003	118 - Atrial Fibrillation	N/A	N/A
15-Jul-2009	029	901	603 - Electrolyte Imbalance	N/A	N/A

Serious events are in bold, shaded text.

Demographics and History: The subject is an 82-year-old Caucasian male with past medical history of non-insulin dependent diabetes mellitus, hypertension, hyperlipidemia, and hypothyroidism. Medication at admission included: Aspirin, Metformine, Glibenclamide, Atorvastatin, Atenelol, and Thyroxine.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 02:30 on [redacted]-2009. Symptoms at presentation included partial orientation to time, left-sided hemiparesis and left extinction. CT angiogram at admission revealed an occlusion of right MCA-M1 branch with good collateral blood supply and a normal looking brain parenchyma. Baseline NIHSS was 7. The subject was randomized to the control arm of the SENTIS trial at 08:45, [redacted] 2009, 6.3 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 6 hour NIHSS decreased to 5.
On [redacted]-2009 (post enrollment day 1) the subject's neurological deterioration was noticed (decline in muscle strength and poor balance). The 24 hour NIHSS increased to 11 **(SAE #001)**. The 24 hour CT showed a hypodense area in the right basal ganglia that included the internal capsule, the striatum, and the head of the caudate nucleus. No intra-cranial bleeding was noted. Clinical signs indicated stroke progression, likely due to failure of blood supply through collateral arteries.

On [redacted]-2009 (post enrollment day 3) the subject complained of mild headache **(AE #004)** that responded well to Dipirone. The 4 day NIHSS on the following day was 14.

The subject was discharged from the hospital on [redacted] 2009 to a rehabilitation center.

On [redacted]-2009 (post enrollment day 26) the subject had diarrhea **(AE #005)** and an abdominal x-ray was performed. A paralytic ileus was suspected and a rectal tube was inserted. The subject also received Flagyl.

On [redacted]-2009 the subject was transferred from the rehabilitation center to another hospital due to right lower lobe pneumonia **(SAE #002)**. Diagnosis was based on fever, dyspnea, and chest x-ray; Ceftriaxone was started. A routine electrocardiogram upon admission revealed atrial fibrillation **(AE #003)** that was not present on the previous studies. Coumadin was initiated.

At the 30 day follow-up visit on [redacted]-2009, the subject's NIHSS remained at 14 and his mRS was 5. The medication log indicated that a potassium supplement was initiated **(AE #901)** for maintenance. No potassium levels are available.

The 90 day NIHSS on [redacted]-2009 was ranked as 13 with mRS of 5.

APPENDIX N

DEATH LISTING

SENTIS Death Listing

Rand = Randomization
Tx = Treatment Arm
C = Control

NFE = NeuroFlo Exclusions
BL = Baseline
Proc = Neuro Flo Procedure

LR = Likely Related
LNR = Likely Not Related
Unk = Relationship Unknown

Subject ID	Rand Arm	Enroll Date	Sex	Age	TFSO			NIHSS			Date of Death	Days to Death	Cause of Death (specify if 'Other')	Serious Adverse Event(s) Associated with Death	Days to SAE	Device Related	Proc Related
					BL	Rand	Proc	BL	24 Hr	4 D							
[redacted]	Tx	[redacted]08	F	69.8	6.0	6.3	8.1	14	16	21	5-Mar-08	43	Systemic complications associated with stroke	204 - Aspiration pneumonia	23	LNR	LNR
	Tx	[redacted]09	M	82.9	5.8	5.8	7.2	9	17		19-Sep-09	2	Systemic complications unrelated to stroke	199 - Cardiac Other: Cardiac tamponade	1	LNR	Unk
	Tx	[redacted]06	M	78.7	3.0	3.3	4.1	10			19-Jun-06	7	Systemic complications associated with stroke	404 - HT, likely contributing to mass effect	0	Unk	LR
														805 - Sepsis	1	LNR	Unk
	Tx	[redacted]09	M	60.9	5.8	5.9	6.6	18			7-Apr-09	6	Stroke	414 - Neurological worsening	1	LNR	Unk
	Tx	[redacted]08	M	77.5	4.7	4.8	5.2	12		8	6-Apr-08	16	Systemic complications unrelated to stroke	899 - Other: Cardiopulmonary collapse secondary to ruptured viscus and sepsis	15	LNR	LNR
	Tx	[redacted]08	M	86.6	6.9	7.0	8.2	18	17	18	18-Jun-08	70	Systemic complications associated with stroke	205 - Infectious pneumonia	61	LNR	LNR
	Tx	[redacted]10	F	82.5	4.4	5.1	5.8	15	20	19	7-Apr-10	71	Other (metastatic lung cancer)	299 - Pulmonary Other: Stage IV adenocarcinoma lung	9	LNR	LNR
	Tx	[redacted]08	M	66.7	8.8	9.3	11.0	18	22	18	21-Oct-08	74	Systemic complications associated with stroke	899 - Other: Multi-organ failure	74	LNR	LNR
	Tx	[redacted]08	F	84.5	11.6	13.7	14.0	14	25		1-Jan-09	2	Stroke	404 - HT, likely contributing to mass effect	0	Unk	Unk
	Tx	[redacted]07	M	85.3	5.0	5.5	6.2	15	18	15	15-Feb-07	39	Systemic complications associated with stroke	202 - Respiratory failure	39	LNR	LNR
	Tx	[redacted]08	F	81.4	4.1	6.0	4.8	10	20	20	3-Nov-08	19	Stroke	414 - Neurological worsening	0	LNR	Unk
	Tx	[redacted]09	M	47.0	8.6	9.7	9.0	18			27-Jul-09	2	Stroke	414 - Neurological worsening	0	LNR	LNR
	Tx	[redacted]09	M	84.8	8.9	8.9	9.9	18	18	18	9-Mar-09	9	Systemic complications associated with stroke	204 - Aspiration pneumonia	1	LNR	LNR
	Tx	[redacted]10	F	74.0	5.3	5.7	7.2	18	15	13	15-Jan-10	5	Systemic complications associated with stroke	209 - Respiratory dysfunction	4	LNR	LNR
	Tx	[redacted]07	F	73.8	5.3	6.7	7.7	16	16	12	25-Jan-08	46	Systemic complications unrelated to stroke	299 - Pulmonary Other: Lung Cancer	46	LNR	LNR
	Tx	[redacted]08	F	81.2	4.8	5.3	6.2	13	19		7-Mar-08	3	Stroke	414 - Neurological worsening	0	LNR	Unk
	Tx	[redacted]08	F	45.4	6.8	7.8	8.6	13	0	0	30-Jun-08	60	Systemic complications unrelated to stroke	899 - Other: HIV/AIDS (worsening)	53	LNR	LNR
	Tx	[redacted]08	F	63.8	7.5	7.9	8.9	20	19	18	10-Sep-08	4	Systemic complications unrelated to stroke	805 - Sepsis	4	LNR	LNR

SENTIS Death Listing

Subject ID	Rand Arm	Enroll Date	Sex	Age	TFSO			NIHSS			Date of Death	Days to Death	Cause of Death (specify if 'Other')	Serious Adverse Event(s) Associated with Death	Days to SAE	Device Related	Proc Related
					BL	Rand	Proc	BL	24 Hr	4 D							
[redacted]	Tx	[redacted]09	M	60.8	10.2	10.2	11.5	16	18	14	27-Dec-09	9	Systemic complications associated with stroke	301 - Renal dysfunction	4	LNR	Unk
														805 - Sepsis	8	LNR	LNR
	Tx	[redacted]09	M	78.1	2.2	3.0	4.4	17	29	22	6-Apr-09	12	Stroke	414 - Neurological worsening	1	Unk	Unk
	Tx	[redacted]09	M	78.9	6.8	7.1	7.9	14	29		10-Sep-09	3	Stroke	414 - Neurological worsening	1	Unk	Unk
	Tx	[redacted]08	M	64.8	12.0	12.3	13.0	17	14	12	3-Jan-09	17	Systemic complications unrelated to stroke	117 - Tachycardia	17	LNR	LNR
	Tx	[redacted]09	F	58.3	12.0	12.6	13.2	18	20		22-Apr-09	8	Stroke	403 - Cerebral edema	1	Unk	Unk
	Tx	[redacted]09	F	79.0	4.0	4.5	5.0	5	0	0	13-Nov-09	53	Systemic complications unrelated to stroke	599 - GI Other: Adenocarcinoma, gastric - metastic to bone marrow	45	LNR	LNR
	Tx	[redacted]09	F	77.3	11.3	11.3	12.4	8	6	15	21-Nov-09	54	Systemic complications unrelated to stroke	899 - Other: Multi-organ failure	54	LNR	LNR
	Tx	[redacted]09	M	78.8	3.5	4.2	4.3	14	17		29-Nov-09	3	Stroke	204 - Aspiration pneumonia	2	LNR	LNR
	C	[redacted]07	F	66.2	6.3	6.4		16	19		17-Feb-07	3	Stroke	414 - Neurological worsening	3	N/A	N/A
	C	[redacted]09	F	69.3	12.3	12.3		14			3-Oct-09	1	Stroke	404 - HT, likely contributing to mass effect	0	N/A	N/A
	C	[redacted]09	F	73.3	5.8	5.8		17	12		27-Apr-09	3	Stroke	404 - HT, likely contributing to mass effect	2	N/A	N/A
	C	[redacted]09	F	77.6	12.8	12.8		18	19	30	4-Jul-09	13	Stroke	414 - Neurological worsening	4	N/A	N/A
	C	[redacted]08	F	79.1	6.5	6.5		18	31	35	14-May-08	3	Stroke	414 - Neurological worsening	1	N/A	N/A
	C	[redacted]09	M	91.1	5.8	7		9	22	15	17-Dec-09	14	Systemic complications associated with stroke	414 - Neurological worsening	1	N/A	N/A
	C	[redacted]08	F	85.7	6.8	7.3		13	27	7	25-Aug-08	25	Systemic complications unrelated to stroke	899 - Other: Complications of diabetes and vascular disease	25	N/A	N/A
	C	[redacted]08	M	88.6	5.3	5.3		18	16	23	5-Nov-08	8	Stroke	404 - HT, likely contributing to mass effect	1	N/A	N/A
	C	[redacted]08	M	92.9	12.3	12.4		17	25	23	11-Dec-08	7	Systemic complications associated with stroke	414 - Neurological worsening	1	N/A	N/A
	C	[redacted]09	F	76.4	7.3	7.5		8	7	7	24-Mar-09	30	Other (new stroke)	409 - New ischemic stroke	19	N/A	N/A
														805 - Sepsis	25	N/A	N/A
	C	[redacted]08	F	83.3	8	8.5		14	28	31	9-Sep-08	6	Stroke	414 - Neurological worsening	1	N/A	N/A
	C	[redacted]06	F	85.3	3	3.5		15	14	16	18-Mar-06	20	Systemic complications associated with stroke	805 - Sepsis	14	N/A	N/A
	C	[redacted]08	F	70.6	6.8	6.8		7	14	23	7-Apr-08	4	Systemic complications associated with stroke	414 - Neurological worsening	0	N/A	N/A
														108 - Congestive Heart Failure	3	N/A	N/A
	C	[redacted]08	F	83.5	12.8	13.2		18	24		16-Nov-08	11	Stroke	414 - Neurological worsening	0	N/A	N/A

SENTIS Death Listing

Subject ID	Rand Arm	Enroll Date	Sex	Age	TFSO			NIHSS			Date of Death	Days to Death	Cause of Death (specify if 'Other')	Serious Adverse Event(s) Associated with Death	Days to SAE	Device Related	Proc Related
					BL	Rand	Proc	BL	24 Hr	4 D							
[redacted]	C	[redacted]08	F	81.2	5.4	5.4		8	6	4	21-May-08	42	Systemic complications associated with stroke	202 - Respiratory failure	24	N/A	N/A
[redacted]	C	[redacted]09	M	78.2	12.2	12.4		17	20	25	28-Jul-09	51	Systemic complications associated with stroke				
[redacted]	C	[redacted]08	F	57.1	8	8		18	22	21	20-Jan-09	64	Systemic complications associated with stroke	805 - Sepsis	44	N/A	N/A
[redacted]	C	[redacted]08	M	80.3	6.4	6.6		17	17		8-Jul-08	4	Stroke	414 - Neurological worsening	2	N/A	N/A
[redacted]	C	[redacted]09	F	67.8	11.8	11.8		17	21		15-Nov-09	2	Other (new ischemic and hemorrhagic strokes)	404 - HT, likely contributing to mass effect	1	N/A	N/A
[redacted]		[redacted]												409 - New ischemic stroke	1	N/A	N/A
[redacted]	C	[redacted]10	F	88.8	12.1	12.2		16	15	15	3-Feb-10	7	Systemic complications associated with stroke	202 - Respiratory failure	6	N/A	N/A
[redacted]		[redacted]												805 - Sepsis	7	N/A	N/A
[redacted]	C	[redacted]06	F	65.1	6.2	6.2		18	21		16-Jul-06	4	Stroke	414 - Neurological worsening	1	N/A	N/A
[redacted]	C	[redacted]07	M	71.7	4.7	4.9		6	4	4	12-Jul-07	54	Systemic complications unrelated to stroke	899 - Other: Esophageal cancer	0	N/A	N/A
[redacted]	C	[redacted]07	M	70.2	7.8	7.9		18	24		1-Feb-07	3	Stroke	414 - Neurological worsening	1	N/A	N/A
[redacted]	C	[redacted]06	M	74.6	6.3	6.3		11	9	7	23-May-06	10	Stroke	404 - HT, likely contributing to mass effect	7	N/A	N/A
[redacted]	C	[redacted]09	F	87.8	10.3	10.6		18	20		12-Dec-09	7	Stroke	403 - Cerebral edema	7	N/A	N/A
[redacted]	C	[redacted]09	M	58.3	9.3	9.3		13	10	12	2-Apr-09	27	Stroke	415 - Intracerebral Hemorrhage	25	N/A	N/A
[redacted]	C	[redacted]07	M	73.5	6	6		9	30		12-Aug-07	2	Stroke	404 - HT, likely contributing to mass effect	0	N/A	N/A
[redacted]	C	[redacted]09	F	86.3	12	12.3		17	16	12	7-Dec-09	14	Other (new stroke)	409 - New ischemic stroke	9	N/A	N/A
[redacted]	C	[redacted]09	M	59	12.8	14.5		17			5-Jun-09	7	Stroke	403 - Cerebral edema	1	N/A	N/A
[redacted]	C	[redacted]09	F	60	3.7	3.9		5	6	2	12-Oct-09	94	Systemic complications unrelated to stroke	805 - Sepsis	76	N/A	N/A
[redacted]	C	[redacted]08	F	88.5	3.8	4.8		14	13	20	29-May-08	23	Systemic complications associated with stroke	414 - Neurological worsening	4	N/A	N/A
[redacted]	C	[redacted]08	M	90	7.9	8.3		12	8	6	13-Nov-08	65	Systemic complications associated with stroke	205 - Infectious pneumonia	65	N/A	N/A
[redacted]	C	[redacted]08	M	80.6	1.8	2.5		18	22		6-Oct-08	2	Stroke	404 - HT, likely contributing to mass effect	1	N/A	N/A
[redacted]	C	[redacted]09	F	86	2.9	3.3		10		10	4-May-09	19	Systemic complications associated with stroke	499 - Neuro Other: Continuous epileptic activity	6	N/A	N/A
[redacted]	C	[redacted]09	F	87.6	5.3	5.5		16	19		28-May-09	1	Systemic complications associated with stroke	202 - Respiratory failure	1	N/A	N/A
[redacted]		[redacted]												414 - Neurological worsening	1	N/A	N/A

SENTIS Death Listing

Subject ID	Rand Arm	Enroll Date	Sex	Age	TFSO			NIHSS			Date of Death	Days to Death	Cause of Death (specify if 'Other')	Serious Adverse Event(s) Associated with Death	Days to SAE	Device Related	Proc Related
					BL	Rand	Proc	BL	24 Hr	4 D							
[redacted]	C	[redacted]9	M	83.1	5	5		6	4	1	8-Aug-09	17	Systemic complications unrelated to stroke	202 - Respiratory failure	16	N/A	N/A
[redacted]	C	[redacted]9	M	89.4	9.1	9.3		15	11	10	23-Oct-09	11	Systemic complications associated with stroke	204 - Aspiration pneumonia	8	N/A	N/A
[redacted]	C	[redacted]9	M	76.3	11	11.3		16	15	25	28-Jan-09	9	Stroke	414 - Neurological worsening	1	N/A	N/A
[redacted]	C	[redacted]9	F	80.9	13	13.1		16	17	17	31-May-09	12	Systemic complications associated with stroke	205 - Infectious pneumonia	6	N/A	N/A
[redacted]	C	[redacted]9	F	76.8	3.3	3.3		14	12	11	23-Sep-09	14	Systemic complications associated with stroke	204 - Aspiration pneumonia	14	N/A	N/A
[redacted]	C	[redacted]9	F	89.6	8.5	8.6		11	11	11	31-Dec-09	105	Systemic complications unrelated to stroke	205 - Infectious pneumonia	91	N/A	N/A
[redacted]	C	[redacted]9	M	75.3	12.5	12.5		16	20	18	19-Apr-09	13	Systemic complications associated with stroke	805 - Sepsis	6	N/A	N/A

APPENDIX O

DEATH NARRATIVES

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Treatment Arm

Subject[redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
22-Jan-2008	000	003	603 - Electrolyte imbalance	Likely not related	Likely not related
22-Jan-2008	000	901	605 - Dyslipidemia/ Hypercholesterolemia	Likely not related	Likely not related
22-Jan-2008	000	902	103 - Hypertension	Likely not related	Likely not related
22-Jan-2008	000	903	809 - Diabetes mellitus	Likely not related	Likely not related
22-Jan-2008	000	007	301 - Renal dysfunction	Likely not related	Likely not related
23-Jan-2008	**001**	**004**	**414 - Neurological worsening**	**Likely not related**	**Unknown**
24-Jan-2008	002	005	699 - Lab/electrolyte Other: Blood culture contaminant	Likely not related	Likely not related
01-Feb-2008	**010**	**002**	**601 - Anemia**	**Likely not related**	**Likely not related**
14-Feb-2008	**023**	**001**	*** 204 - Aspiration pneumonia**	**Likely not related**	**Likely not related**
05-Mar-2008	043		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 69-year-old African American female with a past medical history of diabetes and hypertension (both untreated), valvular disease and a cholecystectomy. She was a previous smoker. A prior infarct was noted on her admission CT, but it is not stated in her history. The subject was not taking any medications at admission.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 10:00 on [redacted]-2008. Symptoms at presentation included isolated aphasia and an NIHSS of 5 initially, but worsened over the next few hours to include a right facial droop, increased right-sided weakness and no response to commands. CT scan at admission revealed periventricular white matter disease, a probable remote white matter infarct and caudate lacunar infarct on the left with slight ex-vacuo dilatation of the frontal horn of left lateral ventricle. There was a possible new posterior parieto-temporal infarct on the left side versus white matter changes, and no intracranial hemorrhage. She was hypertensive on admission, with an initial BP of 240/140; a Cardene drip was started. Baseline NIHSS was 14. The subject was randomized to the treatment arm of the SENTIS trial at 16:20, [redacted]008, 6.3 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 18:05, [redacted]-2008. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]008 (the day of enrollment), the subject was noted to be hypokalemic; this recurred intermittently during the course of her hospitalization and was treated with IV potassium supplements **(AE #003).** Her total cholesterol and low-density lipoprotein (LDL) were found to be elevated; dyslipidemia was diagnosed and Zocor was initiated **(AE #901).** The subject had a history of untreated hypertension. Her blood pressure was poorly controlled upon admission and anti-hypertensive medication was started **(AE #902).** The subject's blood glucose was in the 200-300 range on admission, so she was started on insulin **(AE #903).** She also showed signs of renal insufficiency**,** but no treatment was given at that time **(AE #007).**

On [redacted]2008 (post enrollment day 1), an MRI showed extension of the infarct **(SAE #004).** The 24 hour NIHSS increased to 16.

On [redacted]2008 (post enrollment day 2), the subject developed leukocytosis of unknown origin. She had a low grade fever and a positive blood culture on [redacted]2008; Vancomycin was initiated **(AE #005).**

On [redacted]-2008 (post enrollment day 7), the subject's feeding tube slipped out of position and she aspirated the feeding. Chest x-ray showed aspiration pneumonia and Zosyn was initiated. Low grade fevers continued throughout her hospitalization. Also on this date, a transient small volume hematochezia was noted without evident hemodynamic instability or drop in hemoglobin, consistent with rectal outlet bleeding.

On [redacted]-2008 (post enrollment day 8), the subject showed signs of renal insufficiency secondary to clinical dehydration (low grade fever and tachycardia). Her blood urea nitrogen (BUN) was 8 and creatinine was 0.8 on admission, and by [redacted]2008, her BUN was 89 and creatinine was 2.6. She was treated with IV fluids and free water and her laboratory values returned to normal **(update to AE #007).**

By [redacted]-2008 (post enrollment day 9), the subject was noted to be more somnolent and non-responsive to stimuli.

On[redacted]b-2008 (post enrollment day 10), the subject's hemoglobin was 9.3, no treatment was given **(AE #002).** The anemia persisted throughout her hospitalization, and her hemoglobin was 9.6 at discharge.

On[redacted]2008 CT scan showed evolution of the index stroke, with a suspected new area of ischemia in the genu of internal capsule on the right **(cont. of SAE #004).**

The subject was discharged to a nursing facility on [redacted]-2008.

On [redacted]-2008 (post enrollment day 21), the subject had nausea, vomiting, diarrhea, and cough. Abdominal x-ray was negative. Chest x-ray showed minimal infiltrates in

the right lower lobe. On [redacted] 2008, she was admitted to the hospital with right upper lobe pneumonia and fever; she was treated with Vancomycin, Zosin, and Augmentin **(SAE #001).** The subject again showed signs of dehydration with hypernatremia; free water was added to her tube feeding and the event resolved by [redacted] -2008.

On [redacted] -2008 (post enrollment day 26), the subject's right forearm was edematous; a doppler study was done to rule out occlusion and the study was negative. The edema was attributed to a previous IV infiltrate in that arm. Also during this admission, the subject's hemoglobin decreased to 7.5; 2 units of packed red blood cells were given **(cont. of AE #002, now SAE).**

The subject was returned to the skilled nursing facility, where she expired on [redacted] 2008 (post enrollment day 43). Her neurological status was unchanged. The cause of death was adjudicated as systemic complications related to stroke, specifically pneumonia.

Subject [redacted] enrolled [redacted] -2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Sep-2009	000	002	701 - Hematoma	Unknown	Likely related
18-Sep-2009	**001**	**001**	***199 - Cardiac Other: Cardiac tamponade**	**Likely not related**	**Unknown**
19-Sep-2009	002		Death	Likely not related	Unknown

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 82-year-old Caucasian male with a past medical history of coronary artery disease, hypertension, hyperlipidemia, paroxysmal atrial fibrillation, and angina. He quit smoking 35 years ago.

On [redacted] -2009 he underwent 4 vessel off pump coronary artery bypass surgery. Post operatively the subject experienced acute blood loss anemia, atrial fibrillation/flutter, and stress-induced hyperglycemia that was treated with insulin for a short period of time, although, diabetes was not diagnosed. Test came back positive for Methicillin-resistant Staphylococcus aureus (MRSA) in his nares. Medications at admission included Amiodarone, Heparin, Coumadin, Aspirin, Plavix, Cardizem, Pepcid, Zestril, Lopressor, Colace, Senekot, and Peridex mouth wash.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at approximately 20:20, [redacted] 2009. Symptoms at presentation included garbled speech, facial droop, change in vision and right-sided weakness. CT scan revealed a left middle cerebral artery stroke with no evidence of hemorrhage, edema or mass effect. Baseline

NIHSS was 9. The subject was randomized to the treatment arm of the SENTIS trial at 02:10, [redacted]-2009, 5.8 hours from last known normal.

NeuroFlo Procedure: The NeuroFlo procedure was initiated at 03:35, [redacted]-2009. Treatment was remarkable for a balloon adjustment 35 minutes into the procedure. 0.5 cc fluid was removed from the SR balloon due to an increasing pressure differential (~40). The differential responded to the change and decreased to 19. Systemic blood pressure remained stable throughout the procedure and the subject was asymptomatic.

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) a half-dollar sized hematoma and ecchymosis at the right insertion site was noted **(AE #002)**. Pedal pulses were palpable. Subcutaneous heparin was changed to a full-dose intravenous heparin due to his atrial fibrillation. Coumadin, Plavix and aspirin were continued. The subject was neurologically stable in the first 24 hours post enrollment and even showed some improvement in his speech and motor function. Head CT at 23:53 showed an evolving left parietal infarct; no hemorrhage.

On [redacted]009 (post enrollment day 1) at 05:30 the subject felt anxious. His skin was mottled, cool and clammy. Respirations increased into the 50's and he was urgently intubated. During the intubation the subject became very hypotensive (systolic blood pressure 70-80's) and was resuscitated with Neo-Synephrine and Dopamine. Cardiac output was 1.9L/min with an index of 1.0 L/min/m^2 and an arterial line and pulmonary artery catheter were placed. The subject's urine output decreased. Significant metabolic acidosis was noted and continuous renal replacement therapy was started. Creatinine of 2.2mg/dl, hyperkalemia and rising liver enzymes were documented.

A transesophageal echo revealed cardiac tamponade **(SAE #001)** which was felt to be due to his anticoagulation. Empty left ventricle, ejection fraction 30-40%, moderate pericardial collection with right atrial collapse and left pleural effusion were observed. Exploratory sternotomy revealed a large quantity of grossly sanguineous fluid and blood surrounding the heart. The subject was in full tamponade with diffuse oozing from all surfaces. The pericardium was drained with immediate hemodynamic improvement. A laparoscopy was completed due to concern for ischemic bowel in the setting of recent catheter manipulation through diseased aorta; results were negative. The subject returned to the intensive care unit with a cardiac output of 3.2L/min. The subject received four units of packed red blood cells and 5 units of fresh frozen plasma. Insulin was started for stress hyperglycemia (glucose 252). The subject remained in guarded condition with full pressor support.

By 09:00 on [redacted]-2009 (post enrollment day 2) the subject was in full multi-system organ failure with no chance of recovery and comfort care measures were instituted. He died at 09:44. Cause of death was adjudicated as systemic complication unrelated to stroke, specifically related to cardiac tamponade.

Subject [redacted], enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
12-Jun-2006	**000**	**001**	***404-HT, likely contributing to mass effect**	**Unknown**	**Likely related**
13-Jun-2006	**001**	**002**	***805- Sepsis**	**Likely not related**	**Unknown**
19-Jun-2006	007		Death	Unknown	Likely related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 78-year-old Caucasian male with a past medical history of insulin dependent diabetes, hypertension, hyperlipidemia, and a left hemisphere transient ischemic attack (TIA) in 2004. At the time of his TIA he began taking Altace. MRI obtained in 2004 revealed a left subdural hematoma, which resolved without treatment, and the Doppler study revealed bilateral carotid artery occlusion 70/80. A right internal carotid stent was placed in 2005. Medications at admission included: Insulin, Glucophage, Lipitor, and Plavix.

Current Stroke Onset and SENTIS Enrollment: On [redacted]-2006 at around 13:00 the subject experienced weakness on the left side. Symptoms at presentation included left-sided weakness of face and upper extremity, some left-sided neglect, but he was alert and oriented. Blood pressure (BP) was 223/107 and came down to 214/99 without medical management. It subsequently fluctuated in the range of 200/110. CT scan at admission revealed faintly diminished attenuation of the cortex in the right temporal occipital parietal region suspicious for acute infarction, old right occipital cortical and posterior parietal subcortical white matter infarcts in the watershed territories. CTA and perfusion CT showed decreased perfusion to the right posterior temporal lobe as well as the right inferior parietal lobe and no definite large vessel occlusion, with no indication of any bleeding. The Core Lab's analysis indicates: "Initial perfusion imaging suggests that there was reperfusion at the time of the initial pre-procedure CT perfusion-- this probably accounts for the hemorrhagic transformation. A large amount of bleeding has occurred [post procedure], which may be a complication of heparinization."

The sponsor was contacted regarding the subject's eligibility for the SENTIS trial. Given the remote history of subdural hematoma, the sponsor felt that the subject was qualified for the trial. Baseline NIHSS was 10. The subject was randomized to the treatment arm of the SENTIS trial at 16:20, [redacted]-2006, 3.3 hours from symptom onset.

NeuroFlo Procedure: Prior to the procedure at 17:05, the subject was given Versed and Fentanyl IV, as he was moving about and trying to sit up. At 17:40 8 units of insulin (blood glucose was 356) and 2000 units of heparin were given. A groin arterial puncture occurred at 17:07. The subject remained alert and oriented but complained of nausea and vomited once. After sedation he was lethargic. NeuroFlo catheter was inserted at 17:41. Labetalol was given at 17:55. The subject remained a little agitated and Fentanyl and Versed were repeated at 18:05 and 18:10. Infrarenal balloon inflation began at 18:13

followed by suprarenal balloon inflation. At 18:50 the subject was unresponsive to verbal and tactile stimuli and his pupils were fixed and dilated. The sheath was removed at 19:05. The subject was taken to CT for a NCT scan.

Post-Enrollment Course: NCT at 19:15 showed "acute right temporal occipital infarct with evidence of hemorrhagic transformation and contrast intravasation… large right and small left subdural hematomas, multiple areas of subarachnoid hemorrhage, mass effect over the right hemisphere and approximately 1.7 cm shift to the left with uncal and transtentorial herniation" **(SAE #001)**. Mannitol and Protamine were given immediately.

The subject was taken emergently to the operating room for a craniotomy and evacuation of hematoma. Right frontotemporal parietal craniotomy with evacuation of acute subdural hematoma as well as intraparenchymal hematoma in the left parietal lobe was performed with placement of subdural and intraparenchymal drains. The brain was noted to be under a severe amount of compression. During the surgery 1 unit of packed red blood cells and 1 six-pack of platelets were given; estimated blood loss was 350-375cc. The subject was kept intubated and transferred to the ICU. He remained in the ICU on mechanical ventilation and did not regain consciousness prior to his death.

On [redacted]-2006 (post enrollment day 1), NCT showed marked improvement in the amount of subdural hematoma, mass effect and midline shift. It also showed new areas of infarction in the right posterior cerebral artery (PCA) and anterior cerebral artery (ACA) territory, near total resolution entrapment left lateral ventricle and no significant change in the left hemisphere subdural hematoma. The subject's left pupil responded sluggishly and the right pupil was 3 and fixed. The right side responded slowly to noxious stimuli by withdrawing. The subject's temperature was 103.4°F and a cooling blanket was ordered. Because of the nausea and vomiting the previous day, the study team suspected the fever was due to aspiration pneumonia. Chest x-rays on day 1 and 2 post-op showed clear lungs. Infiltrate and/or atelectasis of right lung base was not observed until 15-Jun-2006. Respiratory cultures results showed white blood cells (WBC) > 25 and were positive for gram negative rods and enterobacter aerogenes; Ancef was started and then switched to Zosyn **(SAE #002)**.

On [redacted]-2006 (post enrollment day 2), the subject's temperature was 101.4°F, pupils were 4-5/2 with no reaction to light. The subject withdrew feet on painful stimuli. Hematocrit (Hct) was 29.5. The next day the subject's temperature was 100.5°F; WBC 15.4, and Hct was 26.1. No bleeding was noted.

Physician's notes listed respiratory failure, hypernatremia and elevated liver function tests as problems. Albumin went from 3.2 to 2.7; AST, Alk, Phos, and ALT were 199, 127, and 100, respectively. The subject was documented to have anemia. His Hemoglobin (Hgb) decreased to 8.8 and Hct decreased to 22.5 shortly before death.

On [redacted] 2006 (post enrollment day 7), at 01:34 the subject was found in asystole. Cardio-pulmonary resuscitation was started at 01:36. The subject's heart resumed beating at 01:42. A family member consented to discontinuation of resuscitation efforts. The

subject was pronounced dead at 03:32. Cause of death was adjudicated as systemic complications related to stroke, specifically sepsis and hemorrhagic transformation.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
01-Apr-2009	000	003	116 - Bradycardia	Likely not related	Likely not related
02-Apr-2009	**001**	**001**	***414 - Neurological worsening**	**Likely not related**	**Unknown**
02-Apr-2009	001	002	899 - Other: Broken tooth with bleeding in the mouth	Likely not related	Likely not related
02-Apr-2009	001	004	204 - Aspiration pneumonia	Likely not related	Likely not related
02-Apr-2009	**001**	**005**	**113 - Myocardial infarction, non-Q wave**	**Likely not related**	**Unknown**
07-Apr-2009	006		Death	Likely not related	Unknown

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 60-year-old Caucasian male with past medical history of hypertension and low back pain. The subject reported having lung congestion for the few days prior to the stroke onset. A family member reported that for the past few months the subject has been having left-sided weakness, stuttering, as well as episodes of not being able to complete his thoughts. He has not been taking his prescribed blood pressure medications.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 10:30, [redacted]-2009. Symptoms at presentation included left-sided weakness, dysarthria, and neglect. CT scan at admission revealed right hyperdense MCA sign without hemorrhage. MRI revealed perfusion/diffusion mismatch of the right MCA, but no hemorrhage or clot and a complete occlusion of the right anterior cerebral artery (ACA). The left internal carotid artery (ICA) showed a 90% stenosis. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial 16:24, 01-Apr-2009, 5.9 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 17:03, [redacted]-2009. The treatment was unremarkable.

Post-Enrollment Course: Following the procedure, the subject was transferred to the intensive care unit at another SENTIS site due to the size of the stroke and possible impending herniation. The subject had several episodes of bradycardia during the initial MRI, NeuroFlo procedure, and several times during his hospitalization but these episodes were not severe enough to require medication **(AE #003)**.

On [redacted]-2009 (post enrollment day 1), a follow-up MRI revealed extension of the infarct into the remainder of the parasagittal high right parietal lobe **(SAE #001)**; no significant midline shift was seen. The subject had decreased level of consciousness and was intubated for airway protection and carbon dioxide management at 10:30. He had a tooth broken with bleeding in the mouth **(AE #002)** during intubation. At 16:30 on [redacted]-2009, a prophylactic hemi-craniectomy was performed. Sputum cultures were positive for bacterial infection, and this aspiration pneumonia **(AE #004)** was treated with Gentamyicin, Ceftriaxone and Ancef.

On [redacted]-2009 the subject's troponin level became positive at 0.17ng/mL and continued to climb with highest value of 12ng/mL. The electrocardiogram (ECG) showed ST depression in the anteroseptal and inferior leads **(SAE #005)**. Cardiac echocardiogram on the following day revealed ejection fraction (EF) of 30% with an akinetic apex and severe aortic valve stenosis. The subject received Levophed, Lasix, a Dobutamine drip, as well as electrolyte adjustments for ongoing blood pressure and cardiac output maintenance.

A NCT on [redacted]2009 (post enrollment day 2) showed more edema in the right cerebrum with a 12mm shift of the septum pelucidum and herniation at the tentorial level. The subject was placed into pentobarbital coma, with mild hypothermia and hypocarbia to attempt to control intracranial pressure. Despite these efforts, the subject continued to worsen with progression of herniation on [redacted]-2009. Pentobarbital was discontinued, and there was no apparent brain function. The subject was declared brain dead on [redacted]-2009. The cause of death was adjudicated as stroke.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
23-Mar-2008	002	003	599 - GI Other: Clostridium difficile toxin	Likely not related	Likely not related
24-Mar-2008	003	005	403 - Cerebral edema	Likely not related	Likely not related
30-Mar-2008	**009**	**001**	**301 - Renal dysfunction**	**Likely not related**	**Unknown**
30-Mar-2008	009	004	599 - GI Other: Gallbladder stones	Likely not related	Likely not related
05-Apr-2008	**015**	**002**	*** 899 - Other: Cardiopulmonary collapse secondary to ruptured viscus and sepsis**	**Likely not related**	**Likely not related**
06-Apr-2008	016		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: This subject is a 77-year-old Caucasian male with a past medical history of hypertension, hyperlipidemia, atrial fibrillation, subacute bacterial endocarditis, vertigo and bilateral hip and knee replacements. He had recently developed left leg cellulitis with prepatellar septic bursitis after a recent fall, and was on treatment with daptomycin and ceftriaxone. Medications at admission included: Toprol, Diovan, Warfarin, Digitek, Simvastatin, Amlodipine.

Current Stroke Onset and SENTIS Enrollment: The subject's stroke onset began at 10:05, [redacted]-2008. Symptoms at presentation included left-sided weakness, left side neglect and left homonymous hemianopsia. The subject was in atrial fibrillation with a controlled ventricular rate on admission. CT scan at admission revealed no hyper-acute changes. CTA showed obstruction of the right MCA in the proximal M2 posterior division. Baseline NIHSS was 12. The subject was randomized to the treatment arm of the SENTIS trial at 14:50, [redacted]-2008, 4.8 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated on [redacted]-2008 at 15:18. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2008 (post enrollment day 1) an infectious disease consult was obtained for the left leg cellulitis. Flagyl was started for probable Clostridium difficile.

On [redacted] 2008 (post enrollment day 2) the subject's stool culture was positive for Clostridium difficile toxin **(AE #003).** Symptoms included low grade fever, diarrhea and leukocytosis. The next day the subject was noted to be more somnolent and disoriented. CT scan demonstrated mild cerebral edema **(AE #005)** without hemorrhage or mass effect. No further scans were performed**.** The subject was transferred to a rehabilitation facility on [redacted]-2008.

On [redacted] 2008 (post enrollment day 9), the subject was readmitted to the hospital due to dehydration and pre-renal azotemia **(SAE #001).** A distended abdomen and diarrhea, presumed to be a worsening of the clostridium difficile colitis, were noted. The subject was hydrated and started on oral vancomycin. An abdominal gas pattern of ileus was found on the abdominal x-ray, and an abdominal ultrasound revealed a distended gall bladder with stones **(AE #004).** The subject was again discharged to a rehabilitation facility on [redacted]-2008.

Following discharge on [redacted] 2008, the subject became acutely ill with complaints of back pain, vomiting, significant abdominal distension and was less responsive. He was admitted to a different hospital, where an abdominal X-ray showed free air under the diaphragm, suspicious for a ruptured viscus. Surgery was considered but refused by the family. At that point, fluids and support was withdrawn, and the subject expired on [redacted] 2008 (post enrollment day 16). Cause of death was determined to be cardiovascular collapse secondary to a ruptured viscus and sepsis **(SAE #002).** Cause of death was adjudicated as systemic complications unrelated to stroke, specifically cardiopulmonary collapse secondary to ruptured viscus and sepsis.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Apr-2008	008	001	599 - GI Other: Gastritis	Likely not related	Likely not related
22-Apr-2008	013	903	599 - GI Other: Gastroporesis	Likely not related	Likely not related
23-Apr-2008	014	904	899 - Other: Spasticity	Likely not related	Likely not related
09-Jun-2008	**061**	**002**	***205 - Infectious pneumonia**	**Likely not related**	**Likely not related**
11-Jun-2008	063	003	813 - Fall	Likely not related	Likely not related
17-Jun-2008	069	901	818 - Pain	Likely not related	Likely not related
18-Jun-2008	070	902	806 - Agitation/Excitation	Likely not related	Likely not related
18-Jun-2008	070		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 86-year-old Caucasian male with a past medical history of a prior stroke in 2006, transient ischemic attack (1 day prior to stroke onset), hypertension, hyperlipidemia, peptic ulcer disease, pancreatitis, cholelithiasis and coronary artery disease with bypass surgery in 2006. Medications at admission included: Altace, Norvasc, Lipitor, Protonix, and Torsemide.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 15:00 on [redacted] 2008. Symptoms at presentation included left-sided weakness, dysarthria and minimal dysphasia. The subject was in atrial fibrillation with a controlled ventricular rate. CTA at admission showed extensive thrombus throughout the right internal carotid artery extending to the bifurcation with diminished flow to the right middle cerebral artery branches. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 22:00, [redacted]-2008, 7.0 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated on [redacted]-2008 at 23:11. Treatment was unremarkable.

Post-Enrollment Course: The subject's index hospitalization was uneventful. He was discharged from the hospital on [redacted] 2008 to the inpatient rehabilitation facility with NIHSS of 18.

On [redacted] 2008 (post enrollment day 8) the subject had a peg tube inserted for nutritional support. Signs of gastritis were noted during the procedure, but since he was already receiving Prevacid, Protonix and antacids, no further changes were made to his medical regimen **(AE #001).**

On [redacted]-2008 (post enrollment day 13), Erythromycin was initiated for gastroparesis **(AE #903).** The following day Zanaflex was administered for spasticity **(AE #904).**

At the 30 day follow-up visit on [redacted] 2008, the subject's NIHSS was 15, mRS was 5, Barthel Index was 5, and Glascow Outcome Scale was 3.

On [redacted] 2008 (post enrollment day 61), the subject became hypoxic. A chest x-ray revealed bilateral pneumonia **(SAE #002)** and Avelox was initiated with little improvement.

On [redacted]-2008 (post enrollment day 63), the subject experienced a mild fall **(AE #003)** with a contusion and hematoma to his forehead. There was no change in his neurological status. His respiratory status continued to be labile with periods of hypoxia and the subject was made "do not resuscitate" status on 16-Jun-2008. The next day he was treated with acetaminophen for general discomfort **(AE #901).**

On [redacted]-2008 (post enrollment day 70) the subject was given Lorazepam for restlessness **(AE #902).** He expired later that day. Cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted], enrolled [redacted] 2010

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
26-Jan-2010	000	002	699 - Lab/electrolyte Other: Elevated Digoxin level	Likely not related	Likely not related
27-Jan-2010	**001**	**001**	**414 - Neurological worsening**	**Unknown**	**Unknown**
04-Feb-2010	**009**	**006**	***299 - Pulmonary Other: Stage IV adenocarcinoma lung**	**Likely not related**	**Likely not related**
08-Feb-2010	013	003	816 - Oral thrush	Likely not related	Likely not related
08-Feb-2010	013	004	303 - Urinary Tract Infection	Likely not related	Likely not related
18-Feb-2010	023	901	409 - New ischemic stroke	Likely not related	Likely not related
07-Apr-2010	071		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 82-year-old Caucasian female with past medical history of atrial fibrillation, hypertension, hyperlipidemia, congestive heart failure (2008), chronic obstructive pulmonary disease, depression/anxiety, and left breast cancer status post mastectomy. She was found to have a non-calcified nodule in the left upper lung lobe since 2007. The subject had taken an opioid since 2007 for chronic pain

caused by multiple fractures resulting from a fall. Medications at admission included: Coumadin, Nifedipine, Plavix, Coreg, Crestor, Lanoxin, Moexipril, Nexium, Tylenol #3, Hydromorphone and Demerol.

Current Stroke Onset and SENTIS Enrollment: The subject had an onset of stroke symptoms at 08:15, [redacted] 2010. Symptoms at presentation included hemiparesis, aphasia and facial droop. CT scan at admission revealed acute areas of infarction involving the right MCA territory with large penumbra and no hemorrhage or mass. INR was 2.6 and she was medicated with Octaplax to decrease INR to 1.4 prior to enrollment in SENTIS. Baseline NIHSS was 15. The subject was randomized to the treatment arm of the SENTIS trial at 13:20, [redacted]-2010, 5.1 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 14:02, [redacted] 2010. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2010 (the day of enrollment) the subject's Digoxin level was elevated to 1.4 **(AE #002)**, and Digoxin was withheld until the level normalized.

On [redacted]-2010 (post enrollment day 1) at 06:30 the subject was noted to have decreased level of consciousness and was tachypneic. NIHSS increased to 19 **(SAE #001)**. NCT of the brain showed evolving right MCA infarct with no hemorrhage. The 24-hour NIHSS was 20.

On [redacted]-2010 (post enrollment day 9) a CT of the chest revealed "a 9mm subpleural nodule laterally within the apicoposterior segment of the left upper lobe had enlarged compared to the prior study in 2007; a 2.3cm speculated and lobulated non-calcified nodule now present". The subject developed pleural effusions on 1[redacted]-2010 and a thoracentesis was performed. Cytology exam revealed a stage IV adenocarcinoma of the lung **(SAE #006)**.

On [redacted] 2010 (post enrollment day 13) the subject had oral thrush **(AE #003)**, and was treated with Nystatin. She also developed recurring urinary tract infection **(AE #004)** and was treated with nitrofurantoin.

On [redacted]010 (post enrollment day 23) head NCT revealed further evolution of the previously noted hypodense changes in the right MCA territory and a new infarct in the right ACA distribution **(AE #901)**.

On [redacted]-2010 (post enrollment day 63) the subject complained of severe pain, particularly the lower back pain coexistent with hypogastric abdominal pain; and a pain underneath her right breast with some pleuritic features. She had been given Morphine prn and Duragesic patch, but the pain was poorly controlled. Hydromorphone (around the clock) was then prescribed. Also noted were lower extremity edema, nausea associated with titrating up the G-tube feeding, and oil retention followed by soapsuds enema for no bowel movement. The family chose palliative care only. The subject also had respiratory failure secondary to pneumonia **(cont. of SAE #006)**. The subject

remained in the hospital in the long term care wing until her death on [redacted] 2010, post enrollment day 71. The cause of death was adjudicated as metastatic lung cancer.

Subject [redacted] enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
08-Aug-2008	000	902	809 - Diabetes Mellitus	Likely not related	Likely not related
09-Aug-2008	**001**	**002**	**403 - Cerebral edema**	**Likely not related**	**Unknown**
11-Aug-2008	003	001	811 - Depression	Likely not related	Likely not related
12-Aug-2008	004	903	603 - Electrolyte imbalance	Likely not related	Likely not related
13-Aug-2008	005	005	103 - Hypertension	Likely not related	Likely not related
26-Sep-2008	**049**	**003**	**301 - Renal dysfunction**	**Likely not related**	**Likely not related**
26-Sep-2008	**049**	**901**	**601 - Anemia**	**Likely not related**	**Likely not related**
26-Sep-2008	049	006	602 - Thrombocytopenia	Likely not related	Likely not related
26-Sep-2008	049	004	599 - GI Other: Clostridium difficile	Likely not related	Likely not related
02-Oct-2008	055	904	815 - Skin irritation	Likely not related	Likely not related
21-Oct-2008	**074**	**008**	***899 - Other: Multi-organ failure**	**Likely not related**	**Likely not related**
21-Oct-2008	074		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 66-year-old Caucasian male with a past medical history of borderline diabetes and cataracts. He had not seen a doctor in many years and disliked going to see one. He had not been on any medications prior to his index stroke, but occasionally took Motrin for aches and pains.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptoms onset at 15:00, [redacted]-2008. Symptoms at presentation included global aphasia, dysarthria, right-sided hemiparesis, a positive Babinski sign on the right, right facial droop, right hemianopia and left gaze preference. His blood glucose was elevated at 310. CT scan at admission revealed no hemorrhage, midline shift or mass effect. A small focus of encephalomalacia in the left putamen (interpreted as an old stroke) was observed, however, there was no acute abnormality. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 00:15, [redacted]-2008, 9.3 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 02:00, [redacted]-2008. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2008 the subject's glucose level was 310 at admission. His blood sugar was managed first with regular insulin and then with an insulin drip before it was controlled **(AE #902)**. Hemoglobin A1C was elevated at 10.1. The subject was discharged with a new diagnosis of type 2 diabetes and was prescribed insulin every 8 hours.

The 6 hour NIHSS on [redacted] 2008 was 19. MRI revealed restricted diffusion involving insula, opercular regions, corona radiata and deep periventricular white matter within the territory of the left MCA. MR angiogram revealed occlusion of the upper division of the left MCA beyond the bifurcation of the M1 segment.

On [redacted]-2008 (post enrollment day 1) NCT revealed increased hypodensity within the left MCA distribution including the left parietal lobe, insular cortex, superior temporal lobe and internal capsule. A mild mass effect from edema at the left frontal horn with no midline shift was observed **(SAE #002)**. The subject had no new complaints at the time of the imaging, despite his 24 hour NIHSS increasing to 22. He initially would nod "yes" and "no" to questions, but progressed to having a decreased level of consciousness, decreased ability to follow commands, decreased movement of his extremities, neglect, and finally became mute.

On [redacted]-2008 the subject's depression was first documented **(AE #001)**. The subject's neurological condition had improved, except for his speech and depression, and his NIHSS returned to 18. The subject was treated with Zoloft, Zyprexia and psychiatric evaluation. His depression resulted in decreased food intake leading to poor nutrition, poor fluid intake causing dehydration, and refusal to take medications. It was later compounded with loss of skin integrity, rapid heart rate, abdominal pain and acute renal failure.

On [redacted]008 (post enrollment day 4) the subject's potassium level was low at 3.2 and he was treated with potassium supplements **(AE #903)**. The discharge summary from 1[redacted]-2008 notes that the potassium level was low throughout hospitalization and should be followed through rehabilitation.

On [redacted] 2008 the subject's blood pressure (BP) was first noted to be elevated at 197/73 **(AE #005)**. Hypertension was treated with Norvasc and Hydralazine and appeared to resolve well.

The subject was discharged from the hospital on [redacted]-2008 and transferred to an in-patient rehabilitation facility while still refusing to eat and drink, take medications, and participate in activities of daily living. Initially, the rehabilitation facility attempted to treat him with intravenous feedings, but he removed his IV lines several times. A percutaneuous gastroenterotomy (PEG) tube was then placed, but he became increasingly despondent; the PEG tube was subsequently removed.

On [redacted]008 (post enrollment day 49) the subject was readmitted to the hospital with increased heart rate (122 beats per minute), hypotension (73/42), skin break down, a left shift in white blood cell count with 89% neutrophils, diabetic ketoacidosis, and electrolyte imbalance including a blood urea nitrogen (BUN) of 200 and creatinine of 7.7 **(SAE #003)**. Intravenous normal saline and electrolyte replacement therapy were initiated and his BUN and creatinine improved to 181 and 5.9, respectively. The subject was also treated with a bolus of insulin, followed by an insulin drip for a glucose level of 522 **(cont. of AE #902)**. The subject was also diagnosed with acute blood loss anemia, which required a transfusion of two units of packed red blood cells **(SAE #901)**. He was also found to have thrombocytopenia with a platelet count of 83,000 **(AE #006)**. His platelets had improved to 195,000 by [redacted]-2008. During this second hospitalization, the subject was also found to have abdominal pain and bloody stools. A culture was positive for Clostridium difficile **(AE #004)** and he was prescribed Flagyl. His abdominal pain was also evaluated by x-ray and ultrasound on [redacted]-2008; the latter revealed cholelithiasis, but no treatment was given for this diagnosis.

On [redacted]2008 (post enrollment day 55) impaired skin integrity with skin breakdown on the buttocks and groin was documented **(AE #904)**. Aquaphor and menthol-zinc oxide topical were prescribed.
The subject remained in the hospital until [redacted]008, at which time he was transferred to a hospice facility with an IV line for fluid administration.

The subject expired on [redacted]2008 (post enrollment day 74), 13 days after admission to hospice. The subject's severe depression, associated with the refusal to eat and drink and the decision for hospice care appeared to lead to failure to thrive **(SAE #008)** and his subsequent death. Cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
30-Dec-2008	**000**	**001**	***404 - HT, likely contributing to mass effect**	**Unknown**	**Unknown**
30-Dec-2008	000	002	799 - Vascular Other: Decreased right femoral pulse	Likely not related	Likely related
01-Jan-2009	002		Death	Unknown	Unknown

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 84-year-old Hispanic/Latino female with a past medical history of hypertension, chronic atrial fibrillation, a breast nodule removal and a total abdominal hysterectomy. Medications at admission included Coumadin and an unknown medication for hypertension. The subject lives alone in Columbia and was visiting family in Miami for the holidays at the time of her stroke.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:00 on [redacted]-2008. Symptoms at presentation included left-sided weakness and severe dysarthria. An MRI at admission revealed an acute stroke in the right temporal lobe, with a 16mm meningioma. Baseline NIHSS was 15. The subject was randomized to the treatment arm of the SENTIS trial at 12:42, [redacted] 2008, 13.7 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated on [redacted] 2008 at 12:58 via right groin puncture. The procedure was remarkable for the loss of arterial wave form upon inflation of the infrarenal balloon. The balloon was deflated, and the case was restarted.

Post-Enrollment Course: On [redacted]-2008 (the day of enrollment) at 18:00, the subject was noted to be less arousable, following commands only with repeated stimulation. A follow-up MRI scan showed hemorrhagic conversion with marked mass effect upon the right lateral ventricle with near complete effacement of the anterior horn of the right lateral ventricle **(SAE #001).** Her NIHSS increased to 25 within 24 hours. After a discussion between the physician and the family, the subject's status was changed to "comfort measures only."

During the evening of [redacted] 2008, the right dorsalis pedis pulse could not be palpated **(AE #002),** however, an ultrasound showed normal flow without evidence of occlusion.

On [redacted] 009 (post enrollment day 1), the subject was completely non-responsive with decerebrate posturing noted. Follow-up CT scan showed complete opacification of the right lateral ventricle and a 14mm midline shift to the left. The subject expired at 00:10 on [redacted] 2009. Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
07-Jan-2007	**000**	**002**	**116 - Bradycardia**	**Likely not related**	**Likely not related**
09-Jan-2007	002	003	711 - Pseudoaneurysm	Likely not related	Likely related
25-Jan-2007	**018**	**004**	**304 - Hematuria**	**Likely not related**	**Likely not related**

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
15-Feb-2007	**039**	**901**	***202 - Respiratory failure**	**Likely not related**	**Likely not related**
15-Feb-2007	039		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 85-year-old Caucasian male with past medical history of previous stroke in 1998 with unresolved partial peripheral vision loss (mRS = 1), hypertension, non insulin dependent diabetes, hyperlipidemia, gout, thrombocytopenia, hematuria, seizure, possible syncopal episodes, depression, and renal stones. He has also undergone a transurethral resection of the prostate. Medications at admission included: Plavix, Allopurinol, Prilosec, Lipitor, Zoloft, Toprol, Enduron, Monopril, Depakote, and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject experienced onset of stroke symptoms at 23:30, [redacted]-2007. Symptoms at presentation included slurred speech, left-sided weakness, and dysphagia. CT scan at admission revealed a previous old right occipital infarct and mild chronic small vessels ischemic changes within periventricular white matter of frontal/parietal lobes in both hemispheres; no acute intracranial hemorrhage. The CTA with CT perfusion showed evolving acute infarct in the right parietal region with distal right MCA occlusion. Baseline NIHSS was 15. The subject was randomized to the treatment arm of the SENTIS trial at 05:00, [redacted]-2007, 5.5 hours from symptom onset.

NeuroFlo Procedure: Right groin arterial puncture occurred at 05:40 on [redacted]-2007. An aortogram revealed aortic measurement of 25mm, 1mm wider than the protocol-specified limit. The site had to obtain a waiver for inclusion/exclusion criteria from CoAxia and the local IRB. NeuroFlo insertion was initiated at 07:49, [redacted] 2007. Treatment was unremarkable.

Post-Enrollment Course: Prior to the SENTIS enrollment on [redacted] 2007, the baseline ECG showed sinus bradycardia, and the cardiology consultation was obtained shortly after the subject's hospital admission. The subject was determined to have an intermittent 2:1 atrioventricular (AV) block with associated drop in systolic and mean arterial pressure, Mobitz type 1 block with a ventricular rate in the 40s, right bundle branch and left anterior fascicular block **(SAE #002)**. The subject's blood pressure (BP) at the time of the examination was 120/40mmHg. A permanent dual chamber pacemaker was implanted on the following day without any apparent complications.

On [redacted] 2007 (post enrollment day 1), a large acute infarct over the right temporal-parietal region was seen on CT scan (no additional follow-up imaging data is available). The 24 hour NIHSS had progressed to 18.

On [redacted]-2007 (post enrollment day 2), the subject developed a pulsatile right groin hematoma. An arterial Doppler study showed a right femoral artery pseudoaneurysm **(AE #003)** with the size of 1.35 x 1.70 x 3.15cm. Embolization with thrombin injection was performed on the next day. Per progress note dated [redacted]-2007, no hematoma but ecchymosis was noted on the right groin. His 4 day NIHSS had decreased to 15.

The subject was discharged from the hospital on [redacted]-2007 to a rehabilitation facility. He reportedly had impairments in gait and cognitive function which affected his activities of daily living, and was restless at times during this rehab admission.

During the night of [redacted]-2007 (post enrollment day 17), the subject began to have hematuria associated with pain. A Foley catheter was placed. He had been taking aspirin and Plavix. Hematuria worsened during the morning of [redacted]-2007, and the subject was admitted to the hospital **(SAE #004)**. (Note: The subject's history included two previous episodes of hematuria from his prostate; however, the attending physician thought this hematuria was most likely coming from the subject's urethra.) Urinary analysis was positive for white blood cell (WBC), protein, hemoglobin (Hgb), and glucose. His INR was 1.8 (norm 0.9 - 1.1) and prothrombin time (PT) was 25.6 (norm 10.5 - 14.5). Aspirin and Plavix were stopped, and Cipro was started. No follow-up urinary analysis was recorded. The subject received continuous bladder irrigation and his hematuria was eventually cleared. The subject also had Hgb of 9.4g/dl and hematocrit (Hct) of 27.5 %. The anemia was thought to be due to blood loss from the hematuria, and two units of packed red blood cells were given. Both Hgb and Hct went back to his baseline level by [redacted]-2007.

The subject was discharged from the second hospitalization to a skilled nursing facility on [redacted]-2007.

On [redacted]-2007 (post enrollment day 39), while in the skilled nursing facility, the subject was found in bed in acute respiratory distress **(SAE #901).** He was cyanotic with agonal respiration. He was brought to the emergency room at 11:00. The subject was slightly responsive to pain but otherwise unresponsive. He had profound hypoxemia despite usage of supplemental oxygen. He had a fever of 102.7°F, arrhythmic bradycardia, and was hypotensive. His BUN was 111, creatinine 5.4, glomerular filtration rate (GFR) 11, troponin 0.718 (norm. 0.009 - 0.039), and creatinine kinase (CK) 270 (norm. 45 - 235). The subject was on a do not resuscitate (DNR) code and was given supportive care. The subject died at 12:50 that day. Cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted] enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
15-Oct-2008	000	002	603 - Electrolyte imbalance	Likely not related	Likely not related
15-Oct-2008	**000**	**001**	***414 - Neurological worsening**	**Likely not related**	**Unknown**
18-Oct-2008	003	003	303 - Urinary tract infection	Likely not related	Likely not related
18-Oct-2008	003	901	205 - Infectious pneumonia	Likely not related	Likely not related
03-Nov-2008	019		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 81-year-old Caucasian female with past medical history of valvular disease, atrial fibrillation (in sinus rhythm at the time of presentation), hypertension, hyperlipidemia, gastroesophagel reflex disease (GERD), precancerous colon lesion with partial colectomy, thoracic aneurysm repair (1999), breast cancer with lumpectomy and radiation, and peripherally inserted central catheter (PICC) valve. Medications at admission included: Metoprolol, Simvastatin, Omeprazole, Amlodipine, Benicar, Digoxin, and Ropinirole.

Current Stroke Onset and SENTIS Enrollment: The subject experienced sudden stroke symptoms onset at 18:15, [redacted]-2008. She soon became unresponsive. Symptoms at presentation included left-sided weakness and facial droop. CT scan at admission revealed no abnormality. CT perfusion showed a large perfusion deficit in the right MCA territory. Baseline NIHSS was 10. The subject was randomized to the treatment arm of the SENTIS trial at 00:15, [redacted]-2008, 6 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at approximately 01:00, [redacted]-2008. The diagnostic aortogram revealed suprarenal diameter of 24.9mm. The site received a waiver from CoAxia to enroll the subject despite the slightly large aortic diameter. Treatment was unremarkable.

Post-Enrollment Course: During the hospital stay, the subject had electrolyte imbalance that was managed with replacements **(AE #002).**

The 6 hour NIHSS was not evaluated because the subject was sedated and intubated from the treatment. The 24 hour NIHSS on [redacted]-2008 increased to 20 (or more, due to some subscales marked as untestable) **(SAE #001).** Follow-up NCT on [redacted] 2008 showed a large evolving right middle cerebral artery (MCA) stroke. That scan mentioned that "small hemorrhage cannot be excluded", but NCT scans on [redacted] 2008 and [redacted]-2008 verified that there was no bleeding. The 4 day NIHSS on [redacted] 008 was ranked as 20 (or more, since some sub-scales were marked untestable by the examiner).

On [redacted] 2008 (post enrollment day 3), the subject developed a urinary tract infection that was treated with antibiotics **(AE #003).** Pneumonia was also diagnosed and treated with bronchodilators and antibiotics **(AE #901).** Scattered rhonci with a respiratory rate of 26-30 were still noted on [redacted] -2008.

Follow-up NCT on [redacted] 2008 showed new mild interval effacement of the right lateral ventricle and a 4mm left-sided midline shift **(cont. of SAE #001).** Neurosurgery was consulted regarding possible hemicraniectomy, but the family decided on no further interventions, given the subject's poor prognosis. The subject was placed on a do not resuscitate (DNR) code on [redacted] -2008 and transferred to a hospice care on [redacted] -2008. She died on 0[redacted] -2008. Cause of death was adjudicated as stroke.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
25-Jul-2009	000	002	603 - Electrolyte imbalance	Likely not related	Likely not related
25-Jul-2009	000	901	499 - Neuro Other: Facial twitching	Likely not related	Likely not related
25-Jul-2009	**000**	**001**	***414 - Neurological worsening**	**Likely not related**	**Likely not related**
27-Jul-2009	002		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 47-year-old Caucasian male with past medical history of transient ischemic attack (TIA) in October 2007 and childhood history of seizures (no seizure medication past the age of 18 years). The subject was not taking any medications at admission.

Current Stroke Onset and SENTIS Enrollment: The subject experienced onset of stroke symptoms at 16:45, [redacted] -2009. Symptoms at presentation included mild aphasia and a mild visual field defect on the right. CT scan at admission revealed no abnormality. Subsequent CT perfusion scan revealed a moderate-sized area of acute ischemia involving the left parieto-occipital region. In addition, there was a moderate-sized area of acute ischemia involving the left temporal lobe and the inferior aspect of the left frontal lobe. NIHSS at admission was 3 at 23:00 but progressed to 18 within half an hour with complete aphasia and right hemiplegia. An emergent repeat NCT at 00:59 on [redacted] 2009 suggested early changes of acute ischemic infarct in the distribution of the left posterior cerebral artery (PCA). Follow-up perfusion scan showed no significant changes in the left parieto-occipital region but early signs of acute infarction in the left occipital

lobe. CT angiogram demonstrated left internal carotid artery (ICA) dissection resulting in its complete occlusion. Baseline NIHSS was 18. Having stabilized at NIHSS of 18, the subject was randomized to the treatment arm of the SENTIS trial at 02:27, [redacted] 2009, 9.7 hours from symptom onset.

NeuroFlo Procedure: The subject was sedated and intubated for the cerebral angiogram prior to the puncture. NeuroFlo catheter was inserted at 02:55, [redacted] l-2009. Treatment was unremarkable.

Post-Enrollment Course: During the hospital stay, the subject was given potassium supplements for hypokalemia (potassium level of 3.2) **(AE #002).**

The 6 hour NIHSS on [redacted] 2009 was ranked as 14 but deemed invalid due to sedation and intubation. The subject had intermittent episodes of facial twitching followed by a period of apnea **(AE #901).** Possible seizure activity was suspected. He was given 100% oxygen through ventilator and prophylactic Keppra. Electroencephalography (EEG) showed no evidence of epileptiform activity.

NCT on [redacted] -2009 revealed a large area of decreased attenuation in the left temporal, parietal and occipital lobes, consistent with acute infarct in the left middle cerebral artery (MCA) and left PCA distribution. There was further progression of the left ischemic infarct on the left side **(SAE #001)** compared to the earlier study. Some enfacement of left lateral ventricle and 4mm midline shift were noted. No intracranial hemorrhage was seen. The 24 hour NIHSS on [redacted] -2009 at 23:00 was ranked as 13-17.

On [redacted] 2009 (post enrollment day 1), the subject was still intubated but Propofol was discontinued at 00:30. Per flowsheet at 02:00, the subject was not arousable. MRI showed an evolving left-sided transcortical infarct to the left MCA and PCA with increased (7mm) midline shift **(cont. of SAE #001).** At 16:00, Neurosurgery consult evaluated increased intercranial pressure. Upon exam, the subject's pupils were unequal and the left one was fixed indicating possible early herniation. An external ventricular drain (EVD) was placed immediately without complications. After the EVD placement and Mannitol given, the subject's pupils were equal and reactive.

At 17:16, NCT showed increased cerebral edema and 10mm midline shift with increased compression of left lateral ventricle **(cont. of SAE #001).** An uncal herniation was noted. At 21:29, the progress note indicated that the subject was not responsive to painful stimuli, no spontaneous movement, and pupils were dilated and fixed. Full ventilation support continued. At 23:15, the subject had fever of 101.4°F; systolic blood pressure (BP) was in 170s and heart rate was up to 180s. Labetalol was given to bring systolic BP down to 70s-80s, and heart rate was in 120s.

On [redacted] 2009 (post enrollment day 2), the subject's intracranial pressure (ICP) was 30-40s overnight but down to 7-9 in the morning. He was completely unresponsive at 08:30; comfort measures were addressed. Transcranial Doppler (TCD) conducted at 15:10 showed no right MCA flow and no signal in the left MCA. At 15:38, EEG result was documented as abnormal secondary to very low amplitude activity suggestive of

electrocerebal silence. At 17:30, the subject was declared clinically brain-dead. Cause of death was adjudicated as stroke.

Subject[redacted], enrolled[redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-Feb-2009	000	004	806 - Agitation/Excitation	Likely not related	Likely not related
28-Feb-2009	**000**	**001**	**414 - Neurological worsening**	**Likely not related**	**Unknown**
28-Feb-2009	000	002	113 - Myocardial infarction, non-Q wave	Likely not related	Unknown
28-Feb-2009	000	003	103 - Hypertension	Likely not related	Likely not related
01-Mar-2009	**001**	**005**	***204 - Aspiration pneumonia**	**Likely not related**	**Likely not related**
03-Mar-2009	**003**	**006**	**301 - Renal dysfunction**	**Likely not related**	**Unknown**
09-Mar-2009	009		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 84-year-old Asian male with past medical history of type II diabetes, hypertension, and hyperlipidemia. Medications at admission included Crestor and Avandia. He presented with previously undiagnosed atrial fibrillation. Pre-enrollment ECG did describe a possible inferior infarct, age undetermined, but the troponin level was normal.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 02:00, [redacted]-2009. Symptoms at presentation included global aphasia, complete hemianopsia, and right-sided weakness. CT scan at admission revealed hyperdensity in the left MCA. There were hypodense changes present within the deep basal ganglia on the left. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 10:55, [redacted]b-2009, 8.9 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 11:51, [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: The subject exhibited restlessness and agitation from admission through his death. He was treated with medication, comfort care measures, and soft restraints at times **(AE #004).**

The subject's poor neurological status appeared stable throughout hospitalization until further systemic complications arose. However, the site reported neurological worsening due to his overall course and final demise **(SAE #001).** No intracranial bleeding was noted on follow-up imaging.

The subject was noted to have an elevated troponin level on [redacted]-2009, approximately 7 hours post-treatment. ECGs showed possible inferior infarct (age undetermined) and possible lateral ischemia with ST and T wave abnormalities. Non-ST segment elevation myocardial infarction (NESTMI) was diagnosed **(AE #002)** but no aggressive treatment was given due to the subject's poor condition. The subject's known hypertension worsened from baseline **(AE #003)**, and his medication regimen was altered. During the index hospitalization he was treated with nitroglycerin, Tiazac XL and Coversyl. Beginning [redacted]r-2009, the subject developed increased upper airway secretions and required frequent suctioning **(SAE #005)**. He was given Lasix, ventolin nebulizer and scopolamine with little improvement through time of death. Right lower lobe pneumonia was diagnosed by chest x-ray on 0[redacted]r-2009.

Beginning[redacted]2009 (post enrollment day 3), the subject developed renal dysfunction **(SAE #006)**. The subject exhibited decreased urine output with dark, concentrated urine, elevated sodium, and elevated creatinine. The condition was initially treated with fluid boluses but these were discontinued for palliative care measures only.

The subject's family chose to withhold care and give only comfort measures and the subject passed away on [redacted]-2009, post enrollment day 9. Cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted], enrolled[redacted]-2010

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
10-Jan-2010	000	001	103 - Hypertension	Unknown	Likely related
11-Jan-2010	001	002	403 - Cerebral edema	Unknown	Unknown
12-Jan-2010	002	901	806 - Agitation/Excitation	Likely not related	Likely not related
14-Jan-2010	004	004	608 - Electrolyte imbalance	Likely not related	Likely not related
14-Jan-2010	004	005	815 - Skin irritation	Likely not related	Likely not related

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-Jan-2010	**004**	**003**	***209 - Respiratory dysfunction**	**Likely not related**	**Likely not related**
15-Jan-2010	005		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 73-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, class-II angina (last classified in 2000), myocardial infarction status post percutaneous transluminal coronary angioplasty (PTCA) in 2000, congestive heart failure in 2000, borderline diabetes, depression, rheumatoid arthritis, and osteoporosis. Medications on admission included: Ramipril, Indapamide, Atenolol, Lipitor, Effexor, Methotrexate, Tylenol # 3, and Nitroglycerin spray as needed.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 14:30, [redacted]-2010. Symptoms at presentation included left-sided weakness, aphasia and dysphagia. CT scan at admission revealed sub-cortical areas of low attenuation suggestive of small vessel disease as well as subtle area of low attenuation developing in the right frontal lobe, no hemorrhage. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 20:10, [redacted] 2010, 5.7 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 21:40, [redacted] 2010. During the procedure, the subject's blood pressure (BP) increased to 205/65 **(AE #001)** from baseline of 160/80. IV Labetalol was initiated. The NeuroFlo procedure was not interrupted.

Post-Enrollment Course: On [redacted] 2010 (post enrollment day 1), the 12 hour post enrollment NCT showed cerebral edema causing minor mass effect **(AE #002)**; no hemorrhage was noted. The subject's 24 hour NIHSS on [redacted]-2010 remained stable at 15. Duplex and color Doppler flow study revealed bilateral ICA stenosis (50-69%) and likely severe stenosis/occlusion of intracranial vertebral artery; atrial fibrillation was ruled out.

Also on [redacted] 2010, the subject was noted to be restless. She became agitated on the next day **(AE #901)** and through 14-Jan-2010, pulling nasogastric (NG) tube and curtains, removing covers and adult diapers (with the right hand). She was put on wrist restraints. No other treatment was documented.

On [redacted]-2010 (post enrollment day 4), the subject had electrolyte imbalances including hyponatremia and hypokalemia and was treated with electrolyte replacements **(AE #004)**. She also had skin excoriation under both breasts and groin **(AE #005)**; medicated cream was applied.

The subject was also evaluated for tachypnea **(SAE #003)**. Tube feeding was required due to the subject's dysphagia. She was noted to have tachycardia, was mildly hypoxic, was coughing and was congested. CT of the chest was negative, except for a small amount of pleural effusion. The subject's tachypnea was determined to be due to difficulty in managing secretions despite frequent suctioning. At that time the subject's family opted for "do not resuscitate" status and comfort measures were provided. The subject expired on the following day, [redacted]-2010 (post enrollment day 5) at 09:08, due to respiratory failure. Cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted], enrolled [redacted] 2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
10-Dec-2007	000	002	601 - Anemia	Likely not related	Likely not related
11-Dec-2007	001	007	303 - Urinary Tract Infection	Likely not related	Likely not related
12-Dec-2007	002	902	603 - Electrolyte imbalance	Likely not related	Likely not related
14-Dec-2007	**004**	**003**	**199 - Cardiac Other: Non-infectious thrombotic endocarditis**	**Likely not related**	**Likely not related**
15-Dec-2007	**005**	**005**	**207 - Pulmonary embolism**	**Likely not related**	**Likely not related**
17-Dec-2007	007	006	899 - Other: Abdominal mass	Likely not related	Likely not related
16-Jan-2008	**037**	**001**	**799 - Vascular Other: Circulatory problem in legs**	**Likely not related**	**Likely not related**
25-Jan-2008	**046**	**008**	***299 - Pulmonary Other: Lung cancer**	**Likely not related**	**Likely not related**
25-Jan-2008	046		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Subject Demographics and History: The subject is a 73-year-old Caucasian female with a past medical history of hypertension, hyperlipidemia, a recently diagnosed stage III non-small cell carcinoma of the lung, and peripheral vascular disease with a filter placed 1 month prior to stroke onset. She was undergoing treatment for cellulitis/phlebitis on both lower extremities. Medications at admission included: Coumadin (discontinued 2 days prior to stroke onset for extreme prolongation of INR) and Keflex. The subject quit smoking 1 month prior to the stroke onset, but had been a 50 pack/year smoker.

Current Stroke Onset and SENTIS Enrollment: The subject experienced sudden onset of stroke symptoms at 11:30 on [redacted]-2007. Symptoms at presentation included aphasia with right-sided weakness. CT scan was negative for hemorrhage, but CTA revealed a

large left MCA occlusion. Baseline NIHSS was 14. The subject was randomized to the treatment arm of the SENTIS trial at 18:10, [redacted] 2007, 6.7 hours from symptom onset. The SENTIS Investigator spoke with the subject's oncologist prior to the enrollment, and the oncologist estimated the subject's life expectancy was more than 1 year.

NeuroFlo Procedure: The NeuroFlo procedure was initiated at 19:10, [redacted]-2007. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]007 (day of enrollment), the subject was noted to be anemic **(AE #002)** and iron supplements were started. On the following day, urinary tract infection **(AE #007)** was diagnosed but the subject was already on antibiotics so no additional treatment was ordered. The subject's serum potassium was 3.6 **(AE #902)** and supplemental replacements were given on [redacted] 2007.

On [redacted]-2007 (post enrollment day 4), the subject's trans-esophageal echocardiogram revealed a mitral valve vegetation. Blood cultures were negative at 3 days, and the diagnosis of non-infectious thrombotic endocarditis was made **(SAE #003)**. No further treatment was recommended by her cardiologist. The subject's 4 day NIHSS on [redacted]-2007 decreased to 12.

A CT scan of the chest on 1[redacted]-2007 revealed a pulmonary embolism and hilar lymphadnopathy in the chest **(SAE #005).** The subject was restarted on Coumadin. A CT scan of the abdomen on [redacted]-2007 showed an abdominal mass **(AE #006)** most likely arising from the kidney.

The subject remained profoundly aphasic but her neurological status showed slight improvement in regaining strength and mobility in her right arm and leg. She was discharged from the hospital on 1[redacted]-2007 to a rehabilitation facility.

From the rehabilitation facility the subject was discharged early in January, and was ambulating with a walker at home. On [redacted]-2008 (post enrollment day 37), her chronic peripheral vascular disease worsened, and the subject was admitted with a deep vein thrombosis **(SAE #001)**. Amputation was recommended but the subject refused and was taken home with hospice care.

The subject expired on [redacted]-2008 (post enrollment day 46) due to carcinoma of the lung **(SAE #008).** Cause of death was adjudicated as systemic complications unrelated to stroke.

Subject[redacted], enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Mar-2008	**000**	**002**	***414 - Neurological worsening**	**Likely not related**	**Unknown**
06-Mar-2008	002	901	405 - HT, probably not contributing to mass effect	Unknown	Unknown
07-Mar-2008	003		Death	Likely not related	Unknown

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 81-year-old Caucasian female with past medical history of hypertension, atrial fibrillation, congestive heart failure, chronic lumbar degenerative disc disease, thyroid disorder and smoking. Medications at admission included: Atenolol, Aciphex, Coumadin, Diovan, Spironolactone, Dulcolax, Methimazole, Darvocet, Zofran, multivitamins and calcium.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 16:15, [redacted]-2008. Symptoms at presentation included left-sided weakness and dysarthria. CT scan at admission revealed hyperacute infarct involving the right anterior and much of the middle cerebral artery (MCA) territory. Although no hemorrhage or mass effect was shown, early cytotoxic edema was suggested. Baseline NIHSS was 13. The subject was randomized to the treatment arm of the SENTIS trial at 21:30, [redacted]-2008, 5.3 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 22:26, [redacted]-2008. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour NIHSS on [redacted]r-2008 at 23:50 increased to 18 **(SAE #002)**.

On [redacted] 2008 (post enrollment day 1), the subject was very drowsy and had difficulty staying awake. Her 24 hour NIHSS increased slightly to 19. Repeat NCT revealed "edema in the right anterior and MCA territories presumably related to acute infarction. This has increased since the study of 03/04/08. Cortical sulsi in the involved areas are effaced. There is 4mm right to left midline shift. No acute hemorrhage is evident."

On [redacted]r-2008 the subject had a change in level of consciousness and became more somnolent. The family stated that the subject requested to be "do not resuscitate" status. CT of the brain on that day showed "marked decreased attenuation of the right frontal, anterior parietal, and anterior temporal lobes, and the right basal ganglia, consistent with extensive right MCA and ACA infarct. Marked progression of decreased attenuation compared to previous exam. Marked interval right to left midline shift now nearly 2cm. There is new interval left lateral ventricle and temporal horn dilation. There is hyperattenuation in the distribution of the right MCA, and there is some hyperattenuation

above the suprasellar cistern, which is indeterminate for right MCA clot versus some intraparenchymal hemorrhage" **(AE #901)**.

The subject was pronounced dead at 02:10 on [redacted]r-2008, post enrollment day 3. Cause of death was adjudicated as stroke.

Subject[redacted], enrolled [redacted]2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
23-Jun-2008	**053**	**001**	*** 899: Other: HIV/AIDS (worsening)**	**Likely not related**	**Likely not related**
30-Jun-2008	060		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 45-year-old African American woman known to be human immune deficiency virus (HIV) positive. It is uncertain if she also had a history of diabetes and hypertension, as there are conflicting reports in the medical record. Medications at admission included: Famotidine, Norvir, Reyataz and Truvada. In February 2008 she was hospitalized and treated for an opportunistic pneumonia.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 03:00, [redacted]-2008. Symptoms at presentation included left facial droop and left-sided weakness. She complained of a headache on the right side and vomited once. The daughter also noticed that she had jerking movements on the whole left side of her body. CT scan at admission revealed "Large right MCA territory, acute infarct non-hemorrhagic with moderate diffuse right cerebral and mild leftward subfalcine herniation with slight mass effect on the right lateral ventricle. Abnormal left calvarial defects. One might consider further evaluation with a nuclear medicine bone scan. The bone scan should be correlated with a CT scan." Baseline NIHSS was 13. The subject was randomized to the treatment arm of the SENTIS trial at 10:50, [redacted]-2008, 7.8 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 11:36, [redacted]2008. Ativan was given to the subject prior to the start of the NeuroFlo treatment due to the possible seizure activity on the left side of her body. The infrarenal balloon was slightly overinflated by 0.5cc. A protocol deviation has been received. Treatment was otherwise unremarkable.

Post-Enrollment Course: The 6 hour NIHSS on [redacted]-2008 decreased to 0. Following the NeuroFlo treatment, NCT and perfusion scans were reviewed by the neurologist. He identified the defect seen on the CT scan as possibly an "infiltrative lesion" given the

history of HIV positivity with a low CD4 count. He noted that the perfusion scan was "essentially normal" and the subject's twitching most likely due to a simple partial seizure. His recommendations were for Dilantin, an electroencephalogram (EEG) and MRI scanning to determine the etiology of the mass he observed whether it be infectious (toxoplasmosis), lymphomatous or other.

Neurosurgery was consulted on [redacted]-2008 for potential stereotactic brain biopsy. A positron emission tomography (PET) scan conducted on the following day was consistent with central nervous system infections vs. lymphoma. The brain biopsy on [redacted] 2008 revealed "chronic inflammation and gliosis"; results were negative for toxoplasma and viral cytopathic causes, progressive multifocal leukoencephalopathy and cytomegalovirus.

The subject was discharged from the hospital on [redacted]-2008. The discharge medications included Lantus 25 units at bedtime, but diabetes is not mentioned as a discharge diagnosis.

On [redacted]-2008 (post enrollment day 53) the subject was re-admitted to hospital with a three to four day history of nausea and vomiting. Her evaluation in the emergency department showed that she was in diabetic ketoacidosis (blood sugar of 1047 mg/dl) with an elevated total bilirubin, sepsis, hyponatremia, hyperkalemia and acute renal failure **(SAE #001)**. She was placed on IV hydration with insulin, empiric antibiotics and Nexium. Her white blood cell count (WBC) was 2400 K/uL and hemoglobin was 13.5g/dl. A CT scan of the head showed no acute lesions when compared to her earlier scans.

On [redacted]-2008, she was seen by hematology-oncology for pancytopenia and by neurology for evaluation of options on the lesions in the brain from the earlier admission. The neurologist's consult states that the subject was emaciated, frail and had bilateral ptosis. The neurologist noted that the lesions were resolving at that time and that, although, biopsy did not reveal a definitive cause of lesions, the possibility that it was toxoplasmosis, neurocysticercosis or progressive multifocal leukoencephalopathy (PML). Infectious disease consult on [redacted]-2008 reiterated the advanced state of the subject's AIDS with continued decline of total WBC (0.3 K/uL) and neutrophil count (0 K/uL) since admission. Chest x-ray compared to admission showed increased atelectasis or infiltrates with potential for very small pleural effusion in the right lung. Infectious disease consult recommended adjustment of medications and was awaiting neurology assessment to determine if dexamethasone could be tapered. The neurologist consulted with the subject and her daughter in regards to her advanced disease and prospect for not surviving her illness in the short term.

The subject began to experience respiratory difficulty and shortness of breath on [redacted] 2008 and respiratory failure on the next day. On [redacted]-2008 the daughter expressed that the subject did not wish to be resuscitated due to her terminal illness and she was therefore made "Do Not Resuscitate". She expired on [redacted]-2008 at 05:50. The death certificate noted the immediate cause of death was respiratory failure/pneumonia, HIV (advanced), pancytopenia and diabetic ketoacidosis. Cause of death was adjudicated as

systemic complication unrelated to stroke, specifically worsening of HIV/AIDS. [Note: Although the DSMB's thorough review of this subject noted numerous findings/possible events, their final adjudication of the single SAE of advanced AIDS was intended to capture the linkage and cascade of events that led to death.]

Subject [redacted], enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
07-Sep-2008	**001**	**001**	**202 - Respiratory failure**	**Likely not related**	**Likely not related**
07-Sep-2008	**001**	**003**	**601 - Anemia**	**Likely not related**	**Likely not related**
07-Sep-2008	001	004	603 - Electrolyte imbalance	Likely not related	Likely not related
10-Sep-2008	**004**	**002**	*** 805 - Sepsis**	**Likely not related**	**Likely not related**
10-Sep-2008	004		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 63-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, type II diabetes, coronary artery disease with stent placement, angioedema, hypothyroidism, gout, hysterectomy, cholecystectomy, and renal calculi. Medications at admission included: Coreg, Lanoxin, Lozol, Januvia, Vytorin, Allopurinol, Aspirin, Allegra, Bactrim and Prilosec.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 03:00, [redacted]-2008, while inpatient. She underwent coronary artery bypass graft surgery on [redacted] 2008 and was extubated at 03:00 on [redacted]-2008. The subject immediately had difficulty breathing and was administered racemic epinephrine. She experienced stroke symptom onset soon after. Symptoms included facial drooping, aphasia, and right-sided weakness. CT scan revealed acute non-hemorrhagic CVA involving the left temporal parietal region with evidence of edema with effacement of sulci and effacement of gray-white matter differentiation. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 10:55, [redacted]-2008, 7.9 hours from last known normal. Her platelet count was 88,000; a protocol deviation was recorded.

NeuroFlo Treatment: NeuroFlo treatment was initiated on [redacted]-2008 at 11:56. Treatment was unremarkable.

Post-Enrollment Course: On [redacted] 2008 (post enrollment day 1), the subject's respiratory status began to decline **(SAE #001)**. Pulmonary and infectious disease

consults were obtained, and she was intubated to protect her airway due to copious amount of oral and nasal secretions. She was febrile. Blood cultures were negative but sputum culture was positive, so Zoxyn was initiated. Chest x-ray showed bilateral atelectasis with pleural effusions and pneumonia.

Also on [redacted]-2008, the subject's hemoglobin was 8.3g/dl and two units of packed red blood cells were given **(SAE #003)**. The subject's potassium and phosphorus were low; supplemental replacements were given for each **(AE #004).**

On [redacted] 2008 (post enrollment day 4), the subject became hypotensive, with a systolic pressure in the 70's. The attending physician noted "critically ill" with an impression of "sepsis syndrome" **(SAE #002)** with increased temperature, decreased systolic blood pressure and oliguria. The dopamine and neosynepherine drips were increased and levophed was added; packed red blood cells were given. The subject was tachypneic with decreased breath sounds on the left side. Chest x-ray showed a questionable hemothorax; a thoracentesis was performed. She also had a pericardiocentesis, no fluid was obtained. The subject became bradycardic, cardiopulmonary resuscitation was initiated, but the subject was unable to be resuscitated. Cause of death was adjudicated as systemic complications unrelated to stroke.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
19-Dec-2009	001	901	403 - Cerebral edema	Unknown	Unknown
19-Dec-2009	001	902	899 - Other: Scapular abscess	Likely not related	Likely not related
22-Dec-2009	**004**	**001**	***301 - Renal dysfunction**	**Likely not related**	**Unknown**
26-Dec-2009	**008**	**002**	***805 - Sepsis**	**Likely not related**	**Likely not related**
27-Dec-2009	009		Death	Likely not related	Unknown

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 60-year-old Caucasian male with past medical history of hypertension, hyperlipidemia, left-sided stroke (1991) with total recovery, occlusion of the left carotid artery and asymptomatic stenosis of the right carotid artery (status post endarterectomy), macrovascular disease with percutaneous angioplasty of the left superficial femoral artery (2004), relapse of right calf claudication with percutaneous recanulization (additional stenting) of the right external iliac artery and origin of the right common femoral artery, cardiac arrest (1996), Grave's disease with subsequent thyroid toxicity, thyroidectomy (1998) with post operative hypoparathyroidism, calcium metabolism problems, and orbitopathy for which he

received radiation therapy (1999), prostate cancer, and sleep apnea. Medications at admission included: Fraxiparine, Co-aprovel (Irbesartan Hydrochlorothiazide), Ezetrol, Metoprolol, Elthyrone.

The subject had increased tiredness and shingles during the 3 weeks preceding the stroke. Shingles on his right neck and thorax were treated with Zovirax. On 14-Dec-2009 the subject underwent an elective trans-urethral resection of the prostate (TURP). He remained hospitalized at the time of his index stroke.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 21:00, [redacted]c-2009. Symptoms at presentation included left hemiplegia, dysarthria, neglect and forced gaze to the right. CT scan at admission revealed a large infarct in the right middle cerebral artery (MCA) territory with acute thrombus in the right MCA and right internal carotid artery (ICA); no hemorrhage. Baseline NIHSS was 16. The subject was randomized to the treatment arm of the SENTIS trial at 07:12, 1[redacted]-2009, 10.2 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 08:27, [redacted]-2009. When an attempt to calibrate the pressure monitoring equipment was made, the suprarenal mean arterial pressure could not be obtained. An attempt to aspirate the central lumen was unsuccessful. The NeuroFlo catheter was removed and flushed, revealing a clot that appeared to come from the top of the catheter. NeuroFlo was reinserted and the procedure proceeded without incident.

Post-Enrollment Course: On [redacted]-2009 (post enrollment day 1) the subject had progressed from drowsy to somnolent. His 24 hour NIHSS increased to 18. The 24 hour MRI showed an extensive large ischemic zone in the whole right MCA territory and partially in the anterior right territory as well as in right basal ganglia. Secondary edema **(AE #901)**, with limited mass effect and slight left midline shift, was also noted. The left ICA was totally occluded and the right ICA was 90% occluded. Multiple old left hemisphere ischemic lesions were also noted.

Also on 19-Dec-2009 a consult was obtained for possible drainage of an abscessed left scapular cyst **(AE #902)** that the subject had for 20 years. On [redacted]-2009 incision and drainage of the abscess was performed.

On [redacted]-2009 (post enrollment day 4) the subject developed a urinary tract infection that progressed into a full blown urosepsis **(SAE #001)** causing a somnolent state. Tazocin was initiated.

On [redacted]-2009 (post enrollment day 8) the subject remained somnolent and did not open eyes spontaneously; there was no light reflex. He was febrile with rhonchi. C-reactive protein was 6.2 and white blood cell (WBC) count was 18,000. A decrease in pre-renal well-being was also noted; urea was 60 and creatinine 2.8 (1.4 at admission) **(SAE #002)**. The next day the subject continued to deteriorate with metabolic deregulation, kidney failure, and hyperosmolarity. Comfort measures only were instituted and the subject expired in the evening of [redacted]2009, post enrollment day 9.

Cause of death was adjudicated as systemic complications associated with stroke, specifically renal dysfunction and sepsis.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
25-Mar-2009	000	901	806 - Agitation/Excitation	Likely not related	Likely not related
26-Mar-2009	001	002	701 - Hematoma	Unknown	Likely related
26-Mar-2009	**001**	**001**	***414 - Neurological worsening**	**Unknown**	**Unknown**
27-Mar-2009	**002**	**902**	**204 - Aspiration pneumonia**	**Likely not related**	**Likely not related**
06-Apr-2009	012		Death	Unknown	Unknown

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 78-year-old Caucasian male with past medical history of Parkinson's disease, non insulin dependent diabetes, transurethral resection of the prostate, urinary tract infection (2008), and hyperlipidemia. Medication at admission included: Prolopa, Glucophage, Praxilene, and Molsidomine.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 14:30 on [redacted]-2009. Symptoms at presentation included aphasia and left hemiplegia. CT scan at admission revealed old small calcified lesions in the basal ganglia and signs of peri-ventricular leukoencephalopathy; no hemorrhage. Baseline NIHSS was 17. The subject was randomized to the treatment arm of the SENTIS trial at 17:30, [redacted]-2009, 3.0 hours from symptom onset.

NeuroFlo Procedure: The NeuroFlo procedure was initiated at 18:53 on [redacted]-2009. Treatment was unremarkable except for an episode of agitation **(AE #901)** during the procedure. Two doses of Valium were administered and the subject remained sedated at the time of his 6 hour follow-up.

Post-Enrollment Course: On [redacted] 2009 (post enrollment day 1) a hematoma was noted at the right arterial puncture site **(AE #002)**. NCT at 09:30 showed sub-acute infarct zone in the right middle cerebral artery (MCA) territory as well as age-related cortical and sub-cortical atrophy, no hemorrhage. The 24 hour NIHSS at 17:10 deteriorated to 29 as the subject became unconscious **(SAE #001)**; he did react to pain stimuli.

On [redacted]-2009 the subject remained comatose. An MRI showed a hyper-intensity consistent with a right MCA territory infract. MRA showed no filling of the right MCA

and minimal filling of the right internal carotid artery (ICA). The subject's C-reactive protein (CRP) was elevated at 2.7 and a chest-ray was performed for suspicion of aspiration pneumonia. Lungs fields were unclear and this was thought to be due to hypoventilation with underlying infiltrates **(SAE #902)**; Augmentin was started.

On [redacted]-2009 the subject was placed on palliative care as there was no clinical improvement. The subject expired on [redacted]-2009, post enrollment day 12. Cause of death was adjudicated as stroke.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
08-Sep-2009	001	001	409 - New ischemic stroke	Unknown	Unknown
08-Sep-2009	001	901	412 - HT, no concomitant mass effect	Unknown	Unknown
08-Sep-2009	**001**	**902**	*** 414 - Neurological worsening**	**Unknown**	**Unknown**
08-Sep-2009	001	002	819 - Infection	Likely not related	Likely not related
09-Sep-2009	002	003	701 - Hematoma	Likely not related	Likely related
10-Sep-2009	003		Death	Unknown	Unknown

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 78-year-old Caucasian male with past medical history of insulin-dependent diabetes, hypertension, hyperlipidemia, cholecystectomy and cataract surgery. Medications at admission included: Aspirin, Delix, Norvasc, Clexane, Protaphane, Elrantil, and Parcemtamol.

Current Stroke Onset and SENTIS Enrollment: The subject was admitted to the hospital on [redacted] 2009 for blood pressure management. He was confused that night but did not show any focal neurological symptoms. The subject was last known normal at 10:00 on [redacted]-2009. Symptoms at presentation included right gaze deviation and left lower extremity weakness. An MRI scan revealed a right posterior and middle cerebral artery infarct with mismatch and signs of microangiopathy. Baseline NIHSS was 14. The subject was randomized to the treatment arm of the SENTIS trial at 17:05, [redacted]-2009, 7.1 hours from last known normal.

NeuroFlo Procedure: The NeuroFlo procedure was initiated at 17:56, [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: The subject was stable post-procedure and his neurological status initially improved. The 6 hour NIHSS at 19:00 on [redacted] 2009 improved to 10.

On [redacted] 2009 (post enrollment day 1) at 03:00 the subject was found unconscious and unresponsive to pain stimuli. At 08:32, a CT scan showed no new findings. An MRI at 09:40 showed basal artery embolism that led to the new disseminated right posterior and medial cerebral artery infarcts **(AE #001)** with increasing right posterior occlusion and bilateral subacute infarct in the thalamic region as well as in the anterior part of the middle brain with new bleeding in the thalamus and right midbrain **(AE #901)**. At 14:30, the subject's 24 hour NIHSS increased to 29 **(SAE #902)** and comfort care was provided. The subject was noted to have a fever and an elevated C-reactive protein **(AE #002)**; no treatment was provided.

On [redacted] 2009 (post enrollment day 2) a right access site groin hematoma **(AE #003)** was noted; no treatment was provided.

The subject remained in a comatose state until his death on [redacted]-2009. The cause of death was adjudicated as stroke.

Subject [redacted], enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Dec-2008	000	001	412 - HT, no concomitant mass effect	Likely not related	Unknown
21-Dec-2008	004	002	503 - Nausea/Vomiting	Likely not related	Likely not related
29-Dec-2008	012	003	811 - Depression	Likely not related	Likely not related
03-Jan-2009	**017**	**004**	***117 - Ventricular Tachycardia**	**Likely not related**	**Likely not related**
03-Jan-2009	017		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: This subject is a 64-year-old Caucasian male with a past medical history of non-insulin dependent diabetes, hypertension, hyperlipidemia, myocardial infarction, coronary artery bypass grafting (1996), low grade aortic insufficiency, and peripheral artery disease. Medications at admission included: Aspirin, Isoket, Beloc, Euglucon, Delmuno, Rekawan and Insidon.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:00, [redacted]-2008. Symptoms at presentation included dysarthria, facial paresis, left hemiparesis and left-sided neglect. CT scan at admission revealed early infarct signs in the lentiform nucleus and suspected right insular infarct with suspicion of thrombus in the

right M1 segment; no bleed. MRI revealed acute infarct in the right middle cerebral artery (MCA) with distinct perfusion deficit in the mid and proximal area of the MCA territory. Occlusion of the right MCA with presumed right periventricular residual bleeds and petechial hemorrhage (HI-1) in the right superior frontal gyrus was also seen. [Note: Per enrolling protocol, this was not recorded as deviation due to no finding on NCT.] Baseline NIHSS was 17. The subject was randomized to the treatment arm of the SENTIS trial at 10:15, [redacted]-2008, 12.3 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 11:00, [redacted]-2008. Treatment was unremarkable, except for slight overinflation of the infrarenal balloon by 0.5cc.

Post-Enrollment Course: On [redacted] 2008 (post enrollment day 1) the 24 hour MRI revealed hemorrhagic transformation without concomitant mass effect **(AE #001)**. No clinical signs of neurological deterioration were present. The subject's 24 hour NIHSS decreased to 14.

On 2[redacted]-2008 (post enrollment day 4) the subject reported nausea **(AE #002)** for which he was treated with pantozol and metoclopromide. His 4 day NIHSS was 12.

On [redacted] c-2008 (post enrollment day 12) the subject reported feeling depressed **(AE #003)** and was treated with citalopram.

On [redacted]-2009 (post enrollment day 17) the subject developed ventricular fibrillation and resuscitation was attempted; after 40 minutes sinus rhythm was restored **(SAE #004)**. Subject underwent emergency cardiac catheterization which revealed severe coronary atherosclerosis. No intervention was performed. Later that day the subject went into cardiogenic shock (abrupt decrease in blood pressure that did not respond to increasing doses of adrenalin) for which resuscitation failed and the subject expired. Cause of death was adjudicated as systemic complications unrelated to stroke, specifically ventricular fibrillation.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
15-Apr-2009	**001**	**001**	***403 - Cerebral edema**	**Unknown**	**Unknown**
22-Apr-2009	008		Death	Unknown	Unknown

Serious events are in bold, shaded text.
*Indicates serious event is associated with death

Demographics and History: The subject is a 58-year-old Caucasian female with a past medical history of atrial fibrillation and severe rheumatic valvular heart disease (2004).

The subject was awaiting surgery for correcting her heart failure (NYHA II-III). Medication at admission included: Warfarin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 01:00 on [redacted]-2009. Symptoms at presentation included oculocephalic preference to the left, right hemianopsia, right facial hemiparesis and right hemiplegia. CT scan at admission revealed hypodensity in left anterior cerebral artery territory and less than 30% of left middle cerebral artery (MCA) territory and a hyperdense left MCA sign. Baseline NIHSS was 18. The subject was randomized to the treatment arm of the SENTIS trial at 13:35, [redacted]-2009, 12.6 hours from last known normal. Note: The subject was enrolled with an INR of 1.9. A protocol deviation was completed.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 14:13 on [redacted]-2009. During the procedure the supra-renal balloon was slow to inflate/deflate; however, this did not impact the inflation treatment time. The device was returned to CoAxia and was found to be working within the normal specifications.

Post-Enrollment Course: On [redacted] 2009 (post enrollment day 1) the 24 hour NIHSS increased to 20. At 15:00 the subject had a decrease in consciousness; NIHSS was 23. CT showed stroke progression with edema and a 1cm midline shift **(SAE #001)**. The subject was intubated and a decompressive hemicraniectomy was performed. The subject remained intubated until her death.

On [redacted]-2009 (post enrollment day 2) a progressive coma due to uncontrolled intracranial hypertension was documented. CT showed malignant MCA stroke with cerebral herniation and on the following day brain death was suspected. The subject's brain death was confirmed by electroencephalogram on [redacted]-2009, post enrollment day 8. Cause of death was adjudicated as stroke.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
21-Sep-2009	**000**	**001**	**601 - Anemia**	**Likely not related**	**Likely not related**
30-Sep-2009	**009**	**002**	**805 - Sepsis**	**Likely not related**	**Likely not related**
05-Nov-2009	**045**	**003**	***599 - GI Other, Adenocarcinoma, gastric – metastatic to bone marrow**	**Likely not related**	**Likely not related**
13-Nov-2009	053		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 79-year-old Caucasian female with past medical history of hypertension, non-insulin dependent diabetes mellitus, hyperlipidemia, aortic valve replacement (2001), macrocytic anemia (2007), elbow dislocation and humeral condyle fracture (2005). The subject was diagnosed with diffuse duodenal adenocarcinoma after presenting with digestive symptoms and anemia (May-2009). She was being treated with 5-Fluoro-uricil and radiation. Medications at admission included: Bisoprolol, Metformin and Clexane.

Current Stroke Onset and SENTIS Enrollment: The subject experienced a sudden onset of stroke symptoms at 11:45, [redacted]-2009. Symptoms at presentation included mixed aphasia with hypofluency, and difficulty in naming and repeating. CT scan at admission revealed predominantly cortical cerebral atrophy with no acute lesions. Baseline NIHSS was 5. The subject was randomized to the treatment arm of the SENTIS trial at 16:15, [redacted]-2009, 4.5 hours from symptom onset.

During her emergency room (ER) stay, the subject was transfused with two units of blood for hemoglobin of 7.8 **(SAE #001)**. Post transfusion hemoglobin was 9.0.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 16:45, [redacted]-2009. Treatment was unremarkable.

Post-Enrollment Course: On [redacted]-2009 the subject's 24 hour NIHSS decreased to 0 and her follow-up CT was normal. The subject was discharged from the hospital on [redacted]-2009 to home.

On [redacted]-2009 (post enrollment day 9), the subject presented to ER with general deterioration (asthenia, superior anorexic dysphagia, diarrhea and dehydration) which was suspected to be a gastric neoplasm relapse. She was transfused with two units of blood for hemoglobin of 7.8 **(cont. of SAE #001)** and admitted. The subject was febrile (39.2°C) and urine and blood cultures were positive for Klebsiella pneumoniae **(SAE #002).** Tazocel was started and was later deemed to be the cause of the subject's thrombocytopenia. Chest CT showed acute pulmonary edema, bilateral pleural effusion, and anasarca. Cultures were positive for Candida albicans (secondary to the antibiotic treatment) and Fluconazole was started. A bone marrow biopsy was done during this admission. The subject improved and was transferred to a rehabilitation facility on [redacted]-2009 in stable condition with limited mobility.

On [redacted]-2009 (post enrollment day 45) the subject was sent to the index hospital for a blood transfusion with hemoglobin of 7.3 **(cont. of SAE #001)**. At that time, the bone marrow biopsy results were reviewed and stage IV metastasis of the adenocarcinoma was found **(SAE #003)**. Due to the poor prognosis, the subject was discharged back to the rehabilitation hospital and comfort measures were instituted. The subject deteriorated and died on [redacted]-2009, post enrollment day 53. Cause of death was adjudicated as systemic complications unrelated to stroke, specifically gastric adenocarcinoma.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
30-Sep-2009	**002**	**001**	**404 - HT, likely contributing to mass effect**	**Unknown**	**Unknown**
30-Sep-2009	002	002	303 - Urinary Tract Infection	Likely not related	Likely not related
02-Oct-2009	004	003	118 - Atrial Fibrillation	Likely not related	Likely not related
03-Oct-2009	005	901	403 - Cerebral edema	Likely not related	Likely not related
06-Oct-2009	008	902	504 - GI Motility Disorders	Likely not related	Likely not related
21-Nov-2009	**054**	**004**	***899 - Other: Multi-organ failure**	**Likely not related**	**Likely not related**
21-Nov-2009	054		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 77-year-old Caucasian female with past medical history of non-insulin dependent diabetes, hypertension, hyperlipidemia, and anxiety/depression. Medications at admission included: Unidiamicron, Metformin, Quinapril, Amlodipine and Simvastatin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 02:00, [redacted]-2009. Symptoms at presentation included global aphasia, slight facial paralysis and probable right homonomous hemianopsia. CT scan at admission revealed a left frontal-insular cortical/subcortical hypodense image consistent with left middle cerebral artery (MCA) territory acute ischemic infarct. Baseline NIHSS was 8. The subject was randomized to the treatment arm of the SENTIS trial at 13:20, 2[redacted]-2009, 11.3 hours from last known normal.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 14:25, [redacted]-2009. Treatment was unremarkable, except for slightly elevated pressure differential peri- and post treatment.

Post-Enrollment Course: The 6 hour NIHSS on [redacted]-2009 improved to 6.

On [redacted]-2009 (post enrollment day 2) right brachial and crural hemiparesis with global aphasia was noted. CT showed hemorrhagic transformation **(SAE #001)** in the left frontal-insular territory with mass effect in the ventricular system and midline structures; low molecular heparin was stopped. The subject had a pathological urine sample (abnormal sediment in her urine) **(AE #002)** and was started on Augmentin. Urine and blood cultures were negative.

On [redacted]-2010 (post enrollment day 4) at 15:23 the subject's neurological status deteriorated. She was awake with predominately motor global aphasia, no visual field deficits, facial hemiparesis, brachial, crural, and probable ipsilateral hypoesthesia. NIHSS increased to 15. Holter monitoring revealed atrial fibrillation without significant pauses **(AE #003)** which was thought to be the cause of her stroke. Due to the hemorrhagic transformation the site decided against anti-platelet therapy.

On [redacted] 2009 the subject was hypertensive (systolic blood pressure of 180's) and more somnolent with Cheyne-Stokes respirations. She did not open her eyes to pain stimuli. CT showed an increase in the hemorrhagic area mainly in the basal ganglia and in the area of the internal capsule near the centrum semiovale. There was also a clear progression of the mass effect **(AE #901)**, showing herniated left lateral ventricle and displacement of the interhemispheric fissure. Mannitol and lasix were given to decrease intracranial pressure.

Following the placement of a nasogastric tube the subject had several days of diarrhea **(AE #902)**. The volume of nutrition was adjusted and morphine was given to calm associated abdominal pain. The origin of the diarrheal syndrome is unknown.

At the time of the 30 day follow-up assessment on [redacted]-2009, the subject's NIHSS increased to 30 and mRS was ranked as 5.

CT on [redacted]t-2009 showed a hematoma in acute-subacute phase with a peripheral hypodensity in the frontal lobe (secondary to infarct and peripheral ischemia in the hemorrhagic zone) without midline shift.

The subject was transferred from the hospital on [redacted] 2009 to rehabilitation and was made "do not resuscitate" upon admission. Bilateral phlebitis was noted but no treatment was given. The subject continued to deteriorate and expired on [redacted]-2009 (post enrollment day 54) as a result of multisystem organ failure **(SAE #004)**. Cause of death was adjudicated as systemic complications unrelated to stroke, specifically multi-system organ failure.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-Nov-2009	**002**	**001**	***204 - Aspiration pneumonia**	**Likely not related**	**Likely not related**
29-Nov-2009	003		Death	Likely not related	Likely not related

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 78-year-old Caucasian male with past medical history of hypertension, hyperlipidemia, left hip replacement (2005), urinary incontinence and mild cognitive deterioration. The subject had 4 episodes of language disturbance and left-sided lateralization within 13 days prior to index stroke onset. Transcranial Doppler on [redacted]-2009 showed mild stenosis of the right internal carotid artery (ICA) and a severe occlusion of the left ICA. CT on the same day revealed cerebral atrophy, predominately cortical. The subject was admitted on [redacted]-2009 for complete work-up. Medications at admission included: Eprosartan, Amlodipine, multivitamin, Acetaminophen, Omeprazole, Vesicare, Aspirin and low molecular weight heparin.

Current Stroke Onset and SENTIS Enrollment: The subject had a sudden onset of clinical worsening at 09:00, [redacted]-2009, while still inpatient. Symptoms included aphasia, decreased level of consciousness, facial palsy, and weakness. CT scan at onset revealed no change from the [redacted]-2009 scan. Baseline NIHSS was 14. The subject was randomized to the treatment arm of the SENTIS trial at 13:10, [redacted]-2009, 4.2 hours from symptom onset.

NeuroFlo Procedure: NeuroFlo procedure was initiated at 13:20, [redacted] 2009. Treatment was unremarkable.

Post-Enrollment Course: The 6 hour NIHSS on [redacted]-2009 at 16:00 increased to 17 and remained at 17 at the 24 hour NIHSS assessment.

On [redacted] 2009 (post enrollment day 2) NCT showed slight hypodensity in the left hemisphere affecting the frontal-temporal lobe and the basal ganglia, including the internal capsule.

Also on [redacted] 2009 the subject aspirated **(SAE #001)** and Augmentin and oxygen therapy was initiated.

In the morning of [redacted] 2009 (post enrollment day 3) the subject showed a diminished level of consciousness and difficulty breathing. The family decided to withdraw aggressive medical treatment and provide comfort measures only. The subject expired at 11:30, [redacted]-2009. Cause of death was documented as acute respiratory insufficiency secondary to the left MCA ischemic stroke. Cause of death was adjudicated as stroke.

Control Arm

Subject [redacted], enrolled [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-Feb-2007	**000**	**001**	**601- Anemia**	**N/A**	**N/A**
17-Feb-2007	**003**	**002**	***414- Neurological worsening**	**N/A**	**N/A**
17-Feb-2007	003		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 66-year-old Caucasian female with past medical history of transient ischemic attack, peripheral vascular disease, tuberculosis, chronic obstructive pulmonary disease, hyperlipidemia, hypertension and heavy tobacco use. She was being treated at another facility at the time of stroke onset for acute right lower extremity occlusion with clot removal (popliteal thrombectomy). During the hospitalization for the politeal thrombectomy she was also found to have a possible infective endocarditis, pericardial effusion and left upper lobe mass with recent weight loss of 45 pounds. Medications at admission included: Tegretol, Lipitor, Lisinopril, Albuterol, Vicodin, Lopressol, Xanax, Zoloft, iron supplements and B12.

Current Stroke Onset and SENTIS Enrollment: The subject had sudden onset of symptoms at 06:00, [redacted] 2007. Symptoms at presentation included left-sided weakness of the extremities, a left facial droop and slurred speech. CT scan was negative for hemorrhage. Baseline NIHSS was 16. The subject was randomized to the control arm of the SENTIS trial at 12:25, [redacted] 2007, 6.4 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2007 (the day of enrollment) the subject's hemoglobin dropped from 8.4 g/dl to 7.1 g/dl, hematocrit from 24.6% to 21.3% and platelets from 104 k/ul to 73 k/ul **(SAE #001)**. Hematology was consulted. There was no evidence of acute bleeding and repeat CTs of the head on [redacted]-2007 continued to be negative for blood. The subject declined blood transfusions due to religious beliefs. Procrit, vitamin B12 and folic acid were initiated. Hematologic status continued to decline with hemoglobin 6.7 g/dl and platelets 50 k/ul by [redacted]-2007.

The subject's stroke continued to evolve post-enrollment. NIHSS increased to 19 by 4 hours **(SAE #002)**. CT report stated "developing edema secondary to evolving infarct." Physician note on [redacted]-2007 cited declining cognitive status. A discussion was held with subject's family, and, in light of her declining neurological status, her pulmonary

status with lung mass, and peripheral vascular disease, the decision was made to provide comfort measures only. The subject was discharged to home with hospice on [redacted] 2007 and expired the following morning, [redacted] 2007. Cause of death listed on the death certificate reads "massive cerebral infarct, hypertensive cardiovascular disease, emphysema, and lung mass". Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted] 009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
02-Oct-2009	000	001	503 - Nausea/ Vomiting	N/A	N/A
02-Oct-2009	000	002	812 - Fever	N/A	N/A
02-Oct-2009	**000**	**003**	***404 - HT, likely contributing to mass effect**	**N/A**	**N/A**
03-Oct-2009	001		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 69-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, mitral valve disorder, and newly diagnosed atrial fibrillation two weeks ago. Medications at admission included: Altace, Lortrel, Toprol XL, and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:30, [redacted] 2009. Symptoms at presentation included right-sided weakness and speech deficits. NCT and CT perfusion scans at admission revealed acute stroke without hemorrhage along the territory of the left posterior division of middle cerebral artery (MCA). Also, loss of grey white differentiation was seen in the left temporal and parietal lobes. Baseline NIHSS was 14. The subject was randomized to the control arm of the SENTIS trial at 10:50, [redacted] 2009, 12.3 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 009 (the day of enrollment), the subject was reported to have fever of 101.2°F treated with Acetaminophen **(AE #002)** and nausea treated with Compazine **(AE #001)**.

The subject became less responsive and somnolent in the evening. NCT of the brain revealed a new intra-parenchymal hematoma in the left temporal lobe in the area of known left MCA infarct with mass effect and 11mm left to right midline shift; uncal herniation was also suspected **(SAE #003).** The subject was also having dyspnea. A chest x-ray showed mild pulmonary venous hypertension. Laboratory work-up revealed PO_2 of 63 mmHg, white blood cells (WBC) of 13.5, serum potassium of 3.3, blood

glucose of 151, as well as positive red blood cells (RBC) and leukocyte esterase in urine. The subject was clinically deteriorating. After a long discussion with the family, the subject was placed on palliative care. The subject expired on the evening of [redacted]-2009 (post enrollment day 1). Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
24-Apr-2009	000	003	606 - Hyperglycemia	N/A	N/A
25-Apr-2009	001	002	413 - Headache	N/A	N/A
25-Apr-2009	001	004	603 - Electrolyte imbalance	N/A	N/A
26-Apr-2009	**002**	**001**	***404 - HT, likely contributing to mass effect**	**N/A**	**N/A**
26-Apr-2009	002	901	409 - New ischemic stroke	N/A	N/A
27-Apr-2009	003		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 73-year-old African-American female with past medical history of hypertension, hyperlipidemia, Crohn's disease, cervical fracture and goiter. The subject reported smoking 2 to 3 cigarettes a day for 50 years and smoking marijuana occasionally. Medications at admission included: Hydrochlorothiazide, Toprol, Lovastatin, Asacol, Lomotil, Vicodin and Fosamax.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 12:00, [redacted] 2009. Symptoms at presentation included slurred speech, left-sided weakness and numbness. CT scan at admission revealed a dense right middle cerebral artery (MCA) and a very early right MCA infarct. Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 17:50, [redacted]-2009, 5.8 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2009 (the day of enrollment) a possible urinary tract infection (UTI) was documented and the subject was started on Bactrim. A culture was ordered and cancelled on the next day. Bactrim was discontinued later in the day and no other medications relative to a UTI were prescribed. Due to the limited notes available and no clear diagnosis of a UTI, this was not recorded as an AE.

On [redacted] 2009 the subject experienced mild hyperglycemia that was treated with sliding scale insulin throughout her hospitalization **(AE #003)**.

On [redacted]-2009 the subject experienced a headache **(AE #002)** and was treated with intravenous Fentanyl. The headache resolved on the same day. Also, the subject's phosphorus level was low at 2.2 mg/dl (norm 2.4 - 4.5) **(AE #004)**. Supplemental electrolytes were given.

On [redacted] 2009 a follow-up NCT and CTA revealed a very large acute infarct involving the right anterior choroidal and MCA territories. MRI without contrast at 16:00 additionally noted petechial hemorrhages within the infarct and mass effect on the right lateral ventricle with mild uncal displacement.

On [redacted]-2009 at approximately 02:00 the subject was found unresponsive to painful stimuli. Her vitals were stable but a significant downward trend in blood pressure over a 3 hour period was noted. Pupils were non-reactive. A normal saline bolus was given and the subject was transferred to intensive care for intubation. NCT at 04:07 reported a new hemorrhage in the massive right MCA and anterior choroidal artery infarct with significant leftward midline shifting with extensive transtentorial herniation with infarction of the posterior cerebral artery (PCA) territory **(SAE #001, AE #901)**, and mass effect on the brainstem. NCT performed 6 hours later was unchanged.

On 2[redacted] 2009 (post enrollment day 3) the subject was placed on palliative care only and was extubated. She was pronounced dead at 08:41 that day. Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
21-Jun-2009	000	001	102 - Hypotension	N/A	N/A
25-Jun-2009	**004**	**002**	***414 - Neurological worsening**	**N/A**	**N/A**
04-Jul-2009	013		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: This subject is a 77-year-old Caucasian female with a past medical history of hypertension, irritable bowel syndrome, and a pituitary tumor (status post resection with cyberknife). She has temporal hemianopsia secondary to the pituitary tumor. Medications at admission included: ASA, hydrochlorothiazide, Klor-Con, Librax, Dicyclomine HCL, Hydrocortisone, Cortef, Ciprofloxacin, Clonidine, Toprol, Ambien, Amlodipine, Levothyroxine, Nexium, and Micardis.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:00 on [redacted] 2009. Symptoms at presentation included aphasia with significant right-sided weakness. CT scan at admission revealed some loss of sulci in the left middle cerebral artery (MCA) territory, suggesting early stroke; no hemorrhage. Baseline NIHSS was 18. The subject was randomized to the control arm of the SENTIS trial at 10:45, [redacted] 2009, 12.8 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (day of enrollment) at 17:15 the subject had cool clammy skin and a blood pressure (BP) of 63/34 **(AE # 001)**. She was minimally arousable. Following placement in trendelenburg position and giving a 250ml normal saline bolus, the subject's BP increased to 108/48. Two hours later her BP dropped again but spontaneously increased to systolic BP of 122. No further treatment was given and BP rebounded to 190/100.

On [redacted] 2009 (post enrollment day 1) MRI revealed increased signal intensity of the left fronto-temporal parietal basal ganglia region in the distribution of the left MCA causing minimal mass effect. No hemorrhage was seen. NIHSS was 19.

On [redacted] 2009 (post enrollment day 4) NCT revealed left MCA infarction with typical evolutionary changes. The subject had progressively deteriorating neurological function and was essentially non-responsive; NIHSS increased to 30 **(SAE # 002)**.

On [redacted] 2009 a family member described the subject having occasional tremor/shaking that was very brief. Due to the subject's "do no resuscitate" status no treatment or investigation was performed.

On [redacted] 009 the subject was non-responsive and NIHSS remained at 30. She was discharged from the hospital to home with hospice care. She expired on 04-Jul-2009 at 01:58 (post enrollment day 13). Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
12-May-2008	**001**	**001**	***414 - Neurological worsening**	**N/A**	**N/A**
12-May-2008	001	002	812 - Fever	N/A	N/A
14-May-2008	003		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 79-year-old Caucasian female with a history of atrial fibrillation, hypertension, hyperlipidemia, depression, Fuch's dystrophy, squamous cell skin cancer and a remote history of breast cancer. Medications at admission included: Sertaline, Simvastatin, Atacand, and Warfarin.

Current Stroke Onset and SENTIS Enrollment: The subject's stroke onset began at 13:15, 1[redacted]-2008. Symptoms at presentation included inability to speak and move her right side. The subject was in atrial fibrillation, her INR was 2.0. CT scan at admission revealed hyperdensity of the left middle cerebral artery (MCA) and left insular ribbon sign. No bleeding was noted. A thrombectomy procedure was initiated but was aborted due to the tortuosity of the left internal carotid artery. The sponsor granted a waiver to enroll the subject into the SENTIS trial with an INR of 2.0. Baseline NIHSS was 18. The subject was randomized to the control arm of the SENTIS trial at 19:45, 11-May-2008, 6.5 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2008 (the day of enrollment), the 6 hour follow-up NIHSS remained at 18.

On [redacted]-2008 (post enrollment day 1) in the morning, the subject's condition was unchanged. At 13:57 CT scan revealed an interval development of marked hypodensity involving the left frontal, parietal, and temporal lobes consistent with left middle and anterior cerebral artery infarction. There was mass effect and edema with compression of the left lateral ventricle, left to right 8mm midline shift, as well as some effacement of the suprasellar cistern on the left. There was no acute hemorrhage. At 19:00 the 24 hour NIHSS increased to 31 **(SAE #001)**. The subject was comatose with left pupil fixed at 4mm. Neurosurgery was consulted for possible intervention. Given the poor prognosis, the subject's family decided against decompression surgery. Aggressive medical care was instituted to allow for the family to arrive.

On 1[redacted]2008 (post enrollment day 2), the subject's temperature spiked to 38.8ºC **(AE #002),** which was not treated due to the subject's rapidly deteriorating condition. The family asked for care to be withdrawn. Comfort care measures only were instituted on [redacted]2008. She expired at 14:55 that day. Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Dec-2009	**001**	**004**	***414 - Neurological worsening**	**N/A**	**N/A**
04-Dec-2009	001	002	204 - Aspiration pneumonia	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Dec-2009	002	003	303 - Urinary Tract Infection	N/A	N/A
17-Dec-2009	014		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 91-year-old Caucasian male with past medical history of stroke in Feb-2009 (mRS=1), transient ischemic attack in Oct-2009, hypertension, hyperlipidemia, non insulin dependent diabetes, bilateral carotid stenosis of 60-99% via Doppler, low grade papillary urethelial carcinoma, kidney stones, status post urethral stent and recent lithotripsy, and benign prostatic hypertrophy. Medications at admission included: Atenolol, Benicar, Crestor, Flomax, and Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject developed acute onset of stroke at 08:15, [redacted]-2009. Symptoms at presentation included right arm weakness, right facial droop and expressive aphasia. The subject's symptoms began to resolve but never came back to baseline. CT scan at admission revealed no evidence of acute ischemic stroke or hemorrhage. The subject had recurrence of the symptoms at around 10:15. His symptoms fluctuated with NIHSS of 3-9 over the next 4 hours. An angiogram revealed complete bilateral ICA occlusions at their origins which appeared chronic in nature; no interventional treatment was recommended. A repeat CT scan revealed no acute intracranial changes. Baseline NIHSS was 9. The subject was randomized to the control arm of the SENTIS trial at 15:15, [redacted]-2009, 7.0 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) at 16:00, the NIHSS improved to 6.

On [redacted]-2009 (post enrollment day 1), the subject's neurological condition significantly deteriorated **(SAE #004)**. The 24-hour NIHSS was 22. Follow-up CT scan showed left MCA infarction with surrounding edema and mild effacement of the body of the left lateral ventricle. The subject was placed in the Trendelenberg position to enhance brain perfusion. He required frequent suctioning due to increased secretions since he had failed the swallow test. A chest x-ray showed indications for pneumonitis with a small left pleural effusion; additional opacity was noted at the right lung base which slightly represented atelectasis; however, developing infiltrate could not be entirely excluded **(AE #002).** Atrovent was given to reduce respiratory secretions.

On [redacted]-2009 (post enrollment day 2), the subject had low grade fever. Urinalysis was significant for leukoesterase, white blood cells and blood **(AE #003)**. Pan cultures were sent. There was no growth in blood and urine cultures in the first two days; Levaquin and Clindamycin were started.

On [redacted]-2009 (post enrollment day 4), his NIHSS was 15. The family requested a palliative care consult. The subject was on do not resuscitate/do not intubate orders due to his poor prognosis for meaningful recovery. The subject was placed on comfort care only and discharged to a hospice unit on [redacted]-2009. He died on the following day. Cause of death was adjudicated as systemic complications related to stroke.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
31-Jul-2008	000	002	806 - Agitation/Excitation	N/A	N/A
02-Aug-2008	**002**	**001**	**113 - Myocardial infarction, non-Q wave**	**N/A**	**N/A**
02-Aug-2008	002	003	814 - Sleeping Disturbance/Disorder	N/A	N/A
11-Aug-2008	**011**	**004**	**412 - HT, no concomitant mass effect**	**N/A**	**N/A**
25-Aug-2008	**025**	**005**	***899 - Other: Complications of diabetes and vascular disease**	**N/A**	**N/A**
25-Aug-2008	025		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 85-year-old Caucasian female with a past medical history of insulin dependent diabetes, hypertension, hyperlipidemia, peripheral vascular disease with claudication and amputation of the right large toe (six weeks prior to admission), transient ischemic attack ([redacted]-2008), osteoporosis, depression, chronic obstructive pulmonary disease, gastro-esophageal reflux disease, hypothyroidism, coronary artery disease (prior myocardial infarction and prior angioplasty with stent placement), sick sinus syndrome with pacemaker implant, chronic atrial fibrillation, chronic dependent edema, treatment for H. pylori infection, appendectomy, cholecystomy, left parotid tumor removal and ovarian cyst removal. Medications at admission included: Plavix, Aspirin, Norvasc, Synthroid, Effexor, Dioxin and Lescol. The subject had refused Coumadin therapy.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke onset at 17:00 on [redacted]-2008. Symptoms at presentation included slurred speech and left-sided weakness. CT scan at admission was essentially unremarkable, however a perfusion CT scan done at 18:25 showed diminished time to peak perfusion and delayed blood flow involving the right temporal lobe, lateral occipital lobe and inferior right frontal lobe (approximately 2/3 of the dorsal right MCA territory). Baseline NIHSS was 13. The subject was randomized to the control arm of the SENTIS trial at 00:15 on [redacted]-2008, 7.3 hours from the time of symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject showed signs of agitation and confusion intermittently throughout the hospitalization, beginning the day of enrollment. She was treated with Ativan and Haldol **(AE #002).** Her 24 hour NIHSS was recorded at 27, but was deemed invalid due to the sedation. "Do not resuscitate" status was confirmed in the medical record beginning of [redacted]-2008 (post enrollment day 1).

On [redacted]-2008 (post enrollment day 2), the subject complained of chest pain that was treated with 2 sublingual nitroglycerine tablets. Her electrocardiogram showed paced rhythm, and her troponin levels peaked at 1.71. A cardiology consult was obtained; it was determined that the subject had a non-Q wave myocardial infarction **(SAE #001).** Nitropaste was ordered and no further episodes of chest pain were reported. Also on this date, the subject was noted to have episodes of sleep apnea **(AE #003)**. A pulmonary consult documented that the episodes were likely drug-induced, but suggested a sleep apnea workup in the future**.**

On [redacted]-2008 (post enrollment day 4), the subject was transferred to the rehabilitation floor.

On [redacted]g-2008 (post enrollment day 11), the subject had three episodes of increased lethargy with thickened speech. NCT scan showed focal intracerebral hemorrhage **(SAE #004)**. Neurology was re-consulted; Lovenox and aspirin were discontinued, and the subject was transferred from the rehabilitation floor to a regular floor to monitor her neurological status. Follow up CT scan on [redacted]2008 showed a subacute right temporal infarct with two small focal areas of hemorrhage without mass effect or midline shift. On [redacted]-2008, a CT scan showed stable hemorrhagic transformation of the right fronto-parietal subacute infarct.

The subject was discharged from the hospital on 1[redacted]-2008 to home.

On [redacted]2008 (post enrollment day 25) the subject expired at home. The cause of death listed on the death certificate is "complications of diabetes and vascular disease" **(SAE #005).** Cause of death was adjudicated as systemic complications unrelated to stroke.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
29-Oct-2008	**001**	**001**	***404 - HT, likely contributing to mass effect**	**N/A**	**N/A**
29-Oct-2008	001	004	117-Tachycardia	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
30-Oct-2008	**002**	**002**	**108 - Congestive Heart Failure**	**N/A**	**N/A**
02-Nov-2008	005	901	812 - Fever	N/A	N/A
03-Nov-2008	006	005	603 - Electrolyte imbalance	N/A	N/A
04-Nov-2008	007	006	116 - Bradycardia	N/A	N/A
05-Nov-2008	008		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 88-year-old Caucasian male with a past medical history of coronary bypass surgery one year ago, chronic atrial fibrillation (not on Coumadin), myeloproliferative disorder with chronic thrombocytopenia and platelets routinely about 50,000 (no known problems with bleeding), hyperlipidemia, hypertension, hypothyroidism, vertigo and acid reflux disease. Medications at admission included: Zetia, Altace, Lasix, Lopressor, Digoxin, Antivert, Synthroid, Nexium, Norpace, Aspirin and potassium.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke onset at 12:15 on [redacted]008. Symptoms at presentation included left-sided weakness and a left facial droop. CT scan at admission revealed no evidence of acute infarct. Electrocardiogram showed atrial fibrillation with controlled ventricular rate and right bundle branch block. A waiver was granted to enroll the subject into the SENTIS trial with chronically low platelet count at the discretion of the Investigator. Baseline NIHSS was 18. The subject was randomized to the control arm of the SENTIS trial at 17:30 on [redacted]-2008, 5.3 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2008 (post enrollment day 1), a 24 hour CT scan showed a new hypodensity involving the right basal ganglia suggesting a small developing hemorrhage **(SAE #001)**. No significant mass effect was noted. In view of the subject's thrombocytopenia, a hematology consult was obtained. Non-sustained ventricular tachycardia **(AE #004)** was noted on the telemetry monitor; the arrhythmia self terminated.

On [redacted]2008 (post enrollment day 2), an echocardiogram showed an ejection fraction of 35-45% with mild to moderate tricuspid and aortic regurgitation and a possible pleural effusion. A new diagnosis of congestive heart failure **(SAE #002)** was made and a cardiology consult was obtained. The subject was short of breath and Coreg, Altace and Lasix were initiated. He was later noted to have Cheyne stokes respirations.

On [redacted]-2008 (post enrollment day 3), a CT scan showed additional hemorrhagic conversion with intraventricular extension and minimal right to left shift **(update to SAE**

#001). No NIHSS was recorded in the notes that day, but by the next day, the subject's NIHSS increased to 23. Aspirin therapy was held. The subject's family requested "do not resuscitate" status.

On [redacted]-2008 (post enrollment day 5), the subject developed a low-grade fever of 100.5ºF, which was not treated **(AE #901).** Over the next several days, the subject's condition continued to deteriorate. A chest x-ray on [redacted] 2008 showed a moderate left pleural effusion with atelectasis or infiltrate at the left base. The subject was diaphoretic and had a systolic blood pressure in the 70s. Hypokalemia was noted and potassium supplements were given **(AE #005).**

On [redacted] 008 (post enrollment day 7), the subject became markedly obtunded and lethargic. Sinus bradycardia (heart rate in the 30's) was noted intermittently on the monitor, no treatment was given **(AE #006).** The subject expired on the following day. The cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Dec-2008	**001**	**001**	***414 - Neurological worsening**	**N/A**	**N/A**
10-Dec-2008	006	002	407 - Seizure	N/A	N/A
11-Dec-2008	007		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 92 year-old Caucasian male with a past medical history of, hypertension, right bundle branch block, hyperlipidemia, Paget's disease, left knee cyst, gout, hypothyroidism, diverticulosis, macular degeneration, osteoporosis, benign prostatic hypertrophy, hearing loss, and bilateral cataract surgery. Medications at admission included: Levoxyl, Celebrex, Nadolol, Lyrica, Niacin, Aspirin, Allopurinol, Flomax, Actonel, multivitamins, vitamin B 12, and calcium.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 09:00 on [redacted]-2008. Symptoms at presentation included right-sided weakness and aphasia. CT perfusion scan at admission revealed an early infarct involving a single left MCA branch. Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 21:25 on [redacted]-2008, 12.4 hours from last known normal.

NeuroFlo Procedure: N/A

Post Enrollment Course: On [redacted] 2008 (post enrollment day 1), the subject's 24 hour NIHSS increased to 25 from 16 at the 6 hour assessment **(SAE #001).** A family member stated that the subject would not want to be in a nursing home, so he was referred to hospice care on [redacted] 2008 (post enrollment day 4) with NIHSS of 23.

On [redacted]-2008 (post enrollment day 6), the subject was noted to have seizure activity on two separate occasions and was treated with valproic acid suppositories **(AE #002).**

The subject expired on [redacted]-2008 (post enrollment day 7). Cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
22-Feb-2009	000	002	605 - Dyslipidemia / Hypercholesterolemia	N/A	N/A
23-Feb-2009	001	001	199 - Cardiac Other: Intra-atrial septal aneurysm	N/A	N/A
25-Feb-2009	003	003	303 - Urinary Tract Infection	N/A	N/A
13-Mar-2009	**019**	**004**	***409 - New ischemic stroke**	**N/A**	**N/A**
15-Mar-2009	021	005	603 - Electrolyte imbalance	N/A	N/A
18-Mar-2009	024	006	899 - Other: Swollen tongue	N/A	N/A
19-Mar-2009	**025**	**902**	***805 - Sepsis**	**N/A**	**N/A**
24-Mar-2009	030		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 76-year-old Caucasian female with a past medical history of hypertension and hypothyroidism, who also complained of sweats and increased thirst over the last few days. Medications at admission included Lisinopril and Synthroid.

Current Stroke Onset and SENTIS Enrollment: The subject was last seen normal by her husband at 12:00 on [redacted]-2009. Symptoms at presentation included facial droop, slurred speech and difficulty walking. CT scan at admission revealed no definite evidence of early acute changes. CT perfusion scan at admission revealed a large area of perfusion deficit in the right middle cerebral artery (MCA) territory. Baseline NIHSS was 8. The subject was randomized to the control arm of the SENTIS trial at 19:30, [redacted]-2009, 7.5 hours from last known normal.

NeuroFlo Procedure: N/A

Post Enrollment Course**:** On [redacted]-2009 (the day of enrollment), the subject's LDL was elevated **(AE #002)** and statins were initiated.

On [redacted]-2009 (post enrollment day 1), an echocardiogram revealed an intra-atrial septal aneurysm without intracardiac shunt **(AE #001).** An echocardiogram showed no cardioembolic source for her stroke.

On [redacted] 2009 the subject's urine culture was positive **(AE #003)** and antibiotics were started**.** She was discharged from the hospital to a rehabilitation facility on the same day and discharged to home on [redacted] 2009.

On [redacted]-2009 (post enrollment day 19), the subject decided to walk around her house with her walker. A few minutes later, her husband found her unresponsive on the floor. Her breathing was labored. The subject was intubated and transported to the emergency room. A chest x-ray showed bilateral pleural effusions and minimal basilar atelectasis. On exam the subject exhibited some semi-purposeful movements with her left arm, but posturing movements on the right side. Initial NCT showed little change from her prior admission, but a repeat CT on [redacted]-2009 revealed an acute ischemic infarct involving a large portion of the left MCA territory **(SAE #004).**

On [redacted]-2009 (post enrollment day 21), the subject's serum potassium was 3.3; replacements were given **(AE #005)**.

A CT scan on [redacted]-2009 (post enrollment day 24) showed an evolving infarct with mass effect on the left. The subject's tongue had started to swell **(AE #006)**, and moist dressings were applied. On the following day the subject had fever of 101.5 degrees and tachycardia. Sputum and urine cultures were positive **(SAE #902)**; Vancomycin and Maxipime were initiated.

The family struggled with the idea of withdrawal of life support, but on [redacted]-2009 (post enrollment day 28), they agreed and the subject was extubated. A nasal trumpet was placed to keep her airway open, and she did breathe spontaneously but remained unresponsive. The next day the subject was transferred to hospice care and expired on [redacted] 2009 (post enrollment day 30). Cause of death was adjudicated as systemic complications associated with a new stroke.

Subject [redacted], enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
04-Sep-2008	**001**	**001**	***414 - Neurological worsening**	**N/A**	**N/A**
06-Sep-2008	003	002	205 - Infectious pneumonia	N/A	N/A
09-Sep-2009	006		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 83-year-old Caucasian female with past medical history of hypertension and hyperlipidemia. Medications at admission included: Norvasc, Tenormin, Zestoretic, Niacin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 15:00, [redacted]-2008. Symptoms at presentation included left-sided weakness and slurred speech. CT scan at admission revealed decreased attenuation in the left parietal lobe distribution near the vertex possibly representing changes of early ischemia. Baseline NIHSS was 14. The subject was randomized to the control arm of the SENTIS trial at 23:32, [redacted] 2008, 8.5 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject's condition worsened within 12 hours following enrollment. The 6 hour NIHSS had increased to 19 due to worsening of left-sided symptoms and speech **(SAE #001)**. Imaging performed the morning of [redacted]-2008 revealed thrombosis at the basilar tip and brainstem and cerebellar infarctions. Intra-arterial tPA was administered for this new finding but it was not successful at dissolving the clot. The subject was soon intubated to protect her airway. The 24 hour NIHSS on [redacted]-2008 increased to 28.

On [redacted]-2008 the subject had a positive sputum culture, fever and elevated white blood cell count (WBC). Zosyn was started to manage pneumonia **(AE #002)**.

The 4 day NIHSS on [redacted]008 increased to 31. The subject's family chose to make her "do not resuscitate" and provide comfort care measures only. The subject passed away in the hospital on 0[redacted] 2008, post enrollment day 6. Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
26-Feb-2006	000	001	118 - Atrial Fibrillation	N/A	N/A
26-Feb-2006	000	901	606 - Hyperglycemia	N/A	N/A
27-Feb-2006	001	009	403 - Cerebral edema	N/A	N/A
27-Feb-2006	001	005	405 - HT, probably not contributing to mass effect	N/A	N/A
02-Mar-2006	004	002	303 - Urinary Tract Infection	N/A	N/A
02-Mar-2006	004	003	397 - Genital Other: Vaginal bleeding	N/A	N/A
02-Mar-2006	004	902	116 - Bradycardia	N/A	N/A
04-Mar-2006	006	004	299 - Pulmonary Other: Cough	N/A	N/A
12-Mar-2006	**014**	**007**	**118 - Atrial Fibrillation**	**N/A**	**N/A**
12-Mar-2006	**014**	**008**	***805 - Sepsis**	**N/A**	**N/A**
18-Mar-2006	020		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 85-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, atrial fibrillation and a prior left-sided cerebral infarction (mRS = 0). The subject had a laparoscopic hysterectomy for endometrial carcinoma four days prior to this admission and was recovering at home. Medications at admission included: Atenolol, Hydrochlorothiazide, Simvastatin, Digoxin, Aspirin and Coumadin, but she had been off of her Coumadin due to the surgery.

Current Stroke Onset and SENTIS Enrollment: The subject was last seen normal at 09:30 on [redacted]-2006. Symptoms at presentation included left-sided weakness and altered mental status. CT scan at admission revealed acute infarcts of the right MCA and PCA territories. Baseline NIHSS was 15. The subject was randomized to the control arm of the SENTIS trial at 13:00, [redacted] 2008, 3.5 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2008 at admission, the subject's electrocardiogram (ECG) showed atrial fibrillation and treatment with heparin was started **(AE #001)**. Sliding scale insulin was initiated for elevated blood glucose **(AE #901).**

A CT scan done on [redacted]-2006 (post enrollment day 1) showed evolving right MCA and PCA territorial infarcts **(AE #009)**. An MRI scan revealed "punctate hyperdensities

at the lateral margins of the lentiform nuclei which may represent artifact versus petechial hemorrhage" **(AE #005)**. "Increased edema and mass effect" were also visualized. The subject's NIHSS was 14. Heparin therapy was suspended temporarily.

On [redacted] 2006 (post enrollment day 4), the subject developed a urinary tract infection **(AE #002)** that was treated with ciprofloxacin. Vaginal bleeding **(AE #003)** was also noted, and was thought to be due to heparin administration following the laparoscopic surgery. The subject's serum digoxin level was elevated; her ECG showed intermittent bradycardia **(AE #902)** that spontaneously resolved.

On [redacted] -2006 (post enrollment day 6), the subject had a moist cough that required naso-tracheal suctioning **(AE #004)**.

On [redacted] 2006 (post enrollment day 12), the subject's urine culture was again positive, ciprofloxacin was restarted **(cont. of AE #002)**. The subject was discharged to a transitional care unit on the following day.

On [redacted] 2006 (post enrollment day 14), the subject had an episode of atrial fibrillation with rapid ventricular response **(SAE #007)**. She was treated with carotid massage and diltiazem with good results. She also had a fever of 103ºF and elevated white blood cell count. The treating physician determined that the subject was most likely septic **(SAE #008)**, so blood and urine cultures were drawn and Vancomycin was initiated. The subject was initially transferred back to the inpatient acute care unit, but her children decided to take the subject home with hospice care.

The subject expired on [redacted] -2006 (post enrollment day 20). Cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted] enrolled [redacted] -2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
03-Apr-2008	**000**	**001**	***414 - Neurological worsening**	**N/A**	**N/A**
03-Apr-2008	000	901	603 - Electrolyte imbalance	N/A	N/A
04-Apr-2008	001	003	803 - Cellulitis	N/A	N/A
06-Apr-2008	**003**	**005**	***108 - Congestive Heart Failure**	**N/A**	**N/A**
07-Apr-2008	004		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 70-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, atrial fibrillation, chronic obstructive

pulmonary disease (COPD), emphysema, insulin dependent diabetes, and prior MI with coronary artery bypass graft surgery greater than 10 years ago. Medications at admission included: Coumadin, Spironolactone, Prevacid, Allopurinol, Bisoprolol, Ramipril, and Lasix.

Current Stroke Onset and SENTIS Enrollment: The subject had sudden onset of stroke symptoms at 05:30 on [redacted]008. Symptoms at presentation included right-sided weakness and difficulty with speech. CT scan at admission revealed a hyperdense left ICA; a transcranial Doppler (TCD) showed decreased flow in the left MCA. Although, there was some question of past congestive heart failure, cardiac exam appeared normal. Baseline NIHSS was 7. The subject was randomized to the control arm of the SENTIS trial at 12:20, 03[redacted]2008, 6.8 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2008 (the day of enrollment) at 19:00, the subject's NIHSS worsened to 14 **(SAE #001)**. The subject was on Lasix at baseline, potassium 4.6, and treated with supplemental potassium **(AE #901)**. Treatment with Kayexalate for hyperkalemia (potassium 5.4) was initiated on [redacted]-2008.

On [redacted]2008 (post enrollment day 1), the subject was noted to have a swollen, warm, painful right arm, and a painful right leg **(AE #003)**. Venous Doppler did not reveal deep vein thrombosis.

The 24 hour follow-up MR on [redacted]-2008 revealed an elliptical area of hyperintensity of T2 imaging that "appeared to be an acute parenchymal hemorrhage in the left basal ganglia extending from lentiform nucleus across the anterior limb of the internal capsule" **(part of SAE #001).** There was mild mass effect, and a thin rim of edema. In addition, there was a suspected subarachnoid hemorrhage in the left frontal sulci. MRA demonstrated visualization of the supraclinoid ICA, A1 and M1 segments indicating recanalization of the MCA.

On [redacted]2008 (post enrollment day 3) at 08:45, the subject was in rapid uncontrolled atrial fibrillation and congestive heart failure with respiratory distress **(SAE #005)**. Right lower lobe lung infiltrates were noted and were suspected to be related to aspiration pneumonia **(part of SAE #005)**. The subject was off her medications at that time and Bisoprolol was restarted. Due to the subject's significant co-morbidities and severity of her stroke, intubation was not felt to be in her long-term best interest.

On [redacted]2008 (post enrollment day 4), with continued severe neurological deficit (NIHSS was 23), the family decided to make the subject do not resuscitate/do not intubate. The subject suffered cardiopulmonary arrest and expired later that day at 15:35. The cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Nov-2008	**000**	**001**	***414 - Neurological worsening**	**N/A**	**N/A**
16-Nov-2008	011		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 83-year-old Caucasian female with past medical history of arthritis. Medications at admission included: Celebrex, Codeine for joint pain, Prednisone and Synthroid.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:45, [redacted]-2008. Symptoms at presentation included: complete right side paralysis, right facial droop, and left gaze deviation. CT scan at admission revealed no acute changes. Baseline NIHSS was 18. The subject was randomized to the control arm of the SENTIS trial at 12:58, [redacted]-2008, 13.2 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject's neurological status worsened in the 6 hours following enrollment, with NIHSS increasing to 26 **(SAE #001).** The 24 hour NCT showed development of a large ischemic infarction involving the left parietal lobe (within the posterior division of the left MCA territory) and evidence of an associated infarction involving left internal capsule. No evidence of intracranial hemorrhage was present.

The subject had decreased level of consciousness and was very difficult to arouse with left gaze deviation and a flaccid right side. She had previously expressed wishes regarding end of life care, stating she did not want to be on life support nor be in a nursing home facility. The family requested terminal compassionate care on 06-Nov-2008. The subject expired on [redacted]-2008, post enrollment day 11. Cause of death was adjudicated as stroke.

Subject [redacted] enrolled 0[redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
10-Apr-2008	001	005	601 - Anemia	N/A	N/A
10-Apr-2008	001	004	301 - Renal dysfunction	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Apr-2008	008	003	602 - Thrombocytopenia	N/A	N/A
17-Apr-2008	008	901	899 - Other: Edema	N/A	N/A
18-Apr-2008	009	002	118 - Atrial Fibrillation	N/A	N/A
28-Apr-2008	019	903	811 - Depression	N/A	N/A
Unk-Apr-2008		902	815 - Skin irritation	N/A	N/A
03-May-2008	**024**	**001**	***202 - Respiratory failure: Pulmonary embolism and pneumonia**	**N/A**	**N/A**
03-May-2008	024	904	207 - Pulmonary Embolism: Right-sided pulmonary emboli	N/A	N/A
21-May-2008	042		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 81-year-old Caucasian female with past medical history of Sjögren's syndrome status post Whipple procedure, vasovagal attacks, stroke (mRS=1), glaucoma, hypertension, hiatal hernia, diverticulosis, bowel obstruction, osteoporosis, cholecystectomy, hysterectomy, gastroesophageal reflux disease and breast cancer status post left mastectomy.

The subject presented to the emergency room with diffuse abdominal pain on [redacted] 2008 and was admitted. Medications prior to admission included: Colace, Plavix, Senokot, Percocet, Vasotec, Amlodipine, ASA, Prednisone, and Zantac. During the hospital stay, the subject was diagnosed with pancreatitis and electrolyte abnormalities, including hyponatremia and hypokalemia, which were managed medically. She was also being treated with antibiotics for urinary tract infection.

Current Stroke Onset and SENTIS Enrollment: The subject had onset of stroke symptoms at 05:40, [redacted]-2008, while inpatient. Symptoms included left arm plegia, dysarthria, facial palsy and partial hemianopsia. CT scan revealed bilateral lacunar-type infarctions seen adjacent to the insular rib in both the left and right hemispheres and diffuse cortical atrophy consistent with the subject's age. In addition there were hypodensities within the periventricular and subcortical white matter of the left insula, right basal ganglia and the right parietal lobe. Apical bilateral pleural effusions with underlying alveolar disease and fibrosis were noted on CTA. Baseline NIHSS was 8. The subject was randomized to the control arm of the SENTIS trial at 11:05, [redacted] 2008, 5.4 hours from symptom onset.

NeuroFlo Procedure: N/A.

Post-Enrollment Course: The subject's pancreatitis resolved while the subject was under the care of the Neurosciences intensive care unit (ICU). The 24 hour NIHSS on [redacted]-2008 decreased to 6. The 24 hour follow-up CT scan revealed several small subcortical hypodensities throughout the right cerebral hemisphere. There was a stable hypodensity in the left insula. No new sites of ischemia were observed.

On [redacted] 2008 (post enrollment day 1), the subject's hemoglobin (Hgb) dropped to 9.4g/dL **(AE#005)** from baseline of 10.2g/dL. The subject was given packed red blood cells (but no source or further information is available to determine amount). Hgb rebounded to 12.4g/dL the next day.

On [redacted]-2008 the subject developed acute renal dysfunction with a peak creatinine of 2.24 mg/dL **(AE #004)**, which was treated with hydration. Creatinine was still elevated at the time of hospital discharge.

On [redacted]-2008 (post enrollment day 8) the subject's platelet count decreased to 44,000/µL and she was diagnosed with thrombocytopenia **(AE #003)** which was treated with a bolus of Argatroban. Antibodies for heparin-induced thrombocytopenia were negative. The subject was also noted to have extensive subcutaneous edema **(AE #901)**. The medication log indicates that the subject received Lasix and Bumex during the index hospitalization.

A CT of the chest on [redacted]-2008 revealed alveolar infiltrates indicative of infection which had progressed when compared to a CT done on [redacted]-2008. The bilateral pleural effusions were again noted, as well as associated compressive atelectasis. The infectious disease department was consulted. The subject was transferred to the ICU on the following day with respiratory distress.

On [redacted] 2008 the subject developed paroxysmal atrial fibrillation **(AE #002)** which was easily controlled with IV Dilitiazem. She later converted to atrial fibrillation with resistance to Dilitiazem drip and was switched to Amiodarone with good return to normal sinus rhythm by 2[redacted]-2008. Subsequent to consultation, it was decided in the setting of atrial fibrillation and thromboembolic risk, not to give any additional Argatroban.

The subject was prescribed Remeron on [redacted]-2008 (post enrollment day 19) for situational depression and decreased appetite **(AE #903)**. The medication log also indicates that the subject received Ativan for anxiety during the index hospitalization.

The subject was discharged (with a low platelet count <100,000/µL) from the hospital on [redacted]-2008 to an in-patient rehabilitation facility. The discharge summary for the index hospitalization notes the subject developed pink macules and patches involving her chest and face **(AE #902),** while in the ICU, which eventually cleared with application of topical agents. This was interpreted as a possible drug-induced lupus in the setting of her known Sjögren's syndrome.

On [redacted] 2008 (post enrollment day 24), the subject was readmitted to the hospital for shortness of breath and fatigue suspicious of pneumonia **(SAE #001)**. She also was

confused, febrile, tachycardic, tachypneic, required increased oxygen, and had pyuria. Her urinary tract infection (Pseudomonas and Candida) was treated with Zosyn and Fluconazole. A chest x-ray revealed worsening of what was considered to be developing pneumonia. She was started on Vancomycin. A CT scan of the chest revealed right-sided pulmonary emboli **(AE #904)**. The subject was started on Lovenox while waiting for Coumadin to become therapeutic. Her platelet count had stabilized at 178,000/µL on [redacted]-2008.

On the evening of [redacted]-2008 (post enrollment day 36) the subject was evaluated for worsening respiratory distress and was tried on bi-level positive airway pressure (BiPAP), but was unable to sustain her oxygenation, tired out and eventually was intubated **(cont. of SAE #001)**. Subsequent chest x-rays showed worsening of the pneumonia. The subject required pressure support and went into renal failure **(cont. of AE#004)**, however, the family opted not to do dialysis. The family then decided to make her no resuscitation status, and on [redacted]-2008 the subject was changed to palliative care and was extubated. She died on [redacted]-2008 (post enrollment day 42) due to respiratory failure likely caused by pneumonia complicated by pulmonary emboli. Cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
07-Jun-2009	**000**	**901**	**414- Neurological worsening**	**N/A**	**N/A**
07-Jun-2009	000	001	404 - HT, likely contributing to mass effect	N/A	N/A
07-Jun-2009	000	004	806 - Agitation / Excitation	N/A	N/A
07-Jun-2009	000	002	603 - Electrolyte imbalance	N/A	N/A
08-Jun-2009	001	003	205 - Infectious pneumonia	N/A	N/A
10-Jun-2009	003	006	117 - Tachycardia	N/A	N/A
10-Jun-2009	003	005	503 - Nausea / Vomiting	N/A	N/A
28-Jul-2009	051		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 78-year-old Caucasian male with past medical history of stroke in 2006 with residual mild right-sided hemiparesis (mRS=1), hyperlipidemia, type II diabetes, hypertension and tobacco use.

The subject was admitted to a Veterans Administration (VA) hospital on [redacted]-2009 for stroke-like symptoms. He left against medical advice the next day but returned to the

hospital on [redacted]-2009 with recurrence and worsening of his symptoms of mild expressive aphasia and confusion. Onset of these symptoms was unknown. NCT and MRI on [redacted]-2009 showed possible acute to sub-acute infarct involving the head of the left caudate nucleus, an age-indeterminate infarct within the left temporal lobe, an old small infarct in the right cerebellum and moderate chronic small vessel ischemic changes. Carotid ultrasound showed 60% occlusion of the right ICA and complete occlusion of the left ICA. Medication at admission included: Aggrenox, Atenolol, Glipizide, Hydrochlorothiazide/Triamterene and Lisinopril.

Current Stroke Onset and SENTIS Enrollment: The subject was last known with symptoms of mild right hemiplegia, mild confusion and word-finding difficulty (mRS=1) at 22:30, [redacted]-2009, while still an in-patient at the VA hospital. Newly presenting symptoms included global aphasia, worsening of right-sided hemiparesis, sensory defect and difficulty following simple commands. CT scan revealed subacute infarct in basal ganglia and left temporal lobe with some maturing of left basal ganglia infarct since [redacted]-2009; no hemorrhage. The SENTIS site was contacted regarding possible transfer and study enrollment. No beds were available to allow quick transfer of the subject. The receiving physician proceeded to confirm the subject's eligibility for the trial over the phone. Baseline NIHSS was 17. The subject's family presented to the SENTIS site where they signed the SENTIS consent form. The receiving physician then randomized the subject to the control arm of the SENTIS trial at 10:55, [redacted]-2009, 12.4 hours since the last known previous "baseline" status, prior to the subject's transfer to the SENTIS site. The subject actually presented at the enrolling hospital at 14:45. [Note: A protocol violation has been documented. The site's IRB was notified and on-going education and training was conducted with the site.]

NeuroFlo Procedure: N/A.

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) the 6 hour NIHSS deteriorated to 20 **(SAE #901)**. MRI confirmed acute/subacute left MCA infarction involving the left temporal and parietal lobes and left basal ganglia with associated edema and mass effect, no midline shift or herniation, early subacute hemorrhage **(AE #001)** within the left basal ganglia most consistent with hemorrhagic transformation of the left MCA infarct, and chronic bilateral cerebellar infarcts. MRA showed complete occlusion of left MCA and partial ICA occlusion. The subject was generally agitated and combative with staff. He suffered abrasions on his knees from thrashing in bed **(AE #004)**. Medication and restraints were used to treat the agitation.

The subject's potassium, sodium, phosphorus, calcium were intermittently outside of normal range between admission and discharge **(AE #002)**. The electrolytes were replaced as needed.

On [redacted]-2009 (post enrollment day 1) the subject was noted to have a loose cough and crackles on respiratory exam. A chest x-ray performed the following day showed bibasilar densities and sputum culture was positive for pneumonia **(AE #003)**. The subject's respiratory rate was increased and he became hypoxic. Oxygen and antibiotic

therapy were administered along with a chest decongestant and respiratory treatments. The 24 hour NIHSS remained at 20.

On [redacted]-2009 (post enrollment day 2), NCT showed evolutionary changes of subacute left MCA infarct with vasogenic edema and areas of hemorrhagic conversion, the largest in the anterior left basal ganglia; persistent enfacement of the body and frontal horn of the lateral ventricle was slightly more pronounced on this study, no midline shift **(cont. of SAE #901).**

On [redacted]009 (post enrollment day 3) the subject began having runs of premature atrial contractions and heart rate up to 120 beats per minute **(AE #006)**. Lopressor was successful in decreasing the heart rate. Electrocardiogram (ECG) was within normal limits.

Also on 1[redacted]-2009 the subject vomited multiple times **(AE #005)**. Tube feeds were halted, the vomitus was suctioned and a nasogaastric tube was inserted. The subject concurrently had loose stools and twitching was noted in his leg. Stool culture was negative for clostridium difficile and electroencephalogram was negative for seizure. Another episode of vomiting was reported on the following day.

On [redacted]-2009 (post enrollment day 4) the 4 day NIHSS had deteriorated further to 25. NCT of the head was mostly stable compared to the scan on 09-Jun-2009. A follow-up NCT on [redacted]-2009 showed slightly decreased area of hemorrhagic conversion and decreased mass effect upon left lateral ventricle and decreased (1-2mm) midline shift. There was slightly more cytotoxic edema extending into the high left frontal lobe **(cont. of SAE #901)**.

The subject was discharged back to the VA hospital on [redacted]009.

The SENTIS site learned that the subject expired in a hospice facility on [redacted]-2009. The family did not return calls and the VA physician would not provide information about the post-discharge course or cause of death citing Health Insurance Portability and Accountability Act regulations. The cause of death was considered by the Principal Investigator and adjudicated by the DSMB as systemic complications associated with stroke.

Subject [redacted] enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Nov-2008	000	902	103 - Hypertension	N/A	N/A
18-Nov-2008	001	002	405 - HT, probably not contributing to mass effect	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
18-Nov-2008	**001**	**006**	**403 - Cerebral edema**	**N/A**	**N/A**
18-Nov-2008	001	008	303 - Urinary tract infection	N/A	N/A
18-Nov-2008	001	903	809 - Diabetes mellitus	N/A	N/A
19-Nov-2008	002	001	301 - Renal dysfunction	N/A	N/A
21-Nov-2008	004	003	117 - Tachycardia	N/A	N/A
23-Nov-2008	006	004	102 - Hypotension	N/A	N/A
30-Nov-2008	**013**	**005**	**202 - Respiratory failure**	**N/A**	**N/A**
02-Dec-2008	015	901	409 - New ischemic stroke	N/A	N/A
02-Dec-2008	**015**	**904**	**498 - Neuro Other Bleed: Subgaleal/ epidural hematoma**	**N/A**	**N/A**
02-Dec-2008	**015**	**007**	**601 - Anemia**	**N/A**	**N/A**
31-Dec-2008	044	009	199 - Cardiac Other: Left atrium thrombus	N/A	N/A
31-Dec-2008	**044**	**010**	***805 - Sepsis**	**N/A**	**N/A**
20-Jan-2009	064		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 57-year-old African American female with a past medical history of Type 2 diabetes, a prior stroke (mRS=0), fever, weight loss and unknown hypertension. Medications at admission included Metformin, but she was not compliant with her medications.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 11:30, [redacted]-2008. Symptoms at presentation included left-sided weakness and right-sided gaze preference. CT scan at admission revealed an acute ischemic infarct involving the right MCA territory without evidence of bleeding. White blood cells (WBC) were elevated on admission at 13.3. Baseline NIHSS was 18. The subject was randomized to the control arm of the SENTIS trial at 19:30, [redacted]-2008, 8.0 hours from last known normal.

NeuroFlo Procedure: N/A

Post Enrollment Course: On [redacted] 2008 (the day of enrollment), the subject's baseline blood pressure was 180/110. She was initially treated with permissive hypertension for her stroke, but was later given Captopril, Enalapril, hydrochlorothiazide, and Clonidine to control her blood pressure **(AE #902).**

On [redacted] 2008 (post enrollment day 1), the subject's 24-hour NIHSS had increased to 22. A CT scan showed an evolving right MCA infarct with hemorrhagic transformation and effacement of the sulci with minimal mass effect **(AE #002)**. A repeat CT scan on the following day showed increased edema with a 4mm midline shift **(SAE #006).**

Also on [redacted]-2008, urine analysis showed 4+ bacteria with WBC of 20, and the subject displayed fever and leukocytosis on the following day. Urine culture came back positive and urinary tract infection was treated with Levaquin **(AE #008).** The subject's blood glucose was 204; Glipizide was started **(AE #903).**

On [redacted]-2008 (post enrollment day 2), the subject's creatinine increased from 0.6 to 1.1 **(AE #001)**. The subject was treated with normal saline. The next day, the subject was more lethargic.

On [redacted]-2008 (post enrollment day 4), the subject was placed on sliding scale insulin to control her blood sugar **(AE #903, update).** She also had transient episodes of sinus tachycardia treated with labetolol **(AE #003)**. The subject was slightly more alert, but had rhonchi and secretions on chest exam. Temp remained at 38.0ºC. A chest x-ray revealed pulmonary edema with bibasilar airspace disease (probably atelectasis).

On [redacted]008 (post enrollment day 6), the subject became hypotensive, and received a fluid bolus for a systolic blood pressure of 99 **(AE #004)**. She also had diarrhea due to glucerna (C difficle negative x3). Continued episodes of tachycardia were observed, but a Holter monitor placed on [redacted]-2008 showed only brief runs of tachycardia, and no treatment was recommended by cardiology consult.

Over the next 6 days, the subject appeared to be slowly improving, with resolution of her diarrhea, better control of her diabetes, and slight neurological improvement.

On [redacted]-2008 (post enrollment day 13), the subject was more lethargic in the morning and became obtunded in the afternoon. She was placed on a ventilator **(SAE #005)**. A repeat CT scan showed cerebral edema with a >10mm midline shift and hydrocephalus **(SAE #006, update)**. The cause of the worsening edema was not apparent. The subject underwent a decompressive craniectomy on the following day [redacted]-2008), but her neurological status did not improve. The subject was taken back to the operating room on [redacted] 2008 for evacuation of a new cerebral hematoma **(SAE #904)**; again, there was no improvement in her neurological status**.** A new midbrain hypodensity consistent with infarction was noted **(AE #901).**

The subject's hemoglobin dropped below 10 for the first time, and stayed around 10 or below for the remainder of her hospitalization **(SAE #007)**. The subject's neurological status continued to fluctuate over the next several days despite treatment with mannitol and hypothermia. She remained intubated following surgery and was never extubated prior to her death.

On [redacted]-2008 (post enrollment day 17), the subject was in acute renal failure, with a creatinine of 1.5 which increased to 3.3 the next day; she had minimal urine output. The event gradually resolved over the next week **(AE #001, update)**.

Throughout December, the subject remained critically ill, intubated, and obtunded. She underwent a feeding tube placement on 10-Dec-2008 (post enrollment day 23). Attempts to wean her from the ventilator were unsuccessful; a tracheostomy was performed [redacted]-2008. On [redacted] 2008 (post enrollment day 35), she underwent placement of ventriculoperitoneal shunt **(SAE #006, update)**.

On [redacted] 2008 (post enrollment day 43), an angiogram was performed to rule out vasculitis; none was found. The following day, a TEE was performed for suspected endocarditis. None was seen, but a left atrial thrombus was discovered **(AE #009)**. The subject was placed on a heparin drip and warfarin was added to her regimen. She also had a bronchial alveolar levage performed; sputum culture was positive for Staph aureus and acinetobacter. Contact precautions were instituted but no treatment was initiated at this time **(SAE #010)**.

By [redacted] 2009 (post enrollment day 51), a chest x-ray showed pulmonary edema; the subject appeared to be in heart failure; digoxin and lasix were started. By [redacted]-2009 the pulmonary edema had worsened, and the subject's lasix dose was increased **(SAE #005, update)**.

On [redacted]-2009 (post enrollment day 57), the subject's blood cultures came back positive for enterobacter; she was treated with Cefipine **(SAE #010, update)**. Her hemoglobin had dropped to 7.0 and she was transfused with 2 units of packed red blood cells **(SAE #007, update)**.

On [redacted] 2009, the subject's family requested palliative care only. She was placed on a morphine drip for comfort. The subject expired on [redacted]-2009 (post enrollment day 64). The cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted], enrolled [redacted] 2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
06-Jul-2008	**002**	**001**	***414 - Neurological worsening**	**N/A**	**N/A**
08-Jul-2008	004		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 80-year-old Caucasian male with past medical history including hypertension, hyperlipidemia, old right frontal stroke (mRS=0),

and atrial fibrillation. Medications at admission included: Coumadin, Lisinopril, Lipitor, Metoprolol, Hydrochlorothiazide.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 07:00, [redacted]-2008. Symptoms at presentation included left-sided weakness and visual field deficit. CT scan at admission revealed no hemorrhage and right ICA occlusion. Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 13:35, [redacted] 2008, 6.6 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject was neurologically stable until the morning of [redacted] 2008 (post enrollment day 2). He exhibited increasing somnolence throughout the morning. Head CT showed evolving right hemispheric infarction with edema and midline shift with herniation **(SAE #001).** There was no hemorrhage. The family chose to withdraw all but comfort care measures. The subject died the morning of [redacted]-2008 (post enrollment day 4), while still hospitalized. The cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
14-Nov-2009	001	002	119 - Elevated cardiac enzymes	N/A	N/A
14-Nov-2009	001	003	699 - Lab/electrolyte Other: Elevated white blood cell count	N/A	N/A
14-Nov-2009	**001**	**901**	***404 - HT, likely contributing to mass effect**	**N/A**	**N/A**
14-Nov-2009	**001**	**001**	***409 - New ischemic stroke**	**N/A**	**N/A**
14-Nov-2009	001	902	603 - Electrolyte imbalance	N/A	N/A
15-Nov-2009	002		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 67-year-old Caucasian female with past medical history of hypertension, hyperlipidemia, Type II diabetes, possible transient ischemic attack, coronary artery disease with bypass surgery in 1997 and gout. She is a current smoker. Medications at admission included: Captopril, Norvasc, Imdur, Lasix, Klonopin, Aspirin, Clonidine, Lexapro, Glucovance, Metformin, Simvastatin and Zylorpriem.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 06:00, [redacted] 2009. Symptoms at presentation included left hemiplegia, visual defect

and dysarthria. CT scan at admission revealed <1/3 right middle cerebral artery (MCA) territory subtle hypodensity, no evidence of hemorrhage. CT arteriogram showed complete occlusion of the right internal carotid artery, high grade stenosis of the left common carotid, and atherosclerotic calcifications involving the proximal V1 segment of the left vertebral artery. Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 17:50, [redacted] 2009, 11.8 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: At 09:25 on [redacted] 2009 (post enrollment day 1) the subject's cardiac enzymes were elevated **(AE #002)**. There were no electrocardiogram (ECG) changes and due to drowsiness (sedated for MRI during the night) the subject was unable to communicate any presence of chest pain. At 11:10 CT showed prominent regions of acute/subacute infarct throughout much of the right MCA vascular territory with no significant midline shift or intracranial mass effect; although NIHSS was increasing. At 17:55 the cardiac enzymes had risen and a cardiac consult was ordered but not completed due to the subject's neurological decline.

Also on [redacted]-2009 the subject was noted to have elevated white blood cell count and granulocytes **(AE #003)** and was treated with antibiotics. The source of infection was not identified at the time of her death.

On the evening of [redacted]-2009 the subject was found to have left eye deviation and generalized stiffness. These symptoms were originally thought to be related to seizure activity coming from her cortical right hemispheric stroke and she was started on anti-seizure medications. The subject did not improve and was then found to have extension in the upper extremities with triple flexion in the lower extremities; a MRI was ordered. The MRI demonstrated a new prominent left basal ganglia hemorrhage with intra-ventricular extension **(SAE #901)**. Also noted were new left MCA and left anterior cerebral artery (ACA) territory infarcts that also involved the basal ganglia territory **(SAE #001)**.

The subject was noted to have an electrolyte imbalance that was treated with supplements **(AE #902)**.

Her family decided to withdraw care and the subject expired on [redacted]-2009, post enrollment day 2. Cause of death was adjudicated as new ischemic and hemorrhagic strokes.

Subject [redacted] enrolled [redacted]-2010

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-Jan-2010	001	001	118 - Atrial Fibrillation	N/A	N/A
28-Jan-2010	001	007	303 - Urinary Tract Infection	N/A	N/A
29-Jan-2010	002	002	115 - Patent foramen ovale (PFO)	N/A	N/A
30-Jan-2010	003	003	806 - Agitation/Excitation	N/A	N/A
30-Jan-2010	003	004	603 - Electrolyte imbalance	N/A	N/A
02-Feb-2010	**006**	**005**	***202 - Respiratory failure**	**N/A**	**N/A**
02-Feb-2010	006	901	103 - Hypertension	N/A	N/A
03-Feb-2010	**007**	**006**	***805 - Sepsis**	**N/A**	**N/A**
03-Feb-2010	007	008	301 - Renal dysfunction	N/A	N/A
03-Feb-2010	007		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 88-year-old Caucasian female with past medical history of hypertension, gastroesophageal reflux disease, hysterectomy, essential hand tremors and resection of colon polyps. Medications at admission included: calcium supplement, Norvasc, Nexium and Inderal.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 08:00, [redacted]-2010. Symptoms at presentation included aphasia, dysarthria, right facial droop and right hemiparesis. CT scan and CTA at admission revealed a left MCA occlusion with associated ischemic change in the left temporal region. Baseline NIHSS was 16. The subject was randomized to the control arm of the SENTIS trial at 20:10, [redacted]-[redacted]-2010, 12.2 hours from the last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2010 (post enrollment day 1) the subject had an ECG that revealed atrial fibrillation with periods of tachycardia **(AE #001)**. Digoxin was started.

Also on [redacted]-2010 the subject had a positive urinalysis **(AE #007),** although antibiotics were not started immediately. Urine culture was positive on [redacted] 2010 at which time antibiotics had already been initiated for pneumonia.

On [redacted]-2010 (post enrollment day 2) a routine trans-esophageal echocardiogram revealed a patent foramen ovale **(AE #002)**. No treatment was planned.

[redacted]2010 (post enrollment day 3) the subject became agitated **(AE #003)**. Seroquel was effective in controlling her agitation. The subject's potassium and calcium were also noted to be low **(AE #004)**. She was treated with potassium replacement.

On [redacted]-2010 (post enrollment day 6) the subject became lethargic and distressed. She had labored breathing, wheezing and rhonchi. She was febrile and had a cough. She vomited three times due to gag reflex from suctioning. IV antibiotics were initiated. Chest x-ray on the following day showed bilateral atelectasis and evidence of aspiration pneumonia. Her respiratory status continued to decline and she was intubated **(SAE #005)**. The subject had an episode of systolic blood pressure (BP)>200 and Cardene IV was prescribed **(AE #901)**.

On[redacted]-2010 (post enrollment day 7) she became septic **(SAE #006)**. Pan cultures were positive. Her hemoglobin was 9.2g/dl, hematocrit 29%, and white blood cell count was $1.7x10^3$/uL. The subject's oxygen saturation continued to decline and she was hypotensive (mean arterial pressure <50 at times). She developed renal failure exhibited by severe electrolyte imbalance and decreased urine output; creatinine level increased to 1.8 from 0.9 at baseline **(AE #008)**. Lasix was given. The subject's family chose comfort measures only. The subject expired later that day. Cause of death was adjudicated as systemic complications associated with stroke, specifically respiratory failure and sepsis.

Subject [redacted] enrolled 1[redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
12-Jul-2006	000	001	103 - Hypertension	N/A	N/A
13-Jul-2006	001	002	413 - Headache	N/A	N/A
13-Jul-2006	**001**	**003**	***414 - Neurological worsening**	**N/A**	**N/A**
16-Jul-2006	004		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 65-year-old Caucasian female with past medical history of coronary artery disease and MI status post percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass graft (CABG), insulin-dependent diabetes, hypertension, hyperlipidemia, and breast cancer with bone metastasis. Medications at admission included: Femara, Plavix, Avandia, Celexa, Synthroid, Nexium, Avapro, Digitek, Buspar, Coreg, Lipitor, Lasix, Flonasc, Zyrtec, Ambien, Clonazepam, Nitrostat, Aspirin, Novolin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 06:30, [redacted]-2006. Symptoms at presentation included decreased level of consciousness, gaze deviation, left facial droop, left hemiparesis, sensory loss and dysarthria. CT scan at admission revealed no definite acute infarct or intracranial hemorrhage. Baseline NIHSS was 18. The subject was randomized to the control arm of the SENTIS trial at 12:43, [redacted]-2006, 6.2 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: Starting in the evening of [redacted]-2006 (the day of enrollment) and until her death, the subject's blood pressure was difficult to control **(AE #001)**. IV labetalol was initiated.

On [redacted]-2006 (post enrollment day 1) the subject was treated with Tylenol and Vicodin for headache **(AE #002)**. NCT revealed right MCA acute infarct with mild mass effect and right side uncal herniation, but no evidence of bleeding. The 24-hour NIHSS progressed to 21 **(SAE #003)**.

In the morning of [redacted]-2006 (post enrollment day 4) the subject was found unresponsive in her room; pupils were fixed and dilated at 4mm with no corneal reflex bilaterally. She displayed decerebrate posturing with her left arm to noxious stimuli. NCT was ordered, but the subject suddenly became apneic when she was about to be transported for the exam. Cardiopulmonary resuscitation (CPR) was initiated. The subject's family asked that CPR be discontinued and the subject was pronounced dead at 10:44. Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
19-May-2007	**000**	**001**	***899 - Other: Esophageal cancer**	**N/A**	**N/A**
12-Jun-2007	**024**	**901**	**805 - Sepsis**	**N/A**	**N/A**
12-Jul-2007	054		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 71-year-old Caucasian male with past medical history of coronary artery disease with angina status post coronary artery bypass graft (CABG) in 1992, hypertension, hyperlipidemia, chronic back pain, depression and left pneumonectomy with a recent diagnosis of adenocarcinoma at the gastroesophageal junction with suspicion of liver and lung metastases. The subject had been using significant amounts of oxycodone prior to admission for abdominal and back pain

presumably related to the cancer. The subject also had a pre-existing dysphagia related to the gastroesophageal tumor. He was also noted during current admission to have a submandibular mass, for which the family deferred further work-up. Medications at admission included: Lexapro, Aspirin, Avapro, Vytorin, and Oxycontin.

Current Stroke Onset and SENTIS Enrollment: The subject had onset of stroke symptoms at 09:[redacted] 2007. Symptoms at presentation included right facial droop, decreased speech output and decreased movement of his right side. CT scan at admission revealed a dense left MCA territory. Baseline NIHSS was 6. The subject was randomized to the control arm of the SENTIS trial at 14:31,[redacted]-2007, 4.9 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: During the hospitalization, the subject suffered from multiple complaints related to the progressive malignancy **(SAE #001),** including refractory hiccups treated with thorazine and non-cardiac chest pain and back pain. A percutaneous endoscopic gastrostomy tube was placed on [redacted]-2007 due to progressively worsening dysphagia that was evaluated to be secondary to dyscoordination of pharyngeal muscles due to stroke and malignancy.

The subject's neurological status improved throughout the hospitalization despite co-morbidities. The 4 day NIHSS on [redacted]-2007 decreased to 4. The subject was discharged from the hospital on [redacted]-2007 to home with home health care.

On [redacted] 2007 (post enrollment day 24), the subject was admitted with abdominal pain (esophageal cancer progression) to another hospital. The subject was thought to be septic **(SAE #901)** with elevated white blood cell (WBC) count of 22 and hypotension. Blood cultures were sent. Chest x-ray noted complete opacification of the left lung (unsure if causality secondary to effusion or surgical origin). The subject was treated with broad spectrum antibiotics, rehydration, antihypertensives were held and the subject was treated with continued hydration. The subject's WBC and blood pressure started to improve.

On [redacted] 2007 the subject had a near syncopal episode with gastrointestinal bleeding that required transfusion of 3 units of packed red blood cells. An endoscopy revealed an obstructive tumor in the esophagus that was determined to be the source for the bleeding **(cont. of SAE #001).**

The family chose to discontinue the subject's care and to provide comfort measures only. The subject was discharged from this hospitalization on [redacted]-2007 to home with hospice care. The subject expired on [redacted]-2007, post enrollment day 54. Cause of death was adjudicated as systemic complications unrelated to stroke.

Subject [redacted], enrolled [redacted] 2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
29-Jan-2007	000	002	209 - Respiratory dysfunction	N/A	N/A
30-Jan-2007	**001**	**003**	***414 - Neurological worsening**	**N/A**	**N/A**
Unk-Jan-2007		901	602 - Thrombocytopenia	N/A	N/A
Unk-Jan-2007		902	303 - Urinary Tract Infection	N/A	N/A
01-Feb-2007	003		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 70-year-old Pacific Islander male with past medical history of non insulin dependent diabetes, hypertension, coronary artery disease (CAD), atrial fibrillation, cardiomegaly, asthma, chronic obstructive pulmonary disease (COPD), and stage I lung cancer in 2005 status post radiation and chemotherapy. Medications at admission included: Digoxin and an antihypertensive agent but stopped all medications recently.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 20:00, [redacted]-2007. Symptoms at presentation included slurred speech, left-sided facial droop, left-sided weakness, and some confusion. CT scan at admission was reported negative. However; the neurologist noted that there was blurring of the gray-white junction and effacement of the sulci in the right hemisphere. The CT perfusion scan showed a large evolving infarct of the right hemisphere. Baseline NIHSS was 18. The subject also presented with atrial fibrillation with heart rate of 50s and Digoxin was started. The subject was randomized to the control arm of the SENTIS trial at 03:54, [redacted]-2007, 7.9 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2007 (the day of enrollment), echocardiogram showed mild left ventricular hypertrophy with estimated ejection fraction (EF) of 55%, moderate to severe pulmonary hypertension (estimated 55mmHg), and left pleural effusion **(AE #002).** The next day on 30-Jan-2007, the subject complained of shortness of breath. It was determined that he was in respiratory distress. CT of the chest revealed bilateral pleural effusion but ruled out pulmonary embolus. The supplemental oxygen was increased from 3L to 4L through nasal cannula. He was considered a "full code" at that time. It was also documented in the daily note that the subject had hypotension which was thought to be medication-related; dopamine was ordered.

Also on [redacted]-2007 (post enrollment day 1), the 24 hour NIHSS progressed to 24 **(SAE #003).** The subject had complained of headache in the previous 24 hours. NCT revealed large acute infarct in the right middle cerebral artery (MCA) and part of anterior cerebral

artery distribution with considerable midline shift to the left compressing the lateral and third ventricles, as well as uncal and hippocampal herniation. Mannitol was given. At 07:40, the subject was documented to be unresponsive to verbal command; the pupils were unequal, the right one was fixed and the left one was nonreactive and sluggish. After consulting with the family, the subject was on a do not resuscitate (DNR) code and comfort care was given.

Per discharge summary report, the subject was also documented to have thrombocytopenia **(AE #901)** and urinary tract infection **(AE #902)** during his hospitalization.

On [redacted]-2007 (post enrollment day 3), the subject expired at 07:55. Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2006

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
15-May-2006	002	001	504: GI Motility Disorders	N/A	N/A
20-May-2006	**007**	**002**	***404: HT, likely contributing to mass effect**	**N/A**	**N/A**
23-May-2006	010		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 74-year-old Caucasian male with past medical history of atrial fibrillation, hypertension, hyperlipidemia, and coronary artery disease with coronary artery bypass graft (2001). Medications at admission included: Labetalol, Aspirin, Metolprolol, Simvastatin, and Valsartan.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 10:30, [redacted]-2006. Symptoms at presentation included right arm weakness, aphasia, right-sided sensory deficit, and partial hemianopsia. CT scan at admission revealed no abnormality. Baseline NIHSS was 11. The subject was randomized to the control arm of the SENTIS trial at 16:45, [redacted]-2006, 6.3 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 24 hour follow-up MR on [redacted] 2006 showed a left parietotemporal acute infarct. The 24 hour NIHSS decreased to 9.

On [redacted]-2006 (post enrollment day 2), the subject complained of constipation and was treated with docusate **(AE #001)**.

The subject was discharged from the hospital on [redacted]-2006 with NIHSS of 7 to a rehabilitation facility.

On [redacted] 2006 (post enrollment day 7), the subject complained of headache and was dizzy. He also experienced an increase of right-sided weakness, decrease in level of consciousness, vomiting and severe hypertension for which he was given hydralazine. The subject was transferred to the intensive care unit and intubated. NCT revealed a large left hemispheric intracranial hemorrhage with mass effect **(SAE #002)**, midline shift, and ventricular extension. The subject dropped into deep coma. The subject's family understood the lethal nature of this hemorrhage and elected to withdraw mechanical ventilator support and switch to palliative care. The subject was transferred to the general medical floor on [redacted]-2006 and demonstrated reasonably stable vital signs with a strong breathing pattern. Because it appeared as though death would not be imminent, the subject was transferred to a nursing home hospice closer to the family's home on [redacted]-2006. The subject died on the following day, [redacted]-2006, post enrollment day 10. Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
07-Dec-2009	002	901	899 - Other: Oropharangeal bleeding	N/A	N/A
12-Dec-2009	**007**	**001**	***403 - Cerebral edema**	**N/A**	**N/A**
12-Dec-2009	007		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 87-year-old Caucasian female with past medical history of hypertension, osteoarthritis/osteoporosis, hemorrhoids, anxiety disorder, mild coagulopathy and microcytic iron deficiency anemia. She was previously on Coumadin but it was stopped in Sep-2009 due to anemia of unclear etiology. She was admitted to the hospital on [redacted]c-2009 to received blood transfusions for anemia. During the hospitalization she was found to have atrial fibrillation, sick sinus syndrome, mild aortic stenosis and mild-moderate aortic regurgitation. She had a permanent pacemaker placement on [redacted] 2009 (1 day prior to stroke onset). Medications included: Hydrochlorothiazide, Atenolol, Fosamax, potassium and iron supplements.

Current Stroke Onset and SENTIS Enrollment: The subject experienced onset of stroke symptoms at 06:27, [redacted]-2009, while still an inpatient. Symptoms at presentation included decrease in mental status with left-sided paralysis and left-sided facial droop. CT scan revealed a clot in the proximal M2 segment of the right MCA and a large area of

infarction in right frontal and right parietal lobes. Baseline NIHSS was 18. The subject was randomized to the control arm of the SENTIS trial at 17:00, [redacted]-2009, 10.6 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrollment) the 6 hour NIHSS progressed to 20.

On [redacted]-2009 (post enrollment day 1) the 24 hour NCT revealed interval evolution of the right MCA infarct involving nearly the entire right frontal and parietal lobes with diffuse edema and loss of sulci in these regions without midline shift or hemorrhage. Her 24 hour NIHSS remained at 20.

On [redacted]-2009 (post enrollment day 2) the subject developed significant latrogenic oropharyngeal bleeding due to IV heparin anticoagulation following stroke **(AE #901)**. Heparin was never discontinued per the discharge summary report.

The subject and family opted for no extreme measures to be used. The subject was discharged from the hospital on [redacted]-2009 to home under hospice care.

On [redacted]-2009 (post enrollment day 7) the subject died at home. DSMB review of the subject's stroke progression and edema led to adjudication of **(SAE #001)** as cerebral edema. The cause of death was adjudicated as stroke.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
06-Mar-2009	000	002	103 - Hypertension	N/A	N/A
06-Mar-2009	000	005	603 - Electrolyte imbalance	N/A	N/A
07-Mar-2009	001	902	605 - Dyslipidemia/ Hypercholesterolemia	N/A	N/A
08-Mar-2009	**002**	**004**	**202 - Respiratory failure**	**N/A**	**N/A**
09-Mar-2009	003	003	118 - Atrial Fibrillation	N/A	N/A
10-Mar-2009	004	006	405 - HT, probably not contributing to mass effect	N/A	N/A
13-Mar-2009	007	901	303 - Urinary Tract Infection	N/A	N/A
15-Mar-2009	009	903	814 - Sleeping Disturbance/ Disorder	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
16-Mar-2009	010	904	811 - Depression	N/A	N/A
31-Mar-2009	**025**	**001**	***415 - Intracerebral hemorrhage**	**N/A**	**N/A**
02-Apr-2009	027		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 58-year-old Hispanic/Latino male with past medical history of hypertension. Medications at admission included: Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject experienced onset of stroke symptoms at 02:00, [redacted] 2009. He fell, hit his head and developed a left frontal scalp hematoma involving the left eye and had a swollen left hand. Symptoms at presentation included left-sided weakness and slurred speech. CT scan at admission revealed an acute ischemic infarct in the right MCA territory, segment M1. Baseline NIHSS was 13. The subject was randomized into the control group of the SENTIS trial at 11:20, 06-Mar-2009, 9.3 hours from symptom onset.

NeuroFlo Procedure: N/A

Post Enrollment Course: On [redacted]-2009 (day of enrollment) the subject was hypertensive, and was treated with Normodyne. Cozar and Vasotec were added later for better blood pressure control **(AE #002)**. The subject's serum potassium was low, supplemental replacements were given. Magnesium and phosphate supplements were also given during this hospitalization **(AE #005)**.

On [redacted] 2009 (post enrollment day 1), the subject's lipid panel was elevated, so Lipitor was initiated **(AE #902).**

On 0[redacted]-2009 (post enrollment day 2), the subject developed respiratory difficulty. His lungs were clear, no treatment was given. On [redacted]-2009, the subject's respiratory difficulty increased, his respiratory rate was 40-50 and he was intubated **(SAE #004)**. By the following day, the subject's respiratory distress was thought to be an upper respiratory infection with tracheal edema. Unisyn and steroids were initiated, and the subject was extubated.

ECG on [redacted] 2009 showed atrial fibrillation **(AE #003)** with rapid ventricular response and premature ventricular contractions. A cardiology consult was obtained and Verapamil was begun.

On 1[redacted]-2009 (post enrollment day 4), CT scan showed a small hemorrhage and increased cerebral edema with mass effect and no midline shift **(AE #006)**. The 4 day NIHSS increased slightly to 12 from 10, compared to the 24 hour NIHSS assessment on [redacted]-2009.

On [redacted] 2009 (post enrollment day 7), Levaquin was started for a urinary tract infection **(AE #901)**.

On [redacted] 2009 (post enrollment day 8), the subject's INR was 2.9. It was increasing over the next two days and reached highest of 5.1 on [redacted]-2009. Coumadin was held until [redacted]-2009, when the subject's INR decreased to 2.8.

On [redacted]-2009 (post enrollment day 9), the subject was started on Ambien and Xanax at bedtime for insomnia **(AE #903).** Zoloft was started on the following day for depression **(AE #904).**

The subject was transferred from the hospital on [redacted] 2009 to an inpatient rehabilitation facility.

On [redacted] 009 (post enrollment day 25), the subject suddenly lost consciousness. He was transferred back to the emergency room, where he was totally non-responsive with dilated pupils. CT scan showed massive intracerebral hemorrhage with 4mm midline shift **(SAE #001)**. His INR was 4.1. The subject's admission blood pressure of 206/129 was treated with Normodyne and Vasopressin. He was intubated, and given 6 units of fresh frozen plasma, 10 units of platelets, and vitamin K. On [redacted] 2009, the subject showed no improvement, and was referred to follow the Lifelink protocol.

On [redacted] 2009 (post enrollment day 27), the subject was declared brain dead. Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted] 2007

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
10-Aug-2007	**000**	**001**	***404 - HT, likely contributing to mass effect**	**N/A**	**N/A**
12-Aug-2007	002		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 73-year-old Caucasian male with past medical history of transient ischemic attacks, previous stroke (mRS =1), hypertension and hyperlipidemia. Medications at admission included: Crestor, Coversyl, Aspirin.

Current Stroke Onset and SENTIS Enrollment: The subject's stroke symptom onset began at 07:00 on [redacted]-2007. Symptoms at presentation included global aphasia and subtle right facial weakness. CT scan at admission revealed an acute left frontal

infarction with no evidence of hemorrhage. Baseline NIHSS was 9. The subject was randomized to the control arm of the SENTIS trial at 13:02, [redacted] 2007, 6 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject's condition began to deteriorate around 15:30 on [redacted] 2007 (the day of enrollment). The subject had progressive right-sided weakness and increasing drowsiness. Right gaze preference was also noted. At 16:52 he was noted to be agitated and diaphoretic. The subject was taken for repeat CT. He vomited while at CT. The CT showed a large parenchymal hemorrhage **(SAE #001)** in the left hemisphere. Post-CT the subject was drowsy and not following commands. He was globally aphasic with a right gaze preference, right facial weakness and spastic right-sided extremities. NIHSS increased to 18. The family was made aware of the grim functional prognosis. They opted against surgical intervention and, due to the change in the status, made the subject "do not resuscitate" with supportive and comfort measures only provided on the evening of [redacted] -2007.

Through [redacted] -2007 the subject's symptoms continued to worsen and he had labored breathing with heavy secretions. At 08:40 on [redacted] 007 the subject was pronounced dead after no brainstem reflexes, no breathing and no spontaneous circulation for 60 seconds. Cause of death was adjudicated as stroke.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
23-Nov-2009	000	004	303 - Urinary Tract Infection	N/A	N/A
24-Nov-2009	001	003	503 - Nausea/Vomiting	N/A	N/A
25-Nov-2009	002	001	405 - HT, probably not contributing no mass effect	N/A	N/A
26-Nov-2009	**003**	**005**	**814 - Sleeping Disturbance/ Disorder**	**N/A**	**N/A**
02-Dec-2009	**009**	**002**	***409 - New ischemic stroke**	**N/A**	**N/A**
07-Dec-2009	014		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 86-year-old Caucasian female with past medical history of hypertension, atrial fibrillation, and apneic spells. Medications at admission included: Warfarin, Metoprolol, and Hydrochlorothiazide.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 22:00, [redacted] 2009. Symptoms at presentation included left-sided weakness, forced eye deviation to the right side, dysarthria, neglect, decreased level of consciousness. The subject's blood pressure (BP) at admission was 199/108mmHg and IV Labetalol was given. CT scan at admission revealed evidence of low attenuation in the right frontal lobe. Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 10:15, [redacted] 2009, 12.3 hours from last known normal. Her BP was 201/112 at the time of randomization and Enalapril IV was given at 10:55.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject's BP at 6 hour assessment was 175/110 and at 24 hours decreased to 160/70. She had intermittent hypertensive episodes which were treated with Enalapril IV as needed per stroke protocol.

On [redacted]-2009 (the day of enrollment), a urine culture was positive for E. Coli **(AE #004)**. The subject was treated with Levaquin until her death.

On [redacted]-2009 (post enrollment day 1), the 24 hour NCT showed evolving right MCA territory infarct with no hemorrhage. The 24 hour NIHSS was 16. The subject had nausea **(AE #003)** and received Gravol. She had another episode of nausea on the following day and received Zofran.

On [redacted]-2009 (post enrollment day 2), NCT revealed areas of hemorrhage **(AE #001)** within the right MCA territory infarct. The subject was transferred from intensive care unit (ICU) to stroke unit but was brought back to ICU on [redacted]009 due to a concern of mild upper airway obstruction with jaw thrust, desaturation, and some apnea. Arterial blood gas suggested chronic apnea. This airway obstruction was thought to be obstructive sleep apnea **(SAE #005)** and continuous positive airway pressure (CPAP) was started on [redacted]-2009. The subject no longer experienced apnea with CPAP.

On [redacted]-2009 (post enrollment day 8), the subject had acute neurological deterioration. NCT showed mild mass effect with partial compression of the right lateral ventricle, and minimal shift of the midline towards left side. NCT on the flowing day revealed a new acute infarct **(SAE #002)** involving the left MCA territory with sparing of the left basal ganglia and effacement of the adjacent convexity sulci; there was no significant change in the right MCA territory infarct with hemorrhagic transformation.

On [redacted] 2009 (post enrollment day 11), the subject remained very drowsy and quadriparetic. The family requested palliative care. The subject expired on [redacted] 2009, post enrollment day 14. Cause of death was adjudicated as new stroke.

Subject[redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
30-May-2009	**001**	**001**	***403 - Cerebral edema**	**N/A**	**N/A**
30-May-2009	001	002	603 - Electrolyte imbalance	N/A	N/A
05-Jun-2009	007		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 59-year-old Caucasian male with a past medical history of pineal needle cyst removal from both his back and face. Medications at admission included: multivitamins.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 18:00, [redacted]-2009. Symptoms at presentation included right-sided hemiparesis, a positive Babinski sign on the right, speech disturbance and decreased level of consciousness. CT scan at admission revealed left middle cerebral artery (MCA) ischemic infarction with no hemorrhage, mass effect or midline shift. Subsequent angiography revealed occlusion of both the M1 segment of the left MCA and the left internal carotid artery (ICA). Baseline NIHSS was 17. The subject was randomized to the control arm of the SENTIS trial at 08:30, [redacted] 2009, 14.5 hours from last known normal. A waiver was granted for enrollment >14 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2009 (post enrollment day 1) the subject's condition was stable. His 24 hour NIHSS had slightly increased to 18. At 04:06 an NCT revealed worsening edema **(SAE #001)** in the region of the left MCA infarct. There was mass effect on the left lateral ventricle and slight left-to-right midline shift. An electrolyte imbalance (low sodium, phosphorus and blood urea nitrogen) was also noted. Electrolyte replacement via oral medication, tube feedings and IV fluids were administered but the event remained ongoing **(AE #002)**.

On [redacted]-2009 (post enrollment day 2), the subject became more confused. A repeat NCT performed at 09:10 revealed extensive edema resulting in near complete effacement of the right lateral ventricle. A left decompressive hemicraniectomy was performed and the subject was then returned to the intensive care unit on a ventilator.

The subject's condition deteriorated over the following days; he became lethargic and less responsive. His 4 day NIHSS on [redacted]-2009 increased to 22. After multiple discussions with the family the subject was extubated on [redacted]-2009 and hospice care was initiated to focus on comfort and alleviation of suffering for the subject. The subject expired on [redacted]-2009, post enrollment day 7. Cause of death was adjudicated as stroke.

Subject[redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
11-Jul-2009	**001**	**003**	**207 - Pulmonary embolism**	**N/A**	**N/A**
11-Jul-2009	001	009	603 - Electrolyte imbalance	N/A	N/A
11-Jul-2009	001	907	113 - Myocardial infarction, non-Q wave	N/A	N/A
14-Jul-2009	004	002	413 - Headache	N/A	N/A
14-Jul-2009	**004**	**001**	**109 - Arrhythmia: Ventricular fibrillation**	**N/A**	**N/A**
14-Jul-2009	**004**	**006**	**601- Anemia**	**N/A**	**N/A**
14-Jul-2009	004	008	606 - Hyperglycemia	N/A	N/A
17-Jul-2009	007	004	703 - Venous thrombosis (DVT)	N/A	N/A
21-Jul-2009	011	902	407 - Seizure	N/A	N/A
21-Jul-2009	011	903	403 - Cerebral edema	N/A	N/A
29-Jul-2009	019	904	204 - Aspiration pneumonia	N/A	N/A
02-Aug-2009	**023**	**010**	**113 - Myocardial infarction, non-Q wave**	**N/A**	**N/A**
25-Aug-2009	046	007	303 - Urinary Tract Infection	N/A	N/A
24-Sep-2009	**076**	**905**	*** 805 - Sepsis**	**N/A**	**N/A**
25-Sep-2009	077	906	807- Coagulopathy	N/A	N/A
12-Oct-2009	094		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 60-year-old African-American female with past medical history of hypertension, insomnia, depression, gall bladder cancer (status post cholecystectomy), and hypercoagulable syndrome. She had been admitted to hospital in Jun-2009 for right arm and bilateral lower extremities deep vein thrombosis (DVT) and central embolus in the right lobar artery. She was treated with tPA and an inferior vena cava filter was placed. She was also treated for hyperkalemia. She was diagnosed with another DVT of the right upper extremity on [redacted]-2009 (one day prior to stroke onset). She improved during this hospitalization and was discharged to a rehabilitation facility. Medications at admission included: aspirin, Lovenox, Lasix, Aranesp, Protonix, Restoril, Senokot, Colace and Duragesic patch.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 08:00 on [redacted]-2009, while in the rehabilitation facility. Symptoms at presentation included right-sided weakness and difficulty speaking. CT scan and MRI at

admission revealed new multi-focal ischemic infarcts in the frontal-parietal lobes, no hemorrhage or mass effect. CTA revealed no evidence of occlusion or significant stenosis. Baseline NIHSS was 5. The subject was randomized to the control arm of the SENTIS trial at 11:55, [redacted]-2009, 3.9 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (post enrollment day 1) imaging revealed a right lower lobe pulmonary embolus. The larger pre-existing central embolus at the descending right lower lobar artery demonstrated some resolution. A central embolus at the right upper lobe artery **(SAE #003)**, not seen on [redacted]-2009, was noted along with new left lung consolidation. Lab work showed hypokalemia **(AE #009)** and the subject was treated with potassium.

On [redacted] 2009 the subject had an elevated troponin level of 2.625. No electrocardiogram (ECG) changes were noted and heparin was continued for a non-ST elevation myocardial infarction (MI) **(AE #907)**. A repeat ECG on 13-Jul-2009 showed sinus rhythm with marked sinus arrhythmia with lateral wall ischemia.

On [redacted]-2009 (post enrollment day 4) the subject's NIHSS had improved to 2. She started complaining of frontal headache **(AE #002)** and was treated with Tylenol. That evening the subject went into ventricular fibrillation and had a cardiac arrest **(SAE #001)**. She was resuscitated for approximately one hour and was intubated. She was minimally responsive to painful stimuli.

The subject was also noted to be anemic with her hemoglobin dropping as low as 7.8 g/dl (norm 11.6-15.6). She was transfused periodically throughout her hospital stay **(SAE #006)**. Insulin was started for hyperglycemia **(AE #008)**.

On [redacted]-2009 CT scan revealed multi-focal infarcts with no acute hemorrhage or mass effect. Electroencephalogram (EEG) showed burst suppression pattern with an intermittent period of 1-2 seconds. EEG on the following day showed alpha coma pattern-diffuse severe cerebral dysfunction which was consistent with anoxic encephalopathy. Prognosis for a meaningful recovery was poor. The subject continued to have leukocytosis which was thought to be secondary to stroke and she was in cardiac arrest. Antibiotics were given.

On [redacted]-2009 (post enrollment day 7) venous duplex of the left upper extremity showed evidence of DVT involving the subclavian, axillary, brachial, and basilica veins **(AE #004)**. The basilica vein was thrombosed from the axillary area to the elbow. The subject was on heparin.

On [redacted]-2009 (post enrollment day 11), the subject was noted to have fluttering of the eyelids **(AE #902)**. This was treated with an anti-seizure medication, Keppra. On the same day, an MRI showed extensive bilateral confluent cortical edema **(AE #903)** possibly related to anoxia or seizure activity. There was no hydrocephalus or midline shift.

On [redacted]-2009 (post enrollment day 19), sputum cultures were positive for pseudomonas aeruginosa **(AE #904)**; antibiotics were started. Sputum cultures remained positive on [redacted] 2009.

On [redacted]-2009 (post enrollment day 23) the subject had an episode of bradycardia. ECG showed acute inferior wall MI. A cardiac catheterization was done and two stents were placed **(SAE #010)**.

On [redacted]-2009 additional DVT's were noted within the common femoral, superficial femoral and bilateral popliteal veins **(cont. of AE #004)**. Heparin was continued.

The subject remained in a vegetative state, unchanged from the evening of [redacted] 2009. Her 30 day NIHSS on 10-Aug-2009 increased to 33.

On [redacted] 2009 (post enrollment day 46) the subject had a fever. Urine cultures were positive for E. coli **(AE #007)**. Ancef was started.

The subject was discharged from the hospital on [redacted] 2009 to a rehabilitation facility on ventilatory support. During her stay in the rehab facility, she was able to be extubated on a trach collar.

[redacted]-2009 (post enrollment day 76) the subject was re-admitted to the index hospital brain trauma unit for additional rehabilitation. She had a fever and workup confirmed gram-negative sepsis and septic shock, which was thought to be line related. Blood cultures were positive for gram-negative rods. Sputum culture was positive for pseudomonas and urine culture was positive for viridans Strep **(AE #905)**. She was treated with antibiotics.

On [redacted]009 (post enrollment day 77) thin, frothy, pinkish secretions were noted from the tracheostomy **(AE #906)**. This was thought to be related to underlying congestive heart failure. Diuretics were given. The bleeding worsened to a frank tracheal bleed and was treated with epinephrine. Intermittent bleeding continued and an endoscopy found no site of bleeding in the area of the tracheostomy or in the trachea. Anticoagulants were adjusted and the bleeding resolved on [redacted]-2009.

The subject deteriorated, went into renal and liver failure, and died on [redacted]-2009, post enrollment day 94. Cause of death was adjudicated as systemic complications unrelated to stroke, specifically sepsis.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
06-May-2008	000	001	606 - Hyperglycemia	N/A	N/A
06-May-2008	000	002	603 - Electrolyte imbalance	N/A	N/A
10-May-2008	**004**	**003**	*** 414 - Neurological worsening**	**N/A**	**N/A**
29-May-2008	023		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 88-year-old Caucasian female with past medical history of hypertension, dyslipidemia, congestive heart failure with EF of 35%, atrial fibrillation, mitral regurgitation, and coronary artery disease with the most recent myocardial infarction in Jan-2008. The subject had a previous left frontal "mini" stroke in 2006, and a history of TIA. She had been recently diagnosed with gastric adenocarcinoma (not on chemotherapy). Medications at admission included: Aspirin, Viokase, Omeprazole, Pravastatin, Metoprolol, and multivitamin. Coumadin was discontinued in late Apr-2008 due to tumor-related anemia.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 10:30, on [redacted] 2008. Symptoms at presentation included left facial droop, dysphasia, dense left hemiparesis, and anosognosia. CT scan at admission revealed bilateral regional encephalomalacia consistent with chronic infarcts. A subsequent CT scan showed low density areas of apparent infarction in the left frontal lobe and bilateral parietal lobes. Baseline NIHSS was 14. The subject was randomized to the control arm of the SENTIS trial at 15:15, [redacted]-2008, 4.8 hours from last known normal.

NeuroFlo Procedure: N/A.

Post-Enrollment Course: During the hospitalization, the subject's glucose level was elevated **(AE #001)** and she was treated with insulin sliding scales. The subject's potassium level was also noted to be low **(AE #002)** and potassium supplements were given.

The 24 hour CT scan on [redacted]008 showed change compared to the baseline CT, with a large area of diminished attenuation in the right MCA. Low density edema was seen in the right frontal, right temporal and right parietal areas. The 24 hour NIHSS was 13.

On 10-May-2008 (post enrollment day 4), the subject's neurological condition substantially deteriorated. Her NIHSS increased to 20 **(SAE #003)**. Cerebral edema was reported, but there was no evidence of hemorrhagic transformation and no midline shift.

The subject was discharged from the hospital on [redacted]-2008 to an assisted living facility. It was reported that she "took a turn for the worse" on [redacted] 2008 such that she was completely unresponsive to verbal or physical stimuli and required total care for physical and nutritional support. Her wishes of not being resuscitated were supported by her family, and hospice care was arranged.

On [redacted] 2008, the subject was seen at the assisted living facility for the 30 day follow-up visit. The subject's general health condition had declined, and she was being treated for possible pneumonia. Her NIHSS was 42. The subject died on the following day, [redacted]-2008, post enrollment day 23. Cause of death was adjudicated as systemic complications associated with stroke.

Subject [redacted], enrolled [redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
10-Sep-2008	**001**	**901**	**414 - Neurological worsening**	**N/A**	**N/A**
30-Sep-2008	021	002	815 - Skin irritation	N/A	N/A
13-Nov-2008	**065**	**001**	*** 205 - Infectious pneumonia**	**N/A**	**N/A**
13-Nov-2008	065		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 90-year-old Caucasian male with past medical history of hypertension, hyperlipidemia, atrial fibrillation, atrial dilatation, heart valve replacement (2004) and left-sided stroke (mRS=1) with residual headaches (2004). The subject had resided in a geriatric nursing home since 2007 when he was admitted with a history of fall, confusion, dehydration, acute renal insufficiency with subsequent chronic renal failure. Medications at admission included: Zocor, Atenolol, Coversyl and Amlor.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 12:30, [redacted] 2008. Symptoms at presentation included left hemiparesis and dysarthria. CT scan at admission revealed a right middle cerebral artery (MCA) infarction without evidence of bleeding. Complete occlusion of the right internal carotid was also noted. Baseline NIHSS was 12. The subject was randomized to the control arm of the SENTIS trial at 20:45, [redacted] 2008, 8.3 hours from last known normal. Note: Creatinine was 2.0 (>1.5 times local lab normal) at time of randomization; a protocol deviation has been recorded.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 6 hour NIHSS on [redacted]-2008 had increased to 16 **(SAE #901)**. No scans were performed. The 24 hour follow-up MRI at 17:34 showed a large right MCA infarct with a clear diffusion deficit, important cortical/subcortical and cerebellar atrophy and multiple spread out white matter lesions in the corona radiata and centrum semiovale. (Core lab recorded large area of restricted diffusion and T2 hyperintense lesion in the right inferior gyrus and insular cortex, as well as putamen, caudate, and anterior M2 territory that was much larger than baseline CT). The 24 hour NIHSS at 20:25 decreased to 8.

On [redacted]-2008 (post enrollment day 21) dermatology ordered a topical corticosteroid for dry, itchy skin, and possible eczema **(AE #002)**. Symptoms improved.

The subject was transferred back to the geriatric nursing home on [redacted]008.

On [redacted]-2008 chest x-ray showed infiltrates in the right middle lung lobe. On [redacted] 2008 (post enrollment day 65) the subject was admitted to the hospital with pneumonia and dehydration **(SAE #001)**. The major pulmonary infection in conjunction with metabolic deregulation led to his death on [redacted]2008. Cause of death was adjudicated as systemic complications associated with stroke, specifically pneumonia.

Subject [redacted] enrolled 0[redacted]-2008

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
05-Oct-2008	**001**	**001**	***404 - HT, likely contributing to mass effect**	**N/A**	**N/A**
06-Oct-2008	002		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 80-year-old Caucasian male with past medical history of insulin dependent diabetes mellitus, hypertension, hyperlipidemia, pacemaker placement, transurethral resection of the prostate, obstructive sleep apnea syndrome, arthritis of the knee, cataracts and retinopathy. The subject had two prior strokes in 1992 and 2007 (mRS=1 with some residual left hemi symptoms and amnesia). Medications at admission included: Amlor, Micardis, Zocor, Spironolactone, Praxilene, Lasix, Marevan, Actrapid, Insulard.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 20:45 on [redacted]2008. Symptoms at presentation included right hemiplegia, right facial paresis as well as aphasia and hemianopsia. Subject was alert and responded to commands. CT scan at admission revealed acute ischemia and no hemorrhage. Baseline NIHSS was 18. The subject was randomized to the control arm of the SENTIS trial at 23:15, [redacted]-2008, 2.5 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted] 2008 (post enrollment day 1) approximately 10 hours post admission, the subject neurologically deteriorated with vomiting. Blood pressure increased to 250/140 from baseline of 150/67. CT scan revealed hemorrhage with increased edema in the left hemisphere with compression of the left lateral ventricle **(SAE #001)**. An acute left hemorrhage/left hemispheric stroke with mass effect was diagnosed. Aspirin and Fraxiparine were stopped. The 24 hour NIHSS at 11:30 increased to 22. At 20:00 NIHSS was 23. The subject was transferred to the intensive care unit and expired on [redacted]-2008, post enrollment day 2. Cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
21-Apr-2009	**006**	**002**	***499 - Neuro Other: Continuous epileptic activity**	**N/A**	**N/A**
24-Apr-2009	009	001	812 - Fever	N/A	N/A
04-May-2009	019		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 86-year-old Caucasian female with a past medical history of a transient ischemic attack (2004), atrial fibrillation (2004), hypertension, hyperlipidemia, and diastolic heart failure (Feb-2009).

The subject was admitted to the index hospital on [redacted]-2009 with a cerebellar stroke with limited hemorrhagic transformation per MRI on [redacted] 2009. His mRS prior to SENTIS enrollment was 1. While inpatient, the subject had a fever on 13-Apr-2009 and Maxipime and Amukin for a urinary tract infection were initiated. Medications prior to SENTIS enrollment included: Cozaar, Warfarin, Aldactazine, Amlor, Fraxiparine, Perfusalgan, Litican, Dafalgan, Stilnoct, Forlax, Maxipime, Amukin.

Current Stroke Onset and SENTIS Enrollment: The subject experienced a new stroke onset on [redacted]-2009, while inpatient. The subject was last known normal at 15:15, [redacted] 2009. Symptoms at onset included distinct worsening of the dysarthria and ataxia of the left upper extremity. CT scan revealed a large known subacute right cerebellar infarct and remote hemorrhage, which was now less pronounced than on previous studies. No new hyperacute hemorrhages were noted. There were multiple periventricular ischemic lesions. Prior to SENTIS enrollment, the subject's hemoglobin was 8.8; a hematoma on the leg was noted and Warfarin was stopped. Baseline NIHSS was 10. The subject was randomized to the control arm of the SENTIS trial at 18:[redacted]-2009, 3.3 hours from

last known normal. [Note: A protocol deviation was received for enrolling subject with recent history of intracerebral hemorrhage.]

NeuroFlo Procedure: N/A

Post-Enrollment Course: The 6 hour NIHSS decreased to 8.

On [redacted] 2009 (post enrollment day 1) NCT showed known right cerebellar infarct with some edema and preserved midline supratentorial, with older vascular lesions in the basal ganglia and periventricular regions; also noted was a non-homogeneous left occipital lobe including a subacute left ischemic lesion which now appeared isodense.

The subject was transferred from the index hospital on [redacted]-2009 to a rehabilitation hospital. Shortly after admission the subject again developed high fever, increased pain, rhonchi, and somnolence. The subject was still on Maxipime that was started on 14-Apr-2009. That same day an electroencephalogram (EEG) showed continuous atypical epileptic activity (translated as "non convulsive status epilepticus") **(SAE #002)** potentially related to the treatment with Maxipime. Maxipime was discontinued and Depakine was started. Follow-up EEG on [redacted]-2009 showed reduced seizure activity.

On [redacted] 2009 (post enrollment day 9) a rapid deterioration of neurological condition was observed **(AE #001)**. The decreasing consciousness was thought likely to be related to the subject's fever and rhonchi. NCT showed no hemorrhage, stroke extension or a new stroke. No additional examinations or treatments were performed per the family's request. Comfort measures only were instituted and subject expired on [redacted] 2009, post enrollment day 19. Cause of death was adjudicated as systemic complications associated with stroke, specifically continuous epileptic activity.

Subject [redacted], enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
28-May-2009	**001**	**901**	*** 414 - Neurological worsening**	**N/A**	**N/A**
28-May-2009	**001**	**001**	*** 202 - Respiratory failure**	**N/A**	**N/A**
28-May-2009	001		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 87-year-old Caucasian female with past medical history of stroke in Nov-2007 (mRS = 1), atrial fibrillation, hypertension, sick sinus syndrome (no pacemaker due to age), anemia, patent foramen ovale, and cholecystectomy. Her blood pressure (BP) had also been elevated in the 3-4 days prior to the index stroke onset. Medications on admission included: Aspirin, Amiodarone,

Zyrtec, Lorazepam, Lisinopril, vitamin B12, Fentanyl and Algostase (pain medication containing acetaminophen not available in the US) for back pain, and Movicol (osmotic laxative) for constipation.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 15:30 on [redacted]-2009. Symptoms at presentation included left hemiplegia, right gaze preference and headache. CT scan at admission was negative for acute infarction or hemorrhage and revealed chronic vascular lesions. The old right cerebellar infarction was also visualized. Bilateral rhonchi were noted upon admission; chest x-ray revealed no infiltrates and she was afebrile. Baseline NIHSS was 16. Echocardiogram pre-enrollment showed left ventricular ejection fraction at 34%. The subject was randomized to the control arm of the SENTIS trial at 21:02, [redacted]-2009, 5.5 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (post enrollment day 1), due to the subject's arterial hypertension and dysphasia, preventing oral administration of medications, a peg-tube was inserted. Augmentin was also initiated because of the bilateral rhonchi observed at the baseline.

Her 24 hour NIHSS at 16:45 on [redacted] 2009 had increased to 19 **(SAE #901)**. Later in the evening the subject became tachypneic and passed away around 23:00 on [redacted] 2009, before her 24 hour protocol-required CT scan could be obtained. Chart note says, "the patient expired due to extensive CVA and suspicion of aspiration because of the tachypnea" **(SAE #001)**. Cause of death was adjudicated as systemic complications associated with stroke, specifically neurological worsening and respiratory failure.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
24-Jul-2009	**002**	**001**	**398 - Urinary Other: Metastatic bladder carcinoma**	**N/A**	**N/A**
30-Jul-2009	008	901	411 - Transient ischemic attack	N/A	N/A
01-Aug-2009	010	902	806 - Agitation/Excitation	N/A	N/A
07-Aug-2009	**016**	**002**	***202 - Respiratory failure**	**N/A**	**N/A**
08-Aug-2009	017		Death	N/A	N/A

Serious events are in bold, shaded text.
*Indicates serious event is associated with death

Demographics and History: The subject is an 83-year-old Caucasian male with past medical history of myocardial infarction with percutaneous transluminal coronary

angioplasty in 2002, hypertension, hyperlipidemia, partial thyroidectomy, gastroesophageal reflux disease, liver steatosis, back surgery, vocal cord cystectomy, cataract surgery, transurethral resection of the prostate. In Feb-2007 the subject had prostate fossa polyps removed and was diagnosed with grade III interstitial cell carcinoma.

On [redacted] 2009 the subject was admitted with complaints of abdominal discomfort and fever of unknown origin. CT-guided biopsy of an abdominal adenopathy was performed and the subject was discharged home on the following day with pending results. Medications at admission included: Nifedipine, Cozaar, Lipitor, Metoprolol, Levothyroxine and Lorazepam.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke onset at 16:00 on [redacted]-2009. Symptoms at presentation included right arm drift, severe aphasia, and confusion. CT scan at admission revealed diffuse and focal vascular disease and no hemorrhage. Baseline NIHSS was 6. The subject was randomized to the control arm of the SENTIS trial at 21:00, [redacted]-2009, 5.0 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (the day of enrolment), the subject's C-reactive protein (CRP) was elevated at 6.9; no treatment was initiated.

On [redacted]-2009 the 24 hour follow-up head CT showed an old right cerebellar lesion and no acute pathology. MRI showed a recent left focal temporal ischemic injury and multiple small acute infarcts in the bilateral posterior fossa and supratentorial region, likely of embolic origin.

On [redacted]-2009 (post enrollment day 2) biopsy results revealed metastatic bladder interstitial cell carcinoma **(SAE #001)**. The subject's lactate dehydrogenase (LDH) was 2024 U/I (norm 316 - 618) and it was thought to be related to the subject's cancer progression.

On [redacted] 2009 (post enrollment day 8) the subject had a new onset of left upper extremity paresis. CT showed known previous right cerebral injury and no signs of new acute pathology since the prior exam. A transient ischemic attack was diagnosed **(AE #901)**.

On [redacted]-2009 a port-a-cath was placed with palliative chemotherapy to start on [redacted]-2009.

On [redacted]-2009 the subject became confused and agitated and was given Haldol. The subject calmed down but remained confused **(AE #902)**. On [redacted]-2009 restraints were applied at night and the progress notes on [redacted]-2009 indicated that the subject injured himself despite restraints being in place (type of injury was not identified).

On [redacted]-2009 oncological swelling made swallowing difficult. Because of that, and the subject's increased lethargy, oral medications were discontinued. On [redacted]-2009 palpitations were documented and Metoprolol was restarted (blood pressure readings are not available). Elthyrone was also restarted.

On [redacted]-2009 the subject was unable to urinate independently and expressed pain when his bladder was palpated. He was catheterized for relief and a Foley was placed on the following day.

On [redacted]009 (post enrollment day 16) the subject's temperature increased to 39.2°C with respiratory depression **(SAE #002)**, and reduced consciousness. The subject's family chose to change his level of care status to do not resuscitate and comfort measure were instituted. The subject expired at 01:00 on [redacted]2009. Cause of death was adjudicated as systemic complications unrelated to stroke, specifically respiratory failure.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
16-Oct-2009	004	901	118 - Atrial Fibrillation	N/A	N/A
20-Oct-2009	**008**	**001**	***204 - Aspiration pneumonia**	**N/A**	**N/A**
23-Oct-2009	011		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 89-year-old Caucasian male with past medical history of inferior myocardial infarction (1983), hypertension, glaucoma, cataracts, bilateral ectropion, prostate cancer (1999), osteoarthritis, and left total hip replacement. Medications at admission included: Cardioaspirine, Bisoprolol sandoz, Lasix, Aldactone, Bicalutamide (prostate hormone therapy), Goseralin (prostate treatment) and eye drops.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 03:00 on [redacted]-2009. Symptoms at presentation included right-sided weakness, facial palsy, dysarthria, and complete hemianopsia. CT scan at admission revealed right sinusitis but no acute intracranial pathology. Baseline NIHSS was 15. The subject was randomized to the control arm of the SENTIS trial at 12:15, [redacted]-2009, 9.3 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (post enrollment day 1) the 24 hour MRI showed recent ischemia in the left pons with no other chronic or acute lesions in the left middle cerebral artery territory.

On [redacted]-2009 white blood cell (WBC) count was mildly elevated at 13,900; C-reactive protein (CRP) was 0.7. No treatment was administered.

On [redacted]-2009 (post enrollment day 4) Cordarone was started for atrial fibrillation **(AE # 901)**.

On [redacted]-2009 (post enrollment day 7) a chest x-ray demonstrated increased right infrahilar space which was thought to be related to hypoventilation or chronic inflammation. On the following day the subject became febrile, tachypneic, dyspneic and hypoxic. He had bilateral rhonchi, exceedingly dry mucus and decreased skin tone indicating dehydration. Chest x-ray showed left perihilar densities and increased right infrahilar trauma. Respiratory infection **(SAE #001)** was diagnosed and antibiotics were started. Due to the rapid ventricular response Cordorone was discontinued and IV Lanoxin was administered.

On [redacted]-2009 a do not resuscitate order was instituted. The subject had WBCs of 36,900, CRP 18.9, and creatinine 3.05. The subject expired on [redacted], post enrollment day 11. The autopsy report listed the cause of death as respiratory insufficiency, bronchial pneumonia, atrial fibrillation, and recent myocardial ischemia. Cause of death was adjudicated as systemic complications associated with stroke, specifically aspiration pneumonia.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
19-Jan-2009	000	003	117 - Tachycardia	N/A	N/A
19-Jan-2009	000	001	304 - Hematuria	N/A	N/A
20-Jan-2009	001	002	809 - Diabetes Mellitus	N/A	N/A
20-Jan-2009	001	004	204 - Aspiration pneumonia	N/A	N/A
20-Jan-2009	001	007	412 - HT, no concomitant mass effect	N/A	N/A

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
20-Jan-2009	**001**	**005**	***414 - Neurological worsening**	**N/A**	**N/A**
28-Jan-2009	009		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 76-year-old Caucasian male with a past medical history of hyperlipidemia, arterial hypertension, latent diabetes mellitus (diet controlled), and intermittent atrial fibrillation (2006). Repeated electrocardiograms did not identify atrial fibrillation and anticoagulation with Marcumar had been terminated in 2007. Medications at admission included: Bisoprolol and Simvastatin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 00:00, [redacted] 2009. Symptoms at presentation included dysarthria, facial paresis, gaze paresis, left hemiparesis with hemihypaesthesia and left-sided neglect. CT scan at admission revealed a somewhat hypodense appearance of the right proximal middle cerebral artery (MCA), no hemorrhage. MRI revealed a right subcortical MCA infarction and a discontinuation of flow signal in the right MCA. Baseline NIHSS was 16. The subject was randomized to the control arm of the SENTIS trial at 11:15, [redacted]-2009, 11.3 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (day of enrollment) the subject's heart rate was greater than 120 beats per minute **(AE #003)** and Lanicor and Concor were increased. After insertion of a urinary catheter the subject developed hematuria **(AE #001)** which resolved without treatment.

On [redacted]-2009 (post enrollment day 1) the subject's glucose level was 177 **(AE #002)** and Amaryl was started.

Also on [redacted]-2009 the subject became dyspneic, febrile, and had purulent bronchial mucus extracted by suction. Avelox was started for aspiration pneumonia **(AE #004)**.

The 24 hour follow-up MRI showed complete infarction of the right MCA territory. Minor hemorrhagic transformation of parts of the ischemic area was also detected **(AE #007)**. There was no mass effect. Clinical worsening (complete right middle hemispheric syndrome) was attributed to the stroke progression **(SAE #005)**.

On [redacted]-2009 (post enrollment day 3) the subject continued to have progressive neurological deterioration that was attributed to brain edema with space occupying effect evident on follow-up CT. The subject was treated with Mannitol but worsened (NIHSS on [redacted] 2009 was 25) and died of respiratory failure due to suspected trans-territorial

herniation on [redacted]-2009, post enrollment day 9. The cause of death was adjudicated as stroke.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
22-May-2009	**003**	**001**	**701 - Hematoma**	**N/A**	**N/A**
25-May-2009	**006**	**002**	*** 205 - Infectious pneumonia**	**N/A**	**N/A**
26-May-2009	007	901	301 - Renal dysfunction	N/A	N/A
26-May-2009	007	902	603 - Electrolyte imbalance	N/A	N/A
31-May-2009	012		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 80-year-old Caucasian female with a past medical history of hypertension, hyperlipidemia, atrial fibrillation, aortic valvulopathy, and non-insulin dependent diabetes. Medications at admission included: Actrapid and Digoxin.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 00:30 on [redacted]-2009. Symptoms on presentation included left ocular preference and global aphasia. CT scan at admission showed cerebral atrophy, predominantly cortical. Transcranial Doppler indicated a left MCA occlusion. Baseline NIHSS was 16. The subject was randomized to the control arm of the SENTIS trial at 13:35, 1[redacted]-2009, 13.1 hours from last known normal. Note: the subject was enrolled with an INR of 1.96. A protocol deviation was recorded.

NeuroFlo Procedure: N/A

Post-Enrollment Course: On [redacted]-2009 (post enrollment day 1) the 24 hour follow-up CT showed poorly defined left sub-cortical/cortical hypodensities. The 24 hour NIHSS was 17.

On [redacted]-2009 (post enrollment day 3) a left inguinal femoral hematoma **(SAE #001)** was noted at the groin puncture site (performed for diagnostic angiography). On the following day at 01:00 the subject was intubated and surgical repair of hematoma was performed. Two units of blood were given prior to the procedure and one unit post. The subject was febrile post surgery with a temperature of 38°C; Levafloxacin per the surgical protocol and Augmentin were given. The subject was extubated on [redacted] 2009.

On [redacted] 2009 (post enrollment day 6) the subject was tachypneic, had bilateral lung basal crepitations and an oxygen saturation of 91% **(SAE #002)**. Saline and diuretic therapy was continued.

On [redacted]-2009 the subject's creatinine had increased from 1.0 at baseline to 2.57, urea was 200, and glomerular filtration rate was 19.08. Furosemide was given as a bolus and switched to a continuous infusion as the subject's renal status worsened **(AE #901)**.

The subject received a calcium supplement on [redacted]-2009 for calcium of 8.1mg/dL (norm 8.8-10.2) **(AE #902)**. The calcium level increased to 8.5mg/dL on [redacted]-2009.

On [redacted] 2009 the subject was more somnolent than the day before. She was noted to have mild dyspnea, oxygen saturation of 90-92%, bilateral wet basal crepitations, and temperature of 38°C. On the following day the subject had a progressive reduction in level of consciousness and the family was informed of the subject's poor prognosis as she was not responding to the treatment.

On 3[redacted]-2009 (post enrollment day 12) the subject was tachypneic with diffuse rhonchi and a temperature of 38.5°C. The subject slipped into a coma and comfort care was initiated; the subject expired on the same day. Cause of death was adjudicated as systemic complications associated with stroke, specifically pneumonia.

Subject [redacted], enrolled [redacted] 2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
09-Sep-2009	**000**	**003**	**414 - Neurological worsening**	**N/A**	**N/A**
09-Sep-2009	000	002	606 - Hyperglycemia	N/A	N/A
10-Sep-2009	001	001	118 - Atrial Fibrillation	N/A	N/A
13-Sep-2009	**004**	**901**	**414 - Neurological worsening**	**N/A**	**N/A**
23-Sep-2009	**014**	**004**	***204 - Aspiration pneumonia**	**N/A**	**N/A**
23-Sep-2009	014		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 76-year-old Caucasian female with a past medical history of hypertension, cardiac insufficiency, osteoporosis, anemia due to vitamin B12 deficiency, and depression. Medications at admission included: Aspirin,

Atenolol, Lasix, Atorvastatin, Celexa, Chondroitin, Fosamax and transdermal nitroglycerin patch.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 09:00, [redacted] 2009. Symptoms at presentation included right hemiparesis, aphasia, confusion, right homonymous hemianopsia, left facial paresis and left hypoesthesia. CT scan at admission revealed a left internal carotid artery occlusion and a subacute infarct in the left middle cerebral artery territory; no hemorrhage. Baseline NIHSS was 14. The subject was randomized to the control arm of the SENTIS trial at 12:20, [redacted] 009, 3.3 hours from symptom onset.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject's neurological condition fluctuated during the early hours of her admission to the stroke unit and at 18:00 on [redacted]-2009 her 6 hour NIHSS had increased to 19. CT showed no acute changes and the neurological deterioration was attributed to progression of her index stroke **(SAE #003)**.

The subject's blood glucose level was 140mg/dL at admission and had increased to 658mg/dL on [redacted]-2009; insulin was given **(AE #002)**.

On [redacted]-2009 (post enrollment day 1) electrocardiogram showed rapid atrial fibrillation **(AE #001)** that was controlled with Amiodarone and Digoxin. The 24 hour NIHSS decreased to 12.

The 4 day NIHSS on [redacted]-2009 at 09:00 was 11. Later in a day, significant neurological worsening with global aphasia and right hemiplegia was noted **(SAE #901)**. The NIHSS increased to 20. CT showed no hemorrhagic transformation or acute lesions. The subject was placed in the Trendelenburg's position.

A urine analysis on [redacted]-2009 showed leukocytes 45/µL and bacteria 483/µL. No treatment was documented.

On [redacted]-2009 (post enrollment day 7) the subject's NIHSS remained at 20. On [redacted]-2009 the subject showed no clinical improvement but was deemed stabled. On the following day the subject was in a stuporous state and was afebrile. Chest x-ray done for percutaneous endoscopic gastrostomy (PEG) tube placement did not show any infiltrates.

On [redacted] 2009 (post enrollment day 14) at 14:04, the subject's Glasgow score was ranked as 3, temperature was 37.7°C, and she was tachypneic (respiratory rate of 55) despite good oxygen saturation at 96%. CT ruled out hemorrhagic transformation and cerebral edema. At 16:00 the subject had bronchial spasms, respiratory rate of 60, and an oxygen saturation of 84%. A differential diagnosis of bronchial aspiration **(SAE #004)** was treated with Augmentin, Tazocel, nebulizers, steroids, and morphine. Urinalysis showed leukocytes and bacteria. The subject rapidly deteriorated and died at 20:00, [redacted]-2009. Cause of death was adjudicated as systemic complication associated with stroke, specifically aspiration pneumonia.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
17-Dec-2009	**091**	**001**	*** 205 - Infectious pneumonia**	**N/A**	**N/A**
31-Dec-2009	105		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is an 89-year-old Caucasian female with a past medical history of atrial fibrillation, hypertension, deep vein thrombosis (1997), colon polyps, gastrointestinal bleeding, systemic lupus erythematosus with secondary antiphospholipid syndrome (1998), arthritis, poly-arthralgias, normocytic-normochromic anemia, osteoporosis, and severe aortic stenosis (2004). Medication at admission included: Prednisone, Hydroxychloroquine, Atacand, Lasix, Fosamax, calcium, Sintrom, and Dynamine.

Current Stroke Onset and SENTIS Enrollment: The subject experienced stroke symptom onset at 09:30 on [redacted]-2009. Symptoms at presentation included left-sided weakness, left facial paralysis, and dysarthria. CT showed demylinization with right lacunar lesion in the caudate nucleus. Baseline NIHSS was 11. The subject was randomized to the control arm of the SENTIS trial at 18:05, [redacted]-2009, 8.6 hours from symptom onset. The subject was enrolled with an INR 1.81. A protocol deviation has been received.

NeuroFlo Procedure: N/A

Post-Enrollment Course: The subject's neurological status remained unchanged. Her 4 day NIHSS on [redacted]p-2009 was 11. The subject was discharged from the hospital on the following day to a rehab facility.

At the 30 day follow-up visit on [redacted]2009, the subject's NIHSS was 13. The subject was discharged from rehab on [redacted]-2009 to home.

On [redacted]-2009 (post enrollment day 91) the subject was admitted with a respiratory super-infection (infectious pneumonia) due to bronchoplegia **(SAE #001)**. The subject deteriorated and died following a cardio-respiratory arrest on [redacted]-2009. The cause of death was adjudicated as systemic complications unrelated to stroke, specifically infectious pneumonia.

Subject [redacted] enrolled [redacted]-2009

Event Onset Date	Days to AE	AE #	Adverse Event Code & Description	Relation to Device	Relation to Procedure
06-Apr-2009	**000**	**004**	**414 - Neurological worsening**	**N/A**	**N/A**
07-Apr-2009	001	005	405 - HT, probably not contributing to mass effect	N/A	N/A
12-Apr-2009	**006**	**001**	***805 - Sepsis**	**N/A**	**N/A**
12-Apr-2009	006	003	603 - Electrolyte imbalance	N/A	N/A
13-Apr-2009	007	002	105 - Pulmonary Edema	N/A	N/A
19-Apr-2009	013		Death	N/A	N/A

Serious events are in bold, shaded text.
* Indicates serious event is associated with death.

Demographics and History: The subject is a 75-year-old Caucasian male with past medical history of non insulin dependent diabetes mellitus, hypertension, hyperlipidemia, and radiological evidence of an old left cortical stroke. Approximately 10 days prior to the index stroke the subject presented to the emergency room with a headache. Head CT done at that time showed no unusual findings. The subject also reported falling the day prior to admission due to an unknown reason; he did report general weakness without dizziness or headache at that that time. Medications at admission included: Aspirin, Atenolol, Hydrochlorothiazide, and Simvastatin. The subject was a current smoker.

Current Stroke Onset and SENTIS Enrollment: The subject was last known normal at 23:30 on [redacted]-2009. Symptoms at presentation included drowsiness with right hemiparesis and aphasia. CT angiography showed an old left frontal stroke and a severe stenosis of the left internal carotid artery (>95%) and left middle cerebral artery. Baseline NIHSS was 16. The subject was randomized to the control arm of the SENTIS trial at 12:00, [redacted]-2009, 12.5 hours from last known normal.

NeuroFlo Procedure: N/A

Post-Enrollment Course: At the time of the 6 hour follow-up assessment on [redacted]-2009 at 19:00, neurological deterioration was noted with the subject's NIHSS increasing to 20 **(SAE #004)**.

On [redacted]-2009 (post enrollment day 1) the 24 hour CT showed an extensive acute left stroke with pressure on the lateral ventricle and suspected hemorrhagic transformation **(AE #005)** in the left basal ganglia.

On [redacted]-2009 (post enrollment day 6) the subject had dyspnea, leukocytosis, fever, and infiltrations visualized on chest x-ray. Bilateral pneumonia was initially diagnosed **(SAE #001)** and antibiotic therapy was initiated (cultures were pending). Low potassium was also noted and corrected with supplements **(AE #003)**.

On 1[redacted]-2009 (post enrollment day 7) respiratory deterioration was partially attributed to a pulmonary edema **(AE #002)**. Respiration was temporarily and partially improved with the application of Furosemide and Morphine. That afternoon further respiratory deterioration was observed and the subject was intubated.

On [redacted]-2009 (post enrollment day 8) the subject had fever, hypotension, and renal function deterioration. A septic shock was diagnosed **(update to SAE #001)** and a dopamine drip was initiated.

On [redacted]-2009 (post enrollment day 13) at 09:15 the subject was found unconscious without peripheral pulse but with cardiac electrical activity and cardio-pulmonary resuscitation was initiated. The subject was pronounced dead after half an hour. The cause of death was adjudicated as systemic complications associated with stroke, specifically sepsis.

APPENDIX P

OTHER ADVERSE EVENTS

The non-serious adverse event summary tables in section VI Safety Outcomes only provided the rates of 'Other' adverse events. The table below provides the details of each of the non-serious adverse events that were adjudicated as 'Other'.

Non-Serious Adverse Events Categorized as 'Other'

	Treatment N=230			Control N=257		
Adverse Event Code	**# Events**	**# Subjects**	**% of Subjects**	**# Events**	**# Subjects**	**% of Subjects**
Cardiac Other	**8**	**8**	**3.5**	**7**	**7**	**2.7**
1st degree AV block	1	1	0.4	0	0	0.0
Aneurysm of front heart wall	1	1	0.4	0	0	0.0
Apical aneurysm	0	0	0.0	1	1	0.4
Cardiomyopathy	1	1	0.4	0	0	0.0
Dyspnea on exertion	1	1	0.4	0	0	0.0
Hypertensive cardiomyopathy	0	0	0.0	1	1	0.4
Intra-atrial septal aneurysm	0	0	0.0	1	1	0.4
LV apical aneurysm with thrombus	0	0	0.0	1	1	0.4
Left atrial thrombus	0	0	0.0	1	1	0.4
Left atrium thrombus	0	0	0.0	1	1	0.4
Occasional PVC's	1	1	0.4	0	0	0.0
Orthostatic syncope	1	1	0.4	0	0	0.0
Presyncopal episode with orthostatic event	1	1	0.4	0	0	0.0
ST depression	0	0	0.0	1	1	0.4
Volume overload	1	1	0.4	0	0	0.0
Renal Other	**4**	**4**	**1.7**	**6**	**6**	**2.3**
Abdominal discomfort	0	0	0.0	1	1	0.4
Adrenal mass	1	1	0.4	0	0	0.0
Chronic kidney disease / azotemia	0	0	0.0	1	1	0.4
Exophytic cyst of right kidney	0	0	0.0	1	1	0.4
Fluid imbalance	1	1	0.4	0	0	0.0
Pre-renal azotemia	1	1	0.4	0	0	0.0
Renal calculi	1	1	0.4	0	0	0.0
Right adrenal mass	0	0	0.0	1	1	0.4
Right cyst - kidney	0	0	0.0	1	1	0.4
Syndrome of inappropriate antidiuretic hormone secretio	0	0	0.0	1	1	0.4
Genital Other	**3**	**3**	**1.3**	**4**	**4**	**1.6**
BPH	0	0	0.0	1	1	0.4
Bleeding from penile meatus	1	1	0.4	0	0	0.0
Genital mycosis	0	0	0.0	1	1	0.4
Penile swelling	0	0	0.0	1	1	0.4

Non-Serious Adverse Events Categorized as 'Other'

	Treatment N=230			Control N=257		
Adverse Event Code	**# Events**	**# Subjects**	**% of Subjects**	**# Events**	**# Subjects**	**% of Subjects**
Prostate carcinoma	1	1	0.4	0	0	0.0
Vaginal bleeding	0	0	0.0	1	1	0.4
Vaginal candidiasis	1	1	0.4	0	0	0.0
Urinary Other	**10**	**8**	**3.5**	**7**	**7**	**2.7**
Bladder spasm	1	1	0.4	0	0	0.0
Bladder spasms	1	1	0.4	1	1	0.4
Bleeding via urethra	0	0	0.0	1	1	0.4
Inability to void	0	0	0.0	1	1	0.4
Incontinence	0	0	0.0	1	1	0.4
Intermittent urinary incontinence	1	1	0.4	0	0	0.0
Neurogenic bladder	3	3	1.3	0	0	0.0
Oliguria	1	1	0.4	0	0	0.0
Traumatic foley insertion	0	0	0.0	1	1	0.4
Urethral bleeding	1	1	0.4	0	0	0.0
Urinary burning	1	1	0.4	0	0	0.0
Urinary incontinence	1	1	0.4	2	2	0.8
Neuro Other Bleed	**0**	**0**	**0.0**	**1**	**1**	**0.4**
Diffuse micro-hemorrhage, amyloid angiopathy	0	0	0.0	1	1	0.4
Neuro Other	**23**	**21**	**9.1**	**18**	**18**	**7.0**
Cephalic instablility	1	1	0.4	0	0	0.0
Confusion	2	2	0.9	2	2	0.8
Decreased alertness episodes of staring off	0	0	0.0	1	1	0.4
Decreased sensation in left lower leg	1	1	0.4	0	0	0.0
Delirium	1	1	0.4	0	0	0.0
Delirium, hallucinations, agitation	0	0	0.0	1	1	0.4
Dizziness	1	1	0.4	0	0	0.0
Dysphagia	1	1	0.4	1	1	0.4
Facial twitching	1	1	0.4	0	0	0.0
Increased spasticity	1	1	0.4	0	0	0.0
Left hand neuropathy	0	0	0.0	1	1	0.4
Lethargy	1	1	0.4	2	2	0.8
Lethargy, decreased wakefulness	0	0	0.0	1	1	0.4
Muscle spasms	1	1	0.4	0	0	0.0
Neuropathy	1	1	0.4	0	0	0.0
Numbness, tingling of fingers	1	1	0.4	0	0	0.0

Non-Serious Adverse Events Categorized as 'Other'

	Treatment N=230			Control N=257		
Adverse Event Code	**# Events**	**# Subjects**	**% of Subjects**	**# Events**	**# Subjects**	**% of Subjects**
Parkinson's disease	0	0	0.0	1	1	0.4
Possible new lacunar infarct - asymptomatic	0	0	0.0	1	1	0.4
Presyncopal event	0	0	0.0	1	1	0.4
Right arm twitching	1	1	0.4	0	0	0.0
Right handed weakness	1	1	0.4	0	0	0.0
Somnolence	0	0	0.0	1	1	0.4
Spastic left hemiparesis	1	1	0.4	0	0	0.0
Spasticity	2	2	0.9	1	1	0.4
State of confusion of unclear origin	1	1	0.4	0	0	0.0
Subject found to be drowsy by neuro exam	0	0	0.0	1	1	0.4
Tingling of the left hand	1	1	0.4	0	0	0.0
Tremor	0	0	0.0	1	1	0.4
Vertigo	0	0	0.0	1	1	0.4
Vertigo with mild postional features	0	0	0.0	1	1	0.4
Visual disturbance	1	1	0.4	0	0	0.0
Visual hallucination	1	1	0.4	0	0	0.0
Visual hallucinations	1	1	0.4	0	0	0.0
Vascular Other	**10**	**10**	**4.3**	**6**	**6**	**2.3**
Aneurysm of the abdominal aorta	0	0	0.0	1	1	0.4
Aneurysm, R MCA	0	0	0.0	1	1	0.4
Antecubital area hardened	1	1	0.4	0	0	0.0
Bleeding at pic site	0	0	0.0	1	1	0.4
Blister/erythema at IV site	1	1	0.4	0	0	0.0
Broken blood vessel left eye	0	0	0.0	1	1	0.4
Decreased right femoral pulse	1	1	0.4	0	0	0.0
Diminishied pulse	1	1	0.4	0	0	0.0
Intracerebral aneurysm	1	1	0.4	0	0	0.0
Limb ischemia	1	1	0.4	0	0	0.0
Non-occlusive clot R profunda femoris vein with R leg swelling	0	0	0.0	1	1	0.4
Popliteal trifurcation thrombosis	1	1	0.4	0	0	0.0
Redness and induration at previous peripheral IV site	1	1	0.4	0	0	0.0
Right cephalic thrombus	1	1	0.4	0	0	0.0

Non-Serious Adverse Events Categorized as 'Other'

	Treatment N=230			Control N=257		
Adverse Event Code	**# Events**	**# Subjects**	**% of Subjects**	**# Events**	**# Subjects**	**% of Subjects**
Right groin discomfort	1	1	0.4	0	0	0.0
Thrombophlebitis on right arm	0	0	0.0	1	1	0.4
Pulmonary Other	**22**	**21**	**9.1**	**9**	**9**	**3.5**
Acute bronchitis	1	1	0.4	0	0	0.0
Bi-basilar crackles	1	1	0.4	0	0	0.0
Bilateral pleural effusion	0	0	0.0	1	1	0.4
Bronchitis	1	1	0.4	0	0	0.0
Bronchitis/chronic cough	1	1	0.4	0	0	0.0
COPD exacerbation	2	2	0.9	0	0	0.0
Chest congestion - Rhonchi	0	0	0.0	1	1	0.4
Cough	4	4	1.7	3	3	1.2
Dyspnea	1	1	0.4	0	0	0.0
Exacerbation of asthma	1	1	0.4	0	0	0.0
Non specific lung opacity	1	1	0.4	0	0	0.0
Pleural effusion	1	1	0.4	0	0	0.0
Pulmonary Edema	0	0	0.0	1	1	0.4
Pulmonary congestion	2	2	0.9	0	0	0.0
Pulmonary infiltrates	1	1	0.4	0	0	0.0
Respiratory congestion	0	0	0.0	1	1	0.4
Respiratory distress	0	0	0.0	1	1	0.4
Respiratory wheeze	1	1	0.4	0	0	0.0
Shortness of breath	1	1	0.4	0	0	0.0
Upper respiratory infection	1	1	0.4	1	1	0.4
Upper respiratory tract infection	2	2	0.9	0	0	0.0
GI Other	**19**	**16**	**7.0**	**19**	**18**	**7.0**
Bleeding post PEG tube	1	1	0.4	0	0	0.0
Bloody gastric fluid	0	0	0.0	1	1	0.4
C-difficile	1	1	0.4	1	1	0.4
C-difficle	0	0	0.0	1	1	0.4
C. Difficile	2	2	0.9	0	0	0.0
C. difficile / colitis	0	0	0.0	1	1	0.4
Chest pain diagnosed as GERD	0	0	0.0	1	1	0.4
Clostridium Difficile Diarrhea	0	0	0.0	1	1	0.4
Clostridium difficile toxin	1	1	0.4	0	0	0.0
Decreased appetite	1	1	0.4	0	0	0.0
Diverticulosis	0	0	0.0	1	1	0.4
Dyspepsia	1	1	0.4	0	0	0.0

Non-Serious Adverse Events Categorized as 'Other'

	Treatment N=230			Control N=257		
Adverse Event Code	**# Events**	**# Subjects**	**% of Subjects**	**# Events**	**# Subjects**	**% of Subjects**
Epigastric pain	1	1	0.4	0	0	0.0
Epigastric pain "likely biliary colic"	1	1	0.4	0	0	0.0
Erosive gastritis	0	0	0.0	1	1	0.4
GERD	1	1	0.4	1	1	0.4
GERD/Indigestion	0	0	0.0	1	1	0.4
Gallbladder stones	1	1	0.4	0	0	0.0
Gastric Carcinoid Tumor	0	0	0.0	1	1	0.4
Gastric discomfort	0	0	0.0	1	1	0.4
Gastric polyp	0	0	0.0	1	1	0.4
Gastric upset	0	0	0.0	1	1	0.4
Gastritis	2	2	0.9	0	0	0.0
Gastroporesis	1	1	0.4	0	0	0.0
Heartburn	1	1	0.4	1	1	0.4
Hiatal hernia	1	1	0.4	0	0	0.0
Indigestion	1	1	0.4	0	0	0.0
Intermittent bowel incontinence	1	1	0.4	0	0	0.0
Intestinal discomfort	0	0	0.0	1	1	0.4
Malnutrition	0	0	0.0	1	1	0.4
Meteorism (massive flatulence)	1	1	0.4	0	0	0.0
Probable viral gastroenteritis	0	0	0.0	1	1	0.4
Worsening GERD	0	0	0.0	1	1	0.4
Lab/electrolyte Other	**24**	**23**	**10.0**	**17**	**15**	**5.8**
Abnormal UA	1	1	0.4	0	0	0.0
Bacteremia	1	1	0.4	0	0	0.0
Blood culture contaminant	1	1	0.4	0	0	0.0
Creatinine Elevation	0	0	0.0	1	1	0.4
Creatinine elevated	0	0	0.0	1	1	0.4
Diagnosis of MRSA	1	1	0.4	0	0	0.0
Elevated BNP	1	1	0.4	0	0	0.0
Elevated LFT	0	0	0.0	1	1	0.4
Elevated WBC	0	0	0.0	1	1	0.4
Elevated anticardiolipin antibody	0	0	0.0	1	1	0.4
Elevated digoxin level	1	1	0.4	0	0	0.0
Elevated uric acid	0	0	0.0	1	1	0.4
Elevated white blood cell count	0	0	0.0	1	1	0.4

Non-Serious Adverse Events Categorized as 'Other'

	Treatment N=230			Control N=257		
Adverse Event Code	**# Events**	**# Subjects**	**% of Subjects**	**# Events**	**# Subjects**	**% of Subjects**
Essential thrombocytosis	0	0	0.0	1	1	0.4
Euthyroid sick syndrome	1	1	0.4	0	0	0.0
Glucose intolerance	3	3	1.3	1	1	0.4
Hyperhomocysteinemia	1	1	0.4	0	0	0.0
Hyperhomocysteinemia and Vit. B12 deficiency	2	2	0.9	0	0	0.0
Hypoglycemia	0	0	0.0	2	2	0.8
Increased CRP (C-reactive protein)	1	1	0.4	0	0	0.0
Increased INR	1	1	0.4	0	0	0.0
Increased LFT's	1	1	0.4	0	0	0.0
Increased LFTs	1	1	0.4	0	0	0.0
LFT elevation, diffuse liver parenchyma damage	0	0	0.0	1	1	0.4
Leukocytosis	1	1	0.4	0	0	0.0
Methemoglobinemia	1	1	0.4	0	0	0.0
Nasal swab positive for Staphylococcus Aureus	0	0	0.0	1	1	0.4
Positive blood culture	0	0	0.0	1	1	0.4
Staph Aureus	1	1	0.4	0	0	0.0
Thrombocytosis	0	0	0.0	1	1	0.4
Transaminitis	2	2	0.9	0	0	0.0
Vit D deficiency	0	0	0.0	1	1	0.4
Vit. B12 decrease	0	0	0.0	1	1	0.4
Vitamin B12 deficiency	2	2	0.9	0	0	0.0
Other	**59**	**50**	**21.7**	**63**	**54**	**21.0**
Abdominal mass	1	1	0.4	0	0	0.0
Abdominal wall hematoma	1	1	0.4	0	0	0.0
Adjustment disorder	0	0	0.0	1	1	0.4
Alcohol withdrawal	2	2	0.9	0	0	0.0
Allergies	1	1	0.4	0	0	0.0
Ankle edema	1	1	0.4	0	0	0.0
Ankle swelling	1	1	0.4	0	0	0.0
Anxiety	1	1	0.4	6	6	2.3
Bilateral lower extremity edema	1	1	0.4	0	0	0.0
Bleeding from gums	1	1	0.4	0	0	0.0
Bleeding in both ears - tympanic membrane perforated	1	1	0.4	0	0	0.0

Non-Serious Adverse Events Categorized as 'Other'

	Treatment N=230			Control N=257		
Adverse Event Code	# Events	# Subjects	% of Subjects	# Events	# Subjects	% of Subjects
Broken tooth with bleeding in the mouth	1	1	0.4	0	0	0.0
Bruising	1	1	0.4	0	0	0.0
Capsulitis	1	1	0.4	0	0	0.0
Choking	0	0	0.0	1	1	0.4
Coccyx redness, Stage 1 decubitus	0	0	0.0	1	1	0.4
Common cold	2	2	0.9	0	0	0.0
Contusion glutea	0	0	0.0	1	1	0.4
Decubitus ulcer	2	2	0.9	1	1	0.4
Delirium tremens	0	0	0.0	1	1	0.4
Diaphoresis	0	0	0.0	1	1	0.4
Dizziness	1	1	0.4	3	3	1.2
Dizziness of unknown cause	1	1	0.4	0	0	0.0
Drug overdose-somnolence, difficulty arousal, hypotension	1	1	0.4	0	0	0.0
Ear laceration	0	0	0.0	1	1	0.4
Edema	0	0	0.0	1	1	0.4
Edema right leg	1	1	0.4	0	0	0.0
Edema, left hand and foot	1	1	0.4	0	0	0.0
Epistaxis	1	1	0.4	3	3	1.2
Epistaxsis	0	0	0.0	1	1	0.4
Equinovarus posturing of right ankle	1	1	0.4	0	0	0.0
Erysipee left lower leg	0	0	0.0	1	1	0.4
Erythema	1	1	0.4	0	0	0.0
Exacerbation of gout	0	0	0.0	1	1	0.4
Fatigue	2	2	0.9	0	0	0.0
Flair up of gout	0	0	0.0	1	1	0.4
Forgetfulness	1	1	0.4	0	0	0.0
Fracture right ankle	1	1	0.4	0	0	0.0
Gout	1	1	0.4	0	0	0.0
Hiccups	1	1	0.4	0	0	0.0
Hypothyreosis	0	0	0.0	1	1	0.4
Hypothyroidism	1	1	0.4	1	1	0.4
Intermittent anxiety	0	0	0.0	1	1	0.4
Intermittent dizziness	1	1	0.4	0	0	0.0
Intermittent stiffness	0	0	0.0	1	1	0.4
L3 fracture	1	1	0.4	0	0	0.0
LLE peripheral edema	1	1	0.4	0	0	0.0

Non-Serious Adverse Events Categorized as 'Other'

	Treatment N=230			Control N=257		
Adverse Event Code	# Events	# Subjects	% of Subjects	# Events	# Subjects	% of Subjects
Left chest wound	0	0	0.0	1	1	0.4
Left elbow abrasion	0	0	0.0	1	1	0.4
Left eye conjunctivitis	1	1	0.4	0	0	0.0
Left eye nodule	1	1	0.4	0	0	0.0
Left eye redness and drainage, swelling	0	0	0.0	1	1	0.4
Left hand fracture	0	0	0.0	1	1	0.4
Left sphenoid and posterior right ethmoid sinus disease	0	0	0.0	1	1	0.4
Left upper and lower extremity spasms	0	0	0.0	1	1	0.4
Leg cramps	0	0	0.0	1	1	0.4
Lip laceration	1	1	0.4	0	0	0.0
Macular degeneration	0	0	0.0	1	1	0.4
Maxillar Sinusitis	0	0	0.0	1	1	0.4
Mild to moderate sensorineural hearing loss	1	1	0.4	0	0	0.0
Mood disorder	1	1	0.4	0	0	0.0
Multiple fractures	0	0	0.0	1	1	0.4
Muscle spasm	0	0	0.0	1	1	0.4
Muscle tightness	0	0	0.0	1	1	0.4
Myalgias	0	0	0.0	1	1	0.4
Mycotic toenails/hyperkeratosis	1	1	0.4	0	0	0.0
Nose bleeds	0	0	0.0	1	1	0.4
Oropharangeal bleeding	0	0	0.0	1	1	0.4
Osteoporosis	2	2	0.9	0	0	0.0
Paronychia	1	1	0.4	0	0	0.0
Photophobia	0	0	0.0	1	1	0.4
Planum sphenoidal meningioma	0	0	0.0	1	1	0.4
Possible renal and ovarian cysts	1	1	0.4	0	0	0.0
Pruritis	0	0	0.0	1	1	0.4
Recurrent laryngeal neuropraxia	0	0	0.0	1	1	0.4
Red/itchy eye	1	1	0.4	0	0	0.0
Restless legs	1	1	0.4	0	0	0.0
Rhinitis	1	1	0.4	0	0	0.0
Rib fracture	0	0	0.0	1	1	0.4
Right eye slight edema and ecchymosis	0	0	0.0	1	1	0.4

Non-Serious Adverse Events Categorized as 'Other'

	Treatment N=230			Control N=257		
Adverse Event Code	**# Events**	**# Subjects**	**% of Subjects**	**# Events**	**# Subjects**	**% of Subjects**
Right hand white, cold to touch (forearm & upper arm warm)	1	1	0.4	0	0	0.0
Right heel wound	0	0	0.0	1	1	0.4
Right leg spasms	0	0	0.0	1	1	0.4
Right mastoiditis	0	0	0.0	1	1	0.4
Rotator cuff tear	1	1	0.4	0	0	0.0
Scalp hematoma	1	1	0.4	0	0	0.0
Scapular abscess	1	1	0.4	0	0	0.0
Seasonal allergies	0	0	0.0	1	1	0.4
Shingles	1	1	0.4	0	0	0.0
Side effects of medication prescribed (aggrenox)	0	0	0.0	1	1	0.4
Sinusitis	1	1	0.4	0	0	0.0
Sinusitis and mastoiditis	0	0	0.0	1	1	0.4
Spasticity	1	1	0.4	1	1	0.4
Sublaxation of shoulder	0	0	0.0	1	1	0.4
Swelling right ankle	0	0	0.0	1	1	0.4
Swollen tongue	0	0	0.0	1	1	0.4
Tremor and dizziness, nausea due to theophyllin	0	0	0.0	1	1	0.4
Vertigo	1	1	0.4	0	0	0.0
Viral disease	1	1	0.4	0	0	0.0
Visual disturbance	1	1	0.4	0	0	0.0
Weakness	0	0	0.0	2	2	0.8

APPENDIX Q

LITERATURE REFERENCES

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