MEDTRONIC
RESPONSE

Medtronic

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September 3, 1999

Janet L. Scudiero
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RE: Response to petition to Neurological Advisory Panel September 17, 1999 for reclassification of Totally Implantable Spinal Cord Stimulator for use in the treatment of chronic intractable pain.

Dear Ms. Scudiero;

Enclosed are twenty (20) copies of Medtronic's response to the petition for reclassification of Totally Implantable Spinal Cord Stimulators that will be presented at the September 17, 1999 Neurological Advisory Panel. Under 513(b)(6) we respectfully request that this information be provided to the panel members and FDA for their consideration prior to the meeting.

We wish to reiterate our belief that the petitioner has not demonstrated reasonable assurance that an FDA Class II device classification with "Special Controls" is sufficient to ensure the safety and efficacy of devices within this classification. The proposed reclassification would allow a significant loss in the controls that are in place for the protection of the general public. We believe our response will aid the panel members in their determination to retain the Class III designation for the "Totally Implantable Spinal Cord Stimulator for the use in the treatment of chronic intractable pain."

Medtronic provides this information for the FDA Neurological Advisory Panel and believes to the best of our knowledge that all data and information submitted are truthful and accurate and no material fact has been omitted. Medtronic acknowledges that this document's contents are subject to, and comply with, 18 U.S.C. 1001, chapter 47, Fraud and False Statements; as well as with 18 U.S.C. 1515, chapter 73, Obstruction of Justice (for a proceeding before a federal government agency).

Thank you for your time in reviewing this response. If you have any additional concerns or questions please contact the undersigned or Kathy Jo Fahey at (612) 514-5198.

Sincerely,
MEDTRONIC, INC. NEUROLOGICAL DIVISION

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Discussion

1. Summary

It is the opinion of Medtronic that there is not enough valid clinical and scientific data to support reclassification of this device. Additionally, the panel does not have the data that is required before it. The current Petition does not provide:

- A description of radio frequency (RF) devices compared to internal battery pulse generators (IPG)
- A discussion of predicate devices and their related regulatory history, and
- A discussion of comparative/ similar devices and their related regulatory history

In addition both the MDR descriptions and the literature review are inadequate. As justification to move the device from Class III PMA controls into Class II, the petition advocates labeling and a limited standard as special controls to provide reasonable assurance of the device's safety and effectiveness. The petition fails to show that those controls would be adequate to protect the public. Additionally, the referenced standards are not accepted by FDA and, in general, apply only to testing of external devices.

The "addition of a battery" is written as if one is placing batteries in a flashlight. This is not the case, as multiple manufacturers have discovered. Those technological issues and hazards, which have led to patient injury and harm, have demonstrated the vast complexities of such devices and the requirement to review each manufacturer's device on a case-by-case basis.

The complexity of the device with its various applications (pacing, gastrointestinal, urinary, tremor, epilepsy, etc.) demands strong evidence demonstrating valid scientific data before reclassification should be permitted. Little if any valid scientific evidence supports the petition. We believe a case-by-case PMA review is necessary to protect the public safety and to provide reasonable assurance that the device is safe and effective.

Finally, FDA has previously evaluated the classification of these devices as recently as **July 1999** (FDA Commissioner J. Henney letter, Attachment A) and determined that these devices are "potentially high risk devices". In 1995, FDA (FDA Director S. Alpert letter, provided in Attachment B) confirmed that these devices are Class III because of the significant technological characteristic of a totally implanted power source.

2. Regulatory Discussion

We believe the FDA classification level III, with the corresponding Pre-Market Approval (PMA) review/ approval, is paramount to protect the safety of patients exposed to the highly intricate specialized circuitry that is required to allow the power source to be contained within this device. The complexity of a totally implantable pulse generator greatly increases the level of risk to the patient, and increases the FDA controls required to assure patient safety.

The impact to patients of a device failure could be significant. Medtronic firmly believes that a product-by-product PMA review, and the premarketing inspections that accompany PMA approvals, are necessary to protect consumers.

Prior to marketing, the required level of FDA review/approval for a Class III PMA device includes:

- Full premarket approval review,
- Full premarket approval review of changes requiring PMA supplements,
- FDA inspection and audit of manufacturing facilities,
- Rigorous review of bench, animal and clinical data, and
- Approval of comprehensive labeling.

Examples of how the system works to protect the public (e.g. warning letters and 483 observations)

The current classification and the related FDA review and approval on a case-by-case basis has resulted in the protection of public health.

Patient risks can be identified from both technological issues and actual events. From a technical standpoint, there are significant issues in the attempted validation of an implanted power source, e.g., insulation materials, hybrid circuit, feed-throughs, titanium can sealing, electrical and welding specifications, and battery sealing.

Examples of attempted commercialization of neurostimulators include one neurostimulation company's development of a totally implantable generator (IPG) that was not successful because of the failure of the battery and (its associated control circuitry) manufacturing methods, and facilities. The resulting patient injuries were significant.

The risks to human health were so significant that FDA had to terminate the company's IDE clinical study because the "unreasonable risk to public health owing to the inadequacy of the methods, facilities, and controls used in the manufacture of the device."

This device's technological failures included:

- Fluid leakage into the device causing battery failure (loss of hermetic seal),
- Battery failure due to insufficient or no welding,
- Battery feed throughs' performance and process validation not documented,
- Inadequate battery cell and battery outer can validation/ qualification testing,
- High battery impedance,
- Transient programmer failure,
- Battery insulation redesigned and implemented, but not qualified and no FDA notification or approval,
- Programmer/ Transmitter circuitry redesigned and implemented, but not qualified, and no FDA notification or approval,

This company's clinical usage of the device with patient injuries included:

- Not reporting patient injuries (such as **"shocks", "getting zapped", or "electrical shocks"**) to FDA via MDR or IDE,
- Not reporting to FDA Unanticipated Adverse Device Effects, such as **"intolerable increase in stimulation", "increased stimulation to intolerable levels", and "battery thoroughly discharged**."

These failures demonstrate actual patient harm, as well as the increased risk inherent in the devices. These observations would not have been discovered if not for the pre-approval inspection of the manufacturing site.

A second **neurostimulation** company's attempt to design and manufacture an implanted device with internal battery also failed. This device failed because issues relating to the battery and its technology resulted in patient harm. This battery's electrolytes diffused through its silicone holder, i.e., the electrolytes leaked within the implanted device. This leakage caused the control circuit to fail, which in turn caused the device to either (a) not be programmable (not able to turn off the device), (b) change parameters on its own, or (c) cease functioning. At a minimum all of the failures resulted in device explant, and some in patient harm.

Since totally implantable IPG technology is very similar between neurostimulators and pacemakers, pacemakers can also be reviewed for risks of technology failures:

- The loss of the hermetic seal, (the battery feed through had a glass to metal seal which failed) in one **pacemaker** company's devices, resulted in the battery shorting out within 4 to 18 months.
- Another **pacemaker** company issued a safety alert for pacemakers which could fail without warning due to the loss of "hermeticity" because of cracked ceramic feed throughs or separation of a braze joint between ceramic and titanium components, resulting in fluid ingress into the pacemaker.

3. Technical Discussion

As stated previously, the "addition of a battery" is written by the petitioner as if one is placing batteries in a flashlight. As multiple manufacturers have discovered this is not the case. The technological issues and hazards (those that have resulted in patient injury and harm) have demonstrated the vast complexities of such devices and the requirement to review each manufacturer's device on a case-by-case basis.

What is necessary to internalize the battery is not the only difference between an IPG and a Radiofrequency system. A comparison of RF receivers and IPGs follows:

Table 1: Comparison of RF and IPG Devices

RF Devices –(Receiver only implanted)	**IPG (with battery)**
Antenna to receive **power**	Antenna to receive **communication**
Circuit = Simple remodulator and switch circuit Does **NOT**: 1. Generate stimulation pulses 2. Control stimulation parameters	Circuit = 1. Generates pulses 2. Controls stimulation parameters 3. Self-contained system 4. Reliability important because may not turn off when desired (vs. simply removing RF antenna)
Encapsulation = epoxy	Container = Titanium
No Internal Power Source, Power received from external transmitter	Internal Power Source 5. Large amount of chemical energy 6. Potential for electrical shorts 7. Potential for heating 8. Potential for battery chemical leaks 9. Potential for fluid leakage into battery 10. Extensive manufacturing controls required 11. Potential explosive reactions
Emergency Stop = Remove external transmitter Antenna	Emergency Stop = Requires either: • Programmer telemetry or • Communication with IPG or • Emergency explant
Engineering Design = Simple	Engineering Design = Complex
Manufacturing = Simple	Manufacturing = Complex

There are no FDA guidance documents on the appropriate testing of implantable pulse generators, with internal power sources. For Class III devices, it is up to the manufacturer to submit data demonstrating safety and effectiveness. For Class II devices, the manufacturer only has to demonstrate "substantial equivalence" (510(k) approval) to a pre-1976 device, or to one that has already received 510(k) approval.

Examples of the differences in testing are as follows:

Table 2: Medtronic Testing Requirements - Differences

RF Devices –(Receiver only implanted)	**IPG (with battery)**
N/A	Battery - Electrical discharge testing - Longevity at nominal outputs
N/A	Hybrid Circuit testing - Current Drain - Rate limit - Circuit Signal and converter - Battery monitor - Battery End of Life threshold Integrated Circuit Testing - Telemetry linkage - Signal converter - Power on Reset
N/A	Programmer Testing - Software - Keyboard - Programming Wand - Components - Function/ Telemetry capability - Mechanical shock and vibration
Software Testing	Software Compatibility
Incompatible Transmitter Interaction	Programmer Compatibility

Table 3: Medtronic Testing Requirements - Similarities

RF Devices –Implanted Receiver	IPG (with battery)
Stimulation Parameter testing (Amplitude, Rate, Pulse Width)	Stimulation Parameter testing (Amplitude, Rate, Pulse Width)
Electrical Tests - Power up power on reset - Amplitude calibration / max. limit - Electrode programming/ channel - Net DC Current - Rate range - Pulse width range - Signal cross talk - Stimulation disable - Receiver implant depth max. - Receiver/ antenna offset max. - Multiple systems interaction	Hybrid Circuit testing - Rate - Pulse width - Output pulse - Switches - Circuit components - Burn in Integrated Circuit testing - Timing and interface - Voltage reference - Failure modes - EMC - System compatibility - In-vitro test systems
Biocompatibility Testing	Biocompatibility Testing
Electromagnetic Compatibility (EMC) Testing	Electromagnetic Compatibility (EMC) Testing
Environmental Stress, e.g., mechanical shock and vibration	Environmental Stress, e.g., mechanical shock and vibration
Connector Testing, e.g., fluid leakage and impedance	Connector Testing, e.g., fluid leakage and impedance
Extension and Lead Testing	Extension and Lead Testing

4. <u>Medical Device Reporting (MDR)</u>

A search of the MDR database was performed using Medline and Diogenes. The specified parameter was "spinal cord stim". This search resulted in reports dated from April 14, 1981 to December 1,1998. There were 2299 entries, of which 780 were specific reports on implantable pulse generator (IPG) or radio frequency (RF) devices. There are three MDR Categories: death, serious injury and malfunction. There was one death reported (0.10%), 305 serious injuries (39%) and 474 malfunctions (61%). The definitions of the last two FDA categories are provided for reference.

"Serious Injury/(Serious illness) [§803.3(a)(1)]

- Is life threatening, even if temporary in nature;
- Results in permanent impairment of a body function or permanent damage to a body structure; or

- Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure."

"Malfunction [§803.3(m)]
A "malfunction" is a failure of the device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. A malfunction should be considered reportable if any one of the following is true:

- The chance of a death or serious injury resulting from a recurrence of the malfunction is not remote;
- The consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;
- The malfunction causes the device to fail to perform its essential function and compromises the device's therapeutic, monitoring or diagnostic effectiveness (emphasis provided by Medtronic) **Which could cause or contribute to a death or serious injury, or other significant adverse device experiences. The essential function of a device refers not only to the device's labeled use, but for any use widely prescribed within the practice of medicine;**
- **The malfunction involves a long-term device implant that would prevent the implant from performing its function;**
- **The device is considered life-supporting or life-sustaining, and thus essential to maintaining human life;** or
- The manufacturer takes or would be required to take action under section 518 or 519(f) of the FD&C Act as a result of the malfunction of the device or other similar devices."

It is essential to remember the underlined portion above when reviewing this reclassification petition. Consideration should be given to the fact that an IPG can be prescribed for other stimulation therapies besides Spinal Cord Stimulation (SCS). A physician may deem a stimulation system medically necessary and prescribe it for other anatomical locations or symptoms of disease such as cardiac pacing, gastrointestinal and urinary disorders, and tremor and epilepsy.

The reports by company, model number and type of event were reviewed and are reported in Tables 4 through 6.

The MDRs were also reviewed by type of event. These were placed into eight categories: device malfunction, battery, programming, stimulation, patient sequelae, elective removal, improper implant procedure, and explanted – unknown reason.

The single death that was reported was due to meningitis and text from this report is contained within the MDR "sample text" section of this document. The most frequently reported event was "no output" at 160/780 (21%). Intermittent stimulation at 136/780 (17%) was the next most frequently reported event. Device malfunction at 132/780 (17%) had a similar number of events reported.

Within the category of patient sequelae, the most frequently reported event was infection 33/780 (4%). Pain was reported in 10/780 (1%) of MDR events. All of the above events resulted in the patient undergoing an additional operative procedure in which the device was explanted.

The petitioner has failed to recognize many MDR reported events related to these devices. On page of 14 of this document are examples of MDR text in which the respective manufacturers reported the events. This text is provided to show evidence of events that can occur with an internal battery. The petitioner has suggested that battery depletion is the only issue related to an internal battery, although the battery has caused reportable events, not all are due to increased voltage which minimizes the life of the battery. The petitioner has suggested labeling would be an adequate control for this occurrence. Medtronic concurs; in fact we have already implemented such labeling. However, the MDR text describes additional events which affect the battery such as: a hybrid failure resulting in a current drain, a discrepant control gate also resulting in a current drain and in a possible battery leak. None of these events would have been resolved or minimized by the proposed labeling control. They clearly demonstrate the need for additional bench testing for IPGs (see Table 2, page 6).

It is also important to take note of the number of "programming" events that were reported: 228/780 (29%), approximately a third of all the MDRs reviewed. As stated previously all of these events resulted in the device being explanted. Since the circuitry required to internalize the battery is complex, if there is an issue with programming the device, (e.g., no telemetry, turning on and off on its own, no output or simply not able to program,) in most instances the resolution is to explant the device. For RF devices, programming occurs in the external portion of the system and can be easily remedied with repair or exchange of the external unit.

Likewise, if a device is delivering intermittent stimulation or surges, (and in some cases shocks), the device may have lost its capability to respond to the physician/patient programmer and it may not be possible to turn the device off. In these instances, the only resolution again is emergency surgical removal of the device. The labeling and limited standard controls proposed by the petitioner would be inadequate to minimize these occurrences. To restate, we as a current manufacturer of these devices, have, with the assistance of FDA, instituted significant and rigorous clinical and non-clinical testing to assure that occurrences such as these are minimized prior to commercial release of the product.

The subject of this response as well as the subject of the petitioner's request for reclassification is the totally implantable spinal cord stimulator. The petitioner has included MDR reports unrelated to this device. We have chosen not to include MDR reported events for lead migration, epidural hemorrhage, seroma, paralysis, cerebral spinal fluid leak, lead breakage, or loose connection in our review, differing from the

petitioner's analysis, since these were due to the interaction or failure of the lead and/or extension.

The MDR database does not capture all events, as evidence of the fact is our review of the FDA regulatory actions, a FDA 483 observations had noted that the manufacturer/sponsor of an Investigational Device Exemption (IDE) had not reported events as required by regulation.

Table 4: Type of MDR by Manufacturer

	Medtronic	Neuromed	Cordis	EBI Medical Systems	Total
Death	0	1	0	0	**1**
Serious Injury	181	106	15	3	**305**
Malfunction	199	261	14	0	**474**
Total	**380**	**368**	**29**	**3**	**780**

Table 5a: MDR Type by Manufacturer; by Model #: *Medtronic*

Model	Death	Serious Injury	Malfunction	Total
3272	0	6	1	**7**
3360	0	2	5	**7**
3462/3463	0	0	2	**2**
3464/3465	0	6	21	**27**
3470	0	22	2	**24**
7420/7421	0	10	88	**98**
7424	0	133	80	**213**
7425	0	2	0	**2**
Total	**0**	**181**	**199**	**380**

Table 5b: MDR Type by Manufacturer; by Model #: *Neuromed*

Model	Death	Serious Injury	Malfunction	Total
TI-94	0	6	2	**8**
MNR4	0	0	3	**3**
MNR881	0	0	1	**1**
MNR88	0	46	128	**174**
MNR98	0	8	0	**8**
MNR916	0	17	0	**17**
MNR94	0	18	126	**144**
MNR944	0	2	0	**2**
MNR948	0	2	0	**2**
MBR88	0	1	0	**1**
MNT4D	0	1	0	**1**
MNT46	0	1	0	**1**
MNT88D	0	0	1	**1**
MCR88	0	1	0	**1**
Custom Device	0	1	0	**1**
Unknown	1	2	0	**3**
Total	**1**	**106**	**261**	**368**

Table 5c: MDR Type by Manufacturer; by Model #: *Cordis*

Model	Death	Serious Injury	Malfunction	Total
Mark II- 940D	0	15	14	**29**
Total	**0**	**15**	**14**	**29**

Table 5d: MDR Type by Manufacturer; by Model #: *EBI Medical Systems*

Model	Death	Serious Injury	Malfunction	Total
10-1332W	0	2	0	**2**
10-1370W	0	1	0	**1**
Total	**0**	**3**	**0**	**3**

Table 6: Overall MDR Report by Type of Event

Type of Event	Death	Serious Injury	Malfunction	TOTAL
Device Malfunction				
Malfunction	0	65	67	**132**
Connector or adaptor passage clogged or blocked	0	1	0	**1**
Signs of fluid intrusion and signs of rust in setscrews	0	7	11	**18**
Battery				
End of life/battery depletion	0	13	49	**62**
Leakage – from battery pack	0	2	0	**2**
Programming				
Programming	0	10	21	**31**
No Telemetry	0	3	9	**12**
Turning on or off next to power lines	0	0	1	**1**
Turning on or off on its own	0	14	10	**24**
No output	0	21	139	**160**
Stimulation				
Unsatisfactory Stimulation	0	10	29	**39**
Erratic Stimulation	0	2	1	**3**
Intermittent stimulation/no stimulation	0	68	68	**136**
Overstimulation while passing through security system	0	1	9	**10**
Greater stimulation than anticipated	0	5	4	**9**
Surging	0	5	13	**18**
Strong surges of stimulation	0	2	0	**2**
Surging, Shocking, jabbing jerking movements	0	9	0	**9**
Jolts around implant site and legs	0	2	3	**5**
Shock	0	4	6	**10**
Severe shock	0	1	0	**1**
Massive shock	0	1	0	**1**
Electrical failure	0	1	1	**2**

Type of Event	Death	Serious Injury	Malfunction	TOTAL
Fluctuations in amplitude	0	0	2	**2**
Runaway amplitude	0	1	0	**1**
Abnormal heartbeat	0	1	0	**1**
Vibration	0	1	0	**1**
Short Circuit	0	0	2	**2**
Patient Sequelae				
Constant burning pain	0	2	2	**4**
Alleged permanent disability	0	1	0	**1**
Patient injury	0	7	2	**9**
Pain	0	4	6	**10**
Infection	0	20	13	**33**
Swollen implant pocket	0	1	0	**1**
Hematoma at implant site	0	1	0	**1**
Pocket healing	0	2	1	**3**
Death	1	0	0	**1**
Elective removal	0	6	1	**7**
Improper implant procedure – device explanted	0	2	1	**3**
Explanted – unknown reason	0	9	3	**12**
TOTAL	**1**	**305**	**474**	**780**

Examples of MDR text:

Death

TX - TEXT: A PT, WHOSE HEALTH WAS DETERIORATING RAPIDLY, WAS IMPLANTED WITH A STIMULATOR ON 1/30/96. AFTER A 15 DAY TRIAL THE PT WAS DIAGNOSED WITH MENINGITIS AND PASSED AWAY ONE WEEK LATER. THE DEVICE HAS NOT BEEN RETURNED TO THE MFR FOR EVAL. BASED ON THE ONLY INFORMATION CO HAS RECEIVED, CO DOES NOT FEEL THAT THERE IS ENOUGH INFORMATION TO SUGGEST THAT CO'S PRODUCT CONTRIBUTED OR CAUSED THE PT'S DEATH. IN CO'S LITERATURE FOR THE PHYSICIAN IT STATES THAT IT IS NOT RECOMMEDED ON PATIENTS WHO HAVE RAPIDLY PROGRESSING DISORDER.
DT - DATE OF OCCURRENCE: 19960329
AN - ACCESSION NUMBER: 1551242

Battery

TX - TEXT: THE DEVICE WAS EXPLANTED DUE TO REPORTED **"BATTERY DEPLETION", HOWEVER, ANALYSIS REVEALED A HIGH CURRENT DRAIN FROM THE HYBRID CAUSED BY A LEAKY N-CHANNEL TRANSISTOR** IN THE ANTENNA DRIVEN CIRCUIT OF THE L44 IC.
DT - DATE OF OCCURRENCE: 19960418
AN - ACCESSION NUMBER: 1555967

TX - TEXT: FOREIGN MFR NO LONGER IN BUSINESS. THE RECEIVER WAS EXPLANTED AND RETURNED TO CO ON 10/9/92 WITH A CLAIM THAT THE **PT EXPERIENCED A SWOLLEN POCKET AND STRONG ELECTRICAL SURGES EVEN WHEN THE IMPLANT WAS TURNED OFF. UPON EXPLANT, THE POCKET WAS FULL OF NECROTIC TISSUE EVIDENTLY CAUSED BY A BLACKISH GREEN EXUDATE COMING FROM THE NECK OF THE IMPLANT.** THE BATTERY HAS BEEN SENT TO THE MFR FOR FURTHER ANALYSIS. A FINAL REPORT WILL BE FORWARDED UPON CONCLUSION OF ANALYSIS. THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. IN ADDITION, AVAILABLE FREQUENCY AND SEVERITY DATA DO NOT INDICATE THAT ANY FURTHER INVESTIGATION IS NECESSARY AT THIS TIME. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.
DT - DATE OF OCCURRENCE: 19921215
AN - ACCESSION NUMBER: 1211057

TX - TEXT: PRODUCT WAS RETURNED TO CO FOR EVALUATION WITH A COMPLAINT OF "DEFECTIVE, MALFUNCTIONING". NO PT COMPLICATIONS OR PROBLEMS WERE REPORTED. THE COMPLETED VENDOR ANALYSIS WAS RECEIVED BY CO ON 9/15/89. ALTHOUGH THE UNIT DID MEET THE MINIMUM BATTERY CELL LIFE REQUIREMENTS BASED ON IMPLANT AND EXPLANT INFO RECEIVED FROM THE CUSTOMER, A **DISCREPANT CURRENT CONTROL GATE WAS DETECTED ON ANALYSIS. THIS RESULTED IN AN OUTPUT VOLTAGE WHICH WAS OUT OF SPECIFICATIONS AND A CURRENT DRAIN WHICH WAS HIGH FOR THE PROGRAMMED PARAMETERS.** THIS REPORT WAS REVIEWED FOR SIGNIFICANT PROBLEMS BUT WAS NOT CLOSED. IT IS BEING CLOSED AT THIS TIME AS PART OF A BATCH CLOSEOUT PROCESS IN ORDER TO PREPARE THE DATABASE TO SERVE AS HISTORICAL SUPPORT TO A REDESIGNED DATABASE.
DT - DATE OF OCCURRENCE: 19891005
AN - ACCESSION NUMBER: 1083292

Stimulation

TX - TEXT: FOR THE PAST YEAR **PT HAS EXPERIENCED PRICKLY SENSATION OR NO STIMULATION WHEN DEVICE IS ON. STIMULATION HAS THROWN PT DOWN SEVERAL TIMES WHEN STIMULATION COMES ON. DEVICE HAS NOT WORKED AT ALL FOR THE PAST TWO MONTHS.** THE DEVICE WAS EXPLANTED. EXPLANT DATE: 3/24/96. DEVICE NOT RETURNED TO MFR.
DT - DATE OF OCCURRENCE: 19960405
AN - ACCESSION NUMBER: 1553145

Fluid Intrusion

TX - TEXT: THE RECEIVER WAS EXPLANTED AND **SIGNS OF FLUID INTRUSION WAS FOUND IN THE RECEIVER. THERE WERE ALSO SIGNS OF RUST FOUND IN SETSCREWS.** THE RECEIVER HAS NOT YET BEEN RETURNED TO CO FOR ANALYSIS. A FINAL SUMMARY ANALYSIS WILL BE PROVIDED TO FDA WITHIN 120 DAYS UPON THE RETURN OF THE DEVICE.
DT - DATE OF OCCURRENCE: 19950908
AN - ACCESSION NUMBER: 1486856

TX - TEXT: THE RECEIVER WAS EXPLANTED AND RETURNED TO CO ON 6/15/93 DUE TO RECEIVER MALFUNCTION. A PRELIMINARY MDR, DATED 6/18/93, WAS SENT TO FDA. VISUAL EXAMINATION **REVEALED SIGNS OF FLUID INFILTRATION, AS THE HYBRID LABEL APPEARED WRINKLED. THERE WERE ALSO SIGNS OF FLUID INTRUSION INTO TERMINAL BLOCKS 1 AND 5 WICKING DOWN THE HYBRID LEADS TO THE HYBRID. THERE WAS ALSO SOME DISCOLORATION OF THE HYBRID NEAR LEADS 6, 7 AND 8 ON THE "A" HYBRID AND NEAR LEAD #1 OF THE "B" HYBRID.** THERE WERE NO SIGNS OF BOOT LEAK. ELECTRICALLY THE RECEIVER WOULD NOT PASS AUTOTESTING. FAILURE DUE TO FLUIDS BEING TRAPPED DURING THE IMPLANT PROCEDURE AND EVENTUALLY WICKING DOWN AND CAUSING THE HYBRID TO ELECTRICALLY MALFUNCTION.
DT - DATE OF OCCURRENCE: 19930726
AN - ACCESSION NUMBER: 1289958

No Output

TX - TEXT: THE DEVICE WAS EXPLANTED DUE TO **"NO OUTPUT."** THIS DEVICE WAS MFG AND DISTRIBUTED OUTSIDE THE US. ANALYSIS REVEALED A HIGH CURRENT DRAIN ON THE HYBRID.
DT - DATE OF OCCURRENCE: 19950202
AN - ACCESSION NUMBER: 1448216

Electrical Failure

TX - TEXT: THE RECEIVER AND LEAD WAS EXPLANTED AND RETURNED TO CO ON 5/6/94 WITH A CLAIM THAT THE DEVICE WAS MALFUNCTIONING. **ANALYSIS REVEALED THERE WAS ELECTRICAL FAILURE OF THE RECEIVER, SPECIFICALLY THE HYBRID.**
DT - DATE OF OCCURRENCE: 19940727
AN - ACCESSION NUMBER: 1409253

Programming

TX - TEXT: NEURAL STIMULATOR WAS EXPLANTED AFTER 4 MONTHS DUE TO REPORT THAT **THE PATIENT SUSTAINED A FALL THAT APPEARS TO HAVE RESULTED IN AN INABILITY TO TURN THE STIMULATOR OFF.** SOMETIME LATER, THE NEURAL STIMULATOR REPORTEDLY QUIT ON ITS OWN. NO OTHER INFORMATION IS AVAILABLE. THE NEURAL STIMULATOR WAS REPLACED UNEVENTFULLY WITH A NEW CORDIS UNIT WITHOUT REPORT OF PATIENT INJURY OR COMPLICATION. PATIENT CONDITION IS REPORTED AS SATISFACTORY. THE EXPLANTED STIMULATOR IS TO BE RETURNED TO CORDIS FOR ANALYSIS. THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. IN ADDITION, AVAILABLE FREQUENCY AND SEVERITY DATA DO NOT INDICATE THAT ANY FURTHER INVESTIGATION IS NECESSARY AT THIS TIME. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.
DT - DATE OF OCCURRENCE: 19870130
AN - ACCESSION NUMBER: 1038892

TX - TEXT: THE DEVICE WAS EXPLANTED AND RETURNED DUE TO DIFFICULTIES IN PROGRAMMING. **FAILURE ANALYSIS REVEALED A COLD SOLDER JOINT AT THE CONNECTION BETWEEN THE TWO HYBRIDS.** THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. IN ADDITION, AVAILABLE FREQUENCY AND SEVERITY DATA DO NOT INDICATE THAT ANY FURTHER INVESTIGATION IS NECESSARY AT THIS TIME. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.
DT - DATE OF OCCURRENCE: 19940322
AN - ACCESSION NUMBER: 1371922

Patient Injury

TX - TEXT: LEGAL DEPT RECEIVED A TELEPHONE CALL FROM AN INDIVIDUAL WHO IDENTIFIED HIMSELF AS BOTH A PHYSICIAN AND THE PT ASSOCIATED WITH THE COMPLAINT. **THE PT REPORTED THAT HE HAD RECENTLY HAD HIS NEUROSTIMULATOR AND LEADS EXPLANTED APPROX 9 YRS POST-IMPLANT. THE ALLEGED REASONS GIVEN FOR EXPLANT INCLUDED MULTIPLE MEDICAL PROBLEMS RESULTING FROM SILICONE LEAKAGE FROM THE BATTERY PACK AND LEADS. THE PT INDICATED THAT HE DEVELOPED DUPUYTREN'S CONTRACTURES, ARTHRITIS, PEYRONIE'S DISEASE AND URTICARIA APPROX 4 YRS PRIOR TO THE EXPLANT. TREATMENT OF THE MMP'S INCLUDED ADMINISTRATION OF STEROIDS (UP TO 60MG/GD), WHICH CONTINUES AT PRESENT.** PT INDICATED THAT HE WENT OUT ON DISABILITY 9 YRS PRIOR DUE TO A LOWER BACK INJURY, AT WHICH TIME THE NEUROSTIMULATOR WAS IMPLANTED. APPROX 4 REVISIONS WERE PERFORMED ON THE IMPLANT FOR LEAD AND POCKET PROBLEMS. THE EXPLANTING PHYSICIAN WAS CONTACTED AND INDICATED THAT THE SYSTEM WAS EXPLANTED PER THE PT'S REQUEST AS AN ELECTIVE PROCEDURE. THE PT HAS INDICATED THAT HE WOULD LIKE TO AVOID LITIGATION ON THIS ISSUE AND IS REQUESTING COMPENSATION FOR ALL HIS MEDICAL BILLS. THIS IS THE FIRST SUCH CASE RECEIVED ALLEGING INJURY RESULTING FROM IMPLANTABLE SILICONE DEVICES. THE PT IS IN POSSESSION OF THE EXPLANTED DEVICES AND HAS NOT INDICATED THAT THEY WILL BE RETURNED FOR EVALUATION AND TESTING. DURING THE DEVELOPMENT AND MFG OF BOTH THE PACING AND NEURO PRODUCTS, CO DID EXTENSIVE TESTING ON THE SILICONE PRODUCTS FOR BIOCOMPATIBILITY. THE SILICONE USED IN THESE PRODUCTS, UNLIKE THAT IN A GEL FORM, IS FULLY CURED, WITH A HIGH MOLECULAR WEIGHT, SUCH THAT ONE WOULD NOT ANTICIPATE ANY MIGRATION OF SILICONE. THIS IS SUPPORTED BY THE TEST RESULTS MEETING OR EXCEEDING THE USP STANDARDS FOR LEACHABLES.
DT - DATE OF OCCURRENCE: 19931222
AN - ACCESSION NUMBER: 1323755

TX - TEXT: A PT IMPLANTED WITH AN IMPLANTABLE PULSE GENERATOR WAS BEING DISCHARGED FROM THE HOSP. **UPON ENTERING THE AUTO FOR THE TRIP HOME, HE MOVED THE BAG CONTAINING THE MAGNETS ACROSS HIS LAP AND TURNED THE PULSE GENERATOR ON. A STRONG MOTOR RESPONSE WAS ELICITED WHICH CAUSED HIM TO JAM HIS LEG INTO THE DASH AND CAUSED A FRACTURE OF THE FEMUR HEAD. HE SUBSEQUENTLY HAD A PROSTHETIC HIP IMPLANT.** THERE ARE NO PLANS TO EXPLANT THE SYSTEM AT THIS TIME.
DT - DATE OF OCCURRENCE: 19930113
AN - ACCESSION NUMBER: 1240594

Shocking/Jolting

TX - TEXT: THE ANTENNA REPORTEDLY "SHORTED". **THE PT REPORTED HE RECEIVED A JOLT WHILE DRIVING HIS CAR CAUSING AN ACCIDENT.** THERE WAS NO INJURY HOWEVER IT COULD CAUSE OR CONTRIBUTE TO AN INJURY IF THE MALFUNCTION WERE TO RECUR. ANALYSIS REVEALED A BROKEN WIRE AT THE CONNECTOR END.
DT - DATE OF OCCURRENCE: 19931021
AN - ACCESSION NUMBER: 1318906

TX - TEXT: THE SYSTEM WAS EXPLANTED **BECAUSE IT CAUSED CONSTANT PAIN AND JERKY MOVEMENT.** ANALYSIS IS ONGOING. ANALYSIS HAS SHOWN NO ANOMALY.
DT - DATE OF OCCURRENCE: 19930723
AN - ACCESSION NUMBER: 1272556

TX - TEXT: THE DEVICE WAS EXPLANTED DUE TO **"JOLTS ROUND THE GENERATOR SITE."** THE DEVICE WAS SENT BUT NOT RECEIVED FOR ANALYSIS (LOST IN TRANSIT); THEREFORE, THE REPORTED PROBLEM COULD NOT BE VERIFIED. NO DEATH OR SERIOUS INJURY HAS BEEN REPORTED.
DT - DATE OF OCCURRENCE: 19921109
AN - ACCESSION NUMBER: 1226340

TX - TEXT: PT EXPERIENCED **MASSIVE SHOCK (FROM THE TRANSMITTER) AND THE ASSOCIATED STIMULATOR CAUSED HER TO SHUT HER JAWS QUICKLY; CONSEQUENTLY SHE REQUIRED DENTAL TREATMENT.** THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. IN ADDITION, AVAILABLE FREQUENCY AND SEVERITY DATA DO NOT INDICATE THAT ANY FURTHER INVESTIGATION IS NECESSARY AT THIS TIME. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.
DT - DATE OF OCCURRENCE: 19880620
AN - ACCESSION NUMBER: 1059301

After review of the type of events that can occur with this device and the patient sequelae, it should be concluded that the special controls proposed by the petitioner are not adequate to reasonably assure the safety and effectiveness of the device. We believe that the rigors of the PMA process (clinical and non-clinical testing, and inspection) are required prior to commercial release to assure that the device is safe and effective.

5. Literature

The literature regarding spinal cord stimulation from 1961 to 1999 is rich and includes retrospective and prospective series, review articles, basic science discussions, and case reports. Attachment C is a bibliography of the literature reviewed and Attachment D provides a summary of this literature, sorted by author. Quantity of patients, complications rates, device used, and conclusion are listed.

Two types of literature merit careful consideration. The first is retrospective and prospective series which appear to present quantifiable safety information (especially when controlled). Next we turn to review articles, which may offer insights into the long-term experience of seasoned practitioners in large institutions. While less quantifiable than series articles, review articles are valuable because they include a discussion about the management of risk and may aid in the understanding of safety. IPG safety, as reported in the literature, then, is about understanding the risk of what happens rarely, as well as what happens most frequently.

The 1995 meta-analysis of SCS by Turner, Loeser and Bell[1] sought to assess the relative safety of stimulator types:

> A vast majority (33) of studies involved single-channel stimulators, the only type available at the time most of the studies were conducted. Only one study used a multiple-channel stimulator, and four studies used both single and multiple channel stimulators. The type of stimulator could not be determined in one study...We attempted to compare complication rates of older systems versus those of currently used systems, but this was not possible given the extremely small number of articles that reported complications exclusively for patients with the newer quadripolar or octapolar systems.

Given this conclusion, and the changes in technology since that time, we view Turner's work as a pivotal point for discussions about IPG safety. The literature before 1995 is not poolable for comparative purposes. However, some early studies may contain useful data regarding safety. Advancements in clinical reporting post-1995 greatly increased the quality of safety discussions; this is especially significant in view of new technology.

Of the 72 series articles reviewed, we first reviewed those articles with an explicit discussion of stimulator type. We have defined stimulator type as a radio frequency (RF) device or an implantable pulse generator (IPG). Note that the number of cases of mixed and unknown stimulator type has decreased, while the number of studies identified as IPG studies has increased.

Table 7: Series before and after 1995, by stimulator type

	Number of articles	RF	IPG	Mixed	Unknown
Prior to 1995	42	18	6	12	6
1995 to present	30	7	16	6	1

We then reviewed complications, defined as: SCS-related problems such as; infection, cerebrospinal fluid leakage, pain at the wound site, and/or hematoma. It does not include

[1] "Spinal Cord Stimulation for Chronic Low Back Pain: A Systematic Literature Synthesis", Turner, Loeser and Bell, Neurosurgery, volume 37, number 6, (December 1995).

We then reviewed complications, defined as: SCS-related problems such as; infection, cerebrospinal fluid leakage, pain at the wound site, and/or hematoma. It does not include problems related to lead placement or hardware failure, nor does it include unsatisfactory therapy efficacy. Please note three findings. Relative to the total number of studies, the average rate of complications as a percentage of implants has decreased and the number of studies providing complications discussion has decreased. And, please note that IPG-specific complications, as reported in the literature, have increased since the period prior to 1995.

Table 8: Series before and after 1995, summary of complication

	Articles	Complication discussion	**Complications as a percentage of implants (average)**	IPG-related complications
Prior to 1995	42	36	**5.93%**	6
1995 to present	30	19	**5.23%**	20

Of the 72 series reviewed between 1961 and 1999, 34 studies (16 before 1995, 18 since 1995) include information about both the stimulator used and the complications experienced. Table 8 demonstrates that the overall complication rate has decreased slightly since 1995.

As stated previously we believe literature before 1995 is difficult to consider in regard to a comparative quantitative analysis. Comparisons continue to remain difficult post-1995, based on the lack of complications reported using similar definitions. Thus, our overall review of these articles is inconclusive.

6. Conclusion

After review of:

- The description of radio frequency (RF) devices compared to internal battery pulse generators (IPG),
- The discussion of predecessor devices and related regulatory history, and
- The discussion of comparative/similar devices and related regulatory history.

And review of:

- Adequate MDR descriptions, and
- The literature review.

We believe it can be concluded that the petitioner's proposal has not demonstrated reasonable assurance that reclassification of these devices from Class III to Class II will adequately protect public safety. Reclassification would allow a significant loss in the amount of control that is currently in place, and result in an increase in the level of risks to the patient.

Attachment A
Henney Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 16 1999

Federal Y2K Special Data Request:
Y2K Study of Computer-Controlled Potentially High Risk Devices

Dear Medical Device Firm President/CEO:

I am writing to request your participation in a study to examine manufacturers' assessments and corrections of Year 2000 (Y2K) problems with computer-controlled potentially high risk medical devices (PHRDs). This study will be conducted by the Battelle Memorial Institute and their subcontractors, Unisys Corporation and LGS Corporation. All three organizations have extensive experience in information technology and Y2K verification and validation.

Why This Study Is Needed

Congress, the General Accounting Office (GAO), healthcare facilities and the public continue to express concerns about the Y2K compliance of medical devices. This is especially true for critical care and life supporting devices, where Y2K failures could cause serious adverse consequences. The GAO and the Congress have urged that FDA take additional actions that will provide independent assurance of the adequacy of manufacturers' Y2K assessments, any resulting Y2K corrections, and the safety of device upgrades that correct Y2K problems. This study is part of that effort.

How Your Firm Was Selected

We recently posted a list of PHRD devices on our Y2K Web page at http://www.fda.gov/cdrh for public comment. We then identified those domestic and foreign manufacturers that have listed PHRD devices with FDA for marketing in the United States. Your firm was on this list, and was chosen randomly for participation in the study.

What Will Happen During the Study

The contractor will contact your firm to request voluntary on-site access to examine your firm's procedures and records, both for Y2K assessment of PHRDs and for validation of any Y2K corrections to PHRDs. Scheduling and further details of the site visit will be discussed during this initial phone contact.

Each contract examiner, and any other contractor or subcontractor personnel who will handle confidential trade secret information from your firm, has signed a non-disclosure agreement that is on file at FDA. The non-disclosure agreement will be presented to your staff at the entrance interview for the site visit. All the examiners have participated in a joint contractor/FDA training program to ensure consistency in study performance, data collection and reporting. At the conclusion of the site visit, the examiner will conduct an exit interview and discuss their assessment with your staff. You will later receive a copy of the written report from the site visit, which provides you with an opportunity to make a written response or supply additional information.

This study is designated a Federal Y2K Special Data Request under the Year 2000 Information and Readiness Disclosure Act. Under this law, FDA will not use the results of this study for any civil action, and FDA will not publicly release your specific study results unless we receive your consent for disclosure of that information.

The FDA will prepare a report of this study for the Congress, the GAO and the public, with aggregate results from all study participants. We expect to complete that report in October 1999. Based on the sample in this study, FDA will draw a statistical inference concerning the adequacy of the Y2K-related activities of the remaining PHRD manufacturers, and then decide whether to expand the study to those firms. The scope and nature of any expanded study will depend upon the number and types of problems noted in the sample site visits. Further study of remaining PHRD manufacturers will be undertaken only if the results of the sample site visits show a significant probability of widespread failure to adequately address Y2K problems for PHRDs. If you have any questions regarding this study, please contact Stewart Crumpler at 301-594-4659 ext 119, or via mail at HFZ-340, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, Maryland 20850.

I want to stress that this study serves two purposes. First, it will bolster public confidence in the medical device industry's efforts to identify and resolve Y2K problems with their products; and second, it will also provide confidence to healthcare facilities that manufacturers are adequately assessing Y2K compliance and implementing appropriate Y2K upgrades and/or corrections to critical devices. We are asking that you cooperate in this effort and allow our Y2K contractor access to your firm's personnel and records so that they can complete this crucial study quickly and efficiently. I hope we can count on you.

Sincerely yours,

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration

Attachment B
Alpert Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES - Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1995

Mr. Robert J. Klepinski
Senior Legal Counsel
Medtronic, Inc.
Law Department
7000 Central Avenue, NE
Minneapolis, Minnesota 55432-3576

Re: C950010 -- Classification of Medtronic Itrel™
Dated: November 22, 1995
Received: December 20, 1995

Dear Mr. Klepinski:

This is response to your request to Mr. Fred Sadler for classification information dated November 22, 1995. The Medtronic Itrel™ Totally Implantable Spinal Cord System was determined by FDA to be a class III device by order dated October 29, 1980, (copy enclosed). The Food and Drug Administration (FDA) determined that the Medtronic Totally Implantable Spinal Cord System was not substantially equivalent to any device marketed prior to May 28, 1976, or to any device classified as a class I or class II device; therefore it could not be marketed until FDA approved a premarket approval application in accordance with Section 513(f) of the Federal Food, Drug, and Cosmetic Act.

As specified by Section 513(f) of the Food, Drug, and Cosmetic Act (act), a device to be marketed after May 28, 1976, is classified into class III unless the FDA determines the device to be substantially equivalent to a preamendments device, or the device is reclassified into class I or class II.

FDA determined that this Medtronic device was not substantially equivalent to devices classified in Title 21, Code of Federal Regulations, Section 882.5880 (21 CFR 882.5880) based on significant technological differences. For example, the Medtronic device employs an implanted device containing a power source; whereas, the devices classified in 21 CFR 882.5880 employs an implanted device comprised entirely of passive components with necessary energy being provided by an external device.

As further evidence of this determination, FDA sent to Medtronic, Inc. on August 2, 1989, an order approving the Premarket Approval Application (PMA) for the Medtronic Itrel II™, which includes a Model 7424 Implantable Pulse Generator and a Model 7496 Quadrapolar Extension.

We believe this unequivocally establishes that Medtronic Totally Implantable Spinal Cord System is by statute a class III device for which an approved PMA is required for marketing. If you have further questions, please contact Robert F. Munzner, Ph.D., at (301) 443-8517.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MARYLAND 20910

OCT 29 1980

Mr. Russell W. Felkey
Sr. Product Regulation Manager
Medtronic, Inc.
3055 Old Highway Eight
P.O. Box 1453
Minneapolis, MN 55440

Re: K802514 - Medtronic Totally Implantable Spinal Cord Stimulation System

Dear Mr. Felkey:

The Food and Drug Administration (FDA) has completed its review of your premarket notification submission K802514 under Section 510(k) of the Federal Food, Drug, and Cosmetic Act.

Based upon our review, we have concluded that the Medtronic Totally Implantable Spinal Cord Stimulation System is not substantially equivalent to any device that was in commercial distribution before May 28, 1976, or to any device introduced since that date which has been classified in Class I (General Controls) or Class II (Performance Standards). This decision is based on the fact that your design is based on a totally implanted device as compared to the R-F coupled principle employed in the design of the preenactment device, and also based on major differences in the electrical stimulation parameters being employed.

Therefore, your device is classified by statute in Class III (Premarket Approval), under section 513(f) of the Act.

Premarket Approval. Section 515(a)(2) of the Act requires Class III devices to have an approved premarket approval application before they can be legally marketed, unless the device is the subject of an investigational device exemption under Section 520(g) or unless the device has been reclassified.

To prepare a premarket approval application, statutory provisions appearing in Section 515(c) of the Act must be followed. Until regulations for premarket approval applications have been promulgated, we suggest you follow the pertinent parts of the regulations for new drug applications in 21 CFR, Part 314, as guidelines.

Investigational Use. In the absence of an approved premarket approval application, a Class III device may be distributed only for investigational use. Enclosed for your information, is the final regulation for investigational devices which was published in the Federal Register on January 18, 1980. We believe the regulations set forth desirable procedures and safeguards for the conduct of clinical investigations. The label for such devices must indicate that the devices are for investigational use only.

Petition for Reclassification. If you believe that your device should not have to undergo premarket approval before it is commercially distributed, you may petition FDA for reclassification of your device under section 513(f)(3) of the Act.

Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Any commercial distribution of this device prior to approval of an application for premarket approval or the effective date of any order by the FDA reclassifying your device into Class I or II, would be a violation of the Federal Food, Drug, and Cosmetic Act.

Should you require any additional information concerning our decision or the alternatives available to you under the law, please contact:

James R. Veale
Director, Division of Anesthesiology
and Neurology Devices (HFK-430)
Bureau of Medical Devices

Sincerely yours,

Robert S. Kennedy

Robert S. Kennedy, Ph.D.
Associate Director for
Device Evaluation
Bureau of Medical Devices

Enclosure

Attachment C
Bibliography

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Attachment D
Literature Table

Author	Topic	Year	Article Type	# of Implants	# Complications	Portion complications	Stim Type	Device	Etiology	Journal/Book Chapter	Conclusions		Safety Comment
Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Alo	Computer Assisted and Patient literature	1998	series	80	4	0.05	SCS	RF	chronic pain	Neuromodulation	36 with 2+ limb. Spine ops., 22 CRPS, 22 other; no other complications, no patient requested removal; use of multiple electrodes with advanced programmability in SCS increases paresthesia overlap, reduces pain scores, reduces revision rates, improves patient satisfaction with SCS.		4 explants due to infection (5%); 3/4 reimplanted later
Andersen	Angina and SCS	1997	series	60	3	0.05	SCS	IPG: Itrel I, II	angina pectoris	Acta Cardiologica	78% of patients treated with SCS responded to treatment and stopped/reduced intake of opiate medication. Frequency of electrode tip migrations high, but multipolar electrodes compensated for migration, avoided surgical replacement.		comment on complications in 3 other papers: North, 1993; Augustinsson, 1989; deJongste, 1994; 21 electrode migration, 14 operative replacement, 3 infection, 2 technical electrode complications, 1 technical neurostimulator complication.
Augustinsson	Avoiding difficulties in SCS	1996	review				SCS			Interventional Pain Management	Careful attention to detail is required to avoid problems.		
Barolat	Long-term Outcome of SCS for Chronic Pain	1998	series	102			SCS	IPG: Itrel I, II	neuropathic pain (43%), failed back syndrome (30%); spinal cord injury pain (11%); and miscellaneous (16%)	Neuromodulation	With proper medical and psychological screening and with demonstrated initial pain relief, SCS remains an effective modality		Sixty percent of patients in the series used the stimulator 24 hours/day. Only 12% used it less than 12 hours/day.
Barolat	Current status of SCS	1995	review				SCS	RF and IPG	various, including motor disorders	Neurosurgery Quarterly	87% of patients trialed went on to permanent implant in 1209 patients reviewed "seven series). Considers ads/disads of RF and IPG systems. Reports that several series demonstrate 50% pain relief.		SCS is promising and has advantages over ablative procedures.
Barolat	Experience with 509 Plate Electrodes	1993	series	350	21	0.06	SCS	RF	various	Sterotactic and Functional Neurosurgery	70% of electrodes still being used; 47 patients were explanted.		Infections occurred in 3.4% of patients--none severe. Electrode migration and breakage were minor, fewer than twenty in series. Four CSF leaks; one case of pain due to adjacent spine problem (stenosis). One acute hematoma with sensory and motor deficit.
Barolat	Mapping of sensory responses	1993	series	106			SCS	RF and IPG	various	J. Neurosurgery	Some targets are easy to map, others, such as c-2 and low back, are more difficult.		
Barolat	SCS and RSD	1989	series	18	5	0.28	SCS	Itrel, NeuroMed Octrode, Neuromed Multistim	RSD	Stereotactic Functional Neurosurgery	The success of SCS for RSD might improve if the procedure were used earlier in the treatment paradigm for these patients. Early diagnosis is important.		7 of 14 patients had technical problems including one case of poor connection due to body fluid infiltration at the connector. One device was explanted due to the implanted system that "had the characteristics of an infection"

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Barolat	SCS for persistent pain management		review				SCS		chronic pain		In the late 1970's SCS was used for almost any type of pain (poor patient selection, tech, problems, minimal surgeon experience), viewed with skepticism in early 1980's, past 5-6 years regained acceptance. Exact mechanisms still unclear, has high rate of long-term efficacy.		Neurological damage (intraoperative root or spinal cord injury, intraspinal clot); electrode migration; infection; CSF leak; pain.
Bell	Cost-Effectiveness of SCS	1997	cost				SCS	RF and IPG	FBSS	Journal of Pain and Symptom Management	SCS therapy can lead to medical savings.; improving effectiveness of therapy would improve those savings substantially.		Infection is a persistent problem which is treated by system removal and antibiotic therapy
Broggi	Italian Multicentric Study on SCS (retrospective series)	1994	series	283	5	0.02	SCS	RF and IPG	FBSS (52%), RSD (15%)	Stereotactic Functional Neurosurgery	At two year follow-up, 232 patients were evaluated (283 had been implanted) and were found to have 43% pain relief		Infections of the system (2%) and technical problems (3%); dislocation of electrocatheter (4%)
Brownridge	headache management	1983	review							Anaesthesia and Intensive Care	Reduction of pressure differential, therapeutic blood patch - indisputable efficacy.		
Burchiel	Prospective, multicent trial of SCS (prospective series)	1996	series	182	8		SCS	RF and IPG	FBSS	Spine	SCS can be effective for the mgmt of chronic low back and leg pain		1 CFS leak, 4 pain/burning along lead generator, 3 infection
Burchiel	Prognostic factors for SCS	1995	series	40	2	0.05	SCS	IPG: Itrel I, II	FBSS	Neurosurgery	55% of population reported at least 50% reduction in pain		One patient reported a shocking/stabbing sensation attributed to poor electrical contact between extension wire and IPG. Five patients complained of ineffective stim and four were explanted. One patient had pain at the implant site that resolved with time.
Calvillo	CRPS series	1998	series	36	3	0.08	SCS, PNS	RF	CRPS of upper extremity	Acta Orthopaedica	In late stages of CRPS, neuroaugmentation is a reasonable option when alt. therapies have failed; long-term results remain to be defined.		2 patients developed infection at implant site (generator removed), 1 developed a psychosis and SCS was removed, 2 electrode migrations/increase in pain level (reoperation).
Cameron/Alo	Importance of Posture during SCS	1998	series	29			SCS	RF		Neuromodulation	Multiple settings to address all posture positions		
Campbell	computer modeling for examining possible mechanisms of SCS	1981	modeling				SCS		chronic pain	Applied Neurophysiology	Pain relief results from blockage of conduction of pain pathways in the spinothalmic tract; "spinal axis stim" is more appropriate than SCS because other structures in the spinal cord may account for therapeutic effect		

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Castro-Lopes	rat study - GABA decreases in the spinal cord dorsal horn after peripheral neurectomy	1993	modeling							Brain Research	The level of GABA in the dorsal horn is regulated by the amount of primary afferent input.		
Chaplan	RSD: definition and physiological discussion	1996	indication nomenclature						RSD	Pain Forum	Cause of sympathetic abnormalities in peripheral nerve injury are not clear.		
Cioni	SCS for paraplegic pain	1995	series	25	2	0.08	SCS		paraplegic pain	J. Neurosurg.	best candidates: those experiencing painful spasms or constrictive-type pain, incomplete thoracic lesions; confirms general skepticism of SCS efficacy for paraplegic pain		"no major", aseptic meningitis, infective pocket, electrode dislodge
Claeys	Treatment of chronic phantom limb pain with SCS	1997	series	7	0	0.00	SCS	IPG: Itrel II	phantom limb	Pain Digest	5/7 patients had good initial relief -three months		Implantation complications were not observed by the author.
Cooney	Stim and CRPS of Upper Extremity	1997	series	60	0	0.00	PNS	RF and IPG	CRPS	Hand Clinics	60% had a tolerable level of pain relief.		Complications were few with only one being receiver-related (unconfirmed malfunction). Compared IPG to a pacemaker.
Croom	SCS increases blood flow to extremities may salvage limbs	1997	animal study				SCS		Animal Research	Neurosurgery	Nitric Oxide has a role in SCS induced limb blood flow		
Cui	Receptor Activation GABA and Adenosine	1998	animal research				SCS		Scientific	Neuroscience Letters	GABA and Adenosine impact the effect of SCS		
Cui	Rat Study - Adenosine Receptor Activation and SCS	1997	modeling				SCS		Various	Neuroscience Letters	Adenosine receptor stimulation antagonizes tactile hypersensitivity in a CCI model of mononeuropathy and potentiates the action of SCS		
Cui	SCS attenuates dorsal horn release of excitatory amino acids	1997	basic science				SCS			Pain	SCS leads to increase in GABA dialysate in rats		
de la Porte	SCS in FBSS	1993	series	64	5	0.08	SCS	RF and IPG	FBSS	Pain	Long-term success rates may reasonable be expected in patients with intractable pain due to FBSS.		5 wound infections; 8 cases of electrode migration; 6 cases of wire breakage; 8 patients had operations for changing the battery. "Technical failure still remains a problem in SCS."
de la Porte	SCS for spinal arachnoiditis	1983	series	38	20	0.53	SCS	RF	low back, leg pain	Spine	SCS is very successful and has a low complication rate for this indication and should be considered the treatment of choice.		Complications: 9 skin erosion, 5 pain at site of incision, 4 pain at receptor site, 1 infection, 1 CSF fistule, 21 electrode displacement/not optimal site, 12 other hardware-related problems.

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
DeJongste	SCS Characteristics and Efficacy in Angina Patients	1994	series	22			SCS	IPG: Itrel I, II	Angina	Pace	Anginal attacks were reduced significantly with SCS and after 1 year follow-up parameters had not changed significantly		2 death not related to SCS, 6 lead dislocations. Stim using IPG can cause interference with the function of a pacemaker. Risks can be minimized by using bipolar systems, optimizing sensitivity and avoiding modulated amplit. and freq. below 20 Hz.
Demirel	SCS in pain patients after 2 year observation period	1984	series	50	7	0.14	SCS	RF	Various	Neurochirurgi	33 of 50 patients received implant. Results were disappointing due to too liberal patient selection without psychiatric eval and psych testing. Lead migration needs to be addressed for successful SCS.		11 electrode dislocations, leads migrations, 3 equipment failures, 1 patient had a CSF fistula with meningism that resolved after electrode removal, 4 delayed inflammation outside the spinal canal due to a foreign body.
Devulder	Dual channel stimulation	1998	series	3			SCS	RF	FBSS	Acta Neurol Belg	Dual channel SCS can improve steering of paresthesia, reaching multiple sites of pain		Deep brain electrode combined with a spinal cord electrode and a single IPG
Devulder	SCS: a valuable treatment (prospective series)	1997	series	69			SCS	RF and IPG	FBSS	Journal of Pain and Symptom Management	26 patients stopped using SCS, 43 continued and obtained good relief		Battery systems need significantly fewer electrode interventions than the RF systems
Devulder	SCS in chronic pain	1991	series	69	12	0.17	SCS	RF and IPG	chronic pain (organic origin)	Clinical Journal of Pain	80% pain-free (some with, some without help of medication), multipolar electrode helpful, harder for psychologist to predict the out come for arachnoiditis group than nerve root injury and mononeuropathy		67 replacements (battery failure); 107 revisions due to technical failure, electrode migration, insufficient stim, etc., 5 gait probs., 1 torticollis, 1 causalgia, 2 cooling/warming in the legs, 2 infections
Devulder	SCS in Chronic Pain	1990	series	45	4	0.09	SCS	RF and IPG	Various	The Clinical Journal of Pain	Strict selection criteria and many surgical reinterventions were necessary. 82% exp. good to exc. pain relief. Functional complication: 3 gait problems1 Horner's sign, warm sensation throughout the body and headache during stimulation, cooling of the legs		Technical complications: 2 formation of scar tissue, 8 poor localization of paresthesia, 2 lead migration, 4 lead breakage, 2 pain from electrode, 3 lead dislocations, 1 infection, 1 wound pain, 11 multiple reinterventions.
DiGiovanni	postlumbar-puncture headache management	1970	review							Anesthesia and Analgesia...Current Researches	Technique of placing autologus unclotted blood in the epidural space appears safe and effective.		
Eisenberg	SCS activation by an antitheft device	1997	case report				SCS	RF	upper extremity pain	Neurosurgery	There exists the risk for CNS injury that could reach a life-threatening level with an RF stimulator. Uncontrolled activation is a concern.		Patient experiences tremor, memory loss, gait ataxia and mild dysarthria.

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Eliasson	SCS in severe angina pectoris	1996	review				SCS		angina	Pain	"Provided that the basal requirements are fulfilled, the stimulator is easy to handle." only re. MI risk?		The symptom of angina is a "warning signal" indicating presence of myocardial ischemia. If SCS attenuates this pain without influencing mycardial ischemia, patients will be deprived of a warning signal and will risk ischemic complications. However, study indicated SCS results in reduction in myocardial ischemia.
Fiume	Treatment o FBSS due to epidural fibrosis	1995	series	55	5	0.09	SCS	IPG: Itrel II	FBSS	Acta Neurochir	56% of patients were "successful" with more than 50% pain relief; 10/34 returned to work		Several patients had electrode dislocations and fractures; 5 patients developed infections; 8 had to have their batteries exchanged and 34 overall needed surgical revisions.
Forrest	SCS Therapy	1996	review				SCS			Journal of Perianesthesia Nursing	Patient teaching and follow-up are important to this therapy. Improvements have occurred over the past twenty years. To improve overall results, SCS should be used in conjunction with physical therapy, exercise, weight control and low dose medications		Six possible complications: loss of stim effectiveness; CSF leakage; nerve damage leading to paralysis or death, spinal cord compression; allergy to implanted materials; serious infections
Francaviglia	SCS for Progressive Sclerosis and Raynaud's Disease	1994	series	15	0	0.00	SCS	IPG: Itrel I, II	PVD	British Journal of Neurosurgery	SCS is effective w/patients with PSS and Raynaud's phenomenon		One patient required removal of the device and replacement of the electrode
Galer	IASP diagnostic criteria for CRPS	1998	review						CRPS	The Clinical Journal of Pain	CRPS decision rules may lead to overdiagnosis; up to 37% of diabetic neuropathy patients met the clinical criteria for CRPS		
Gamsa	Review - 50 years of thought on the role of psychological factors in chronic pain	1994	review						Various	Pain	At the turn of the century, pain was attributed entirely to physical causes. Later psychological factors were recognized as having great importance. Now we are once again focusing more on the pathophysiology of chronic pain, but also take into account the modulating influence of psychological factors.		
Gibbons	RSD Score: Criteria for diagnosis	1992	review						CRPS	The Clinical Journal of Pain	RSD score correlates to clinical diagnosis.		
Gordon	RSD	1996	diagnosis						RSD	Brain & Development	RSD should be considered in differential diagnosis of limb pain in children.		
Gragnani	RSD	1994	diagnosis						RSD	Missouri Medicine	The unknown mechanism makes treatment of these conditions difficult and subject To individual practitioner observations.		

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Graziotti	Controlling Pain in Erythromelalgia with SCS	1993	case report				SCS	IPG	Erythromelalgia	J of Pain and Symptom Mgmt	Patient had immediate positive response to TNS. 75% pain reduction with SCS. Same response with second implant after 6 mos. of on stimulation. System rarely turned off. Possible placebo affect		SCS offers a reversible alternative to ablative blocks and medication. Battery failed after 12 mos. of continuous use. Lead required repositioning due to migration.
Gybels	Role of SCS in pain mgmt	1993	review							APS Journal	SCS is reversible, has few complications and has improved implantation techniques and devices. We need to understand more about long-term loss of benefit.		
Gybels	cancer related	1992	review				SCS, PNS, DDB		chronic pain	Acta Neurochir	Neurostim techniques aren't used much in cancer pain but are first choice in neurogenic pain; DDB is controversial but has been found by a few (and the author) to work well for long term intense pain unrelated to cancer		
Gybels	DBS, SCS and PNS Nervous System Stimulation for Chronic Pain	1987	review				DBS, SCS, PNS		chronic pain	Acta Neurosurgical	DBS 663/1193 (55%) success, SCS 66% short term & 52% long term success, PNS 46% success		
Hassenbusch	SCS vs Spinal Infusion for low back and leg pain	1995	series	42		0.00	SCS	IPG: Itrel II	FBSS	Acta Neurochir	16/26 SCS patients received 50% or better pain relief; 2/16 infusion patients had 50% or better relief. 10 infusion patients had long-term pain relief.		One patient underwent a revision for electrode replacement (to surgical lead); no technical problems with stimulator hardware, including infections, connections or generator failure. Five patients required repositioning of electrodes and two required revision.
Hautvast	angina	1997	series	9			SCS	IPG: Itrel II	refractory angina pectoris	European Journal of Neuroscience	The anti-anginal effect of SCS may be the result of centrally mediated analgesic effects.		
He & Barolat	Perception threshold & electrode position for SCS	1994	series	136			SCS	IPG: Itrel I, II	FBSS, CRPS, peripheral nerve injury	Pain	The perception threshold is a function of the spinal level of the implanted electrodes, of the mediolateral position in the spinal canal and the contact separation of electrodes. Perception threshold diff. are due to varying depths of the dorsal CSF layer.		Did not discuss safety considerations; "none suffered from major sensory deficit"
Hendler	RSD and Causalgia	1989	indication						RSD, Causalgia	Handbook of Pain Management	Need to make a distinction between the two diagnoses because the treatments vary.		
Holsheimer	Computer modeling of SCS	1998	modeling				SCS			Spinal Cord	Model is a simplification of reality		
Holsheimer	Paresthesia and cathode position	1998	modeling				SCS		chronic pain	Neuromodulation	Dorsal CSF layer thickness is inversely related to SCS success		

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Holsheimer	Evaluation of transverse tripolar system for SCS	1998	modeling				SCS		neuropathic pain, lower limbs and trunk	Neurosurgery	TTS enables finer stimulation than polarity changes in conventional SCS systems.		
Holsheimer	SCS and electrode design: a computer model	1998	modeling				SCS			Neuromodulation	Reduced space between epidural electrode and the spinal cord is good.		
Holsheimer	Effectiveness of SCS for pain	1997	modeling				SCS			Neurosurgery	To improve efficacy, enhanced DC stimulation is needed.		
Holsheimer	Optimum electrode geometry for SCS	1997	modeling				SCS			Medical and Biological Engineering and Computing	Computer model suggests optimum contact lengths and widths for both perc and lami leads		
Holsheimer	Effect of andode-cathode configuration on SCS	1997	modeling				SCS			Neurosurgery	Relative position of anodes, cathodes and their distance from the spinal cord are major determinants of activation/paresthesia		
Holsheimer	Spinal cord position in SCS	1995	modeling				SCS			Acta Neurochirgica	Dorsal CSF layer is main factor determining perception threshold and paresthesia coverage		
Holsheimer	Electrode geometry/combination and nerve fiber selectivity	1995	modeling				SCS			Medical and Biological Engineering and Computing	Preferential activation is possible with different orientations of a rostrocaudal contact array.		
Hosobuchi	Stimulation of Cervical Spinal Cord Increases Cerebral Blood Flow	1985	series	10			SCS	RF	Pain in one limb	Neurosurgery	Cervical spinal cord stimulation may prove useful in treating difficult cases of cerebrovascular insufficiency.		
Iyer	Mgmt of a pacemaker in a patient with a stimulator	1998	case report				SCS		lower limb ischemia	Pain	Pacemaker safe to use with totally implantable stimulator under certain conditions		Implantable sensing issues of pacemaker
Jessurun	SCS sequelae, angina	1997	series	57			SCS	IPG: Itrel I, II	refractory angina pectoris	Coronary Artery Disease	SCS with quadripolar leads in patients with intractable angina lead to improved system performance and clinical results in properly selected patients. Mortality rate similar to that of patients treated with CAD, stable angina pectoris; treatment is tolerated well by these patients.		leads, mostly; batteries depl.; 9 patients died (2 noncardiac disease, 6 severe heart failure, 1 acute myocardial infraction); 21 SRA, 6 extension lead fractures, 4 epidural lead fractures, 8 lead dislocations, 4 additional SRAs such as dysfunctional block, 2 patients refused to have systems repaired/replaced, all others satisfied
Jivegard	SCS Improves Limb Salvage	1995	series	25			SCS	IPG: Itrel II	PVD	European Journal Vascular Endovascular Surgery	SCS provided pain relief but did not significantly improve limb salvage		
Kemler	Retrospective study of RSD	1999	series	23	5	0.22	SCS	IPG: Itrel II, 3	CRPS/RSD	Journal of Neurosurgery: Spine	Subjective improvement		An infected pulse-generator pocket in one patient and an infected lead wound in another
Kidd, North	SCS: Effective and cost-saving	1996	review				SCS		failed back surgery syndrome	Pain Treatment Centers at a Crossroads	SCS has a low morbidity rate of less than 5% in this experience which always involved infection at the receiver site		

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Krainick	SCS	1984	series				SCS	RF		Textbook of Pain	IPG's are more advantageous as they are simpler for the patient to handle. Disadvantage is battery changes are required and stim parameters cannot be changed easily by the patient.		Complications included CSF loss, slight meningitis and inconstant stim intensity during test stim using a Medt floating lead. Positioning the tip in the middle or higher cervical level should be avoided because of alteration in intensity during head move.
Krames	SCS, spinally administered narcotics	1992	review				SCS, SAN			Medtronic	SCS and SAN should be used after conservative, traditional therapies but before non-reversible therapies for intractable pain.		
Kumar	SCS in the Treatment of Chronic Pain Postlaminectomy	1998	series	182	12	0.07	SCS	RF and IPG	chronic pain	Current Review of Pain	The low morbidity of SCS when compared with destructive surgery or other pain relief procedures makes SCS an attractive alternative.		9 infected systems, 2 electrical leaks, 1 CFS leak.
Kumar	limb salvage (PVD) and SCS	1997	series	46			SCS	IPG: Itrel II	pain from lower extremity ischemic vascular disease	J. Neurosurg.	39 (77%) considered success at long-term follow-up; best results were in patients with severe claudication and rest pain without trophic changes in the foot.		
Kumar	SCS Effective for mgmt of RSD	1997	series	12	0	0.00	SCS	IPG: Itrel I, II	reflex sympathetic dystrophy	Neurosurgery	SCS superior to ablative procedure for RSD; five minor complications; 12 total patients		Percentage of complications high, even if minor
Kumar	DBS for intractable pain	1997	series	53	24	0.45	DBS	RF and IPG	failed back (43); periph neuro (6); thalamic pain (5) other (14)	Neurosurgery	62% pain relief for DBS with various etiologies; headache pain as complication underreported; four infections, two hardware malfunctions and one electrical leak		Complications related to IPG: 7/68, even with major experience curve
Kumar	SCS for chronic pain in peripheral neuropathy	1996	series	30	1	0.03	SCS	RF and IPG	postherpetic neuralgia; intercostal neuralgia; causalgic pain; diabetic neuropathy and idiopathic neuropathy	Surg Neurology	Certain etiologies respond better than others		All complications lead related except for tolerance: 9/19
Kumar	Treatment of chronic pain with SCS	1991	series	121	10	0.08	SCS	RF	various	Neurosurgery	Epidural SCS has been proven to be an effective and safe mean of controlling pain on a long-term basis in a select group of patients.		Complications included wound infection; electrode displacement or fracturing, and fibrosis at the stimulating tip of the electrode.
Kumar	Epidural SCS for Relief of Chronic Pain	1986	series	60		0.00	SCS	RF	Various, but mostly back and leg pain	The Pain Clinic	61% had good or fair results, pain relief dropped off by the end of the first year and then plateaued. Electrode choice did not affect results, but complications were experienced with older leads. Effective for arachnoiditis or fibrosis & M.S. pain.		3 wound infections, 1 CSF leak, 10 electrode displacements, 2 electrode fractures, 3 fibrosis at lead tip, 2 failure to cover pain with paresthesia, 2 burning sensation, 1 death due to rupture of an abdominal aortic aneurysm 2 weeks post-implant.

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Kupers	SCS in Belgium	1994	review	697	5	0.01	SCS		Failed back (61%); Trauma (9%); Iatrogenic (6%); Back pain (4%)	Pain	Large study by health authorities confirmed world literature on pain relief with SCS.		
Law	SCS for pain management	1992	review				SCS		RSD, FBSS	American Journal of Pain Management	Effective as part of comprehensive medical treatment and if done by experienced team		
LeDoux	SCS for FBSS	1993	series	26	4	0.15	SCS	RF	FBSS	Spine	26 patients received systems; 19 were available for follow-up after two years, 14 of whom reported a good result with SCS. After five years, however, with eight reporting, only 3 had good results and 5 had poor results.		Ten electrode migrations; 4 with pain at receiver site; 2 receiver malfunctions; 2 nonspecified system malfunctions; 1 faulty junction box connections; no infections or neurologic deficits.
Licht	History of electrodiagnosis and electromyography	1961	review							History of Electrodiagnosis and Electromyography	The history of electrodiagnosis and electromyography has been one of increasing quantification on diminishing areas. It would seem that we have reached the limits of minuteness in time and tip.		
Liem	MRI and SCS	1997	case report				SCS	Both	Stump pain; leg and back pain; failed back surgery syndrome	Pain	Case studies show various concerns regarding stimulators and use of MRI		All concerns are receiver or IPG related
Linderoth	Pre-emptive Use of SCS Ischemia Reduction	1995	animal research				SCS		Scientific	Neurosurgery	SCS reduces vasospasm and ischemia		
Linderoth	Modulation of somatosensory and autonomic function	1995	animal and human research				SCS		Scientific	The Neurosciences	SCS experimental studies need to be tailored to the therapeutic procedure		
Long	Current status of SCS	1998	review				SCS, DBS, PNS		various	Surg Neurology	SCS is important for FBSS patients; PNS candidate number is small; DBS in investigative.		Risks are low, nervous system injury virtually unreported; infection in 5% of cases; serious complication in DBS in 5% of cases
Long	SCS (posterior columns) for intractable pain	1975	series	69	13	0.19	SCS	RF	intractable pain (chronic low-back, arachnoiditis, injuries, cancer pain etc.)	Surgical Neurology	60 patients with pain of benign origin; of these, 10 had excellent results and 45 were failures (less than 50% pain relief). Improvement in electrical design, surgical techniques, and patient selection would help.		Complications: 1 postoperative clot, two possible paraparesis, 8 post-operative CSF collections in wound sites, 2 excessive stim. In the perineum, 2 primary infections.
Lundberg	Comments on Electrical Stimulation Studies	1996	review				ESCS			The Lancet	Electrical stimulation merits further efforts between scientists and clinicians		

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Mannheimer	Angina (SCS vs. CABG)	1998	series	53			SCS	IPG	angina pectoris	Circulation	SCS and CABG appear to be equivalent methods for symptom relief; SCS may be a therapeutic alternative for patients with an increased risk of surgical complications and no prognostic benefit from surgery.		
Mannheimer	SCS for angina	1988	series	10	0		SCS	IPG	angina pectoris	British Heart Journal	Anti-anginal effect, increased work capacity, decrease ST segment depression, etc.		1 patient electrode tip placed too high, another time electrode migrated.
Marchand	Nervous System Stimulation for Pain	1993	commentary				SCS, DBS			APS Journal	SCS is a good alternative for pain management in patients in whom other conventional pain treatments have failed		
Meglio	SCS low back and leg pain	1994	series	33	5	0.15	SCS	RF and IPG	FBSS	Stero and Functional Neurosurgery	SCS was clinically successful in treating CLBLP in patients w/multiple lumbar surgeries		Electrode wire breakage, hardware malfunction, battery depletion, 2/3 pts need at least one surgical revision
Meglio	Cerebral hemodynamics during SCS	1991	modeling				SCS			Pace	The stimulation of any segmental level of the spinal cord seems to be able to alter CBF; SCS may induce modifications of cerebral hemodynamics, but further studies needed to determine mechanism and applications.		
Meglio	Author's results over 9 year period	1989	series	109	16	0.15	SCS	RF and IPG	chronic pain	Journal of Neurosurgery	Best clinical results are vascular origin and post-herpetic neuralgia		Meningitis and bacterial infections developed in 7 patients. One became a paraplegic, other problems; rejection, CSF leakage, hematoma, dislodgement
Melzack	theory on pain mechanisms	1965	review						pain	Science	"gate control"		
Mittal	SCS in Chronic Pain	1987	series	31	4	0.13	SCS	RF (Avery)	Various, but mostly low back and leg pain	Royal College of Surgeons of England	Response to TENS correlated well to the response to SCS. 60% had good to fair relief of pain with SCS Some had a good response for 5 years or more		4 broken wires, 3 infections, 2 wire displacements, 2 cases of increased discomfort when rate dial turn to a higher level. 1 patient suffered mild pulmonary embolism 10 days after device implant. She recovered and device left in place.
Mullett	Design and Function of SCS	1992	review				SCS, PNS	RF and IPG		Pain Digest	SCS is now an accepted modality for the treatment of chronic, intractable pain		
Murphy	SCS for angina	1987	series	10	0	0.00	SCS	RF and IPG	angina pectoris	Pain	SCS was beneficial in all patients, mechanism uncertain.		1 signal receiver fault (replaced after 3 mos.), 1 electrode readjustment and IPG replacement (posture-related).
Niv	CRPS, towards the Year 2000	1998	indication nomenclature						RSD	Plenary Sessions, World Congress of Pain	It is hopes that a new nomenclature will start a new dialogue among clinicians and provide diagnostic uniformity.		
North	Prognostic Value of Psychological Testing in Patients Undergoing SCS.	1996	series	35			SCS	RF	FBSS (42), spinal cord injury (2), peripheral neuropathic pain (14)	Neurosurgery	There are significant associations between psychological test scores and the results of screening with temp. percutaneous SCS electrodes.		

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
North	SCS and PNS for pain	1996	review				SCS, PNS	RF and IPG		The Practice of Neurosurgery			The author has encountered no morbidity (spinal cord injury, meningitis) with SCS during 2 decades. Surgical wound infections have occurred in 5% of patients However, serious complications (e.g., epidural hematomas and direct spinal cord injuries) may occur.
North	The failed back: augmentative pain procedures	1996	review				SCS, DBS		failed back surgery syndrome	Seminars in Spine Surgery	Neuroaugmentative and minimally ablative procedures have grown significantly.		DBS: Infection risk, 3-6%; hardware failures (2-12%)
North	SCS for chronic pain	1995	review				SCS			Functional Neurosurgery	SCS has resulted in significant improvement in objective clinical and economic outcome for a wide range of conditions		
North	Prospective, randomized trial; comparing SCS vs. reoperation for FBSS	1994	series	12			SCS	RF	failed back surgery syndrome	Stereotactic and Functional Neurosurgery	SCS is probably a useful tool for FBSS.		
North	SCS over two decades	1993	series	249	12	0.05	SCS	RF	FBSS; various	Neurosurgery	Most patients report 50% or better pain relief after five years follow-up; technical advances have improved system reliability and clinical results.		"No major morbidity has occurred in our experience with spinal cord stimulation in the past two decades "; 5% surgical wound infections
North	SCS in contemp pain mgmt	1993	review				SCS	RF	various	APS Journal	SCS has a substantially higher yield--in terms of patient satisfaction, pain relief and ability to perform daily activities -when compared to pain mgmt alternatives for this stage of care		"In our experience with SCS, we have encountered no major morbidity (spinal cord injury, meningitis). Surgical wound infections, all superficial or extraspinal, have occurred in 5% of patients.
North	SCS 5 Year follow-up with 102 FBSS patients (retrospective series)	1991	series	50	6	0.12	SCS	RF	FBSS	Neurosurgery	Successful pain relief in 53% to 60% of SCS patients; Characteristics of youth and women fared best Patient selection criteria for SCS has been identified as relevant toward treatment outcomes.		28% of patients need additional surgery due to technical failure of lead or repositioning of the lead for enhanced coverage.
North	SCS for chronic intractable pain: superiority of "multi-channel" devices	1991	series	67	7	0.10	SCS	RF	chronic intractable pain	Pain	Two significant associations between "success": patient sex (favoring female) and implant type (favoring multi-channel).		7 subcutaneous wound infections, electrode migration, lead fatigue fracture in 13% of patients, receiver failure in 10% of patients.
North	SCS for Intractable Pain: Indications & Technique	1989	review				SCS	RF	Indications and Technique	Current Therapy in Neurological Surgery	Multi-channel devices offer increased flexibility and effectiveness		Rates of failures requiring surgical revisions have been reduced w/new devices
Ohnmeiss	Prospective outcome evaluation of SCS for leg pain	1996	series	40	5	0.13	SCS	IPG: Itrel II	leg pain	Spine	SCS can result in improved function and decreased pain in carefully screened patients		3 patients had discomfort in original location of implant, 4 had to have lead position adjusted, 1 had wound infection; diabetic patient had skin problems at the stimulation site.

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Olin	Postural changes in SCS perceptual thresholds	1998	series	42			SCS	RF	chronic, intractable low back and leg pain	Neuromodulation	Voltage requirements change depending on patient position; paresthesia is related to position		Totally implantable devices: risk of change in position is somewhat more difficult to stop immediately
Omoigui	Therapeutic modalities of chronic pain syndromes	1996	review							Pain Digest	Good pain mgmt requires assessment, treatment, reassessment and sometimes, referral		
Probst	Using SCS for Epi-Intradural Fibrosis Following Operation for Lumbar Disc Herniation	1990	series	112	5	0.04	SCS	RF and IPG	epi-intradural fibrosis following operation for lumbar disc herniation	Acta Neurochir	Radicular pain responds better to SCS than back pain. Relapse of pain occurs mainly during the first postoperative year. SCS decreases need for analgesics and improves return to work. 67% good results with SCS after 4 1/2 years. Better results with epidural implant		20 displacement or instability of electrodes. 7 technical faults. 5 infections. SCS is a simple procedure. Instability as the cause of symptoms should be ruled out. Severe complications do not occur. Re-operation is common, tech advances will decreases reoperation.
Racz	Complex regional pain syndrome	1996	indication							Seminars in Anesthesia	CRPS causes much pain and suffering and is costly to the health care system		
Racz	Percutaneous SCS for Chronic Pain	1989	review				SCS	IPG	various	Spine	Good to excellent pain relief in 65% of patients. Useful technique for patients with no other treatment options		Lead migration in 70% of patients was most common complication. Others: broken leads, IPG replacements, postoperative hematoma, and superficial wound infections
Raj	Complex regional pain syndrome	1996	indication							Pain Digest	Pathophysiologic mechanism is similar in various forms of CRPS disorders; common issue is tissue damage which initiates a reflex response in the PNS and CNS		
Ray	SCS for chronic and severe pain relief	1987	review				SCS		chronic and severe pain	Lumbar Spine Surgery: Techniques & Complications	Neuroaugmentative devices share a high efficacy degree with other established methods of pain control; in benign pain problems, it is superior to many others, especially destructive surgery.		Loss of effectiveness, mechanical failure, infection, CSF leakage, spinal cord compression, dural erosion, allergy to implant materials, fibrosis of traversed muscle along lead path; these are rarely seen in experienced hands; no permanent, untoward side effects beyond cessation of stimulation
Ray	Neurostim results in neuro department over 9 years	1982	series	850			PENS, DBS, SCS		chronic pain, multiple sclerosis, causalgia, FBS, cancer pain, etc.	Applied Neurophysiology	Expect to see more implantable devices; currently neurostim augments rather than replaces functions of the CNS; expect to see more implantable DD pumps		No safety comments listed.
Robaina	TENS and SCS for CRPS	1989	series	6	0	0.00	SCS		CRPS	Stereotactic Functional Neurosurgery	Stim results were better than those obtained with blocks or sympathectomies. Many patients were able to undergo rehabilitation because of the amount of pain relief.		

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Robaina	SCS for relief of vasopathic disorders of upper limbs	1989	series	11	1	0.09	SCS		Patients treated for RSD and idiopathic Raynaud's Disease.	Neurosurgery	Ten patients had very good results with SCS.		Local infection in one patient; no mortality and very little morbidity.
Ronk	SCS for chronic nonmalignant pain	1996					SCS			Orthopedic Nursing	Nurses can play a vital role in evaluating and teaching SCS patients to improve efficacy.		A change in stimulation could cause a loss of control.
Rosner	SCS and DDB for chronic intractable pain management	1997	review				SCS, DDB		chronic intractable pain	Surgical Technology International VI	Advantages of SCS: nondestructive, drug-free, easily reversible; disadvantages: difficult to cover widespread areas of pain, sometimes intolerable sensations caused by high amplitudes necessary for certain kinds of pain, electrode migration		Electrode migration
Rossi	SCS for FBSS	1994	series	45	4	0.09	SCS		FBSS	Proceedings from the American Pain Society	Effective coverage of low back and leg pain areas.		Reintervention for technical or surgical problems were necessary in 15 instances for 12 patients (24%). 3 patients had SCS explanted because of perceived worsening of their condition.
Rossi	SCS for pain control (retrospective series)	1992	series				SCS, ESES		FBSS, others	Australasian College of Rehabilitation Medicine XII	Reduced pain, decreased impairment of ADL's, reduced consumption of meds. SCS is preferentially effective in neuropathic or ischemic pain.		Incidence of re-operations for technical problems is 2-3 times higher if wire-like electrodes and IPG's are used.
Sanchez-Ledesma	SCS in Deafferentation pain	1989	series	49	1	0.02	SCS	RF and IPG	Causalgia; RSD; postherpetic neuralgia; plexus avulsion; phantom limb; stump pain	Stereotactic Functional Neurosurgery	After mean follow-up of 5.5 years, 57% of patients had greater than 75% pain relief.		Two complications: one from lead, the other from connector to receiver
Sanderson	SCS for angina	1994	series	23	1	0.04	SCS	IPG: Itrel I, II	angina	European Heart Journal	Effective, safe alternative therapy for occasional angina patients.		Concern that SCS can allow ischemia to develop (masks "warning sign"); 16 electrodes repositioned, 1 pouch infection, 8 reprogramming/voltage adjustment, 3 electrode fracture/breakage.
Segal	SCS revisited	1998	series	24	0	0.00	SCS	IPG: Itrel II	failed back surgery syndrome; RSD; various	Neurological Research	22 patients still have stimulators of 24 implanted; components of psych evaluation are still unclear.		Only one malfunction of Itrel II requiring revision; 13 of 24 patients use their stimulator 24 hours a day: exposure
Shealy	SCS for pain in lower chest/upper abdomen	1967	case study				SCS		severe diffuse pain	Journal of the International Anesthesia Research Society	Although this patient died because of unexpected subacute bacterial endocarditis with embolism of the left side of the brain, he experienced complete pain relief before his death. The author concludes that technical problems can be overcome and SCS is a potentially practical method for pain relief.		

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Siegfried	Long-term follow-up of SCS for chronic pain after multiple lumbar operations	1982	series	89	7	0.08	SCS		chronic low back/leg pain already operated on 1-8 times	Applied Neurophysiology	Overall results are good and justify further use of SCS for this indication.		Moving electrodes, defects in stim. System, necrosis and infection, rejection of receiver.
Simpson	SCS-editorial	1997	editorial				SCS			British Journal of Neurosurgery	SCS can be helpful when all else has failed; case selection is extremely important		
Simpson	General Review of SCS	1994	review				SCS		Various	Pain Reviews	Largest number of implants have been for 'failed back syndrome,' not one of the best indications. Most implants are percutaneous and are for lower body/limb pain. Despite much speculation for 27 years, we still do not know how SCS works.		Complications have included - cord compression, hardware failure (lead fracture, current leakage, electrode technical failure), lead migration and dislodgement, CSF leakage, hygroma, pseudomeningocoele, infection, prolonged/exaggerated post-operative pain
Simpson	Retrospective pain study	1991	series	56	9	0.16	SCS	RF and IPG	chronic pain	Journal of Neurosurgery and Psychiatry	SCS not universal analgesic, effective w/defferentation, ischemia and nociceptive pain(s). Reversible		Most frequent complication leading to additional surgery was electrode failure.
Spiegelmann	SCS Series	1991	series	30	0	0.00	SCS	RF and IPG	Various	Neurosurgery	30 of 43 patients received implant. Simple procedure that is reversible and remarkably benign when compared with ablative procedures. Success rates of 45% or more may reasonably be expected.		3 infections, 1 meningitis, 1 myocardial infarction, 1 acute hepatitis during trial period, secondary to anesthesia. 13% complication rate. Lead breakage, lead migration after permanent implant. Body posture changes elicited variations in intensity.
Stanton-Hicks	CRPS guidelines for therapy	1998	indication							Clinical Journal of Pain	Functional restoration approach to CRPS treatment		
Stanton-Hicks	Stim of the CNS and PNS for the Control of Pain	1997	review				SCS, PNS			Journal of Clinical Neurophysiology	Methods problems suggest potential for statistical bias. Stimulator use and time used not reported in most series.		Stimulator time and use not reported in most series, and complications from newer systems difficult to connect to earlier series' complication rates.
Stanton-Hicks	RSD: changing concepts and taxonomy	1995	indication							Pain	Presentation of revised taxonomy system for CRPS to allow for differential diagnosis		
Tesfaye	diabetic neuropathy	1996	series	10	2	0.20	SCS	RF	diabetic peripheral neuropathy	The Lancet			2 lead migrations, 2 wound infections that required antibiotics
Torrens	Risk of infection with SCS	1997	review				SCS		peripheral vascular disease, diabetic patient	Lancet	Diabetes patients may be susceptible to infection. Procedure does not carry the risks of surgery, but is not risk free; it may give rise to a "life-threatening infection" (CSF leak discovered). "It is therefore important to be aware of the risk of serious		Diabetes patients may be susceptible to infection. Procedure does not carry the risks of surgery, but is not risk free; it may give rise to a "life-threatening infection" (CSF leak discovered). "It is therefore important to be aware of the risk of serious infections.

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Turner	SCS for Chronic Low Back Pain	1995	meta-analysis				SCS			Neurosurgery	There is insufficient evidence to draw a conclusion about the efficacy of SCS relative to no treatment or to other treatments for this patient population.		Stimulator type could not be studied because of mixed use across studies; most used single channel devices. 0-9% of patients had stimulator complications, with data from 14 studies (39 analyzed in all).
Vaarwerk	SCS in chronic pain syndromes	1998	review				SCS			Spinal Cord	Success with SCS varies by etiology.		Referring to Turner's comments about complications, Vaarwerk notes that "These events almost never resulted in life-threatening situations or new neurological loss."
Vijayan	Late postdural headache following SCS implant	1997	case study				SCS	RF	severe back and leg pain	Pain Digest	Late onset is unusual and features were not typical.		CSF leak is a potential complication of an SCS lead implant
Waisbrod	Direct Nerve Stimulation for Painful Neuropathies	1985	series	19	3	0.16	PNS	RF - Avery Stimulator	chronic pain	Journal of Bone and Joint Surgery	79% of patients received some pain relief		Skin lesion at site of implant, one developed necrosis over lead cable
Waisbrod, Gerbershagen	SCS for Battered Root Syndrome	1985	series	16		0.00	SCS	RF	Battered Room Syndrome	Arch Orthop Trauma Surg	12 of 16 patients achieved good to very good results. SCS may be the treatment of choice for rigorously selected cases of BRS.		5 lead dislocations, one infection. In this study, patients with periradicular fibrosis previously operated on for spinal nerve canal stenosis do not respond as those with fibrosis without stenosis do.
Walker	CRPS	1997	indication							Anaesthesia Intens Care	Review of a treatment ladder for CRPS		Multidisciplinary care and continued research is needed for better understanding and treatment of CRPS.
Waltz	SCS: A quarter century of development and investigation	1997	review				SCS		motor disorders	Sterotactic and Functional Neurosurgery	Maximum therapeutic effect is achieved using field variables of stimulation: field configuration, its polarity and the frequency of stimulation.		Experienced three CSF leaks, one transient cord compression, ten cases of pain at stim site, 122 cases of electrode malfunction, receiver failure in 136 patients, and infections, usually at receiver site or insertion site, in 46 cases--in review of 1336
Wesselink	Analysis of current density and related parameters for SCS	1998	modeling				SCS			IEEE Transactions on Rehab. Engineering	From an electrical safety standpoint, pulsewidth should not be larger than 300 us and the combination of high pulse width and small contact area should be avoided (although it may help pain relief). Nervous tissue adjacent to the contact site may be damaged.		From an electrical safety standpoint, pulse width should not be larger than 300 us and the combination of high pulse width and small contact area should be avoided (although it may help pain relief).
Wester	SCS in Pain Treatment	1987	series	35	3	0.09	SCS	RF	Various	Acta Neurol Scand.	Modest results suggest future restriction on the use of stimulation. Chronic back pain responded better, phantom limb pain most resistant. PVD pain responds well as noted by other authors. SCS is time consuming and expensive.		2 infections, 1 mechanical discomfort, 13 reoperations for lead repositioning, broken wires or mechanical discomfort. Patients selected after psych and pharm criteria in other studies claimed better results, but requires multiprofessional resources.

Al-Ghoul	Rat Study-Sciatic Nerve	1993	modeling				PNS		hyperpathic peripheral neuropathy	Brain Research Bulletin	Glutamate levels in the dorsal horn of rats increased after chronic loose ligature of the sciatic nerve and also after stimulation of C fibers, but not A fibers in the sciatic nerve.		
Yamahita	Treatment of Causalgia by SCS	1981					SCS	RF	severe pain of the median nerve	Neurol Med Chirur	Excellent immediate effect using SCS		Stimulation is easy to perform and should be used before more destructive forms of pain relief.
Young	trigeminal neuralgia	1995	series	23	0	0.00		IPG: Itrel	chronic facial pain	J. Neurosurg.	Chronic electrical stimulation of the trigeminal nerve root appears to be an easy, safe technique for providing relief of chronic facial pain related to injury to the trigeminal nerve.		one displaced electrode
Young	Evaluation of SCS for chronic pain	1978	series	51	14	0.27	SCS	RF	chronic intractable pain	Neurosurgery	SCS for chronic intractable pain has low rate of effectiveness and has multitude of technological problems that further reduce efficacy and patient satisfaction.		Complications: 3 paresthesia not in desired location, 6 infections, 3 CSF leaks, 2 lead erosion through skin, 8 lead migration, 5 lead breakage.
Zdanowica	Single SCS patient led to schizophreniform disorder	1999	case study				SCS	IPG		Psychosomatics	SCS led to psychiatric disorder		IPG removed