MedSun
Medical Product Safety Network

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

August 2018

Volume 18, Issue 8

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/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm595393.htm

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm589381.htm

In Brief

As of August 5, 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

CARDIOSAVE Hybrid Intra-aortic Balloon Pump by Maquet Datascope Corp.: Class I Recall

June 26, 2018

Maquet Datascope Corp. is recalling the IABP due to a design issue that allows fluid (such as saline) to seep into the device. The fluid can cause corrosion of internal components such as the electronic circuit boards, and lead to device malfunction (e.g., sudden stops) which can cause a delay or interruption in therapy.

Various Aortic Endovascular Graft Systems: Letter to Health Care Providers - UPDATE on Type III Endoleaks

June 19, 2018

In a Letter to Health Care Providers from September 2017, FDA communicated its concern related to an increase in the occurrence of Type III endoleaks with the use of endovascular graft systems indicated for a procedure known as endovascular aneurysm repair (EVAR). Endologix has not manufactured the AFX with Strata graft material since July 2014, and in December 2016 requested that all AFX with Strata devices be removed from hospital inventory.

Liquid-filled Intragastric Balloons by Apollo Endosurgery and ReShape Lifesciences: Letter to Health Care Providers

June 4, 2018

In collaboration with the manufacturers, the FDA has approved new labeling for the Orbera and ReShape balloon systems with more information about possible deaths associated with the use of these devices in the U.S. Please see the statements from each manufacturer for additional details about the new labeling.

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.

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 (CO2) 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 July 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:

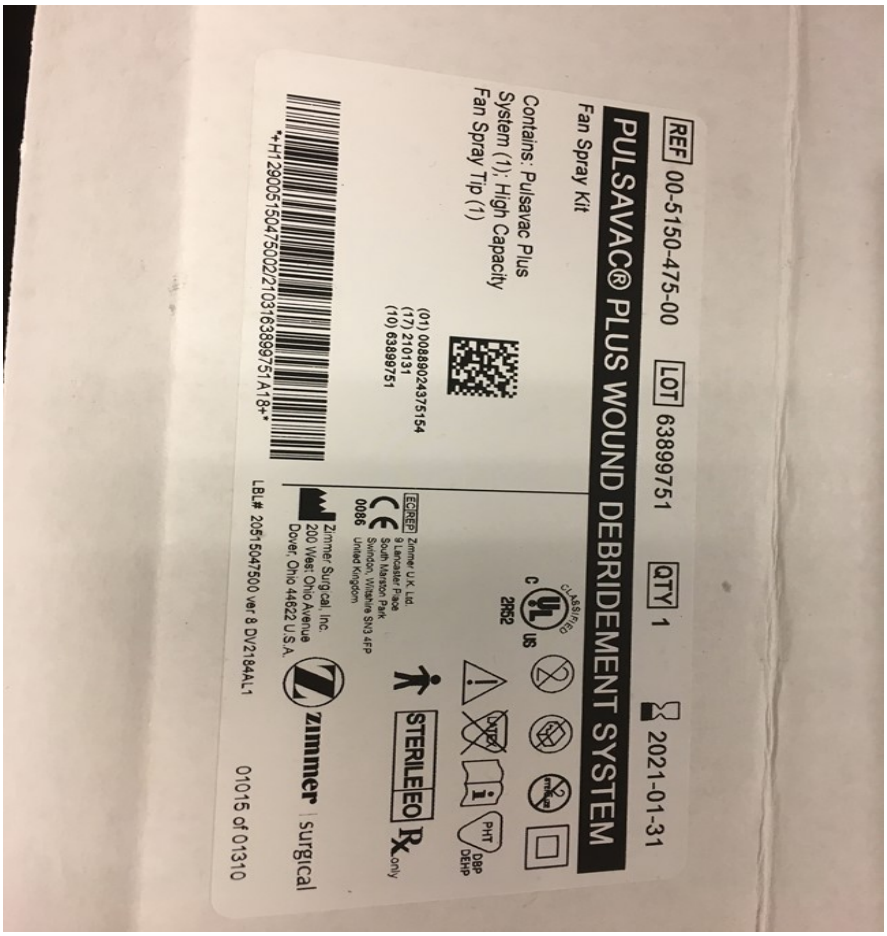
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm


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
Bed, Ac-powered Adjustable Brand: S3 Model#: 3002 Cat #: 3002S3ZOOM	Stryker Medical	Multiple complaints about the Stryker S3 bed not holding a sufficient charge and creating difficult transport of patients when the battery fails. Healthcare team members report that the bed is heavy and is difficult to push, which creates injuries for the team. In addition there are complaints that the drive function on the bed is too close to the stride of the pusher and causes the pusher to inadvertently hit the driver function and put the bed into neutral. The manufacturer was alerted and replaced the charger on the beds, however there continues to be problems with the design with the neutral/drive pedal being too easy to hit when transporting the bed. Per the hospital, the manufacturer responded to the complaint of the charging unit not holding a charge and replaced the charge inverter. In addition, the manufacturer has been made aware of the design flaw (neutral/drive) function being too close to the feet of the transporter while walking.

Device	Manufacturer	Problem
Catheter, Urological Brand: Bard® Urethral Catheterization Tray With Red Rubber Catheter Model#: 772415 Lot #: NGCT0643 Cat #: 772415	C. R. Bard, Inc.	We use this urethral tray to drain urine from a patient's bladder. On 4 trays of the same lot number, each tray was missing the package of Povidone-Iodine Swabsticks (3) that the nurse needs to cleanse the urinary meatus before inserting the bladder catheter. This means that the nurse needs to break sterile technique to search for the Povidone-Iodine Swabsticks, or open another tray to get the items. 4 trays were opened for bladder catheterizations and all 4 were missing the swabsticks.
Lavage, Jet Brand: Pulsavac Model#: 00-5150-475-00 Lot #: 63899751 Cat #: 00-5150-475-00 Other #: H129005150475002	Zimmer Surgical, Inc.	The OR staff were preparing for the case (patient was not in the room) when they noticed smoke and heard a sizzle coming from the battery pack of the device. Staff alerted Fire Safety and Biomed, and reported that the battery pack was smoking and starting to melt. The cord to the device was cut and the battery pack was opened to safely dislodge the batteries that were causing it to smoke and melt. No staff or patients were harmed in the event. The device was removed from service. Please see pictures below: 

Device	Manufacturer	Problem
		
Adult Electrodes, External Defibrillators Brand: Onestep Electrodes Lot #: 2218A Cat #: 8900-0224-01	ZOLL Medical Corporation	The Zoll OneStep Adult electrodes have a wire cable/connector within them that is necessary to test the defibrillator machine. Often times this wire is cracked or broken and when they are hooked up to the machine they give a low voltage error/test failed. I understand that they still will deliver a shock to the patient but what happens if it were not to do that? I am not comfortable proceeding with attempting to shock my patient when the machine is telling me the test failed. I don't like relying on the fact that "well it still delivers a shock --there is no need to worry..." I think that the wire connector is in a bad location. They crack/break during storage, handling and when users are trying to connect the cable to the defibrillators machine.

Device	Manufacturer	Problem
Device, Biopsy, Endomyocardial Brand: Sparrowhawk Lot #: 041813 	ATC TECHNOLOGIES, INC.	Patient presented for post heart transplant routine myocardial biopsies. Two endomyocardial biopsy specimens were removed with a SparrowHawk 5 Fr 50 Cm bioptome. On the third attempt a snap was reported to have been felt. The wire broke and jaws of the bioptome remained in the open position. The bioptome could not be pulled into the 5 Fr long sheath and attempts to close the bioptome jaws using the actuator, wire and outside spring was unsuccessful. A TEE confirmed that the open bioptome jaws were located at the anterior leaflet of the tricuspid valve or in the chordae right below the valve. Attempts to manipulate the bioptome in a rotational fashion did not change the position of the tip of the bioptome. With the bioptome in the valve there was moderate tricuspid regurg. Access was obtained over the 5 Fr sheath. A 7 Fr sheath was place and the bioptome was able to be pulled into the sheath and removed. Heparin was given during this process. There was clot along the bioptome after it was removed. Following removal of the bioptome a TEE was performed. The tricuspid valve was reported to have good function with mild regur (unchanged from prior exams pre biopsy) There was no evidence of flail tricuspid valve. The right and left ventricular function was normal. No clot seen in the RA or RV.
Epidural Anesthesia Kit Brand: Design Options Model#: 552122 Lot #: 0061605305 Cat #: 552122	B. Braun Medical, Inc.	A B. Braun 19 gauge epidural catheter was placed without difficulty in an obstetrics (OB) patient during labor for pain management. The placement was uneventful and the catheter was taped, test dosed and bolused as per routine protocol. There was nothing remarkable about the placement of the catheter. Approximately 90 minutes after the catheter was placed, the patient was sitting up in bed with the assistance of her nurse and they heard a snap. The nurse quickly identified that the epidural catheter snapped apart/shredded and immediately called the OB anesthesia attending physician and the OB anesthesia fellows. On inspection, it appeared that the plastic sheath covering the spring wire broke into two pieces. Fortunately the spring wire was completely intact and the epidural / wire were easily removed with no concerns of a retained catheter or spring. The patient was concerned that the catheter broke with minimal force during a patient position change. A new epidural catheter was placed without complications. The physicians reported that they have never encountered this defect and are concerned about a manufacturing defect.
Recorder, Event, Implantable Cardiac, (Without Arrhythmia Detection) Brand: Confirm Rx Imp Model#: DM3500 Cat #: DM3500 Other #: Loop recorder	St. Jude Medical, Cardiac Rhythm Management Division	Loop recorder inserted on patient, procedure ended, device receiving error. Brought patient back for device removal and new loop recorder insertion.

Device	Manufacturer	Problem
Hydrogel Probe Cover Brand: Ac-cutemp Plus Cat #: 175-S 	Kentec Medical, Inc.	The patient's thermal heart temperature probe does not accurately correlate the correct temperature of the very low birth weigh infant, which causes false low skin temperature readings and increases the isolette temperature. This over heats the infant. Infant found with axillary temp of 37.9 Celsius. This is occurring only with one type of small baby thermal heart probe with foam backing (Ref# 175 -S). Noted over the last couple of weeks the similar elevation in temperature only with this type of probe (not usually stocked on our unit-we were sent a different probe). Despite routine q3h change of these new probe site thermal covers and routine site change taking care not to have infant blankets cover it or baby lay on probe, infant is noted periodically to have this elevated temperature. All probes have been removed from the unit. Manufacturer made aware by nurse manager. Per hospital, the manufacturer informed hospital staff that they have not heard of this problem before with their probes.
Interventional Fluoroscopic X -ray System Brand: Phillips Igt Allura Fd Es-sentials 28 Model#: Allura FD Essentials 28	Phillips Medical Systems, Inc.	This is just a comment about the design of the product. Re: Phillips IGT Allura FD Essentials 28 imaging equipment for cath lab. The imaging equipment takes a picture and then stores the picture on the internal hard drive. The system does not inform you when the hard drive is full. So, the hard drive could be full and you could still be taking pictures thinking that the pictures are being saved onto the drive. However, they are not being saved onto the drive once the drive is full. If you try to retrieve them, they won't be there. By comparison, another manufacturer's equipment will tell you when the hard drive is full, so that you can delete older images and free up space on the drive to store new images.
Laparoscope, General, Plas-tic Brand: Versaone Cat #: ONB12STF	Covidien	The patient was in the OR for a laparoscopic cholecystectomy. A 12 mm laparoscopic access port was used to gain access for cholecys-tectomy. During the surgery the blue rubber gas stopper that is lo-cated in the center of the port came out and fell into the patient's abdomen when the surgeon tried to put a grasper instrument through it. The surgical team realized it had fallen in the abdomen when the peritoneal cavity would not stay inflated with gas. The sur-geon looked in the abdomen with the scope and saw something blue. It was the rubber stopper from the port. A picture was taken of the port, but the port and packaging was discarded because the pa-tient was on C-diff precautions.
Pneumatic Tourniquet Brand: Ats 2200ts Cat #: 60220010100	Zimmer Surgical, Inc.	Patient went to surgery for right below the knee amputation. Sur-geon put tourniquet on right upper thigh in case of heaving bleeding during procedure, but it was intended not to inflate the tourniquet. Right after the incision was closed, while putting the dressing and removing the drapes, the RN first assistant noted the tourniquet was on for 56 minutes at 250mmhg pressure. No staff members turned the device on: it turned on by itself. Immediately, the RN turned it off and notified the surgeon. We waited for 5 minutes after the tourniquet turned off to see if there was any sign of bleeding. No bleeding noted.

Device	Manufacturer	Problem
Laryngoscope, Single Patient Use Brand: Greenlight Lot #: 0001133356 Cat #: Style/ Size MIL 0 4610 Other #: 10885403271151 	Vyaire Medical, Inc.	During emergent intubation of an infant upon birth via C-Section, the physicians experienced extreme difficulty using the disposable laryngoscope with LED light. The patient was resuscitated appropriately but due to difficulties using the laryngoscope, the patient was not intubated until 11 minutes of life. Similar events were also reported in other patients as well. The very experienced providers report concerns with viewing the anatomic landmarks and the glare of the light off secretions also complicated the intubation process. The size and shape of the blade connection into the handle and handle are also of concern - larger than other disposable products. Concerns raised with delays associated with potential delays in intubating infants with this laryngoscope.
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 2420-0007 Lot #: 18023110 Cat #: 2420-0007	CareFusion 303, Inc.	ED staff noted that there have been several occasions over the last week where it was very difficult to prime primary IV tubing or tuning would not prime at all without utilizing a syringe to pull medication through tubing. No harm to patient or adverse event occurred with these reported events.
Suction Catheter Kit Lot #: 0001100568 Cat #: 41-10	Vyaire Medical, Inc.	While discarding soon to expire CareFusion tri-Flo suction Cath-n-glove kits that were to expire 03-31-2018 we noticed the 0.9% Saline Solution inside the kit expired 2018-03-09.
Surgical Gloves Brand: Protexis Pi 8. 5 Lot #: TS17100180 Cat #: 2D72PT85X	CARDINAL HEALTH 200, LLC	When preparing to glove surgeon, scrubber opened the package of gloves and a screw was noted inside the package with the gloves. The package of gloves was handed off the sterile field. Case proceeded normally.

Device	Manufacturer	Problem
Warming Unit, Blood/ intravenous Solution Brand: Level 1 Model#: H-1200	SMITHS MEDICAL ASD, INC.	Incident with new level 1 fluid warmer. The ED staff stated that the unit was not infusing rapidly on a patient and that the blood flow was really slow. Technician ran multiple functional tests but could not duplicate the problem so it was documented as user error. Teaching was done regarding use of hook labelled for use with blood bags. The same incident occurred again after teaching, as well as happening specifically to the Clinical Nurse Specialist who gathered the complaints on the Level 1s not functioning. The device was set to pressure for the blood bag, the blood bag had approximately 100ml of blood left in it. The chamber was pressurizing, but the blood was dripping very slowly. All trouble shooting of IV access, tubing issues, and patient were done per normal procedure, and there were no problems. When the pressure was switched to the 1Liter bag of normal saline, the device ran rapidly without issue. During this whole incident, there was no alarm on the device. This same incident occurred at least 3 more times over a short time period. This is when the decision to pull the devices was made. The error was not able to be replicated on the devices that failed. A similar situation occurred on a different machine two days latter. With further investigation, it was found that the pressure chamber bracket that connects the pressure chamber and the door is 1 inch wider than the 1000 series devices, thus leading to an assumption that a smaller volume bag is not getting the same amount of squeeze, and therefore having slower dripping. The incidents of device failure only occurred when attempting to deliver blood in a case of a patient hemorrhaging.
Ambulatory Infusion Pump Brand: Cadd Legacy Plus Model#: 6500	Smiths Medical ASD, Inc.	Pt had Chemo pump placed and the pump was programmed to run for 46 hours. Pt came to have pump disconnected. Pt states that pump went off this morning at 0600 and kept beeping the patient shut it off, bag empty. Patient dose was 2400mg/m2, patient BSA 1.86. Dose calculated to be 4464mg of 5FU = 89.28cc. Medication was then diluted in 100cc NS for a total volume of 189.28cc. Divided by 46 hours the rate was calculated to go at 4.11cc/hour. Pump was started at 1330pm and should have been completed at 1130am 2 days later. When patient came in he stated the pump alarmed empty at 6:00am. This is 5 hours early.

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

Contact the MedSun Program Staff:

Telephone: 800-859-9821
Fax: 800-859-1292
E-mail: medsun@fda.hhs.gov

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993