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/UCM556295.pdf

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm558385.htm

In Brief

As of May 31st, 2017

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

SpF PLUS-Mini and SpF XL IIB Implantable Spinal Fusion Stimulators by Zimmer Biomet: Class I Recall
May 30, 2017
Recall due to higher than allowed levels of potential harmful chemicals, which may be toxic to tissues and organs (cytotoxicity) and that were found during the company's routine monitoring procedure.

LeadCare Testing Systems (with Blood Obtained from a Vein) by Magellan Diagnostics: FDA Safety Communication
May 25, 2017
Affected devices may underestimate the blood lead levels (BLL) and give inaccurate results when processing venous blood samples. Falsely lower test results may lead to improper patient management and treatment for lead exposure or poisoning.

HeartMate II LVAS Pocket System Controller by Abbott-Thoratec: Class I Recall
May 23, 2017
Patients may sometimes need to change to their backup back-up system controller during the course of ventricular assist therapy. The change should be done quickly and in the hospital, because it can present a significant challenge to patients that are elderly and/or untrained. For these patients, a slow or improper driveline changeover places them at risk of serious injury or death.

V60 Non-invasive Ventilator by Respironics: Class I Recall
May 22, 2017
Recall because pins within the internal cable that connects the ventilator's motor to the control board may become loose over time due to low frequency vibration. The loose pins may prevent data to be transferred between the motor and the control board, triggering the ventilator to shut down unexpectedly and to sound an alarm.

Wingman35 Crossing Catheters by ReFlow Medical: Recall
May 17, 2017
Affected devices have been found to exhibit tip splitting or separation, which has resulted in two adverse events. Tip splitting has the potential to lead to loss of device function. Tip separation may require medical intervention to retrieve a separated segment or may occlude blood flow to end organs.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during May 2017. 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
Device 1: Catheter, Embolectomy Brand: Angiojet™ Avx™ Model#: 105039-001 Lot #: 20196111	BOSTON SCIENTIFIC CORPORATION	Device kept giving check saline error code. Restarted device and checked saline supply multiple times. This is the second time this happened on this particular device this week. No patient harm.
Device 2: Catheter, Embolectomy Brand: Angiojet™ Avx™ Model#: 105039-001 Lot #: 20196111	BOSTON SCIENTIFIC CORPORATION	

Device	Manufacturer	Problem
Bed, Ac-powered Adjustable Hospital Brand: Secure Ii Med/surg Bed Cat #: 3002 EX	STRYKER MEDICAL	Thick smoke with an acrid smell was discovered in the patient's room by the doctor. No fire was seen. He asked for assistance, at which point many people arrived to the room. The Assistant Nurse Manager instructed the charge nurse to call to report the smoke and asked nurses to start shutting all of the other patient's doors. The decision was made to not shut of the oxygen at this point in time. A housekeeper was present with the fire extinguisher. The patient was transferred to a stretcher, because it seemed as if the smoke was thickest near the head of the patient's bed. Prior to transfer, the assistant nurse manager disconnected 2 IVs, one was running blood products and the other was a med line; tube feedings and oxygen was also disconnected; the patient had a yellow surgical mask over her face to protect her airway, she was awake and alert but non-communicative during the incident. Around the time of transfer her HR had increased to 120s, but the doctor declared her stable, and to transfer her off monitor until the situation was resolved. The patient was on a stretcher in the hallway, placed on a travel monitor with another nurse, monitoring her. Once the patient was out of the room, facilities had arrived to inspect the room. I was told that the bed was the issue, and once the fire department cleared the room, the room could be reused. The fire department came, and cleared the area. Pictures were taken of the room after the incident. There was a clear liquid found on the floor near the head of the bed, and some brown liquid on the bed (most likely the tube feedings that were disconnected from the patient). It was unclear when the liquid got on the floor. While facilities and the fire department was inspecting the room, a new bed was ordered for the patient, and she was safely transferred to that room. The bed in question was taken by Biomed. That morning, it was noted that the pts HR was in the 150s, per doctor, after she was settled, she needed an EKG, oxygen status was assessed; there was no concern for smoke inhalation at the time. No intervention was required at this time for the elevated HR. An hour later, the patient's HR started trending downwards.
Catheter, Hemodialysis, Implanted Brand: Reliance Xk Model#: 5327190 Lot #: REA50850 Cat #: 5327190	Bard Access Systems, Inc.	The Quality nurse in Dialysis noted that six venous port catheter clamps have broken between February 2017 and April 2017. Six patients were affected. The clamps are breaking when being open or closed under normal pressure. All six patients have had the catheters replaced. The product representative came on site and helped determine that all six catheters were from the same lot (REA50850). Our purchasing department has been notified and all catheters with this lot number have been pulled from use.

Device	Manufacturer	Problem
Analyzer, Chemistry (Photometric, Discrete) ,For Clinical Use Brand: 8000 C701 Module Model#: 5641489001 Cat #: 5641489001	Roche Diagnostics GmbH	We became aware of inaccurate (falsely elevated) creatinine patient results reported from the cobas 8000 c701 module ("756-1"). We stopped using that module and called the vendor technical assistance hotline. We began pulling and repeating patient samples that were elevated, making corrected reports and notifying providers. Service from the vendor was dispatched. The following day, the field service engineer found worn leaking rinse nozzle vacuum tubing. The leaking vacuum tubing was the same issue we had approximately 2 years ago on this same analyzer and approximately 4 years ago on the other module "756-2". The additional safeguards we implemented to better detect this problem (auto qc, 7 times per and patient moving averages) showed no abnormalities or flags. In the past, the vendor indicated they would increase frequency of tubing change. This does not appear to have occurred. We reviewed the Creatinine test results as follows for the 7 day time period: • A listing of samples and results was created. 5,253 samples had been tested. • Abnormal (elevated) samples were pulled from storage and repeated. • 5 corrected reports were made, and physicians notified. • The earliest instance of a corrected report was on day 2 of the event. With no corrected reports needed in the time frame prior to that, we feel the issue began on that day. The corrected report information is listed below: Patient # TestCode Original Incorrect Result Repeat Result 1 CRET 5.04 0.61 2 CRET 3.07 0.9 3 CRET 4.94 1.18 4 CRET 5.48 1.16 5 CRET 4.51 2.01
Catheter, Intravascular, Diagnostic Brand: Soft-vu Model#: 10722105 Lot #: 5070673 Cat #: 10722105 Other #: UPN H787107221050	ANGIODYNAMICS, INC.	A package with 5Fr x 40cm Angiodynamics Berenstein package was opened for a case and the catheter in the package was not a Berenstein (shaped tip catheter). This was a straight catheter. It was not used, and no harm came to a patient.

Device	Manufacturer	Problem
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: Bd Nexiva Model#: 383531 Lot #: 7020964	Becton, Dickinson and Co. (BD)	Per RN, she attempted twice to place a peripheral IV on the patient. The patient had excellent venous access and the RN had placed IV lines on her in the past, without issue. There were two failed attempts with BD Nexiva 24 gauge, 0.75", lot 7020964. On both attempts, the RN inserted the needle at the appropriate 45 degree angle, a flash of blood was seen, but it only entered the tubing partially, the RN attempted the lay the device flat and fully insert the catheter but was unable to advance the catheter. She attempted to pull back the needle and advance - this also failed and caused bruising on the patient. A second RN, using a different lot number, was able to place an IV on the patient at a different site. Per conversations with other staff nurses, this has been a repeated issue over the last week. It was reported by staff that on 7 other occasions this occurred with the same lot #.
Compressor, Cardiac, External Brand: Lucas	JOLIFE AB	An Emergency Department patient when into cardiac arrest. An automatic chest compression system was placed on the patient and malfunctioned. The malfunction noted was that the system showed a full battery, but after about two minutes in use, one of the battery lights turned orange and the unit made an alarming sound. A staff member replaced the battery, and after another two minutes of use with a new battery, and again, the battery light turned orange and the alarm sounded. The system was removed from the patient while manual compression were performed. The malfunction resulted in a staff member having to leave the patient's side to find another chest compression system. There was no adverse outcome for the patient related to the failure of the initial chest compression system. The chest compression system was pulled from service and brought to the Biomedical Engineering Department. Follow up: The affected chest compression system was purchased in approx 2 years ago and the last preventative maintenance was completed by the manufacturer less than 1 year ago. Biomedical Engineering contacted the manufacturer and requested service on the device after they were unable to reproduce the reported problem. When tested, the device ran as intended. The manufacturer next tested the unit and also could not replicate the complaint. They reseated all connections and reloaded software 2.2. Performed performance inspection procedure and all checks were ok. Unit returned to service.
Coronary Drug-eluting Stent Brand: Xience Alpine Model#: 1125350-15 Lot #: 7020141 Cat #: 1125350-15 Other #: 3.5 x 15	ABBOTT VASCULAR INC.	Upon pulling wire and stylet from stent delivery system, stent became dislodged and stayed in the stylet. When the technologist was threading the delivery system onto the wire is when she noticed the stent was missing. They put aside and saved the product and another vendor of stent was used for this patient. Device problem occurred prior to use on a patient. No patient harm.

Device	Manufacturer	Problem
Device, Hemostasis, Vascular Brand: Perclose Proglide Model#: 12673-03 Lot #: 7022341 Cat #: 12673-03 Other #: Clinical Engineering 315298	ABBOTT VASCULAR INC.	A 6 French Perclose ProGlide was opened and given to physician to achieve a femoral artery closure. Device was inserted into the patient's femoral artery. When physician attempted to deploy the device, the suture simply came out along with the device without tying a knot, and fell onto the sterile field, completely detached from the device. No knot was visible in the suture. Physician then decided to use a different closure device, which performed without incident, achieving hemostasis.
Dial Flowmeter, Oxygen Brand: Precision Medical Model#: BM7M-FA1001 Cat #: 7MFA-1001	Precision Medical Inc.	The dial flowmeters in PACU without float balls are a patient safety issue. If these are set between détentes there is no oxygen flow and no indication that there is no oxygen flow. Anesthesiologist noticed excessive expiratory humidity in his patient's mask and he determined that the flowmeter was sluggish and stuck between settings causing zero O2 flow. Thankfully, the patient maintained sPO2 99%. Recommendation was to remove all non float ball flowmeters from service due to faulty design and replace them with flowmeters that use float balls. The dial flowmeters are being discarded. Incidentally, the dial flowmeters do have an indication written on the device that states, "No Flow Between Settings." This is the manufacturer's warning to users of the issue identified by the anesthesiologist.
Electrode, Ph, Stomach Brand: Bravo Recorder With Accuview Software Model#: FGS-0450	GIVEN IMAGING INC.	Pt. had Bravo placed in EGD (Esophagogastroduodenoscopy). Pt. returned Bravo three days later. The Bravo recorder uploaded without difficulty on the day it was returned. When MD went to review Bravo tracing 4 days after it was returned and uploaded, the file was missing from the computer. Spoke with the IT department with Given Imaging. They were able to locate the patient's file right away, however it would not install on the AccuView 6.0 software or the AccuView 5.2 software. IT states this patient's file has been corrupted and not able to look at any data collected. Clarification: The patient completed the 5 day device recording. The file was uploaded, however, when the MD attempted to open the file a few days later, he was unable to locate the file. When it was found, an error message was received. When contacting Medtronic they attempted to open the file with the current version software (Accuview) and when that was unsuccessful they attempted to open it with the previous version software which was also unsuccessful. Additionally, it is not possible to go back to the recording device and "re-download" the information from the device. The manufacturer didn't seem to know what to make of the situation. The patient is very high-risk patient. Since the files could not be obtained, the patient is returning to his physician in approximately 1 week to discuss all available options. A repeat of the same test may mot be the most optimal choice.

Device	Manufacturer	Problem
Electroencephalograph Brand: Natus Emu40ex Model#: 006562	Natus Medical Inc. DBA Excel-Tech Ltd ((XLTEK)	The break out box on the Xltek EMU40EX is mislabeled. Color coding to indicate right/left side was reversed. No known patient harm occurred with use of the equipment.
Electrosurgical, Cutting & Coagulation & Accessories Brand: Valleylab Ft10 Model#: VLFT10GEN Cat #: VLFT10GEN	Covidien LP	The surgeon was cauterizing tissue and when the tip was lifted, they noticed it was on fire. No patient or staff injury occurred and the fire was immediately extinguished. There have been numerous surgeon complaints about the new FT10 electrosurgery generators. The new generator produces more sparking and is "hotter" than the old models for a given power setting. Sparking can cause tissue build up on the tip to ignite during use. Users also state there is more tendency to spark to nearby instruments. Generator was tested by Clinical Engineering and the power output was found to be within manufacturer specifications. Analysis of the new FT10 against the older Triad model indicates that while the power output is the same for a given setting, the waveform of the output is different and has significantly different tissue effect. ========== Manufacturer response for Electrosurgical Unit, Valleylab (per site reporter) ========== Manufacturer rep stated the new generator design is more efficient and can produce the desired tissue effect at a lower power setting than the older models. Users should use a lower power setting than they used with the old machine.
Automated External Defibrillators (Non-wearable) Brand: Lifepak 15 Model#: LP15	PHYSIO-CONTROL, INC./ Physio-Control Manufacturing, Inc.	After successful cardioversion of a patient while the patient was covered with a reflective warming blanket, clinical staff performing the procedure noticed a burning smell coming from under the blanket. Small first or second degree burns, possibly related, were noted under the defibrillation hands-free-pad electrodes. Testing of the reflective blankets found them to conduct defibrillation current while the manufacturer's documentation indicated that they were non-conductive. ========== Manufacturer response for Warming Blanket, Mistral-air (per site reporter) ========== The manufacturer had a team of engineers and quality assurance representatives visit the facility to investigate the incident. Together with that team, we repeated tests that led us to conclude that these reflective blankets conduct defibrillation current. ========== Manufacturer response for Defibrillator, Physio-Control (per site reporter) ========== The manufacturer has indicated that they may visit the facility to perform testing on this defibrillator.

Device	Manufacturer	Problem
Electrosurgi-cal, Cutting & Coagulation & Accessories Brand: Ligasure Model#: LF1637 Lot #: 70930268X Cat #: LF1637	Covidien LP	When the Covidien LigaSure Blunt Tip Laparoscopic Sealer/Divider handpiece was opened to the field and plugged into the ESU device, it displayed an error message "Instrument not recognized". The LigaSure handpiece was unplugged and replugged in three times, each time with the same error message. The instrument was re-moved from the sterile field and a new LigaSure Sealer/Divider hand-piece was opened and plugged in and it worked without incident.
Endoscope, Ac -powered And Accessories Brand: Olympus Model#: A20977A Lot #: multiple Cat #: A20977A	Olympus Winter & Ibe GmbH	Brief Description of Event: After insertion of a 0.35 guide wire down the neck of the working port of the resectoscope bridge, the surgeon proceeded to pass a 5 French catheter over the guide wire. Upon advancing the catheter the surgeon spotted a brown clump in the urethra. The resectocope was examined in Sterile Processing and found that the weld in the bridge contains a brown glue type binder that covers the welded area in the bridge and it was missing pieces that cover the weld. Brief Description of Problem: Adhesive used in the instrument con-struction is coming off and may be retained in the patient. When glue inside of the bridge deteriorates, it results in the glue flaking off and potentially leaves pieces with sharp edges in patients. It can also af-fect bristles on a brush which can be left in the bridge after repro-cessing. Brief Description of Solution: Working closely with the manufacturer on this issue. The manufacturer has confirmed that the glue is not stable and countermeasures are needed. The manufacturer will re-move the glue from manufacturing of the devices and replace all our bridges.

Device	Manufacturer	Problem
Fastener, Fixation, Nondegradable, Soft Tissue Brand: Cinchlock Model#: CAT02462 Lot #: 17011901 Cat #: CAT02462	STRYKER CORPORATION	Unintentional retained object. Postop Surgical Procedural note - ...repairing the labrum. Three CinchLock suture anchors were ultimately necessary for the labral repair. A base stitch pattern was utilized. The suture was passed through the labrum, followed by drilling and subsequent anchor placement to stabilize the labrum back to the acetabular rim. This sequence was then repeated 2 additional times to complete our 3-anchor repair. This achieved appropriate stabilization of the labrum back to the acetabular rim. The labrum was then probed and noted to be stable. From surgeon: I have commonly used the Stryker CinchLock suture anchor for labral repair during hip arthroscopy. I recently noticed a retained metallic fragment on follow-up x-rays on two separate cases, which generated the retrospective review of my practice and identified the total of four cases affected. This metallic fragment is a small wire that is contained within the anchor and acts to secure the anchor/suture when the insertion device is deployed. The wire is supposed to be retracted back into the delivery device and removed with the sheath. In all cases this small metallic fragment has remained stable on follow-up imaging and does not appear to be located between the femoral head and acetabular articular cartilage. The intra-operative arthroscopic images were reviewed for all patients and the metallic fragment was not visualized. In hindsight, you can see the metal fragment on the intra-operative c-arm views for all cases except (1 patient), however this would have been difficult to pick this up intra-operatively and failed to recognize this at the time of surgery. I suspect in these cases it is partially trapped within the anchor or stuck in the capsule. I do not think it will cause any additional harm or negatively impact the clinical outcome. As such, I recommended observation as I feel revision surgery in an effort to retrieve this metallic fragment would be potentially unsuccessful given the small size, likely cause additional harm and carry a greater risk of further injury/complications when compared to any potential realized benefit. I have disclosed this to the patient.
Gas-machine, Anesthesia Brand: Narkomed 6400	DRAEGER MEDICAL SYSTEMS, INC.	Anesthesia machine Gap module failed before procedure could start and had to be switched out. Patient was bagged while getting new machine. No patient harm. Prolonged anesthesia time. This is the second similar event with this device. The manufacturer was contacted.

Device	Manufacturer	Problem
Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms) Brand: Flo-lab Model#: 2100 sx	PARKS MEDICAL ELECTRONICS, INC.	As a vascular Doppler study was in the process of being initiated a staff nurse using a TV remote control "clean remote" to turn the volume of the TV down but this actually caused the screen display to change on the Parks model 2100 SX. Clinical Engineering has since tested this and in fact does indeed change the screen and will freeze the screen on the Park when various keys are pushed.
Pump, Infusion, Elastomeric Brand: Lma Model#: IP-N046570 Lot #: 74J1600429 Cat #: MVBXL-CPNB Other #: A150731-PSCFB000US	TELEFLEX INCORPORATED	The pump was retrieved from the Pyxis to be used on a patient. After retrieval, the internal bladder holding the medication split open and medication leaked from the bladder. The pump was ordered for a patient but never used on the patient.
Pump, Infusion, Implanted, Programmable Brand: Synchromed ®Ii Model#: 8637-20	MEDTRONIC INC.	Approx 6yrs ago, the pt with a diagnosis of increasing spasticity had a implantable programmable infusion pump placement for drug delivery of baclofen. Earlier this month, the pt underwent MRI studies and the pump began to alarm approximately one hour after the customer had arrived back home. The warning beep continued through the day. Pt contacted physician and withdrawal symptoms were covered by oral baclofen. Unfortunately, the pt did begin to experience more spasticity because of the change in baclofen administration. The pt and physician arranged to meet at this facility. The physician noted that interrogation of the customer's pump revealed that there was a motor stall at time of the MRI (understandable given the effect of the magnet), but it also showed that there was battery failure. The customer's dose was reduced from 109 mcg per day to 3 mcg per day per settings of the Synchromed pump. There were several interrogations to be certain that this was the case. The physician contacted Medtronic tech support and reviewed the findings on the programmer. While the pump was coming near the end of its useful life, based on analysis of the baclofen pump logs, it appeared that the battery life should have lasted until at least the end of the current calendar year. Harm to Pt: The event caused the pt to develop increased spasticity (as expected with pump failure). Oral dosing was not effective (oral dose peaks and valleys vs. cont. IV dosing). Also, because of the failure, the pt required surgical replacement of the malfunctioning baclofen pump much sooner than anticipated.

Device	Manufacturer	Problem
Pump, Infusion, Pca Brand: Cadd Solis Other #: Solisa	Smiths Medical ASD, INC.	While reviewing patient's empty medication cassettes the pharmacy noted that all cassettes sent back had significant medication remaining in cassettes. Pharmacist was informed that pumps stated empty reservoir each time. Pharmacist informed trauma nurse practitioner that patient did not receive medication. Patient was placed on PRN doses of medication and PCA pumps was discontinued and sequestered for Biomedical analysis and reporting. Biomedical downloaded pump event and delivery history and retrieved cassettes for reporting event to mfg. This is an additional report on the same PCA pump used at our facility.
Set, Administration, Intravascular Brand: Spinning Spiros Cat #: CH2000S-PC	ICU MEDICAL, INC.	Received 2 events related to the Spiros device. First stated Chemotherapy tubing attached to Spiros found to be leaking during Carboplatin infusion. Infusion stopped and chemo pharmacy made new dose to restart. The second stated RN called to bedside to find that the Spiros connection to the IV Chemotherapy tubing was broken off between the Spiros and the tubing and the Spiros remained connected to the patient. Sent back to chemo pharmacy for new bag to be prepared. Per unit supervisor, ICU Medical aware and looking into equipment vs. application process. ICU Medical does have the tubing.
Subcutaneous Implantable Cardioverter Defibrillator Model#: 3401 Lot #: 3401A132449 Other #: 3401A132449	Boston Scientific	A female patient underwent implantation of subcutaneous implantable cardio-defibrillators (S-ICDs) in the spring and fall of last year. For the two procedures, the duration of the implant was approximately one month before explantation respectively due to an infection. Recently, the patient presented for another S-ICD. While in the operating room a retained suture sleeve (thought to be from one of the prior explantations) was identified and removed. The surgeon indicated that the suture sleeves are usually affixed directly to the leads on other ICD devices. Hence when extracting other leads, the suture sleeve, which is affixed directly to the lead, automatically comes out when extracting the lead. The surgeon has been in contact with the manufacturer with concerns related to the design of the device. Suggestions to the manufacturer include designing the sleeve to adhere to the lead and making the lead and sleeve radiopague.
Syringe, Balloon Inflation Brand: Caliber Lot #: 15042595, 15075851 Cat #: CL3030	Bard Peripheral Vascular, Inc.	The inflation device (lot# 15042595) would not hold pressure to keep balloon dilated. A second device (lot# 15075851) was opened and it also would not hold pressure. A third device (lot# 15075851) was then opened and had the same issue, however, the third device did hold enough pressure to complete the procedure. All three devices were catalog number CL3030. There was no known injury to the patient.

Device	Manufacturer	Problem
System, Hypothermia, Intravenous, Cooling Brand: Coolguard Catheter	Zoll Circulation, Inc.	Patient had a right femoral coolguard catheter. The NS bag from the coolguard machine was nearly empty and a new bag was spiked (approximately around 1800). Assessed patient for signs/symptoms of leakage; none were noted. No leakage was noted at the site of the catheter, on the bed, on the floor, or from the tubing. The line was changed and there was still leakage, so it is believed to be a catheter leakage. No patient injury except for the patient required a replacement central line.
System, X-ray, Angiographic Brand: Artis Biplane C-arm System Model#: 553921 Other #: 1734	Siemens AG/ Siemens Healthcare GmbH	During a Vertebral Aspiration on a patient the I-guide software package on the Siemens Biplane machine did not function properly. The software stated that all angles were unachievable. Therefore the physician had to manually drive his needle to the entry point without the 3D operations. The physician was able to get the specimen needed, however additional radiation was needed. An extra 16cc of contrast was given. The Siemens applications specialist was informed and was able to confirm that the application was not operating appropriately. The manufacturer came on-site to evaluate the device and fix the problem.
Tubes, Gastrointestinal (And Accessories) Brand: Carey-alzate-coons Gastrojejunostomy Set Model#: UL-T10.2-NT-100-P-NS-GJS Cat #: G27044	Cook, Inc.	Patient had to undergo replacement of GJ Tube because the red cap on distal end of tube broke apart making the feeding tube unusable.
TV Remote Brand: Universal Clean Remote	Unknown	As a vascular Doppler study was in the process of being initiated a staff nurse using a TV remote control "clean remote" to turn the volume of the TV down but this actually caused the screen display to change on the Parks model 2100 SX. Clinical Engineering has since tested this and in fact does indeed change the screen and will freeze the screen on the Park when various keys are pushed.

Device	Manufacturer	Problem
Vena Cava Filter Remover Brand: Recovery Cone Removal System Lot #: GFBN3372	Bard peripheral vascular, inc	The patient had an inferior vena cava (IVC) filter placed at an outside hospital several months ago. He was referred for filter retrieval. The IVC filter was retrieved without trouble. However, a little band or ring placed on the tip of the catheter used to retrieve the sheath broke off and embolized to a small, distal branch of a pulmonary artery. This ring is placed on the catheter to make it visible on fluoroscopy/x-ray during the procedure. The procedural team attempted to retrieve it but could not easily do so and elected to stop. This is a small metal ring (3mm diameter) in a small distal branch without clinical consequences at present.
Ventilator, Continuous, Facility Use Brand: Hamilton -g5 Model#: 159001 Cat #: 159001	Hamilton Medical AG	Ventilator stopped working when testing out the generator. Ventilator did have an audible alarm when power was lost. Found battery was dead. Issue is the meter on the front of ventilator was reading full battery. Also on the diagnostic screen the indications were such that the battery appeared to be fine. The ventilator log indicated that the ventilator did call out an internal empty battery for the prior month generator testing. It is possible was missed as therapist was not in the room to witness it during prior month generator testing. Not sure why ventilator wouldn't continually call out empty internal battery at that point forward. Per site reporter; manufacturer is checking into the Ventilator issue.
Ventilator, Non-continuous (Respirator) Brand: Vital Signs Model#: 5503EU Lot #: 0001044498 Cat #: 5503EU 	Carefusion Corporation	Anesthesia MD was effectively bagging patient with mapleson while transferring patient from induction room to MRI suite when the mapleson stopped working. The bag /valve would not work (blow up the bag) and could not get a breath to the patient. After a few failed attempts, Anesthesia MD was able to get a few breaths in with 'plugging' the blue valve with her finger while the GA nurse ran to get a new mapleson. Pt remained stable and MRI was completed as scheduled.
Tube, Tracheal (W/wo Connector) Brand: Rusch Lasertubus 7mm Model#: IP-N040900 Lot #: 16291 Cat #: 102004-000070	TELEFLEX INCORPORATED	The endotracheal tube kinks over on itself - as described by clinicians, the tube is too soft. As the tube is warmed in the patient's airway, that softness allows the tube to collapse.

Device	Manufacturer	Problem
Walker Brand: Guardian Signature	Medline Industries, Inc.	The patient was found on the floor calling for help. While holding onto her walker, the patient reached for something on the window sill. The patient reported that the walker broke causing her to fall. Please see pictures below:  

Device	Manufacturer	Problem
Electrosurgical, Cutting & Coagulation & Accessories Brand: Valleylab Straight Extension Model#: E1502 Cat #: E1502	Covidien LP	The surgeon was using the surgical pencil extender with the surgical pencil in the abdomen. After several minutes the resident noticed burns and holes in the bowel. The surgical tech and surgeon inspected the surgical pencil and they both found a hole in the insulation around the it. The hole in the insulation was deep enough that metal was being exposed on the extender resulting in burns and holes in the bowel. The bovie extender was given to our inventory specialist to send back to the manufacturer for inspection and follow up. The grounding pad was placed on the patients right buttock and the generator settings were 50cut/70coag.

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 Ill 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 June 2017 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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