

MedSun Newsletter #27, August 2008

Articles

Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion

FDA Public Health Notification

Issued: July 1, 2008

Dear Healthcare Practitioner:

This is to alert you to reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine. Note that the safety and effectiveness of rhBMP in the cervical spine have not been demonstrated and these products are not approved by FDA for this use.

The following information provides the adverse events reported to the FDA, the risks associated with the use of rhBMP products in the cervical spine, recommendations for mitigating those risks and the current regulatory status of rhBMP products in the U.S.

Public health concerns: Adverse events and risks to health

FDA has received at least 38 reports of complications during the last 4 years with the use of rhBMP in cervical spine fusion. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. Some reports describe difficulty swallowing, breathing or speaking. Severe dysphagia following cervical spine fusion using rhBMP products has also been reported in the literature.

Anatomical proximity of the cervical spine to airway structures in the body has contributed to the seriousness of the events reported and the need for emergency medical intervention. The mechanism of action is unknown, and characteristics of patients at increased risk have not been identified.

Most complications occurred between 2 and 14 days post-operatively with only a few events occurring prior to day 2. When airway complications occurred, medical intervention was frequently necessary. Treatments needed included respiratory support with intubation, anti-inflammatory medication, tracheotomy and most commonly second surgeries to drain the surgical site.

Mitigating the risks

Since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

Patients treated with rhBMP in the cervical spine should know:

- the signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area
- that they need to seek medical attention immediately at the first sign of an airway complication
- that they need to be especially watchful 2 -14 days after the procedure when airway complications are more likely to occur

Regulatory Status of rhBMP

FDA has approved the use of two rhBMPs for well-defined medical conditions in limited patient populations:

- rhBMP-2 (contained in InFuse Bone Graft) has received premarket approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury. rhBMP-2 is also approved for certain oral and maxillofacial uses.
- rhBMP-7 (referred to as OP-1 and contained in OP-1 Implant and OP-1 Putty) has received humanitarian device exemption approval as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed. It is also approved as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion. Examples of compromising factors include osteoporosis, smoking and diabetes.

Both rhBMPs are contraindicated for all uses in patients who are skeletally immature (<18 years of age) or pregnant, and in those with a known hypersensitivity to the specific rhBMP, bovine Type 1 collagen or to other components of the formulations.

Reporting to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of rhBMP, you should follow the reporting procedure established by your facility.

Reporting adverse events is everyone's responsibility, even if the event involves off-label use of medical devices.

To report your experience regarding the devices in this Notification, please use MedWatch, the FDA's voluntary reporting program. You may submit reports to

MedWatch by phone at 1-800-332-1088; by FAX at 1-800-332-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at <http://www.fda.gov/Safety/MedWatch/default.htm>.

Additional Information:

Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion. FDA Public Health Notification. July 1, 2008.

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062000.htm>

Does the type of out-of-hospital airway interfere with other cardiopulmonary resuscitation tasks?

*By Abo, BN; Hostler, D and Wang, HE
PubMed*

BACKGROUND: Out-of-hospital rescuers often perform tracheal intubation (TI) prior to other cardiopulmonary resuscitation (CPR) interventions. TI is a complex and error-prone procedure that may interfere with other key resuscitation tasks. We compared the effects of TI versus esophageal tracheal combitube (ETC) insertion on the accomplishment of other interventions during simulated cardiopulmonary resuscitation.

METHODS: In this prospective trial using a human simulator, two-paramedic teams simulated resuscitation of a ventricular fibrillation cardiopulmonary arrest using standard Advanced Cardiac Life Support guidelines. In each of two trials, teams used either TI or ETC as the primary airway device. Following delivery of three rescue shocks, we measured time intervals to successful airway placement, intravenous (IV) line insertion, drug administration, delivery of fourth rescue shock and completion of all four tasks. We also measured the total time without chest compressions. We compared task completion times using non-parametric statistics (Wilcoxon signed-ranks test) with a Bonferroni-adjusted p-value of 0.008.

RESULTS: Twenty teams each completed two scenarios. Participants required a median of 172.5 s (IQR: 146.5-225.5) to accomplish all four tasks. Elapsed time to airway placement was significantly less for ETC than TI (median difference 26.5 s (IQR 13-44.5), $p=0.002$). Time without chest compressions was less for ETC than TI (median difference 8.5 s (IQR 2.5-23.5), $p=0.005$). There were no differences between ETC and TI in times to IV placement (median difference 23.5 s (IQR -20 to 61), $p=0.11$), drug delivery (39.5 s (IQR -18 to 63), $p=0.07$), delivery of fourth rescue shock (39.5 s (IQR -21.5 to 87.5), $p=0.07$) or completion of all four tasks (33 s (IQR -11 to 74.5), $p=0.08$).

CONCLUSION: Compared with TI, ETC reduced time to airway placement and time

without chest compressions, but did not affect elapsed times to accomplish other interventions. Additional time differences may be realized if translated to clinical out-of-hospital conditions.

PMID: 17126472 [PubMed - indexed for MEDLINE]

For more information, please visit PubMed, as service of the U.S. National Library of Medicine and the National Institutes of Health

Additional Information:

Does the type of out-of-hospital airway interfere with other cardiopulmonary resuscitation tasks? Abo, BN; Hostler, D and Wang, HE. PubMed. February 2007.
<http://www.ncbi.nlm.nih.gov/pubmed/17126472>

Prevention of Inadvertent Perioperative Hypothermia

Pennsylvania Patient Safety Authority - Safety Advisory

Perioperative hypothermia may result in serious cardiac, coagulation, and wound-healing complications, especially among vulnerable pediatric and elderly patients. More than 50 reports have been submitted through PA-PSRS about patients experiencing perioperative hypothermia. Many reports involved hypothermia that was detected in the postanesthesia care unit. Only a few reports indicated that measures were in place to prevent hypothermia.

Additional Information:

Prevention of Inadvertent Perioperative Hypothermia. Pennsylvania Patient Safety Authority - Safety Advisory. June 2008.

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http://www.psa.state.pa.us/psa/lib/psa/advisories/v5n2june_2008/jun_2008_v5_n2_article_hypothermia.pdf

Dangers Associated With Shared Multidose Vials

Pennsylvania Patient Safety Authority - Safety Advisory

Research shows that up to 25% of healthcare practitioners re-enter vials with needles just injected into patients. There has been at least one report in PA-PSRS documenting this behavior, and similar actions may not have been reported because practitioners may be

unaware that routinely re-entering vials with used needles and reusing syringes is placing patients at risk for infection from contamination.

Additional Information:

Dangers Associated With Shared Multidose Vials. Pennsylvania Patient Safety Authority – Safety Advisory. June 2008.

http://www.psa.state.pa.us/psa/lib/psa/advisories/v5n2june_2008/jun_2008_v5_n2_article_multidose.pdf

Inadvertent Retention of Angled Drill Guides After Volar Locking Plate Fixation of Distal Radial Fractures: A Report of Three Cases

*By Timothy Bhattacharyya, MD and Ajay D. Wadgaonkar, BS
The Journal of Bone and Joint Surgery*

Advances in locking plate technology have proven especially valuable for fixation of distal radial fractures, and preliminary results have been excellent. However, new technology can sometimes lead to new complications. In some systems, the locking plates are preloaded with angled drill guides to allow for easy placement of locking screws in the proper direction. The drill guides are designed to be removed prior to closure. We report the cases of three patients in whom the angled drill guides were retained after surgery.

MedSun also received a report in which the OR staff were not aware of this counting requirement and a post-operative X-ray revealed the presence of one of the screw guides. The patient was returned to the OR and the guide was removed without complication.

Additional Information:

Inadvertent Retention of Angled Drill Guides After Volar Locking Plate Fixation of Distal Radial Fractures: A Report of Three Cases. By Timothy Bhattacharyya, MD and Ajay D. Wadgaonkar, BS. The Journal of Bone and Joint Surgery. March 2008.

<http://www.ejbs.org/cgi/content/extract/90/2/401>

ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: Executive Summary

*By Epstein, AE; Ellenbogen, KA; Estes, NA III; et al
PubMed*

* in process *

Additional Information:

ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: Executive Summary. By Epstein, AE; Ellenbogen, KA; Estes, NA III; et al. PubMed. June 2008.

http://www.ncbi.nlm.nih.gov/pubmed/18534377?ordinalpos=3&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum

Problems with Implantable Cardiac Device Therapy

*By Kowalski, M; Huizar, JF; Kaszala, K; Wood, MA
PubMed*

ABSTRACT:

Implantable cardioverter-defibrillators (ICDs) improve survival in patients who have left ventricular dysfunction; however, they are associated with numerous problems at implant and during follow-up. The diagnosis and management of these problems is usually straightforward, but more difficult problems may include the management of patients who have elevated energy requirements to terminate ventricular fibrillation or of those who have postoperative device infections. Long-term issues in ICD patients include the occurrence of inappropriate or frequent appropriate shocks. ICD generators and leads are more prone to failures than are pacing systems alone; management of patients potentially dependent on "recalled" devices to deliver life-saving therapy is a particularly complex issue. The purpose of this article is to review the diagnosis and management of these more troublesome ICD problems.

For more information, please visit PubMed, as service of the U.S. National Library of Medicine and the National Institutes of Health

Additional Information:

Problems with Implantable Cardiac Device Therapy. By Kowalski, M; Huizar, JF; Kaszala, K; Wood, MA. PubMed. August 2008.

http://www.ncbi.nlm.nih.gov/pubmed/18538190?ordinalpos=1&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum

Recently Recalled Devices

To view recently recalled devices, please visit the website listed under Additional Information below.

Additional Information:

Recently Recalled Devices

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/medicaldevicesafety/recalls.cfm>

KidNet

Medical Device Problem Summaries

Please see this month's Medical Device Problem Summaries describing issues summarized from reports received by MedSun hospitals.

Additional Information:

Summary of Medical Device Adverse Event Reports Describing Adverse Events With Umbilical Artery Catheters And Related Article

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=27#11>

Summary of MedSun Reports Describing Adverse Events With Infant Radiant Warmers and Neonatal Incubators And Related Recalls and Articles

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=27#12>

Highlighted MedSun Reports

Highlighted Reports

This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during the period May 1 through May 31. All other reports can be searched under the 'MedSun reports' menu pane. Note: the two month delay is due to quality control and follow-up.

NEUROLOGY

Device: Liquid Embolic System; Onyx 34
Lot# 4725495
Catalog# 105-7100-080
Manufacturer: EV3, Inc.

Device: Liquid Embolic System; Onyx 34
Lot# 3904009
Catalog# 105-7100-080
Manufacturer: EV3, Inc.

Device: Microcatheter; Echelon
Manufacturer: EV3, Inc.

Problem: Patient undergoing stage III embolization of left frontal AVM, arterio-venous malformation. The microcatheter was placed from the femoral artery up into the head in the AVM. During the gluing process, the microcatheter became adhered into the AVM and was unable to be removed. The microcatheter was cut so that 3/4 of the microcatheter was in the patient's arterial system. The remaining portion will be removed at a later time following discharge from this admission. In previous MAUDE reports the manufacturer warns to not allow more than 1 cm of Onyx to reflux back over catheter tip. Reportedly, less then the recommended amount of Onyx was used in the procedure.

OBSTETRICS/GYNECOLOGY

Device: Uterine Manipulator/Retractor; VCARE
Lot# 0801281
Manufacturer: ConMed Corporation

Device: Robotic Surgical System
Manufacturer: Intuitive Surgical, Inc.

Problem: During a laparoscopic robotic assisted procedure, the VCARE broke down in parts into the patient's uterus. The physician scrubbed in, removed the uterus and all of the remaining parts of the VCARE (Uterine manipulator) through the vagina. No additional intervention was needed at the time.

ANESTHESIOLOGY

Device: Bag, Resuscitation

Model# VN4100

Manufacturer: Ventlab Corp.

Problem: Patient experienced laryngospasm in the OR, which was controlled with medication. She was taken to the recovery room, where she again went into laryngospasm. The CRNA tried to open the patient's airway, but she was obstructing. The team started to bag the patient with a pediatric-sized resuscitation bag. There was no chest rise. The bag was replaced with another pediatric-sized resuscitation bag. That one also resulted in no chest rise. The team switched to an adult sized resuscitation bag made by a different manufacturer. The patient was intubated, and they were able to bring her saturation rate back to normal. The whole event lasted approximately 90 seconds, and the patient suffered no sequelae. After the event, the team examined the two bags, and one had a 0.5 cm tear in it. The other had a hole near the connection to the circuit. All the bags by this manufacturer were inspected, and the rubber appears to be deteriorating. The rubber is thin, and exposure to the heat of the lights on the headrail where the resuscitation bags are kept may be a contributing factor to their deterioration.

Device: Holder, Endotracheal Tube; Anchor Fast Oral Endotracheal Tube Fastener

Model# 9799

Manufacturer: Hollister Inc.

Problem: Oral ET fastener was in place on patient. While patient was being repositioned, ET fastener broke. The tube holder was firmly on the ETT and the holder was firmly secured on face, but the white plastic connection broke off and the patient became extubated.

Device: Anesthetic Gas Module; Intellivue

Model# G5

Manufacturer: Phillips Medical Systems

Problem: The CO2 monitor was reading 34-0-34-2-34-0 instead of a steady 34. When a blood gas was sent, it confirmed a CO2 level of 34. This is a recurring problem with this monitor. The hospital has had 5 occurrences in the last week. It is unclear what is causing the problem. Of note, this is being used in the OR in addition to the ICU's and we're only experiencing this problem in the OR setting.

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Manufacturer response for anesthetic gas module, Intellivue

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The Phillips representatives are uncertain what is causing the variation. They state that the problem may be due to the use of a different manufacturers' sample tubing instead of Philips sample tubing. This has been known to cause a problem with falsely low ETCO2 readings. Philips is shipping sample tubing to the facility to see if this solves the problem.

GENERAL & PLASTIC SURGERY

Device: Cuff, Tourniquet; Zimmer 34" Tourniquet Cuff

Model# 60-7070-106

Lot# 137475

Catalog# 60-7070-106

Manufacturer: ASCENT Healthcare Solutions

Problem: 34" Zimmer leg tourniquet cuff which had been reprocessed and packaged by Ascent Healthcare Solutions x1 deflated after being up for a few minutes, it appeared to be leaking, possibly from the connection of the hoses to the cuff. The procedure was done without the tourniquet.

To read a January 2007 Safety Tip entitled, "FDA Safety Tip: Pneumatic Tourniquet Cuffs with a Tourniquet," please visit:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=11#1>

Device: Dermatome, Electric

Manufacturer: Zimmer, Inc.

Problem: The patient was undergoing a skin graft to the right ankle from the left thigh. The Padgett blades that were being used with the Zimmer Dermatome were not compatible with the Dermatome, which resulted in a deep cut to the patient's left thigh. The blade was switched out with another Padgett blade and it too was incompatible. This resulted in another deep tissue injury to the patient. Both lacerations were sutured.

Please see recent article describing these issues posted in July 2008's Newsletter online available:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=26#4>

PHYSICAL MEDICINE

Device: Aid, Transfer, Bathroom; Lumex Portable Bath Bench/Transfer Board

Lot# A080131

Manufacturer: Graham Field Health Products, Inc.

Problem: Patient's family member called and reported that the back of the transfer bench would not lock into place. We pulled another transfer bench to replace this one and found the same problem with the entire shipment. In another one of our home health medical equipment locations, the same equipment was inspected and found to have the same

problem. All locations have been instructed to isolate this equipment. The manufacturer's representative has been notified.

Device: Cold Therapy Unit; DonJoy Iceman Cooler

Model# 1100

Lot# 112907-01B

Manufacturer: DJO, LLC

Problem: Staff reports that they were applying the cooling unit at the end of the surgical case. When they turned the unit on, it began leaking from the point where the blue tubing exits the main cooling unit. Staff was concerned that it could have contaminated the fresh surgical site. They also report that they have had the same problem with this device in the past.

Device: Heat Therapy Unit; T Pump

Model# TP 200

Manufacturer: Gaymar Industries, Inc.

Problem: Patient admitted for redo repair of his paraesophageal hernia, and Nissen fundoplication. He was taken to surgery and given general anesthesia with an epidural for post-operative pain management. Post-operatively he complained of neck pain. A heating pad and PT were ordered by the physician. He was given a pad for heat the day after surgery. Two days later it was noted his back was red with blisters. The reddened areas and blisters were in the shape of the pattern on the pad. The patient states he slept on the pad but could not feel it burning because of the epidural.

GENERAL HOSPITAL

Device: Catheter, IV; BD Insyte Autoguard

Lot# 7348099

Manufacturer: BD Insyte Autoguard

Problem: An 18 gauge Insyte Autoguard was being inserted into the patient's arm. When then the retraction was deployed using the push button, the green hub of the IV was seen dangling from the patient's arm/insertion site. The catheter was "missing." The catheter could not be located at first. The patient was x-rayed and the catheter was not located. The BD representative came out and was able to see with microscopic lenses that the catheter had actually retracted back into the retraction device of the IV.

Device: warmer, infant;

Model# RW82-1

Manufacturer: Drager Medical Systems, Inc.

Problem: Infant warmer ignited while unit was in the Operating Room pending delivery of the infant. The unit was in operation but infant was not in the bed. A manufacturer's representative came to the facility to replace parts on the damaged unit and will be replacing the heater elements on all units in our facility. The hospital's Biomedical Engineering Department has replaced heating units on four other warmers at the facility in the past year, which they consider a high failure rate.

Device: Incubator, Infant; OmniBed

Model# 600

Manufacturer: Datex-Ohmeda

Problem: The Air Mode was being used to preheat the OmniBed incubator while awaiting the infant's return from surgery. When the infant was placed in the OmniBed, the bed was not put into Baby Mode. This caused the OmniBed to maintain an air temperature of 41.7 degrees C (107 degrees F). This elevated air temperature resulted in an increase of the infant's axillary temperature.

Device: Thermometer, Digital

Model# KD-192

Other Device # P/N: 8219200015

Manufacturer: K-JUMP HEALTH CO., LTD

Problem: Parents of infant used CVS brand digital thermometer at home to check child's temperature. Temperature read as 102.5. Family presented to ER with infant. In ER setting temperature obtained was 98.9. Sepsis work-up performed, including multiple lumbar puncture attempts. IV antibiotics administered. Parents brought thermometer in from home. When tested, the infant temperature was 103 on the CVS thermometer and 99.2 on the hospital thermometer.

Device: Incubator, Infant; Airshields

Model# C2000

Manufacturer: Draeger Medical, Inc.

Problem: Infant being assessed when nurse smelled electrical smoke. Smoke seen above isolette. Infant removed from isolette immediately and placed in a clean isolette. Change nurse notified. Security called. Hospital biomedical called and notified. Biomedical sheet filled out and isolette taken to dirty utility room to be cleaned. No problems with infant.

Device: Infusion Pump; Outlook

Model# Outlook 100 - 13215

Manufacturer: B.Braun Medical, Inc.

Problem: Our hospital recently began using B.Braun's Outlook 100 Infusion Pumps. These pumps have a programmable drug library. During the course of implementing the pumps and continuing to present we have had multiple (23+/-) instances of the pumps "losing" their drug libraries (i.e. the pumps default to their factory preset and prompt the user to enter the dosing information rather than allowing the user to pull information from the drug library). This does not impact the patient as the RN's can revert back to programming the rates manually, but our staff have been trained to utilize the libraries which is the safest method. In troubleshooting the issue, B. Braun did send a software upgrade (version 151510) which has not fixed the problem (with the software upgrade, we no longer see error 75, but we now see error 74, and the pumps still "lose" their drug libraries). B.Braun has suggested this is possibly a result of the pumps running low or out of battery power. Our staff has been pulling these pumps from service, have sent them to Clinical Engineering for "re-loading" of the software and the issues have not subsided. Our Bio-med does indicate they have had several pumps which have run out of battery

power completely (purposefully while trying to troubleshoot the problem) and these pumps have retained the library despite the battery being depleted. B.Braun is now in the process of replacing the batteries in our pumps as we may have gotten a bad batch of batteries.

Device: Patient Bed; Versa Care

Model# P3200

Manufacturer: Hill Rom Company, Inc.

Problem: The right intermediate side rail did not latch in raised position. This caused the patient to fall out of bed when she was holding on to the bed rail to turn in bed.

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Manufacturer response for Patient Bed, Versa Care

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The manufacturer's representative at Cape Fear Valley Medical Center was already aware of this problem with other beds in this facility and was in the process of replacing these latches on other beds. Unfortunately his job was not completed prior to this incident happening. Bed was removed from service until repair made. He states that the patient right intermediate side rail will not latch in the raised position due to latch pins that will not fully extend.

CARDIOVASCULAR

Device: Defibrillator, External

Model# M-series

Manufacturer: Zoll Medical Corporation

Problem: Morbidly obese post-op patient had witnessed cardiac arrest. Underwent five unsuccessful rounds of ACLS medications and defibrillation using the Zoll M series biphasic defibrillator charged to 200 joules (the maximum) for pulseless ventricular tachycardia rhythm. The code team obtained and applied a different manufacturer's biphasic defibrillator that allows 360 joules defibrillation. The rhythm was captured and converted to normal sinus rhythm with a single biphasic shock at 360 joules.

Device: Cannula, Vascular, Cardiopulmonary Bypass; Soft Flow Aortic Cannula

Lot# 0495730

Manufacturer: Terumo Medical Corporation

Problem: The cap did not tear easily to open the blood flow and enable connection to bypass cannula. The procedure calls for insertion of the aortic cannula, suturing it in place and removal of cap for connection to bypass. The surgeon attempted to tear the cap off for approximately 2 minutes and eventually successful. The surgeon had to use the scalpel to pry it off. There was no patient harm.

Device: Instrument, Surgical, Cardiovascular; PerfectCut

Lot# 3099303H

Manufacturer: Quest Medical, Inc.

Problem: PerfectCut lancet failed to cut in a 4 mm, cross-cut pattern. The lancet made a linear cut instead, approximately 6 mm in length, thus cutting a larger hole than necessary in the aorta. Per the surgeon, this could have lethal to patient. Patient suffered minor harm.

Device: Injector, Contrast; Angiomat Illumena Injector

Manufacturer: Covidien Mallinckrodt

Problem: Clinical Engineering was notified of a problem with a Mallinckrodt Illumena injector used in the cath lab. The cath tech stated that the injector had blown the catheter off of the syringe during a “test” injection to verify the position of the catheter. CE took the injector “out of service” and gave them a spare injector to use. CE called Mallinckrodt service and a technician came in to check the injector the next day. CE and the service tech gathered information from the cath tech on the event and tested the injector. The cath tech stated that he was using the “fill-control bar” for the test injection and that the stop-cock on the manifold was closed during the test injection and should have been open. The service report states that the service tech verified that the pressure limiting system in the injector was operating properly and that when the “fill-control bar” was used “there was no pressure limiting”. He felt that the “fill-control bar” should not be used for injection. I verified that the Instruction manual states that the “fill-control bar” can be used for “test” injections. I called Mallinckrodt to question whether the “fill-control bar” should be used for a test injection if there was not pressure limiting and Mallinckrodt was also concerned about this situation. They strongly recommended that the “fill-control bar” should NOT be used for a “test” injection until they can do testing and verification of this product. The Director of Cardiology was notified and the Cardiology and Radiology staff received education. Manufacturer response for injector, Mallinckrodt, they will check other devices.

OPHTHALMIC

Device: Ophthalmic Gas, SF₆; Sulfa Hexa Fluoride (SF₆)

Lot# 623308

Catalog# 8065-7970-01

Manufacturer: Alcon Laboratories, Inc.

Problem: The physician performed the following procedure due to a flash related traumatic macular hole in right eye, reducing vision to 20/200: 25g pars plana vitrectomy, Indocyanine green assisted membrane peeling, fluid air exchange, and injection of 30% SF₆ gas (right eye). 25g sclerotomy sites X2 were used as well as one 20g site. The 20g site was closed w/7 ovicryl. According to surgeon, SF₆ gas dissipated faster than it should, which could have resulted in the failure of the macular hole to close. A second surgery was performed by the same physician approximately 5 months later for macular hole, right eye. Surgery: 23g pars plana vitrectomy, fluid air exchange, injection 20% C3F₈ gas right eye. Outcome unknown.

EAR NOSE & THROAT

Device: Bronchoscope;
Model# BF 160
Manufacturer: Olympus America Inc.

Device: Bronchoscope
Manufacturer: Olympus America, Inc.

Problem: The biopsy port and/or channel of two bronchoscopes cultured positive for *Pseudomonas putida*, *Stenotrophomonas* and *Pseudomonas aeruginosa* after a cluster of patients was cultured positive for at least one of the three bacteria. Olympus inspected the scopes and found loose biopsy ports. Prior to this incident, a third party vendor, was engaged in the fall of last year to "repair" the scopes. The third party vendor was also invited to inspect the scopes. During a recent investigation, it was determined that the third party vendor was not able to employ Olympus's standard for biopsy port repair because Olympus considers that information "proprietary." Therefore, the third party vendor attempted to repair the scopes using "industry standards" of which they were aware. Two key issues may be the type of adhesive used to secure the biopsy ports, as well as the "foot pounds" of torque applied to the nut that holds the stem in place. The third party vendor did not have access to Olympus's "proprietary" specifications with regard to these two items. This may have contributed to the loosening of the ports over time and subsequently to the harboring of bacteria.

RADIOLOGY

Device: Computer, CT Stereotaxy Location Detection; iPlan
Model# 109004B
Manufacturer: BrainLab, Inc.

Problem: Brainlab program not working, software not working. The rep for Brainlab was contacted and able to pull up the software on his laptop computer and assist with the case. The surgery was delayed about 45 minutes. There was no patient harm. After the case, the tech installed an updated license on the facility's planning stations to include the required ARC localizer for iPlan Stereotaxy. The system was checked by Biomed and returned to service.

Additional Information:

To read a January 2007 Safety Tip entitled, "FDA Safety Tip: Pneumatic Tourniquet Cuffs with a Tourniquet," please visit:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=11#1>²⁸

Please see recent article describing these issues with the Zimmer Dermatome posted in July 2008's Newsletter online available:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=26#4>²⁹

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Medical Device Problem Summaries

Summary of Medical Device Adverse Event Reports Describing Adverse Events With Umbilical Artery Catheters And Related Article

[Print Item](#)
[E-mail Item](#)

By Elizabeth Eydelman, Patient Safety Staff, 2008

Since January 1st 2007, FDA's Center for Devices and Radiological Health (CDRH) has received 36 medical device adverse event reports involving umbilical artery catheters associated with three manufacturers: Covidien (25), Utah Medical Products, Inc. (8), and Vygon (3). Four of the 36 reports were submitted by MedSun reporters. The remainder of the reports were submitted by manufacturers (27), voluntary reporters (6), and one report was submitted by a distributor.

The reported device problems are:

- Device Breakage/ Defective Device (13)
- Device Leakage (15)
- Evisceration/Extravasation or clot formation (8)

There are no reports involving a patient death with umbilical artery catheters during this time period. There are 22 reports that list malfunction as the type of adverse event, 5 list event type as injury, 4 list event type as "other", and five reports do not list the type of event. The most frequently reported patient problems are:

- Need For Removal of Foreign Body (11)
- Need For Reinsertion of Device (18)
- Need For Drainage of Mass Accumulations in Liver (7)

All of the reports feature neonatal patients in the NICU in each respective hospital.

These reports contribute to FDA's post-market experience and understanding of problems associated with the use of these devices. The reported events are consistent with umbilical artery catheter problems reported in the literature. Factors that influence the risk of complications provided in a Journal of Infusion Nursing article entitled, *Umbilical Catheters, Placement, and Complication Management* (29(6), November/December

2006, p346-352, include:

- The procedure for insertion
- The location of the catheter
- The size and composition of the catheter
- The care of the catheter
- The number of manipulations and
- The dwell time of the catheter.

Umbilical Catheter Adverse Event Reports Received Since January 1st, 2007		
Device	Device Identifiers	Event Description
Utah Medical Products, Inc./Umbilical Artery Catheter	Device Identifiers Not Provided/Unknown	DURING AN ATTEMPT TO REMOVE THE UMBILICAL VENOUS CATHETER (UVC), THE PRACTITIONER WAS UNABLE TO PULL OUT THE LINE. THE UVC BROKE LEAVING 9CM OF LINE IN THE UMBILICAL VEIN.
Covidien/ Umbilical Artery Catheter	Lot: 153466	IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE IN 2006, THAT A CUSTOMER HAD A PROBLEM WITH A DUAL UVC CATHETER. THE CUSTOMER REPORTS "LEAK ABOVE CONNECTION OF DUAL LUMEN. UVC REMOVED AND REINSERTED."
Covidien/Umbilical Artery Catheter	Model: 8888160341	IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE THAT A CUSTOMER HAD A PROBLEM WITH THE UMB CATHETER. THE CUSTOMER REPORTS LEAKAGE OF CATHETERS DISTAL TO HUB. INFUSION. REQUIRED RE-INSERTION OF UVC LINE FOR 1 NEONATE. NO ILL-EFFECTS TO PATIENT REPORTED. PATIENT STATUS REPORTED AS RECOVERED. THE DEVICE IS BEING RETURNED FOR EXAMINATION.
Covidien/ Umbilical Artery Catheter	Model: 8888160333	IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE THAT A CUSTOMER HAD A

		<p>PROBLEM WITH THE UMB CATHETER. THE CUSTOMER REPORTS LEAKAGE OF CATHETERS DISTAL TO HUB. INFUSION. REQUIRED PICC FOR 1 NEONATE. NO ILL-EFFECTS TO PATIENT REPORTED. PATIENT STATUS REPORTED AS RECOVERED. THE DEVICE IS BEING RETURNED FOR EXAMINATION.</p>
<p>Covidien/Umbilical Artery Catheter</p>	<p>Model: 8888160341</p>	<p>IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE ON 03/13/07 THAT A CUSTOMER HAD A PROBLEM WITH THE UMB CATHETER. LEAKAGE OF CATHETER DISTAL TO HUB. ATTEMPTED REINSERTION OF UVC LINE UNSUCCESSFUL. NEONATE THEN WENT FOR FLUORO GUIDED PICC. CUSTOMER HAS NOT CHANGED PROTOCOLS IN 5 YEARS, NO CLAMPS USED. CATHETER WAS INITIALLY INSERTED AT A DIFFERENT HOSPITAL (MOUNT SINAI), DITAILS AS TO LOT NUMBER AND INSERTION DATE REQUESTED BY TYCO PRODUCT SPECIALIST BUT NOT PROVIDED TO DATE. MULTIPLE DIFFERENT RNS PROVIDED CARE TO THE NEONATE. THE 1- 3 ML SYRINGES POTENTIALLY USED FOR PUSH MEDS. IV TUBINGS CHANGED EVERY 48 HOURS. WITH THIS CHANGE, THE CATHETER WAS CLEANED WITH CHLORHEXIDINE. PT STATUS REPORTED AS RECOVERED. THE DEVICE IS BEING RETURNED FOR EXAMINATION.</p>
<p>Covidien/Umbilical Artery Catheter</p>	<p>Model: 888160341</p>	<p>IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE ON 3/22/07 THAT A CUSTOMER HAD A PROBLEM WITH THE UMB CATHETER. THE CUSTOMER STATES THAT THE CATHETER IS LEAKING DISTAL TO THE HUB. CUSTOMER</p>

		HAS NOT CHANGED PROTOCOLS, NO CHANGE IN INSERTION, NO CHANGE IN STAFF, NO CHANGE IN CLEANING SOLUTION (CHLORHEXIDINE), MAXIMUM TIME LINE IS 14 DAYS, HOWEVER, IT IS UNK IN THIS CASE. NOTED UPON VISUAL INSPECTION. REINSERTION OF CENTRAL LINE VIA FLUORO. PT CURRENT STATUS REPORTED AS STABLE. THE DEVICE IS BEING RETURNED FOR EXAMINATION.
Covidien/Umbilical Artery Catheter	Model: 8888160341	IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE ON 3/22/07 THAT A CUSTOMER HAD A PROBLEM WITH THE UMB CATHETER. THE CUSTOMER STATES THAT THE CATHETER IS LEAKING DISTAL TO THE HUB. CUSTOMER HAS NOT CHANGED PROTOCOLS, NO CHANGE IN INSERTION, NO CHANGE IN STAFF, NO CHANGE IN CLEANING SOLUTION (CHLORHEXIDINE), MAXIMUM TIME LINE IS 14 DAYS, HOWEVER, IT IS UNK IN THIS CASE. NOTED UPON VISUAL INSPECTION. REINSERTION OF CENTRAL VENOUS LINE. PT CURRENT STATUS REPORTED AS STABLE. THE DEVICE IS BEING RETURNED FOR EXAMINATION.
Covidien/Umbilical Artery Catheter	Lot: 710308	IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE THAT A CUSTOMER HAD A PROBLEM WITH THE UMB CATHETER. THE CUSTOMER REPORTS "THERE WAS BREAKAGE OCCURRING NEAR THE HUB OF THE CATHETER. THEY WERE EXPERIENCING THE BREAKING AFTER INSERTION OF THE CATHETER."
Covidien/ Umbilical Artery Catheter	Lot: 710308TD>	IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE THAT A CUSTOMER HAD A

		PROBLEM WITH A UMB CATHETER. THE CUSTOMER REPORTS "THERE WAS BREAKING OCCURRING NEAR THE HUB OF THE CATHETER. THEY WERE EXPERIENCING THE BREAKING AFTER INSERTION OF THE CATHETER."
Covidien/Umbilical Artery Catheter	Device Identifiers Not Provided/Unknown	IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE IN 2007 THAT A CUSTOMER HAD A PROBLEM WITH THE UVC CATHETER. THE CUSTOMER REPORTS "UVC BEGAN TO BLEED OR LEAK THREE DAYS AFTER INSERTION. INSERTED ON FIVE DAYS EARLIER, LEAK NOTED ON TWO DAYS PRIOR TO ORIGINAL DATE. CUSTOMER BELIEVES THE LEAK OCCURRED IN THE JUNCTION BETWEEN THE STOP COCK HUB AND THE CATH TUBING."
Covidien/Umbilical Artery Catheter	Model: 8888160333	IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE THAT A CUSTOMER HAD A PROBLEM WITH A UMB CATHETER. THE CUSTOMER STATES THAT THERE WAS A LEAKAGE DISTAL TO HUB. DETECTED VISUALLY AFTER LESS THAN 72 HOURS IN USE. VENOUS AND ARTERIAL INFUSION. ANOTHER DEVICE WAS USED. NO ILL-EFFECTS TO THE PT. SAMPLES ARE BEING RETURNED FOR EXAMINATION.
Covidien/Umbilical Artery Catheter	Model: 8888160556	IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE THAT A CUSTOMER HAD AN ISSUE WITH AN UMB CATHETER. THE CUSTOMER STATES THAT THERE WAS A LEAKAGE DISTAL TO HUB. DETECTED VISUALLY AFTER LESS THAN 72 HOURS IN USE. VENOUS AND ARTERIAL INFUSION. ANOTHER DEVICE WAS USED. NO ILL-EFFECTS TO THE PT. SAMPLES

		ARE BEING RETURNED FOR EXAMINATION.
Covidien/Umbilical Artery Catheter	Model: 8888160341	IT WAS REPORTED TO TYCO/KENDALL HEALTHCARE THAT A CUSTOMER HAD A PROBLEM WITH A UMB CATHETER. THE CUSTOMER STATES, THAT THERE WAS LEAKAGE DISTAL TO HUB. DETECTED VISUALLY AFTER LESS THAN 72 HOURS IN USE. VENOUS AND ARTERIAL INFUSION. ANOTHER DEVICE WAS USED. NO ILL-EFFECTS TO THE PATIENT. SAMPLES ARE BEING RETURNED FOR EXAMINATION.
Covidien/Umbilical Artery Catheter	Lot: 715909	IT WAS REPORTED TO TYCO HEALTHCARE/KENDALL IN 2007 THAT A CUSTOMER HAD A PROBLEM WITH A UMBILICAL CATHETER.CUSTOMER REPORTED; "WITHIN 24 HOURS OF PLACING THE UVC IT STARTED LEAKING WHERE THE CATHETER JOINS THE HUB. UVC WAS REMOVED AND A PICC WAS PLACED TO MAINTAIN CENTRAL VENOUS ACCESS."
Covidien/Umbilical Artery Catheter	Model: 8888160341	IT WAS REPORTED TO TYCO HEALTHCARE/KENDALL IN 2007 THAT A CUSTOMER HAD A PROBLEM WITH AN UMBILICAL VESSEL CATHETER. THE CUSTOMER REPORTS THAT THE UVC WAS INSERTED ON EIGHT DAYS EARLIER AT 19:00 HRS IN THE NICU. THE CUSTOMER REPORTS THAT THE LINE WAS IN GOOD POSITION IN THE UMBILICAL VEIN. TPN, LIPIDS, AND MAINTENANCE HEPARIN SOLUTION (DEXTROSE AND HEPARIN) WERE INFUSED THROUGH THE LINE FOR SIX DAYS. ON THE SIXTH DAY, THE LINE DEVELOPED A LEAK RESULTING IN THE REMOVAL OF THE UVC AND UNSUCCESSFUL ATTEMPTS TO PLACE A PICC LINE. A

		PERIPHERAL IV WAS INSERTED. NO CONSEQUENCE TO THE PT WAS REPORTED.
Covidien/Umbilical Artery Catheter	Model: 9999160341	IT WAS REPORTED TO TYCO HEALTHCARE/KENDALL IN 2007 THAT A CUSTOMER HAD A PROBLEM WITH AN UMBILICAL VESSEL CATHETER. THE CUSTOMER REPORTS THAT THE CATHETER HAD A HOLE IN IT. THE LINE WAS INSERTED ON THE MONTH BEFORE, AND THIS OCCURRED 5 DAYS LATER. FOLLOWING THIS EVENT THE LINE WAS REMOVED AND THE PT HAD A PIV STARTED. THE PT WAS TRANSFERRED BACK TO A LEVEL 2 CENTER A FEW DAYS LATER.
Covidien/Umbilical Artery Catheter	Catalog: 8888160341	IT WAS REPORTED ON DEC 11 2007 TO TYCO HEALTHCARE/KENDALL THAT A CUSTOMER HAD A PROBLEM WITH AN UMBILICAL VESSEL CATHETER. THE CUSTOMER REPORTS, THAT THE PT (INFANT) WITH THE DEVICE HAD ASCITES. THE DEVICE WAS REMOVED AND LIVER ACCUMULATION NOTED. WHEN SENT FOR ANALYSIS, IT CAME BACK AS TPN-UVC EVISCERATION. THE INFANT IS RECOVERING. THE INFANT HAD A LOW LYING UVC. NO SAMPLE OR LOT NUMBER.
Covidien/Umbilical Artery Catheter	Model: 8888160333	IT WAS REPORTED TO TYCO HEALTHCARE/KENDALL ON 12/11/2007 THAT A CUSTOMER HAD A PROBLEM WITH A UMBILICAL VESSEL CATHETER. THE CUSTOMER REPORTS, THAT THE PATIENT (INFANT) HAD LIVER ACCUMULATION NOTED AND ABDOMINAL X-RAY REVEALED THE SAME. THE INFANT HAD A LOW LYING UVC. THE PATIENT IS RECOVERING. NO SAMPLE OR LOT NUMBER.

Covidien/Umbilical Artery Catheter	Model: 8888160333	IT WAS REPORTED TO TYCO HEALTHCARE/KENDALL ON 12/11/2007 THAT A CUSTOMER HAD A PROBLEM WITH A UMBILICAL VESSEL CATHETER. THE CUSTOMER REPORTS, THAT THE PATIENT (INFANT) HAD LIVER ACCUMULATION NOTED AND ABDOMINAL X-RAY REVEALED THE SAME. THE INFANT HAD A LOW LYING UVC. THE PATIENT IS RECOVERING. NO SAMPLE OR LOT NUMBER.
Covidien/Umbilical Artery Catheter	Device Identifiers Not Provided/Unknown	IT WAS REPORTED TO TYCO HEALTH CARE/KENDALL ON 01/30/08 THAT A CUSTOMER HAD A PROBLEM WITH A UMBILICAL VESSEL CATHETER. CUSTOMER REPORTED THAT AN INFANT HAD PLACEMENT OF UMBILICAL VESSEL CATHETER IN 2008, THAT WAS VERIFIED VIA X-RAY FOLLOWING INSERTION. POSITION HIGH AT T7 ON PLACEMENT, THEN PULLED BACK TO T12-L1. PT SUFFERED FROM COMPLEX CYSTIC MASS/MASSES IN LIVER CONFIRMED BY ULTRA SOUND SCAN. UMBILICAL VESSEL CATHETER REMOVED AND LIVER ACCUMULATION NOTED. CLINICAL DIAGNOSIS OF TPN INFUSION INTO LIVER. INFANT IMPROVED QUICKLY FOLLOWING REMOVAL OF UMBILICAL VESSEL CATHETER. PT TREATED WITH ANTIBIOTIC INFUSION VIA PICC LINE FOR 7-14 DAYS.
Utah Medical Products, Inc. /Umbilical Artery Catheter	Catalog: 4173505	AN UMBILICAL CATHETER, REPORTED BY THE CUSTOMER AS POSSIBLY NICKED, BROKE WHILE THE CATHETER WAS BEING REMOVED. THE CATHETER WAS REMOVED WITHOUT ANY SURGICAL INTERVENTION AND WITHOUT ANY

		<p>RESIDUAL PATIENT EFFECTS. HOWEVER, DURING THE REMOVAL OF THE CATHETER THE BABY LOST ABOUT 6-8ML OF BLOOD. AFTER REMOVAL OF THE CATHETER, THE INFANT HAD AN ARTERIALSPASM, WHICH WAS RESOLVED WITH WARM COMPRESSION.</p>
Utah Medical Products, Inc. /Umbilical Artery Catheter	Catalog: 4175005	<p>DURING AN ATTEMPT TO REMOVE THE UMBILICAL VENOUS CATHETER (UVC), THE PRACTITIONER WAS UNABLE TO PULL OUT THE LINE. THE UVC BROKE LEAVING 9CM OF LINE IN THE UMBILICAL VEIN.</p>
Vygon Corp. /Umbilical Artery Catheter	Lot: 27.04.06EC	<p>"A DOUBLE LUMEN UMBILICAL CATHETER DEVELOPED A LEAK AT THE DISTAL LUMEN LUER LOCK CONNECTION. A CLOSE EXAMINATION REVEALED THAT THE CONNECTOR HAD A CRACK IN IT THAT ALLOWED TPN AND LIPIDS TO LEAK OUT. THIS HAS HAPPENED NUMEROUS TIMES OVER THE LAST TWELVE MONTHS AND THE MFR HAS NOT BEEN ABLE TO RESOLVE THE ISSUE. DEVICE USAGE PROBLEM: DEVICE FAILED (E.G. BROKE, COULDN'T GET IT TO WORK OR STOPPED WORKING)". THE RETURNED CATHETER HUBS WERE EXAMINED VISUALLY AND MICROSCOPICALLY. THE VISUAL EXAM SHOWED THAT THE HUBS WERE CRACKED VERTICALLY. THE MICROSCOPIC EXAM SHOWED EVIDENCE OF TOOL MARKS ON THE HUBS. THE CRACKING WAS CONSISTENT WITH MECHANICAL STRESS. THE HUB OF THE CATHETER IS BELIEVED TO HAVE BEEN LIGHTENED TOO TIGHTLY, WITH OR WITHOUT THE USE OF TOOLS, WHICH MAY RESULT IN CRACKING OF THE HUB. VYCON RECOMMENDS THAT CARE BE</p>

		TAKEN IN MAKING ATTACHMENTS, SO THAT THE CONNECTIONS ARE NOT OVER TIGHTENED, AND TOOLS, SUCH AS FORCEPS SHOULD NEVER BE USED TO TIGHTEN THE HUBS, AS THIS MAY RESULT IN CRACKING.
Vygon Corp./Umbilical Artery Catheter	Catalog: 1274.14	A DOUBLE LUMEN UMBILICAL CATHETER DEVELOPED A LEAK AT THE DISTAL LUMEN LUER LOCK CONNECTION. A CLOSE EXAMINATION REVEALED THAT THE CONNECTOR HAD A CRACK IN IT THAT ALLOWED TPN AND LIPIDS TO LEAK OUT. THIS HAS HAPPENED NUMEROUS TIMES OVER THE LAST TWELVE MONTHS AND THE MANUFACTURER HAS NOT BEEN ABLE TO RESOLVE THE ISSUE.
Vygon Corp./Umbilical Artery Catheter	Catalog: 1270.03	AN UMBILICAL CATHETER DEVELOPED A LEAK AT THE LUER LOCK CONNECTION. A CLOSE EXAMINATION REVEALED THAT THE CONNECTOR HAD A CRACK IN IT THAT ALLOWED TPN, LIPIDS, FENTANYL AS WELL AS BLOOD TO LEAK OUT. FLUID LOSS AS WELL AS INADEQUATE MEDICATION CONTRIBUTED TO A SITUATION WHERE THE NEONATE WAS TEMPORARILY VERY UNSTABLE.
Utah Medical Products, Inc./ Umbilical Artery Catheter	Model: CE 0344	THE INFANT WAS DISTRESSED AND INCONSOLABLE. THE INCREASED MOVEMENT AT THE INFANT-LINE CAUSED IT TO BREAK AT THE HUB SITE FROM THE CATHETER.
Covidien/Umbilical Artery Catheter	Model: 8888160333	IT WAS REPORTED TO TYCO HEALTH CARE/KENDALL IN 2008 THAT A CUSTOMER HAD A PROBLEM WITH A UMBILICAL VESSEL CATHETER. THE CUSTOMER STATED THAT THERE WAS A FORMATION OF A CLOT AT THE CATHETER TIP. THERE WAS EXTRAVASATION OF PARENTERAL

		<p>NUTRITION IN LIVER TISSUE SURROUNDING THE VESSEL - PSEUDOCYST CONFIRMED BY ULTRASOUND, CARDIOTOCOGRAPHY. PT INFO: FEMALE, THROMBUS IN INFERIOR VENA CAVA, ULTRASOUND PERFORMED ON DAY 28 (VENTILATED, HYALINE MEMBRANE DISEASE, BRONCHOPULMONARY DYSPLASIA).</p>
Covidien/Umbilical Artery Catheter	Lot: 06K514E	<p>IT WAS REPORTED TO TYCO HEALTH CARE/KENDALL IN 2008 THAT A CUSTOMER HAD A PROBLEM WITH A UMBILICAL VESSEL CATHETER. THE CUSTOMER STATED THAT THERE WAS A FORMATION OF A CLOT AT THE CATHETER TIP. THERE WAS EXTRAVASATION OF PARENTERAL NUTRITION IN LIVER TISSUE SURROUNDING THE VESSEL - PSEUDOCYST CONFIRMED BY ULTRASOUND, CARDIOTOCOGRAPHY. PT INFO: ULTRASOUND ON DAY 4 (CONFIRMED SEPSIS - S. AUREUS + DISSEMINATED INTRAVASCULAR COAGULATION)</p>
Covidien/Umbilical Artery Catheter/TD>	Model: 8888160333	<p>IT WAS REPORTED TO TYCO HEALTH CARE/KENDALL IN 2008 THAT A CUSTOMER HAD A PROBLEM WITH A UMBILICAL VESSEL CATHETER. THE CUSTOMER STATED THAT THERE WAS A FORMATION OF A CLOT AT THE CATHETER TIP. THERE WAS EXTRAVASATION OF PARENTERAL NUTRITION IN LIVER TISSUE SURROUNDING THE VESSEL - PSEUDOCYST CONFIRMED BY ULTRASOUND, CARDIOTOCOGRAPHY. PT INFO: ULTRASOUND ON DAY 4</p>

		(CONFIRMED SEPSIS - S. AUREUS + DISSEMINATED INTRAVASCULAR COAGULATION)
Covidien/Umbilical Artery Catheter	Model: 8888160333	IT WAS REPORTED TO TYCO HEALTH CARE/KENDALL IN 2008 THAT A CUSTOMER HAD A PROBLEM WITH A UMBILICAL VESSEL CATHETER. THE CUSTOMER STATED THAT THERE WAS A FORMATION OF A CLOT AT THE CATHETER TIP. THERE WAS EXTRAVASATION OF PARENTERAL NUTRITION IN LIVER TISSUE SURROUNDING THE VESSEL - PSEUDOCYST CONFIRMED BY ULTRASOUND, CARDIOTOCOGRAPHY PT INFO: A MALE – US ON DAY 6 (NOT VENTILATED).
Utah Medical Products, Inc./Umbilical Artery Catheter	Lot: 1062257	UPON REMOVAL OF THE DOUBLE LUMEN UVC, THE CATHETER BROKE, WHILE GENTLY PULLING, AT THE 4CM MARK. CATHETER FELT BRITTLE. THE REMAINDER OF THE CATHETER WAS REMOVED FROM THE INFANT INTACT.
Utah Medical Products, Inc./Umbilical Artery Catheter	Lot: 1062257	THE PATIENT WAS AGITATED AND KICKING, SWADDLED IN A BLANKET. WHEN PATIENT PLACED BACK IN WARMER AND UNWRAPPED, THE UVC LINE WAS BROKEN AT THE 20CM MARK. THE REMAINDER OF THE LINE WAS REMOVED FROM THE BABY. NO ADVERSE OUTCOME.
Covidien/Umbilical Artery Catheter	Lot: 629504 OR 705404	WHILE LOOSENING SUTURES WITH TWEEZERS TO REMOVE UMBILICAL ARTERY CATHETER, CATHETER BROKE. INFANT REQUIRED SURGERY TO REMOVE RETAINED PIECE BROKE AT 13CM MARK.
Covidien/ Umbilical Artery Catheter	Lot: 705406	PLACED CATHETER AND PORT (BLUE) WOULD NOT FLUSH. OPENED ANOTHER ONE WITH SAME LOT

		NUMBER AND HAD THE SAME PROBLEM. OPENED A THIRD CATHETER WHICH WORKED.
Utah Medical Products, Inc./ Umbilical Catheters	Device Identifiers Not Provided/Unknown	MD ORDERED TO PULL UAC OUT 1CM. REGISTERED NURSE SLID DOWN SUTURES IN ORDER TO PERFORM PROCEDURE HOLDING PROXIMAL END OF CATHETER. PLACED FINGER AND THUMB AROUND DISTAL CATHETER TO GENTLY PULL BACK CATHETER WHEN CATHETER SNAPPED IN TWO. REGISTERED NURSE ABLE TO HOLD ONTO PROXIMAL END OF CATHETER TO PREVENT CATHETER FROM ENTERING UMBILICAL ARTERY FURTHER. MD PLACED HEMOSTAT ON PROXIMAL END AND RN COMPLETED REMOVAL OF REMAINING CATHETER. TIP WAS INTACT, NO INJURY TO PT.
Utah Medical Products, Inc./Umbilical Artery Catheter	Device Identifiers Not Provided/Unknown	CATHETER SEPARATED FROM SUTURE AT Y CONNECTION. THE DOUBLE LUMEN UMBILICAL VENOUS LINE BROKE INTO 2 PIECES BEFORE THE Y PORTAL. THE FLUID WAS D12 AND ORAL FEEDING AT THE TIME.

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Summary of MedSun Reports Describing Adverse Events With Infant Radiant Warmers and Neonatal Incubators And Related Recalls and Articles

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By Elizabeth Eydelman, Patient Safety Staff, 2008

Over the past year and a half, MedSun has received 8 adverse event reports involving infant radiant warmers and neonatal incubators associated with three manufacturers: Draeger Medical (5), Datex-Ohmeda, Inc. (2), and GE Medical Systems, LLC (1). The reports were submitted by 8 hospitals between January 1st 2007 and May 16th 2008, and involved neonatal patients. Reported device problems are:

- Melting of incubator components/components ignite or smoke (3)
- Overheating of incubator occupant (2)
- Sharp edges or high temperatures are hazards to health care professionals (2)
- Failure of Incubator to heat (1)

Four of the reports that list adverse event type as malfunction and the remaining have event types listed as invalid/insufficient data. There are no reports with event types listed as death, injury, or other. Of the reports that list patient problems, the most frequently reported patient problems are:

- Elevated infant body temperature (2)
- Burns to health care professional (1)
- Cuts to health care professional (1)

These reports contribute to FDA's post-market experience and understanding of problems associated with the use of these devices.

Additionally, the following recall describes a problem involving a heating failure with the Draeger TI500 Isolette Infant Incubator:

The recall, Z-1051-2008 dated January 31, 2008, was initiated for a Draeger TI500 Isolette Infant Incubator Catalog Number: MU20505 by Draeger Medical, Inc., Telford, PA 18969. The product is under recall due to a heating failure involving a power board which controls the incubator heater that may not regulate the temperature properly. This, in turn, results in a high temperature alarm and a loss of temperature control within the patient compartment.

"Don't Let Radiant Warmers Overheat Infants," an article in the March Issue of Nursing2006, provides the following precautions for infant incubator radiant warmer use:

- Follow your facility's policies and procedures for infant incubators and warmers.
- Review and follow manufacturer service manual and instructions for use
- Verify patient skin temperatures being monitored by incubators/warmers by frequent axillary skin temperature checks.

[Note: The reports have been edited for clarity]

MedSun Infant Radiant Warmers and Neonatal Incubator Adverse Event Reports received between January 1st 2007 and May 16th 2008		
Device	Device Identifiers	Event Description
Draeger Medical Systems,	Model: 7880	RADIANT WARMER USED TO WARM INFANT AFTER AXILLARY TEMPERATURE 97.3F. SKIN

Inc./Infant Radiant Warmer		PROBE PLACED OVER LIVER IN RUQ (RIGHT UPPER QUADRANT) OF ABDOMEN AND CONTROL POINT SET AT 37.1C (98.6F). WHEN SKIN TEMP REACHED 36.1C, MACHINE PRODUCED LITTLE TO NO HEAT AND KEPT ALARMING. AT 2135, INFANT TRANSFERRED TO ANOTHER WARMER WHICH READ HIS SKIN TEMP AT 35.8 (96.6F) AND HIS AXILLARY TEMP WAS 97.2F AT THIS TIME.
GE Medical Systems, LLC/Neonatal Incubator	Model: Giraffe Omnibed	THE PLASTIC MOLDING AROUND THE PLUG OF THE AC POWER CORD WAS MELTED. THIS IS ON THE FEMALE END OF THE POWER CORD THAT INSERTS INTO THE DEVICE ITSELF (NOT THE WALL OUTLET SIDE). IT ALSO HAD A "BURNT ELECTRICAL" SMELL UPON FURTHER EXAMINATION. THIS WAS FOUND DURING ANNUAL PLANNED MAINTENANCE. IT IS UNKNOWN HOW LONG THIS CONDITION EXISTED WHILE THE DEVICE WAS IN USE AS NO COMPLAINTS WERE EVER LOGGED. FOLLOW-UP REVEALS THAT THE AC RECEPTACLE IN THE GIRAFFE IS DESIGNED TO HOLD THE POWER CORD IN PLACE USING AN L-SHAPED BRACKET. THEORETICALLY THIS WOULD PREVENT IT FROM BEING UNPLUGGED ACCIDENTALLY. APPARENTLY THE POWER CORD WAS LOOSE FOR SOME TIME PRIOR TO BEING DISCOVERED DURING A ROUTINE ELECTRICAL SAFETY INSPECTION. THE DAMAGED POWER CORD WAS GIVEN TO A COMPANY SALES REPRESENTATIVE. THE REPRESENTATIVE NOTED THAT THE CORD WAS A DIFFERENT TYPE (BLACK VERSUS GRAY) THAN HE HAD SEEN BEFORE. THE HOSPITAL HAS ONLY ONE OF THESE INCUBATORS.
Draeger Medical Systems, Inc./Infant Radiant Warmer	Model: IICS- 90	EACH INFANT WARMER HAS A DOUBLE CYLINDER HOLDER MOUNTED ONTO EACH UNIT. PLASTIC KNOBS WITH THREADED SCREWS HOLD E OXYGEN CYNLINDER TANKS IN PLACE. THE PLASTIC KNOBS STICK OUT, AND 2 HAD BECOME BROKEN JUST BY MOVING THE WARMERS AROUND IN THE STORAGE ROOM. WHEN THE PLASTIC KNOB BREAKS, THEY BREAK IN SUCH A MANNER

		<p>THAT LEAVES VERY SHARP EDGES. MYSELF AND ANOTHER BIOMED HAD OUR FINGERS SLICED BY THE SHARP PLASTIC, AND THEREFORE REPLACED THE PLASTIC KNOBS WITH DIFFERENT SCREWS MADE STRICTLY OUT OF METAL, WITH A FLAT END THE USER CAN GRIP TO TURN AND TIGHTEN.</p>
<p>Draeger Medical Systems, Inc./Neonatal Incubator</p>	<p>Model: C2HS-1</p>	<p>RN FOUND NEONATE TACHYCARDIC, TACHYPNEIC AND DECREASED SATURATIONS. BOTH BABY AND ISOLETTE WERE VERY WARM. WAS SET ON SERVO CONTROL BUT WAS FOUND ON AIR CONTROL, ATTEMPT TO CHANGE BUT ALARMED 'PROBE MALFUNCTION.' UNABLE TO CHANGE TO SERVO CONTROL. HAD TO TURN BED OFF TO DECREASE NEONATE'S TEMP FROM 101.9. AFTER TEMP DECREASED, ATTEMPT TO TURN BED BACK ON WAS UNSUCCESSFUL.</p>
<p>Datex-Ohmeda, Inc./Infant Radiant Warmer</p>	<p>Catalog: 6650-004-901</p>	<p>WHEN THE NURSE BENT DOWN TO PLUG IN AN INFUSION PUMP, HER KNEE GAVE OUT WHEN ATTEMPTING TO STAND, WHICH CAUSED HER TO BUMP INTO AND LEAN ON THE HUMIDIFIER END OF THE DATEX-OHMEDA GIRAFFE OMNIBED. THE HUMIDIFIER WAS ON AND RUNNING, SO THE WATER WAS HEATED. INVESTIGATION FOUND THE WATER RUNNING AT GREATER THAN 150 DEGREES F (158 F), AND THE TOP SURFACE AREA TO BE AT 118 DEGREES F (NORMAL). AFTER THE EVENT WAS DISCUSSED WITH DATEX-OHMEDA TECHNICAL SUPPORT ENGINEER, IT WAS CONFIRMED THAT THE HEATER ELEMENT ITSELF RUNS AT 200 DEGREES F. THE OPERATING TEMPERATURES AND THE TEMPERATURE WAS WITHIN NORMAL SPECIFICATIONS, THOUGH NOT LISTED IN THE SERVICE MANUAL. WE BELIEVE THE JARRING OF THE UNIT WHEN THE STAFF MEMBER ATTEMPTED TO GAIN HER BALANCE CAUSED THE WATER TO SLOSH IN THE RESERVOIR, AND CAUSED A SMALL 2ND DEGREE BURN (ABOUT THE SIZE OF A NICKEL) WHERE SHE WAS USED THE UNIT FOR SUPPORT. WE HAVE ATTACHED</p>

		WARNING LABELS TO THE RESERVOIR ON ALL OF OUR DATEX-OHMEDA GIRAFFE OMNIBEDS SO STAFF IS AWARE THAT THIS AREA IS HOT WHEN HUMIDIFIER IS RUNNING.
Draeger Medical Systems, Inc./Infant Radiant Warmer	Model: RW82-1	INFANT WARMER IGNITED WHILE UNIT WAS IN THE OPERATING ROOM PENDING DELIVERY OF THE INFANT. THE UNIT WAS IN OPERATION BUT INFANT WAS NOT IN THE BED. A MANUFACTURER'S REPRESENTATIVE CAME TO THE FACILITY TO REPLACE PARTS ON THE DAMAGED UNIT AND WILL BE REPLACING THE HEATER ELEMENTS ON ALL UNITS IN OUR FACILITY. THE HOSPITAL'S BIOMEDICAL ENGINEERING DEPARTMENT HAS REPLACED HEATING UNITS ON FOUR OTHER WARMERS AT THE FACILITY IN THE PAST YEAR, WHICH THEY CONSIDER A HIGH FAILURE RATE.
Datex-Ohmeda, Inc./Neonatal Incubator	Model: 600	THE AIR MODE WAS BEING USED TO PREHEAT THE OMNIBED INCUBATOR WHILE AWAITING THE INFANT'S RETURN FROM SURGERY. WHEN THE INFANT WAS PLACED IN THE OMNIBED, THE BED WAS NOT PUT INTO BABY MODE. THIS CAUSED THE OMNIBED TO MAINTAIN AN AIR TEMPERATURE OF 41.7 DEGREES C (107 DEGREES F). THIS ELEVATED AIR TEMPERATURE RESULTED IN AN INCREASE OF THE INFANT'S AXILLARY TEMPERATURE.
Draeger Medical Systems, Inc./Neonatal Incubator	Model: C2000	INFANT BEING ASSESSED WHEN NURSE SMELLED ELECTRICAL SMOKE. SMOKE SEEN ABOVE ISOLETTE. INFANT REMOVED FROM ISOLETTE IMMEDIATELY AND PLACED IN A CLEAN ISOLETTE. CHANGE NURSE NOTIFIED. SECURITY CALLED. HOSPITAL BIOMEDICAL CALLED AND NOTIFIED. BIOMEDICAL SHEET FILLED OUT AND ISOLETTE TAKEN TO DIRTY UTILITY ROOM TO BE CLEANED. NO PROBLEMS WITH INFANT.