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):

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm596872.htm

Premarket Approval Final Decisions:
https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM606672.pdf

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm607016.htm

In Brief

As of June 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

STAT-Check and Medline Manual Resuscitator Bags by SunMed Holdings: Recall

June 1, 2018

End users who have STAT-Check or Medline resuscitator bags within the lot numbers listed below should stop using them and immediately contact SunMed Holdings or further instructions on the return of these products. The recalled products were distributed nationwide and can be identified by the part number, description, and lot number on the case labels, as well as a label on the individual packaging bag.

HeartMate 3™ Left Ventricular Assist System: Class I Recall

May 22, 2018

Occlusion of the outflow graft can reduce or stop pump flow and set off a persistent low flow alarm in the system. Patients experiencing a persistent low flow alarm should contact the physician managing their HeartMate 3 Left Ventricular Assist System immediately. Abbott is recommending not to remove the device because of this issue.

Fabius Anesthesia Machines by Dräger Medical: Class I Recall

May 9, 2018

Dräger Medical is recalling the Fabius Anesthesia machines due to excessive oil that was not removed at the time of production. Such excess oil may interfere with the position detector of the ventilation motor during operation and may cause ventilation to fail. The company is instructing customers to continue to operate the devices with the usual attention and to ensure that a manual resuscitator for emergency ventilation is kept ready according to the instructions for use.

Neurovascular Stents Used for Stent-Assisted Coiling (SAC): Letter to Health Care Providers

May 8, 2018

FDA received reports associated with the use of these devices in the treatment of unruptured brain aneurysms that suggest some events of peri-procedural stroke and/or death may have been related to procedural risks or patient selection related factors. These factors include patients who had serious co-morbidities resulting in a reduced life expectancy, or who were intolerant to required anticoagulation or anti-platelet therapy.

Recommendations to Reduce Surgical Fires and Related Patient Injury: FDA Safety Communication

Background:

The FDA is reminding health care professionals and health care facility staff of factors that increase the risk of surgical fires on or near a patient. The FDA is also recommending practices to reduce these fires from occurring, including the safe use of medical devices and products commonly used during surgical procedures. Although surgical fires are preventable, the FDA continues to receive reports about these events. Surgical fires can result in patient burns and other serious injuries, disfigurement, and death. Deaths are less common and are typically associated with fires occurring in a patient's airway.

Recommendations to Reduce Surgical Fires:

Health care professionals and staff who perform surgical procedures should be trained in practices to reduce surgical fires. Training should include factors that increase the risk of surgical fires, how to manage fires that do occur, periodic fire drills, how to use carbon dioxide (CO_2) fire extinguishers near or on patients, and evacuation procedures.

Specific recommendations to reduce surgical fires include:

- A fire risk assessment at the beginning of each surgical procedure.
- Encourage communication among surgical team members.
- Safe use and administration of oxidizers.
- Safe use of any devices that may serve as an ignition source.
- Safe use of surgical suite items that may serve as a fuel source.
- Plan and practice how to manage a surgical fire.

For more information and to read the complete communication please click here.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during May 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
Apparatus, Autotransfusion Brand: At3 Autotransfusion Set- Model#: 9005444 Lot #: FIT 063 Cat #: 9005444	Fresenius Kabi AG	Fresenius continuous autotransfusion system (CATS) unit stopped working at beginning of use, was not able to finish a cycle. After initiating use, the unit displayed a "Blood In" and "Blood Flow" error. Unit was removed from service and brought to Clinical Engineering for inspection. Manufacturer was called in and after troubleshooting the unit found a problem with the AT3 Autotransfusion Set. The manufacturer's engineer found the set tubing that goes to the HTC sensor not long enough (a possible manufacturing error) to allow the sensor to reach its proper placement in the CAT unit, having the user to pull on the tubing in order to make it reach. While the user pulled on the tubing, inadvertently decreased the tubing internal size, preventing the blood to flow through it, thus causing the system error and stopping operation. The AT3 part number is 9005444 and the Lot number is FIT 063. A new AT3 from a different lot was used to test the CAT unit and the system worked fine, according to manufacturer's specifications.

Device	Manufacturer	Problem
Accessories, Catheter Brand: Cath Grip/uni Grip Lot #: D04403 Cat #: 51300NS	Bioderm, Inc.	Catheter securement device new out of the package is ripping at the seam around the tabs. Please see picture below: 
Balloon Aortic Valvuloplasty Brand: True Dilatation Balloon Valvuloplasty Catheter Lot #: GFBP3257A Other #: Perfusion Catheter 24 x 3.5 x 110	C.R. BARD, INC.	Bard Peripheral Vascular had shipped in new consignment to Cath Lab. When the product arrived, we noticed the label on the box was peeling off. When we looked at the label, we noticed that a new sticker with a new expiration date was placed over an old sticker with an expiration date of over a year ago. Three new stickers had been placed over old stickers. The inner package holding sterile product was sealed but the outer packaging was opened.
Bilirubin Meter Brand: Drager Jaundice Meter, Model Jm-103 Model#: MU20606 Lot #: NA Cat #: JM-103	Draeger Medical Systems, Inc.	The meter (JM-103) has a value of 1- that indicates one more flash needs to be completed before the numbers can be averaged and the result is calculated. The problem is that this number has the mg/dl under it which makes it really seem like a result..... extremely easy to misread and I'm surprised this doesn't happen more often. Granted, the second screen does have 2 dashes before the value and isn't in a decimal format, but still potential for error (obviously).

Device	Manufacturer	Problem
Cannula, Nasal, Oxygen Brand: Ram Cannula Cat #: N4901 	NEOTECH PRODUCTS, LLC	The patient was receiving nasal CPAP via the RAM Cannula (preemie size, item# N4901 manufactured by Neotech). On first assessment of the day, it was discovered the patient's nasal septum was perforated by the cannula. The cannula removed and switched to nasal CPAP via mask. The patient required an ointment applied to the injured site. The perforation has since healed.
Catheters, Suction, Tracheobronchial Brand: Halyard Closed Suction System For Adults Lot #: M18017L601	Halyard Health Inc.	When changing the inline catheter, the fitting from the catheter to the patient y-connection was loose and did not stay. The {MICU} patient is very critically ill requiring aggressive ventilator settings, and induced coma to maintain his oxygenation. The loose connection caused him to derecruit which caused a significant drop in his oxygenation. The connector supplied with the catheter by our institution was used to avoid continued insult to the patient. The manufacturer of the device has been aware of the fact that it is not keeping with the accepted universal measurements that have been agreed upon by international manufacturing standards.
Device 1: Clip, Implantable Brand: Lapra-ty Model#: XC200 Lot #: JE7143 Cat #: XC200 **Device 2: Clip, Implantable** Brand: Lapra-ty Model#: XC200 Lot #: JP7082 Cat #: XC200	Ethicon INC. Ethicon INC.	Sterile packaging ETHICON LapraTy XC200 continues to have holes to the outside, in the malleable foil packaging. When this said packaging is pulled for backup during a case, and then returned to stock after not being used, it begins to become damaged. Two damaged packages were discovered during this particular case. The staff did not use the products inside as they were contaminated. Both packages were sent to Clinical Engineering along with images of the described holes. These will be returned to the manufacturer for failure analysis. Please see picture below: 

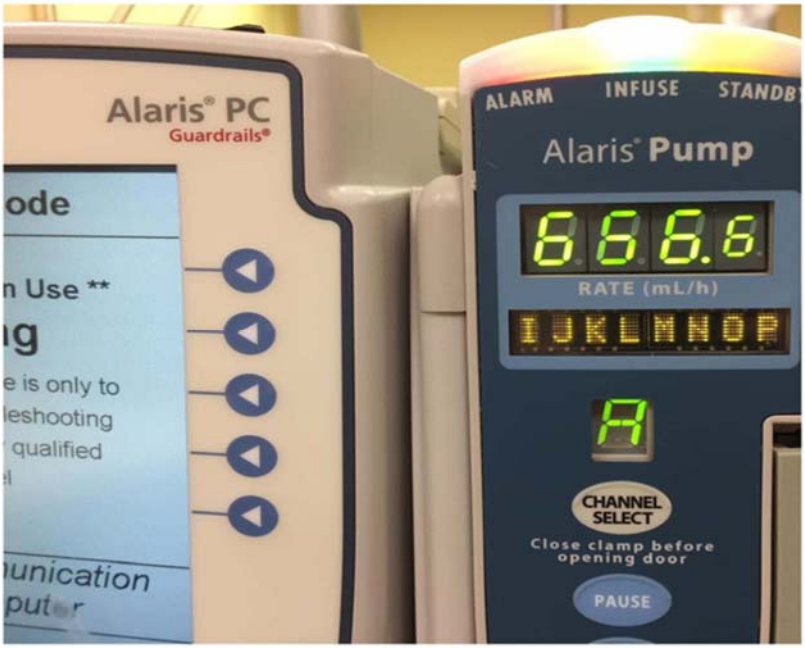
Device	Manufacturer	Problem
Continuous Ventilator Brand: Draeger V500 (Evita Infinity) Model#: V500 Other #: ventilator battery	Draeger Medical Systems, Inc.	It was reported that per the Manufacturer's Instructions For Use for Draeger V500 ventilators, a battery check is required every 90 days. After approximately a year of use, the battery check has provided an error alert on four devices that the batteries are recommended to be changed. Due to the error alert, the devices have been pulled from service. Per the manufacturer, batteries are to last 2 years before recommended replacement. Draeger representatives have indicated that this battery check is causing issues with early battery replacement and a software update is being worked on to resolve the issue. The vendor has indicated that a software update may be available in the future. The batteries are on backorder with no date for when replacements will be provided. To date, there has been no patient harm.
Device 1: Controller, Temperature, Cardiopulmonary Bypass Brand: Hemotherm 400 Ce Other #: 27250 **Device 2: Controller, Temperature, Cardiopulmonary Bypass** Brand: Hemotherm 400 Ce Other #: 27249 **Device 3: Controller, Temperature, Cardiopulmonary Bypass** Brand: Hemotherm 400 Ce Other #: 33558	CINCINNATI SUB-ZERO PRODUCTS, LLC CINCINNATI SUB-ZERO PRODUCTS, LLC CINCINNATI SUB-ZERO PRODUCTS, LLC	This facility currently has eight Cincinnati Subzero (CSZ) heater cooler devices, all of which have had monthly surveillance cultures as per the state Department of Health recommendations. Four weeks after modifying our cleaning process to align with the manufacturers updated IFUs, six of the eight CSZ devices tested positive for either Heterotrophic Plate Counts (HPCs) > 500 or presence of pseudomonas. The six devices were removed from service, disinfected, and the water was changed. One patient's surgery was rescheduled to the next day. No patient harm reported.

Device	Manufacturer	Problem
Device 4: Controller, Temperature, Cardiopulmonary Bypass Brand: Hemotherm 400 Ce Other #: 33557 **Device 5: Controller, Temperature, Cardiopulmonary Bypass** Brand: Hemotherm 400 Ce Other #: 33122 **Device 6: Controller, Temperature, Cardiopulmonary Bypass** Brand: Hemotherm 400 Ce Other #: 33121	CINCINNATI SUB-ZERO PRODUCTS, LLC CINCINNATI SUB-ZERO PRODUCTS, LLC Manufacturer: CINCINNATI SUB-ZERO PRODUCTS, LLC	This facility currently has eight Cincinnati Subzero (CSZ) heater cooler devices, all of which have had monthly surveillance cultures as per the state Department of Health recommendations. Four weeks after modifying our cleaning process to align with the manufacturers updated IFUs, six of the eight CSZ devices tested positive for either Heterotrophic Plate Counts (HPCs) > 500 or presence of pseudomonas. The six devices were removed from service, disinfected, and the water was changed. One patient's surgery was rescheduled to the next day. No patient harm reported.
Dialyzer, High Permeability With Or Without Sealed Dialysate System Brand: Prismaflex Model#: Prismaflex	BAXTER HEALTHCARE CORPORATION	The Prismaflex "ADVISORY: Cannot Detect Return" alarm User Interface (UI) workflow creates a hazardous situation with potential for patient harm. The UI labeling and alarm light notifications relating to this alarm can be easily missed, and the Baxter advised workaround creates non-intuitive critical tasks that can be forgotten. When running CRRT using the Prismaflex system - Significant changes in return pressure can trigger a "WARNING: Return Disconnection" alarm which can lead to a "ADVISORY: Cannot Detect Return" alarm. After assessing the patient and determining the line is not disconnected the nurse must override the alarm to resume therapy; however, overriding the alarm deactivates the return disconnection alarm until it is reset. This is a major safety concern because if the return line were to actually become disconnected while the alarm is deactivated, the patient could exsanguinate in minutes with no alarm. There is a work around where nurses can press stop and resume after troubleshooting, but this requires clinicians to rely on memory for a low volume, high risk therapy used among very complex patients. Baxter has responded to this issue, but clinicians and clinical engineering are not satisfied with the manufacturer's solution due to the safety hazard.

Device	Manufacturer	Problem
Duodenoscope And Accessories, Flexible/ rigid Brand: Video Duodenoscope Model#: ED-3490TK	PENTAX OF AMERICA, INC.	A couple months ago, the patient (referred to as Patient B) underwent an Endoscopic Retrograde Cholangio-Pancreatography (ERCP) for primary sclerosing cholangitis with Pentax Duodenoscope. Two days after initial ERCP, the patient presented from home to the Emergency Room with right upper quadrant (RUQ) pain, body aches, shaking chills and fevers to 101.8. Six days post initial ERCP, the patient underwent another ERCP; a bile duct aspirate grew out multi-drug resistant (MDR) Pseudomonas aeruginosa (PsA). The patient had no prior history of this organism. Infection Control was alerted to Patient B by the Infectious Disease (ID) consult physician seeing the patient fourteen days post initial ERCP. Infection control unit investigation identified a patient who had undergone an ERCP in early January of 2018 with the same Pentax Duodenoscope who was known to carry a MDR PsA prior to the procedure. This patient (referred to as Patient A) had MDR PsA with identical antibiotic resistance pattern as Patient B. Given the isolation of an MDR PsA in two patients with an epidemiologically linked duodenoscope, the Pentax Duodenoscope was sequestered and taken out of service pending further investigation near the end of April 2018. Review of patient records who had been exposed to duodenoscope was begun, and at the end of April 2018, an additional patient (Patient C) with an ERCP performed in mid-April 2018 with Pentax Duodenoscope, developed bacteremia with MDR PsA. This PsA had a slightly different antibiogram than Patient A and Patient B, but with many similarities, and was considered as potentially related to Patient A. Patient C had no known history of MDR PsA. To determine if the infections were similar, the Pseudomonas isolates were sent out for genomic analysis including Multilocus sequence typing(MLST) and whole genome sequencing(WGS) in mid-May 2018. Seven days post testing being sent out, preliminary results demonstrated the isolates from Patients B and C were highly related to Patient A. Near the end of May 2018, the final results were provided confirming this finding, with between 1-3 Single nucleotide polymorphisms(SNP) differences between Patient A to Patient B and C. Infection Control continues to investigate any additional potential infections in patients exposed to this scope. In mid-May 2018, an additional patient (Patient D*) who underwent ERCP with the same scope in mid-April 2018 was found to have a positive bile culture for PsA in early May 2018 (not included on original surveillance report performed in early May 2018 as it was not speciated or susceptibilities done until after early May 2018,). Both MDR PsAs from Patient D have the same antibiogram as Patient A; genomic analysis to confirm relatedness is pending at this time.

Device	Manufacturer	Problem
Epidural Anesthesia Kit Brand: Design Options Model#: 552122 Lot #: 0061589452 Cat #: 552122 Other #: Periflex Catheter Connector-Clamp style plastic connector	B. BRAUN MEDICAL INC.	The patient was admitted to labor and delivery. A B. Braun Epidural catheter was placed on at approximately 12:15. During the night, the epidural catheter started to leak at the distal end of the catheter site, and the IV pump was alarming. The IV tubing was properly connected to the plastic catheter connector hub, but there was leaking from the connector clip piece housing the catheter. Upon inspection, the MD noted that the catheter had migrated approximately 1 mm from the plastic clip portion of the connector which secures the catheter in place. The doctor opened the clip and re-advanced the catheter to the distal end of the plastic catheter clip, bolused the patient and rechecked all catheter connections. Approximately two hours later, a stat C-section was required. The doctor attempted to re-bolus the patient through the epidural. Again, the catheter was leaking. The doctor re-advanced the catheter through the plastic injection port, and it was still leaking. The decision was made to convert the patient to general anesthesia. We have also experienced this issue with the Model: 552122, Lot: 0061589452; Model: 552127, Lot: 0061547773. In looking over the catheter connector we noted the following: 1. It looks like there is only ½ turn required on the thread that the epidural medication infusion tubing attaches to. I believe there are usually 2-3 threads on the hub where the tubing connects. This could lead to easier detachment of the tubing at the hub site. 2. It is visually difficult to tell whether distal tip the catheter is fully engaged within the connector before clamping. 3. The clamp locking mechanism is not very secure and is easily opened. 4. It is unclear whether the pressure of the infusion into the catheter may push it out of the connector lock and cause leaks. 5. Ideally there should be a second locking mechanism on the catheter. 6. The connector plastic may be too pliable, which may allow flexing of the grasp mechanism on the catheter allowing leaking, infusion hub separation or accidental opening from the clamp hinge. Please see picture below: 

Device	Manufacturer	Problem
Fiber, Medical, Absorbent Brand: Medline Model#: MDT2168210 Lot #: 84318010065 Cat #: MDT2168210 Other #: sterile disposable towel	Medline Industries, Inc.	Patient was prepped and draped to have a dialysis catheter installed on right upper neck. Sterile towels were draped around incisional area. While doctor was trying to advance dialysis catheter over wire he encountered difficulty and the catheter was unable to make a smooth transition. It was noted there was a string wrapped around the catheter preventing the catheter to be advanced. String was a lose thread from the sterile towel. The thread had to be removed from around the catheter and before the catheter could be installed and placed successfully.
Gauze/sponge, Internal, X-ray Detectable Brand: Vistec Model#: 7317 Lot #: 17L069462 Cat #: 7317	Covidien LLC	As the Surgical Technologist was setting up for their surgical procedure prior to patient arrival in OR room, the tech identified a concern with the X-Ray detectable Sponges 4x4 (Vistec). Black pieces of something were identified in between the woven material. Upon further review the RN and tech in the room identified what looked to be bugs in the sponges. The sponge pack was removed from the surgical field and the entire lot of this specific product was pulled from the shelf. The vendor supplier (Cardinal health care) will be notified about the product from Covidien.
Heartware Ventricular Assist Device (Hvad) Controllers Brand: Heartware Model#: HVAD Controller 2.0 Cat #: 1403	Medtronic Inc.	The patient came in to clinic for troubleshooting after experiencing several instances of inappropriate power connection beeping and a couple 'high watt' alarms on his LVAD controller. During the troubleshooting, we consulted with the manufacturer. The manufacturer attributed the problems to a battery problem, and not a controller problem and as such, recommended we replace the three batteries that were giving the patient problems. We replaced 3 batteries and sent the patient home. The next day the patient experienced a 'double power disconnect' alarm and resulting pump off event. The patient had symptoms of dizziness and feeling light-headed. The patient changed power sources and the controller restarted. The patient called the VAD emergency line, and a VAD nurse practitioner walked the patient and caregiver through changing to his backup LVAD controller.

Device	Manufacturer	Problem
Pump, Infusion Brand: Alaris Model#: 8100	CAREFUSION 303, INC.	The issue has been ongoing for a couple years but recently there has been an increase in the dim LED segments on the rate display of the Alaris 8100 Infusion pump module display boards. There is potential for harm due to the fact that the boards can be misread and numbers can be misinterpreted as another number. Photos attached. It seems most common with units that have a manufacturer time around 7/2014 and 8/2014 in our inventory. Many affected display boards were marked "Rev: 07". Between Oct 2015 and March 2018 100 displays have had the issue and needed replacing. The hospital has been replacing the boards but it comes at a significant cost and amount of time. Becton Dickinson was notified of the problem and their response is attached where the problem is acknowledged but a clear plan on how to correct this issue is not provided. Please see picture below: 
Set, Administration, Intravascular Brand: Alaris Smartsite Pump Module Administration Set Model#: 2420-0007 Cat #: 2420-0007	CareFusion 303, INC.	The faulty anti-reflux valve allowed piggy back IV fluid to flow into the primary tubing and the primary fluid bag.

Device	Manufacturer	Problem
Laparoscope, General & Plastic Surgery Brand: Single-site Model#: VER 03 Lot #: S10170620 0132 Cat #: 478059	Intuitive Surgical Inc.	Patient was scheduled for Robotic laparoscopic cholecystectomy with grams, during the process of the procedure; a Crocodile XI instrument was used and broke inside the patient's abdomen. A piece of the instrument jaw that was broken was recovered and was easily removed while the other piece required an x-ray to determine its location. X ray was done and the missing piece was located and removed inside the patient's abdomen. Upon inspection by the surgeon, the OR personnel and the Robot representative, everyone agreed that all the missing pieces were recovered and NO other instrument piece/s were left inside the patient.
Mobile Basic Diagnostic X-ray System, Digital Brand: Ge Optima Model#: XR220AMX	GE MEDICAL SYSTEMS, INC.	There is a design flaw with the Optima XR220AMX. This portable X-ray unit is manufactured by GE. The power distribution system has a flaw causing the batteries to fail within 10 months. This causes a safety concern since the device can fail at any time, and in any position. This potentially can fail while being used on a patient. I have two brand new devices and both of them have shown these symptoms.
Pump, Infusion Brand: Alaris Model#: 8110 	Carefusion 303, INC.	During a syringe pump fentanyl infusion to an infant, the pump alarmed that the dose was complete though it was noted to have 0.3 ml of dose remaining. Examination of the syringe module revealed that the clasp mechanism that closes around the top of the plunger was not closing properly. Infusion was completed on a different pump. Please see picture below: 

Device	Manufacturer	Problem
Set, Administration, Intravascular Brand: Maxzero Model#: MZ1000-07 Cat #: MZ1000-07	CAREFUSION 303, INC.	Over the past few days multiple nurses have had patients tubings/ caps leak. It sounds like, now that people are talking about it, it has happened very sporadically over the last few weeks but not been reported as it seemed to be an isolated occurrence We think it most probably isn't the tubing as we have had leaks using standard chemo tubing, specialty chemo tubing, blood tubing...the only constant being the caps that we all use. That said, I have a used blood tubing setup bagged and saved, not sure if you want it. The nurse said when she removed the cap, it flushed without leaking. The patients mostly have their ports accessed on the other side of the clinic and it is hours before we in Infusion see them, so there are no lot numbers available for the caps used. For the time being, I am going to have the CAs remove all the caps from the clinic nurses' carts and replace with a new lot of caps and see if the problem continues. I have four of them to return to the manufacturer for evaluation.
Staple, Implantable Brand: Multifire Endo Ta Model#: 010901 Lot #: P7F1390 Cat #: 010901	Covidien LP	Patient was undergoing a voluntary kidney transplant (Donor)- risk of bleeding is always part of the procedure. In this event the staples did not stop the vein and artery from bleeding as intended. The surgery was going as planned and when preparing to remove the kidney TA-30 stapler was fired across the renal artery as proximally as possible. The renal vein was lifted up and the endovascular TA-30 stapler was fired across the junction of the renal vein with the IVC and the renal vein was transected leaving a 2 mm cuff. The kidney was removed and handed off to the waiting team. There was significant bleeding noted. Pressure was held over the aorta and the cava while we set up suction. It seemed that there were two areas of ongoing bleeding. One from the artery and a venous source above where the surgeon had stapled the renal vein (Cava junction). The bleeding was controlled with titanium clips. The surgeon noted that the stapler potentially misfired causing the bleeding.
Syringe Infusion Pump Brand: Medfusion 4000 Model#: 4000	Smith’s Medical Inc.	A large number of medfusion pumps in our fleet have been showing the fault 'System Failure: Supercap Post' which we have already reported. We have see an even more significant increase since the last report from Mid March leading us to file a 2nd report. As a result of so many of our pumps being out of service waiting for parts, there have been numerous cases where therapy was delayed while staff searched for a working pump and the problem seems to be getting worse. 224 pumps out of our 700 pumps are reporting errors now. This serious increase in fault errors can be viewed on the graph attached.

Device	Manufacturer	Problem
System, Endovascular Graft, Arteriovenous (Av) Dialysis Access Circuit Stenosis Brand: Fluency Plus Endovascular Stent Graft Lot #: ANBW2753 Cat #: FEM08040 Other #: 8mm x 40 mm (9F, 80cm catheter)	Bard Peripheral Vascular Inc.	When deploying the stent, a small radiopaque artifact piece (small circular ring) came off the deployment system and ended up in the patient's lung, specifically the patient's left lower lobe pulmonary artery. Radiology initially tried to snag the piece but was unsuccessful. Piece was left in place as the risks for retrieval outweighed the benefits.
System, Irrigation, Urological Brand: Stryker Strykeflow Ii Suction /Irrigator Model#: 250-070-500 Cat #: 250-070-500	STRYKER ENDOSCOPY	Suction Irrigator was leaking during the case. This has occurred maybe only 2 times in the past few months. However, we only started using the Stryker irrigator recently because the product was unavailable. When we were using it on a regular basis it seemed to occur rather frequently but only on Bariatric cases with the long suction tip. The rep told us that the long tip was disposable after 10 uses. No one was ever able to find the IFU that stated this fact. The rep also suggested not placing full pressure on the button when irrigating. This message was given to the RNFA who seemed to have the most issues. At the point in the surgery when the irrigator is used, she is pressing very gently on the button so this was not the cause.
Catheter, Electrode Recording, Or Probe, Electrode Recording Brand: Lasso Nav Model#: D134301 Cat #: D134301	BIOSENSE WEBSTER INC.	EP lab reviewed. This was a mapping catheter and there were noises on the channel when the catheter was connected to the cable. The catheter was replaced. No injury to the patient. This is an ongoing issue with these catheters.
Clamp, Vascular Brand: Tracelet™ Model#: TRACR Lot #: 2017045080 Cat #: TRACR	MEDTRONIC, INC.	The device remained on patient for 2 hours without any signs of bleeding or hematoma. The air was decreased 2 notches at a time as per protocol. After all the air was removed, tracelet was removed from the wrist and oozing was noted. Manual pressure was applied to the site and the cath lab called to assist. Right wrist devleoped a smal 1"x2" ecchymosis over the access site with small amount of blood oozing. A different device was applied to control bleeding. This is a recurring problem with this device at this facility.

Device	Manufacturer	Problem
Clamp, Vascular Brand: Traclet™ Model#: TRACR	MEDTRONIC VASCULAR	Hematoma noted to r wrist upon arrival to CVL RR (Cardiovascular Recovery Room). CVT (Cardiovascular Tech), holding manual pressure x 5-10 min in RR (Recovery Room). Tech stated pt's wrist was too small for smallest Traclet. Once the bubble was inflated, the Traclet would not sit right on the wrist.
Set, Administration, Intravascular Brand: Alaris Model#: 10016073 Lot #: 108854032301110 Cat #: 10016073 Other #: H3701001607311	CAREFUSION 303, INC.	Pt had fluids running at 500ml/hr prior to initiation of chemotherapy. Secondary IV tubing became disconnected from drip chamber and fluids ran out all over the floor. The patient noticed immediately and was able to reconnect it until a nurse could evaluate it. Pt states that the line was not being touched when it came loose. No harm came to anyone due to the type of fluids that were running. If there had been chemotherapy running, it could have caused potential harm to the patient/visitors as well as staff involved in the hazardous spill.

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 June 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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