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/UCM561666.pdf

510(k)s Final Decisions: https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM569547.pdf

In Brief

As of November 1, 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

Infant/Child Reduced Energy Defibrillation Electrodes by Cardinal Health: Voluntary Field Action
November 6, 2017
Voluntary field action for specific production lots of Infant/Child Reduced Energy Defibrillation Electrodes (defibrillation electrodes) produced by Cardinal Health. The company is notifying customers of an issue with the artwork on the defibrillation electrodes, as manufactured by Cardinal Health, which shows incorrect electrode placement for an infant. There is no issue with the performance or function of the defibrillation electrodes; this is limited to incorrect artwork on the defibrillation electrodes within the packaging.

Absorb GT1 Bioresorbable Vascular Scaffold (BVS) by Abbott Vascular: Letter to Health Care Providers
October 31, 2017
The FDA issued an update to the March 18, 2017 letter to health care providers to inform the health care community that interim study results through three years from the pivotal clinical trial (ABSORB III) continue to show an increased rate of major adverse cardiac events and BVS scaffold thrombosis in patients receiving the Absorb GT1 Bioresorbable Vascular Scaffold (BVS), when compared to patients treated with the approved metallic XIENCE drug-eluting stent. The FDA was made aware that the manufacturer has stopped global sales of the Absorb GT1 Bioresorbable Vascular Scaffold as of September 14, 2017.

Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) by St. Jude Medical: FDA Safety Communication
October 19, 2017

On August 28, 2017, St. Jude Medical notified physicians of the availability of Battery Performance Alert (BPA), a new battery performance management tool that detects and notifies physicians of abnormal battery performance that may lead to premature battery depletion in Implantable Cardioverter Defibrillators.

Infant Sleep Positioners: FDA Warning
October 3, 2017
FDA is reminding parents and caregivers not to put babies in sleep positioners. These products—sometimes also called “nests” or “anti-roll” products—can cause suffocation (a struggle to breathe) that can lead to death. The federal government has received reports about babies who have died from suffocation associated with their sleep positioners. In most of these cases, the babies suffocated after rolling from their sides to their stomachs.

Covers for Hospital Bed Mattresses: Learn How to Keep Them Safe

Safety Concerns:
Over time, hospital bed mattress covers can wear out and allow blood and body fluids to penetrate and get trapped inside mattresses. If blood or body fluids from one patient penetrate and get absorbed in a mattress, the fluids can leak out the next time the mattress is used. Coming into contact with these fluids poses a risk of infection to patients using the bed.

Recommendations:
Recommendations to help health care providers, health care facility staff, and caregivers ensure hospital bed mattress covers are safe for use in health care settings can be found on FDA's webpage. FDA has also developed a poster addressing key safety aspects about hospital bed mattress covers. This poster is available for free download and can be used as a safety reminder about hospital bed mattress covers in health care settings. To download the poster please go to: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/ucm585737.htm.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during November 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
Accessories, Blood Circuit, Hemodialysis Brand: Crit-line Iii Blood Chamber Ii Model#: 191058 Lot #: 16071307 Cat #: 191058 Other #: CL80020033 	Fresenius USA, Inc.	Hemodialysis was initiated via catheter lines running A-A/V-V with good flow noted. Approximately 5 minutes into treatment the RN noticed a small blood leak in circuit where crit line connecting piece and arterial line meet. The leak was not alleviated by tightening of the connection. Connection piece removed from circuit and blood line attached directly to dialyzer with no further leaking noted. Because of the open circuit per policy blood cultures were drawn and empiric vancomycin and ciproflozacin were provided. Toward the end of the vancomycin infusion the patient developed reddening around the face and ears without swelling or shortness of breath. The patient remained hemodynamically stable. The patient received Benadryl and Tylenol for presumed re man syndrome reaction with excellent response. Ciproflozacin was administered for total of 3 days. Blood cultures were negative. The patient returned for hemodialysis and remained afebrile.

Device	Manufacturer	Problem
Catheter, Urological (Antimicrobial) And Accessories Brand: Surestep Foley Tray System Bardex Ic Complete Care Model#: A303316A Cat #: A303316A	C. R. Bard, Inc.	Opened the foley tray. No tip on end of inflating syringe and only a few drops of water was in the inflating syringe. Since fluid invasion of sterile pack may have occurred, sterility questionable. This is the second occurrence. First occurrence, no packaging information was saved. No Lot # or expiration date found on package.
Echelonflex 45 Articulating Endoscopic Linear Cutter Lot #: P91M30	Ethicon	Device malfunctioned during surgery and a larger incision was required to remove the device. On the phone the prompts by manufacturer to correct were ineffective but Ethicon rep came in to meet and to pick up the product.
Immunoassay Method, Troponin Subunit Brand: I-stat Ctnl Cartridges Lot #: c17063	Abbott Point Of Care Inc.	I stat troponin cartridge error x 2 for 1 RN. I stat troponin cartridge error on third attempt by second RN. 4th attempt by third RN was successful. Patient arrived in emergency department (ED) with chest pain/suspected myocardial infarction (MI). MD ordered a bedside troponin level. When troponin bedside test was attempted, RN received "cartridge error" message from ISTAT machine so he attempted the troponin test with a second cartridge. The same message appeared for the second cartridge. Patient's blood was redrawn and a third cartridge was attempted. Third cartridge attempt with redraw of patient's blood stated "cartridge error" again. Fourth cartridge attempted and was successful. Patients troponin was elevated. Cartridge error x 3 delayed proper and important patient care.
Hysteroscope (And Accessories) Model#: 27040XA Lot #: OV 05 Cat #: 27040XA	Karl Storz GmbH & Co. KG	During a Cystourethroscopy with transurethral resection of 4 cm bladder tumor, the resectoscope tip broke apart while inside of patient / "cystoscopy, TURBT" procedure. Both parts were retrieved and removed from patient without harm. No complications as a result.

Device	Manufacturer	Problem
Electrode, Cutaneous Brand: Cutaneous Eeg Electrode Model#: DCPE-23/B Lot #: F2076 Cat #: DCPE-23/B Other #: IDC-001-Rev A; IVES EEG leads (special package); IVES EEG Electrode System Disposable Plastic electrode	IVES EES Solutions	Patient came to MRI on the 3T scanner for a brain, MRA head and MRA neck exam. When he arrived for the MRI he had MRI compatible EEG leads on his head. The MRI Technologist verified the leads were MRI compatible by checking the tags at the ends of the leads. About three minutes into the exam, the patient squeezed the emergency ball and stated that it felt as if his neck was burning. The patient was then removed the patient from the MRI scanner. The tech noticed that there was a MRI compatible lead in the area that the patient stated he felt the burning sensation, which was on the right side of his neck. There was an area of redness on the patient's skin near that lead (MRI staff attribute to being from heat, but the EEG manager replicated the redness and attributes to tape). The patient's nurse from the inpatient floor was notified her and she stated that it was okay for the MRI Tech to remove the EEG leads. All the EEG leads were removed in order to allow for the MRI to proceed. Once the leads were removed, the techs were able to continue the MRI. MRI management was also made aware of the situation.
Indicator, Physical/ chemical Sterilization Process Model#: 260010 Lot #: 709401 Cat #: 260010	Steris Corporation	Steam sterilization in central sterile/sterile processing was completed using required indicator tape for blue wrapped instruments. This tape did not change as required for validation of sterilization.
Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms) Brand: Carescape Monitor B650 Model#: B650 	GE Healthcare Finland Oy	At shortly after 8:00am, all of the GE B650 monitors within our Neonatal Intensive Care unit (NICU), spontaneously rebooted themselves. These devices are on a dedicated monitoring network with other GE Physiological monitors in our institution. This resulted in the loss of cardiac monitoring to every patient within the unit while the monitor rebooted (2-4 min). We are in the process of downloading device and network logs to further investigate this issue.

Device	Manufacturer	Problem
Pulse Generator, Permanent, Implantable Brand: Edora 8Dr-t Model#: 407145 Cat #: 407145	Biotronik, Inc.	A Biotronik Pacemaker that was implanted and was seen back for wound check in 1 week with normal function but also seen six weeks later due to patient symptoms and was not able to be interrogated with numerous attempts and tech service involvement. It also stopped communicating with the home-monitor about a week ago. Likely random component failure but hard to say this device was just released about 6 months ago.
Device 1: Pump, Infusion Brand: Medfusion Model#: 4000 **Device 2: Syringe** Brand: Bd Posiflush Surescrub Model#: 306559 Lot #: Unknown Cat #: 306559	Smiths Medical ASD, Inc. Becton Dickinson and Company	Nurse reported the Medfusion syringe pumps are having trouble recognizing the 10ml BD pre-filled flushes (the PosiFlush 10ml pre-filled normal saline flushes). The pump will read "invalid syringe size" and reseating the flush does not work. The workaround nursing has come up with is to use an alcohol wipe package or the label from a syringe and place it between the flange of the syringe and the slot the flange sits in on the right side of the pump. Then it will recognize the 10ml flush. Medical Engineering evaluated and found the change in the plunger when PosiFlush came out caused increased drag and thereby increased pressure upon deployment of the fluid. After a matter of just a few minutes the pressure reading increases to the point that the pump shuts off. It reads this as an occlusion. Because of this we determined that a different flush has to be used to prevent the pressure increase. Per site reporter: BD does not recommend use of this syringe with pump.
Set, Administration, Intravascular Brand: Liftloc Safety Infusion Set Model#: 0642010 Lot #: AS-BTSO125 Cat #: 0642010	Bard Access Systems, Inc.	There was leaking from the extension tubing for the LiftLoc infusion sets. This happened with several packs from the same lot so the whole lot was removed. No patient impact. Leaking was noticed before the set was used on any patients. The lot was removed from inventory.
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 11607704 Cat #: 11607704	Carefusion 303, Inc.	The nurse attempted to prime IV tubing with fluid to be administered to patient. The chamber filled, but tubing would not prime. There were multiple air and fluid bubbles throughout the tubing. There was no use error identified.

Device	Manufacturer	Problem
Surgical Gauze Sponges Brand: Surgi-count Lot #: 9416 Cat #: SM-8412-7S	Stryker	Surgeons and multiple scrub techs have complained about the safety and quality of the new scannable SurgiCount raytecs safety sponges. The glue which adhere the barcode to the raytec often seeps through many layers and when separated, the raytec frays. These little fibers could easily be retained inside the wound because they do separate easily when pulled at.
Unit, Neonatal Phototherapy Brand: Neoblue Blanket Other #: 006254 	Natus Medical, Inc.	During patient assessment the nurse noticed the bili blanket was flickering. After assessment, there was a burning smell and the unit was hot to touch. The unit was turned off and when the bili blanket paddle was unplugged it was noted that the fibers at the distal end with metal connector was melted. It appears that a second one was placed which had the same result. The unit was then removed from service with the two paddles. The manufacturer is sending a replacement.
Ventilator, Continuous, Minimal Ventilatory Support, Facility Use Brand: Philips Respironics Model#: V60 Cat #: 1053617	Respironics California, Inc.	V-60 stopped working while patient was wearing it. RN took patient off V-60 and informed RT. RT removed equipment and tagged it defective. RT replaced defective equipment with a new one.
Ventilator, Continuous, Facility Use Brand: Puritain Bennett Model#: PB 980	Medtronic	The unit reports that ventilator read "Patient Disconnect" while still connected to the patient. The machine would alarm audibly and visually with all numbers on the screen displaying zero. Nurse reports that she believed she could hear the safety valve open on the back side of the ventilator. After about five minutes, it would stop and return to the previous settings and continue to ventilate the patient. This would occur about every five minutes as observed by the nurse and respiratory therapist. The ventilator was exchanged with no issues with the replacement ventilator. There was no change in the patient's vital signs or harm to patient.

Device	Manufacturer	Problem
Ventilator, Non-continuous (Respirator) Brand: Airlife Model#: 5401L1 Lot #: 0001127073 Cat #: 5401L1 	Carefusion Corporation	When opening packaging of inflating bag the peep valve is found to be cracked and can not be used on patients. This is a life saving product to maintain an airway and if not discovered prior to use on a patient for resuscitation could cause patient harm. The cracked peep valve housing was found in lots 000103004 and most recently lot 0001127073 - 17 quantity found in storerooms and unit storage with the cracked peep valve housing.
Wrist Band Brand: Tendercare Cat #: 7745-11-PDL 	PDC Healthcare	We have had several reports of the wrist band coming loose and falling off the patient/mother. These bands are used with the Totguard infant and pediatric security system from Guard RFID Solutions Inc. A "tag" is attached to the mother by threading the wrist band through the tag. The band then sticks to its self to secure the band to the mother. In one case the tag fell in the toilet and had to be thrown away. It appears the sticky part of the wrist band is not holding.

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 December 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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