MedSun
Medical Product Safety Network

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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In This Issue:

About the MedSun Program:

The MedSun Program, which was launched in 2002 by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), involves the reporting of problems with medical products from a network of approximately 300 hospitals, nursing homes and home health facilities around the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products. MedSun utilizes a secure, on-line system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

Those who are interested in having their healthcare facilities join MedSun may contact medsun@fda.hhs.gov or 800-859-9821 for additional information.

Newly Approved Devices

Recently Approved Devices (searchable listing):
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/mda/mda-list.cfm?list=1

Premarket Approval Final Decisions:
https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM591257.pdf

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm587897.htm

In Brief

As of March 2, 2018

For the FDA Enforcement Report containing the most recent Class I, II and III recalls, go to
http://www.accessdata.fda.gov/scripts/ires/index.cfm

If you see any problems of the type described in these announcements or other device safety issues, please report them through the MedSun reporting system at https://medsun.fda.gov as soon as possible. If you need password information or want to report by phone, please call us at 1-800-859-9821 or e-mail at medsun@fda.hhs.gov.

Recalls and Safety Alerts

Cardiac Resynchronization Therapy with Defibrillation (CRT-Ds) and Implantable Cardiovert-Defibrillators (ICDs) by Medtronic: Class I Recall
February 27, 2018
Medtronic is recalling certain ICDs and CRT-Ds due to a defect in the manufacturing process. This defect causes an out of specification gas mixture inside the device and may prevent the device from delivering the electrical shock needed to pace a patient's heartbeat or revive a patient in cardiac arrest. The delay or inability to deliver a shock to a patient in cardiac arrest or pace a patient's heart whose heartbeat is too slow could result in serious injury and/or death.

HeartStart MRx Defibrillator by Philips Electronics: Class I Recall
February 9, 2018
As a result of this GDT defect, the HeartStart MRx may fail at any time, including when delivering repeated shocks in AED mode, or during the periodic Operational Check outlined in the device's Instructions for Use. If the device is used in AED mode after failure, the device will not deliver patient therapy. Continued use of the device in AED mode after failure may lead to serious patient injury or death.

Pentax Medical Duodenoscope Model ED-3490TK: FDA Safety Communication
February 7, 2018
Pentax issued an Urgent Medical Device Correction and Removal notification informing customers of its voluntary recall of all ED-3490TK duodenoscopes in order to replace the forceps elevator mechanism, O-ring seal and distal end cap, and to update the Operation Manual to recommend annual maintenance. The design changes are intended to reduce the potential for leakage of patient fluids into the closed elevator channel and under the distal cap. The FDA cleared the updated design and labeling for the ED-3490TK on February 7, 2018.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during February 2018 The reports are displayed within clinical specialty areas based on analysis of the information submitted. The reports are presented as submitted by MedSun Representatives and in some instances have been summarized and/or edited for clarity.

A database of all MedSun reports can be found at:

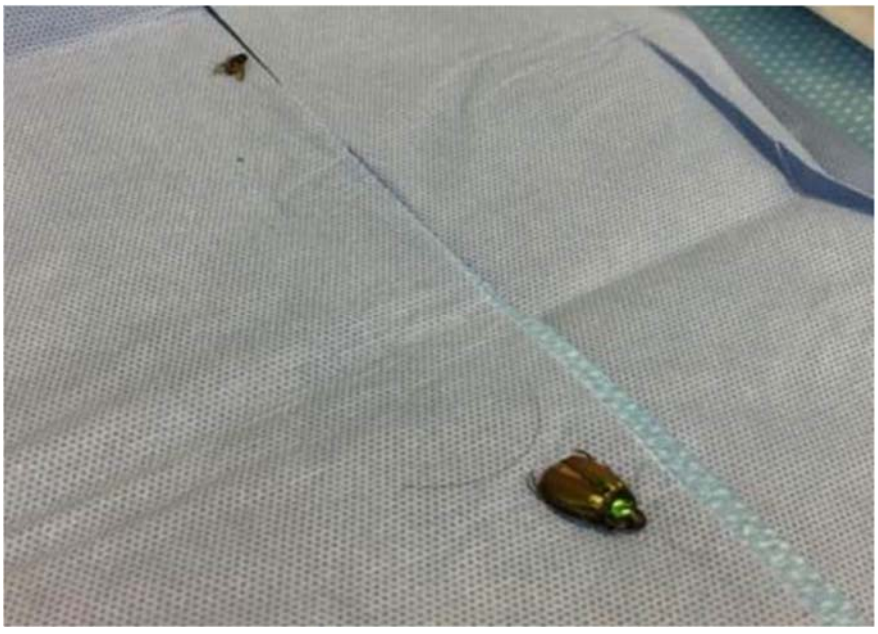
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm


Special Note:

The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years of age or younger (that is, from birth through the twenty-first year of life, up to but not including the twenty-second birthday) at the time of the diagnosis or treatment.

Device	Manufacturer	Problem
Brush, Biopsy, Bronchoscope (Non-rigid) Model#: 130 Lot #: 201709274 Cat #: 130 Other #: Disposable Microbiology Brush, 1mm Diameter, 1.8mm Working Diameter, 110cm Length	Conmed Corporation	A cytology specimen was obtained using a bronchial brush and at the completion of the procedure, the surgical tech went to cut the brush off to send as a specimen when she discovered that the brush tip was missing. The bronchial brush was inspected prior to start of procedure and it was intact. The surgeon was notified and attempts were made to search for the brush on the patient's person as well as in the bronchial lavage specimen but it was not found.

Device	Manufacturer	Problem
Device 1: Catheters, Suction, Tracheobronchial Brand: Kimvent 14fr Dse 12in/30. 5cm (Green) Model#: 221036 Lot #: AB7275U01 Other #: Closed Suction Tracheostomy Catheter	Halyard Health	Nurse was attempting to use the in line suction connected to the ventilator when the line became disconnected and splashed the nurse in the face with matter from patient. This same issue happened a number of times to the point where the nurses had to resort to tape the tube to the vent. product was pulled from shelf and replaced.
Device 2: Catheters, Suction, Tracheobronchial Brand: Kimvent 14fr Dse 12in/30. 5cm (Green) Model#: 221036 Lot #: AB7268U20 Other #: Closed Suction Tracheostomy Catheter	Halyard Health	
Device 3: Catheters, Suction, Tracheobronchial Brand: Kimvent 14fr Dse 21. 3in/54cm (Green) Model#: 22106 Lot #: AB7338U04 Other #: Closed Suction Endotracheal Catheter	Halyard Health	

Device	Manufacturer	Problem
Device 1: Custom Surgical Pack Brand: Dynj Custom Pack - Tr -Add-on Total Knee Knapke Lot #: 17JD2175 Cat #: DYNJ55328 **Device 2: Custom Surgical Pack** Brand: Cmpj Custom Pack - Total Knee Pack Troy -Lf Lot #: 17JD2348 Cat #: CMPJ08240A	Medline Industries Medline Industries	Clinical Engineering received a Medline custom pack with a note of contamination. Foreign material was found inside of folded wrapper. The contamination was noted prior to the procedure and the sterile field was not contaminated. This is an ongoing issue with all custom packs. Per site reporter: Medline is investigating process for assembling custom packs, as contamination has been an ongoing issue. They are collecting samples as they become available for investigation.
General Surgery Tray Brand: Surgical Kit (Hemm 221238 Sheet Three Quarter Reinforced 53x77) Model#: DYNJP2416 Cat #: DYNJP2416	Medline Industries	Operating room (OR) staff began setting up for surgical procedure. As the scrub person opened a 3/4 sheet drape (part of the vascular bypass tote), staff discovered a large beetle, a fly, and hair on the inside of the drape upon opening. Drape was removed from OR. The staff in the room broke down their set up and opened a new tote. Patient was not affected as patient was not yet in OR room. Please see picture below: 

Device	Manufacturer	Problem
Defibrillator Brand: R-series Model#: R-Series	Zoll Medical Corp.	During the shift operational checks on the defibrillator, the defibrillator failed its power on self test [POST] and presented an "Error Code 76". Defib was removed from service and sent to biomedical engineering. Biomedical Engineering confirmed the error code 76 and contacted the manufacturer for troubleshooting. Manufacturer stated the reason for the failure related to a PF engine board and advised us to send in unit for service. This is a re-occurring issue on this model defibrillator as we have sent in other defibrillators of this same model with same failure error code.
Electrosurgical, Cutting, Coagulation Brand: Mega Soft Model#: 0845 Cat #: 0845	Megadyne Medical Products, Inc.	While using the pad during electrocautery, the patient experienced a second degree burn. The pad was returned to Megadyne for evaluation and met all testing requirements. The pad was physically intact and was not out of date. The pad was returned to the surgical center and placed back in use. It is possible that this small patient which had a tonsillectomy and involved the head/neck was placed on a jelly roll for positioning. This roll was placed on top of the Megasoft pad instead of underneath, which may have reduced the surface area on the pad. However, if contact was to low the ESU would not function.
Fiber, Medical, Absorbent Brand: Medline Industries, Inc. Model#: DYNJ17333G Cat #: DYNJ17333G Other #: custom laminectomy pack OR Towels	Medline Industries	Surgeon noticed lint while using the microscope on a neurosurgical procedure. Lint was from towels from a custom pack laminectomy pack.
Guide Wire Brand: Verrata Plus Pressure Guide Wire Model#: 10185P Lot #: 0287 50123160 204 Cat #: 10185P	Philips Volcano	During placement of a cardiac stent the Phillips Volcano Guidewire got stuck on the stent strut and broke off in the patient's artery. This resulted in the need for an emergent open heart aortic valve replacement. Per site reporter: sent an email to local sales rep to begin correspondence on the issue.

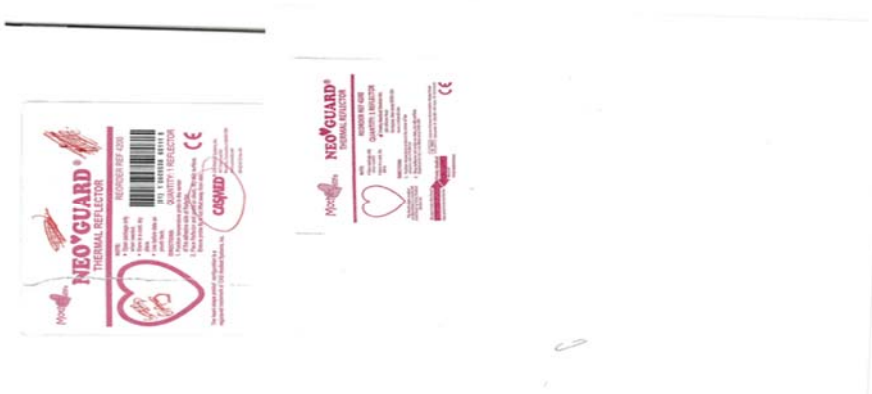
Device	Manufacturer	Problem
Device 1: Holder, Head, Neurosurgical (Skull Clamp) Brand: Mayfield Infinity Xr2 Cat #: A2114 **Device 2: Knob Assembly, Base Unit** Brand: Mayfield Infinity Xr2 Cat #: 437A2409 **Device 3: Base Unit, Accessories, Operating-room, Table** Brand: Mayfield Infinity Xr2 Cat #: A2079 **Device 4: Swivel Adapter, Base Unit** Brand: Mayfield Infinity Xr2 Cat #: 437A2400	Integra Lifesciences Corporation Integra Lifesciences Corporation Integra Lifesciences Corporation Integra Lifesciences Corporation	The Infinity XR2 Radiolucent base unit (A2079) is attached to the OR table and then the skull clamp (A2114) is attached to the patient and then using the knob (437A2409) , the skull clamp is attached to the base. After tightening the knob (Standard Knob Assembly 437A2409) that holds the swivel to the skull clamp, the knob broke, forcing the patient's head which was in the skull clamp to become de-attached from the base. The patient's head was caught by the surgeon, so no injuries to the patient. This is a recurring event with the first occurring last summer, this report reflects the second event and there has been one more occurrence. Please see picture below: 

Device	Manufacturer	Problem
Infusion Pump Brand: Alaris Pc Unit Model#: 8015	Carefusion	Biomed received Alaris pump, note on unit stating system error; 255 -16-275. did not recognize the error; performed functionality and safety checks. upon start up, operating error occurred(800.8000).
Mesh, Surgical, Gynecologic, For Stress Urinary Incontinence, Female Brand: Advantage Fit System Model#: M0068502110 Lot #: 21368395	Boston Scientific	When opening the Advantage Fit System box to place items on the sterile field, it was noted that the box contained only the obturator but no mesh. Another box was obtained to use.
Oximeter, Reprocessed Model#: MAX-N Lot #: 7726303	Stryker Sustainability Solutions, Inc.	The NICU Manager reported that lot# 7726303 of the Stryker Max-N pulse oximeter sensors were defective. When removing the pulse oximeter sensors from the paper that it adheres to, the metal wires on the sensor are exposed. All sensors from this lot were removed from the NICU and sequestered in Central Supply. None of these sensors had been used on any infant. The vendor was notified and will pick up the entire lot for evaluation.
Powered Laser Surgical Instrument Brand: Venacure 1470 Laser	Angiodynamics, Inc.	A loaner Venacure was requested from the manufacturer as the original unit failed to work. Loaner unit was inspected by hospital biomed dept. Prior to accessing the patient vein, the laser fiber was connected to the unit, went through the normal process and unit seemed to be in working order. Patient's vein was accessed and the laser was guided through the sheath. Doctor stepped on pedal to engage the laser and a failure message appeared on the unit "Optical feedback out of range press control to continue". Could not get the unit to be functional. Procedure had to be terminated. Same type of incident occurred one week prior with hospital owned unit.
Spinal Anesthesia Kit Brand: Pencan Model#: 333851 Lot #: 0061591156 Cat #: 333851	B. Braun Medical, Inc.	Partial spinal achieved, doctor. had to turn case into general anesthesia due to partial numbness. Suspect meds are ineffective in spinal kit. Company notified. Per site reporter: Manufacturer for Spinal Kit is contacting their Quality department to see how many we can send back to them. They will not be able to send replacements only credit since the medication for the trays is on backorder.

Device	Manufacturer	Problem
Pulse-generator, Pacemaker, External Brand: Medtronic Model#: 5392	Medtronic	Our facility is experiencing widespread failures of the lead connector of our Medtronic 5392 pacemaker fleet. Degradation, cracks, and damage of the lead wire connector causes the lead set to have a loose, intermittent connection or to fall out completely. About 44% of our fleet is affected at this point. To date, we have identified 25 of our 57 pacemakers with damage to the connector. The fear is that eventually, we will lose functionality of the pacemaker while on a patient, or not have a working pacemaker available when it is needed for patient treatment. Medtronic has indicated that the problem is related to the disinfectant used at the hospital. Medtronic has also indicated that the pacemakers should be cleaned with alcohol. Alcohol is not an effective disinfectant. I am currently awaiting some follow up information from Medtronic regarding proper cleaning of the pacemakers.
Set, Administration, Intravascular Brand: Clearlink/duo-vent Model#: 2H7462 Cat #: 2H7462	Baxter International Inc.	Patient was had an IV pump at his bedside for which the RN hung IVPG of Zosyn, connecting the secondary tubing to the primary tubing. She set the pump in a manner to allow for the Zosyn to infuse. However, the medication did not infuse. The clamp on the tubing was open. RN changed the secondary IV tubing to a new set of the same kind and the same problem occurred; the medication did not infuse. A video clip of Biomed testing verified that the primary bag would back feeds into the secondary line/bag , possible issue with backflow valve.
Syringe, Piston Model#: 302995 Lot #: 732567928 Cat #: 302995 Other #: 00382903029952; BD 10 mL syringe luer-lok tip	Becton Dickinson and Company	A new, unopened 10 mL syringe was identified with a piece of red paper in the barrel.

Device	Manufacturer	Problem
Set, Administration, Intravascular Cat #: 470005 Other #: Product Code US1505		While giving a break to the nurse in the room, it was brought to my attention by MD that the IV tubing has been coming apart spontaneously. The orderly in the room verified that this had been happening a lot lately. I asked if it was the patients from the Same Day unit and they both told me yes. The MD showed me the IV tubing and I could see it had broken apart at the point of the connection between the regular IV tubing and the extension. I told MD he had done an excellent job of "Stop and Resolve" and that I would follow up with the Same Day unit. I talked to the Same Day charge nurse about it and she told me it was the new tubing they have been using. She said the tubing comes with the extension already connected in the package and that is not something any of the Same Day staff assemble. She told me how it had come apart on her while inserting an IV and she told me it had come apart for another nurse on a patient he had in PACU. She showed me the tubing and then the two of us went to talk to the manager. We told her we had been having problems with the new IV tubing set and showed her the new connection. I told her I would write a report on it. The manager asked the RN to pass this on to the Same Day educators for skills day, which is coming up. The staff will be trained to double check the extension connection and tighten it. I told her I would let our educators know about it as well. The product is: Braun IV Administration Set15 drops/ml, REf#470005, product code- US1505 124in (315 cm). Please see picture below: 

Device	Manufacturer	Problem
System, Monitor, Physiological Brand: Intellivue Piic Ix Model#: PIIC IX ST rp5800 PC	Philips Medical Systems	Monitor tech tried to associate a patient to the Philips central monitoring system, P.C. rebooted itself restarted & tried this again and the system rebooted again. Each time the system would come back to a patient monitoring screen but patient was not getting admitted into the system. Philips contacted regarding issue they were aware of this issue and that it had started happening on beginning of the month. Their technicians were working for a solution. This prevented the hospital from admitting patients to telemetry as they could not be centrally monitored. Held inpatients in the ED until Philips could identify a work around. Full function restored after five days.
System, Perfusion, Kidney Brand: Belzer Uw Cold Storage Solution Lot #: BCD11212117B	Preservation Solutions Inc.	Organ recipient was available for a kidney transplant procedure. When the Cold Storage solution was opened, it was determined to have a "rotten egg" odor. Another bag of the same lot was then opened and the fluid also had the "rotten egg" smell. The kidney was in contact with the cold storage solution. The transplant patient declined this organ and the kidney was not used during the case. OPO was made aware of the event following discussion with hospital.
Tubes, Gastrointestinal (And Accessories) Brand: Corflo Ultra Model#: 20-8366 Lot #: 78923 Cat #: 20-8366	Corpak MedSystems, Inc. (subsidiary of Halyard Health)	On inspection of 6F feeding tube prior to insertion, it was noted that the metal stylet was sticking out of one of the ports at the bottom of the feeding tube. Please see picture below: 

Device	Manufacturer	Problem
Unit, Neonatal, Phototherapy Brand: Neoblue Blanket Model#: ne-oBLUE Blanket Cat #: 006254	Natus Medical, Inc.	During phototherapy treatment utilizing an LED phototherapy light source and detachable phototherapy blanket with light coupler, the clinician noted smoke emitting from the attachment point between the light coupler hose and LED light source connection point. The clinician removed the phototherapy system from the patient and turned the unit off. Inspection of the LED light source noted charring and burning of the LED output lens. Charring and burning was also noted on the end of the phototherapy blanket light coupler. Inspection of additional units noted the same charring on an additional LED light source. Both devices removed from service and sent to Biomedical Engineering for reporting and company analysis. No patient harm.
Warmer, Infant Radiant, Reflector Brand: Neoguard Reflectors Model#: 3008595 Lot #: 081731579A Cat #: 4200	Trinity Medical Devices, Inc.	NeoGuard Thermal Reflector provided by CAS Medical Systems was being used in the NICU without problems. The inventory was dropping and a reorder was issued to CAS Medical Systems. The facility was notified of a backorder. Once the backorder was filled the product arrived and was placed into use. The staff noted that the product that filled the backorder was harder to peel, more sticky and harder to remove from the patient. In addition the humidity in the isolette melted the thermal cover and the product was hard to remove from the patient. There was no harm to the patient. On closer inspection, the packaging of the replenished product while the same graphics, color, and name of the product in small print, it was noted the product now to be provided by Trinity Medical with a tagline in small print on the packaging: "same product, new owner". The product was removed from use in all areas and additional products are under trial use for selection of a new product. Please see picture below: 

Device	Manufacturer	Problem
Bacterial Filter, Ventilator Brand: Puritan Bennett Expiratory Bacterial Filter 840 Ventilator Model#: 10078444 Rev B Cat #: 4-070305-00	Covidien LP	Pt on PB840 ventilator. Ventilator stopped working, reading no ventilation, severe occlusion. RT (Respiratory Therapy) was at the bedside and immediately started bagging Pt with Ambu bag. HR, and oxygen saturation remained stable during this time. Ventilator changed out to new PB840 ventilator. BioMed looked at the ventilator and determined that the expiratory filter was the problem, although it was a new filter.
Filter, Bacterial, Breathing-circuit Brand: Gibeck Model#: IP-N044101 Cat #: 28052	Teleflex Incorporated	The patient was undergoing a spinal surgery with general anesthesia. Approximately 4.5 hours into the case, peak pressures on the vent increased. The anesthesia team attempted to trouble shoot and another anesthesiologist assisted to evaluate the situation. No cause was determined: x ray taken w/o change, decision to stop the current procedure in favor of staging the procedure. The patient transferred to the ICU intubated, placed on the vent with normal airway pressures. Extubated early that evening without event. Bio med was notified, tested anesthesia machine ran pre-use check, all tests passed, discussed setting with the anesthesiologist who cared for the patient, set up the vent with the same settings used during the case on a test lung. Ventilator/anesthesia machine operated normally with test setup. Switched inspiratory filter to the filter used during the case and Peak pressures went up, Peak alarm sounded and delivered volumes dropped to keep Peak pressure under set pressure limit.
Generator, Oxygen, Portable Brand: Everflo Model#: 00 Cat #: 1039363	Respironics	The patient was utilizing at Oxygen 2.0 L per nasal cannula at home. Pt was home alone. Pt forgot the O2 was still on when the patient lit a cigarette and the Oxygen caught fire. Pt was attempting to put out the fire when postal worker entered the home. Postal worker pulled pt from home and called 911. Fire Department and ambulance responded to home fire. Pt transported to ED via ambulance. Pt suffered smoke inhalation and had carbonaceous sputum. Pt intubated to support airway and was transferred to another facility to a burn unit. Extensive damage to the home. Currently, uninhabitable at this time.

Device	Manufacturer	Problem
Tube Trache-ostomy And Tube Cuff Brand: Portex Model#: 536080 Lot #: 3503950 Cat #: 536080	Smiths Medical International	Patient undergoing planned trach placement. The cuff was tested by the doctor prior to insertion but once inserted, the balloon on the cuff would not hold air. Dr replaced the trach with a second trach of the same size, make and lot number. The second trach cuff was also tested before insertion and seemed to be in working order; once inserted, it would not maintain air in the cuff. The trach was then replaced again and this third trach worked as we would expect. This issue did cause delay in patient care due to the insertion and removal of 2 trachs prior to the final placement.
Tube, Tracheal (W/wo Con-nector) Brand: Hudson Rci Model#: IP-N044766 Lot #: 73C1600119 Cat #: 5-10314	Teleflex Inco-porated	The adaptor keeps coming loose from the tube. As a result, the pa-tient required an ET tube replacement. This occurred on one of our vented patients. This problem has happened multiple times over the last 3 months.
Catheter, Per-cutaneous Brand: Advance Model#: G50326 Lot #: 8253301 Cat #: PTAX4-14-170-2.5-20	Cook Incorpo-rated	MD removed balloon catheter from hoop and noticed the balloon had an area that was peeling back like a banana. MD called for an-other balloon, product did not enter the patient. Product removed from the sterile field intact.
Catheter, Pe-ripheral, Atherectomy Brand: Dia-mondback Pe-ripheral Model#: DBP–150CLASS145 Lot #: 206397 Cat #: DBP–150CLASS145	Cardiovascular Systems, Inc.	Physician was using the Diamondback 360 Peripheral Orbital Atherectomy System, the device was operating as intended at low and medium speed. When physician switched to high speed the device failed to increase speed. No adverse effect on patient.

Device	Manufacturer	Problem
Suture, Surgical, Absorbable, Polydioxanone Brand: Stratafix Spiral Model#: SXPD2B405 Lot #: AABP642 Cat #: SXPD2B405 Other #: SXPD2B405	Surgical Specialties	Barbs on suture are smaller than before but opening other packages of same suture barbs are of inconsistent lengths. Basically - inconsistent suture quality of three different lot numbers evaluated (other lots are MDDS230 and AAB5721)
Catheter, Intravascular, Therapeutic Brand: Arrow Lot #: 13F17K0202 Cat #: AK-25502 	Teleflex Incorporated	Packaging is incorrect for product. While in a OR case for central line placement, an ARROW pediatric two lumen central venous catheterization kit was opened. The packaging stated 5 French 8cm length for catheter, but inside was a 5 French 5cm length catheter. The catheter was also marked 5cm on the catheter itself. Another one was pulled from the same lot and it also had the same problem. All product from the same lots was pulled from supply.
Shunt, Central Nervous System And Components Brand: Codman Bactiseal Model#: 82-1750 Lot #: HF8716 Cat #: 821750		There was no flow coming from the ventricular catheter indicating that it was not functioning appropriately therefore proceeded to remove the old catheter. Proceeded to place a new catheter into the center of the ventricular system. The catheter was inserted. Cerebrospinal fluid was flowing out of the catheter however the patient was noted to have a very low pressure system. Proceeded to connect the catheter to the existing valve, however, it appeared that there was no flow coming from the distal end of the valve, thus indicating that the valve was malfunctioning. It appeared that the valve reservoir was not filling appropriately and therefore proceeded to place a new valve.

Links to FDA/CDRH Databases and Other Information Sources

Device Listing: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.

Establishment Registration: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This is a searchable database of U.S. and foreign establishments engaged in the manufacturer, preparation, propagation, compounding, assembly, or processing of medical devices for U.S. distribution. Note: This database is updated once a month.

Human Factors Website: http://www.fda.gov/medicaldevices/deviceregulationandguidance/humanfactors/default.htm. This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Luer Misconnections Website:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm
This site provides information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other facilitated by the use of Luer connectors.

MAUDE (Manufacturer and User Facility Device Experience): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Medical Device Safety Website: http://www.fda.gov/medicaldevices/safety/default.htm
One-stop for safety information with links to published safety tips and articles, archived patient safety news programs, safety alerts, recalls, and a link to report a device-related problem.

MedSun Website: http://www.fda.gov/medsun/
This site provides patient safety information via current and past issues of the MedSun newsletter, educational materials, and search capability for MedSun adverse event reports.

Premarket Notifications [510(k)]: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
This database of releasable 510(k) s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information are available via the web interface for more recent records. The database is updated monthly.

Premarket Approvals (PMA): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
This database of premarket approvals of Class III devices may be searched by a variety of fields and is updated on a monthly basis.

Product Classification: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
This database can be used to determine the classification of a device and the regulations it is subject to.

Warning Letters: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
This database contains the most recent manufacturer warning letters.

To access additional March 2018 newsletter articles, including a selection of recent MedSun Reports and product-related and patient safety-related information, go to www.fda.gov/medsun

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