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/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 December 1, 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

Synaptive Medical Recalls BrightMatter Guide with SurfaceTrace Registration Due to Software Defect

November 30, 2018

When the BrightMatter Guide System is used with two configurations of a specific third-party port (the NICO BrainPath device), a software defect may be triggered upon switching between the configurations which affects the system's display and prevents the surgeon from being able to accurately see the location of surgical tools in the patient's brain. In the event this software defect occurs, the surgeon could potentially damage the patient's brain and vascular structures.

Zimmer Biomet, Inc. Recalls Spinal Fusion and Long Bone Stimulators Due to Lack of Adequate Validation and Controls to Ensure Product Cleanliness

November 26, 2018

Zimmer Biomet, Inc. is recalling the EBI Osteogen Implantable Bone Growth Stimulator, SpF® PLUS-Mini (60 µA/W) Implantable Spinal Fusion Stimulator, and the SpF®-XL IIb 2/DM Implantable Spinal Fusion Stimulator due to a lack of adequate validation and controls to ensure that final products were clean and free from bacteria and chemical residue. The lack of adequate validation and controls may or may not cause serious side effects for the patient including infection, tissue death, additional surgery for wound treatment and/or device removal, impaired wound and bone healing, the need for long-term antibiotic therapy, the potential for secondary gastroenteritis, swelling and infection around the spinal cord (epidural abscess), paralysis, damage to other organs or death.

Implanted Pumps: Safety Communication - Use Caution When Selecting Pain Medicine for Intrathecal Administration

November 14, 2018

The FDA is aware that patients undergoing treatment or management of pain are commonly given pain medicines in the spinal fluid (intrathecal administration) that are not FDA approved for use with the implanted pump. While individual patients may experience some relief from using pain medicines not approved for intrathecal administration in their implanted pumps, such use may create additional risks including dosing errors, pump failures, and other safety concerns.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during November 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.

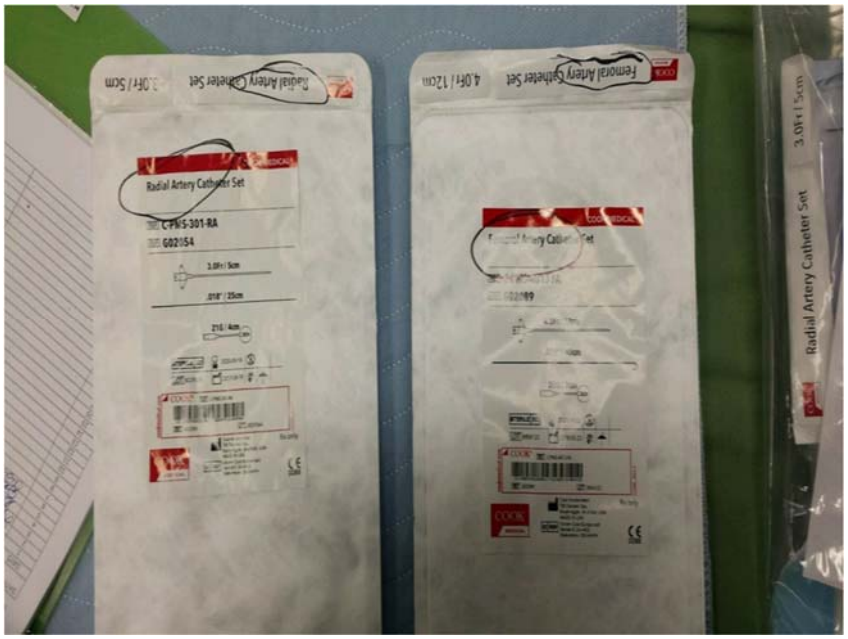
Device	Manufacturer	Problem
Catheter, Indwelling Brand: Bard Foley Catheter 16fr With Urimeter Lot #: NGCV2291	C.R. BARD, INC.	We have had three Bard Foley 16FR catheters with urimeters leak. These Foleys were placed in our operating rooms. These are leaking at the needle port where the adhesive pad is attached to the leg. The existing stock has been removed from our shelves. Bard representative and Bard customer service made aware.

Device	Manufacturer	Problem
Catheter, Intravascular, Therapeutic Brand: Arrow Model#: IP-N037300 Lot #: 23F 18F0005 Cat #: CDC-45052-VPS2	Teleflex Incorporated	RN prepared to place PICC line and discovered upon opening the packaging that the PICC was packaged wrong. A 40cm PICC line had been packaged in error as a 50cm PICC line. The 40cm PICC line was not placed in patient. RN obtained a new 50cm PICC line package and placed the line without complication.
Catheter, Ultrasound, Intravascular Brand: Visions Pv .035 Digital Ivus Catheter Model#: 88901 Lot #: 0301457389(90)	Volcarica S.R.L.	IVUS catheter was used. The wire never entered patient's body. The wire did not pass through the IVUS; guidewire would not pass through catheter. No patient harm.This is one of 3 Hybrid events regarding , reference # 88901. We searched the internet and found a 'medical device advisory notice' for this item dated 10/13/2018. No known formal notification by the company has been received. According to the UDI# ...(10)0301457389...is a batch number that is included in the advisory notice.
Cleansing Enema Set, Boxed Cat #: DYND70100	Medline	While admitted to the facility, a patient experienced constipation. A soap suds enema is ordered. A boxed enema set is utilized for set-up and use. Later in the day the patient is discharged to home. The patient's family called the facility (much later) to share that while at home and providing peri-care to the former patient, a blue object is noted to be protruding from her anus. The blue item is pulled out by family and they notified the facility with photos of the item. The item is thought to be (by family) the blue tip protector, which covers the pre-lubricated tubing. Manufacturer notified by patient's family and facility. No response. Family express wishes to make improvements to the product to prevent such an issue from happening in the fu-
Container, Liquid Medication, Graduated Brand: BD Luer Tip Cap, Sterile Tray Lot #: 8149998 Cat #: 305822 Other #: ns305822	Becton Dickinson and Company	A foreign object can be seen inside the packaging of a sterile syringe cap. This is actually the 2nd pack that a person in Pharmacy experienced this. The first time, the pack was tossed out. This time, the pack was saved and is available for inspection.

Device	Manufacturer	Problem
Device, Hemostasis, Vascular Brand: Mynxgrip Vascular Closure Device (5f) Model#: MX5021 Lot #: F1821801 Cat #: MX5021	AccessClosure, Inc.	Stuck on fibrin, everything came out. This may be an operator issue or a new product issue. I have given the rep a heads up for case support to see if it is something on our end. I also talked to her and she said it was new device for them to use. This is the second incident like this.
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 11171447 Lot #: (10) 18106260 Cat #: 11171447	CAREFUSION 303, INC.	Patient was receiving an antibiotic infusion. Upon completion of infusion nurse went to remove tubing from pump and tubing became disconnected where the foot clamp fits into the pump, releasing the primary bag of normal saline all over the floor. This didn't directly effect the patient because the infusion was complete. However, if the bag had contained chemotherapy or other toxic agent it could have posed a serious safety risk to staff, patient, and visitors. This is our departments 4th incidence with tubing becoming detached from different locations. Please see picture below: 
Fiber, Medical, Absorbent Brand: Disposable Or Towels Model#: MDT2168304	MEDLINE INDUSTRIES, INC.	The patient was receiving a hibiclens prep at the neck for a parathyroid case. The neck was scrubbed and then blotted with a pack of disposable blue towels. Upon removing the towels, the surgeon noticed blue flecks of lint from the towels remaining on the skin after the blot. Pictures were taken and the business director was paged. 3 inventory specialists came to the room to retrieve the towel packaging and obtain the pictures.

Device	Manufacturer	Problem
Laryngoscope, Rigid Brand: Rusch Dispogrip Other #: Disposable Laryngescope Handle	Teleflex Medical	Discovered during routine equipment check that the cap at the end of the laryngescope handle was broken and unable to lock into place. Advised Supervisor on duty whom directed that piece of equipment to be replaced. Of note, this has been discovered on at least three sets of this new equipment and it was noted the small plastics phlanges do not stay intact to hold battery in place.
Pump, Infusion, PCA Brand: Cadd Solis Pump Model#: 2110	Smiths Medical ASD, Inc.	The cassette volume was set electronically on the pump at 100 ml and a "reservoir volume is zero" alarm alerted the nurse when it was electronically depleted roughly six hours later. The nurse found a physically full 100 ml cassette indicating no medication infused. The time range was roughly 6 hours from approximately 10:47 AM until approximately 3:47 PM. The total amount infused during this period would have depleted the cassette based on the PCA settings. The cassette was retrieved and it physically had 100+ ml in the cassette and the contents were assayed with a 98.75% result. The same pump was used previously with almost identical settings and the same medication for twelve hour infusions running at intervals of roughly six hours with no issues.
Replacement Heart-valve Brand: Carpentier-edwards Bioprosthesis Other #: aortic valve	EDWARDS LIFESCIENCES LLC	Patient transferred to our facility for endocarditis. Patient required an aortic valve replacement. The explanted valve was sent to pathology where it was discovered to be infected with the fungus Rhizopus species.
Syringe, Enteral Brand: Neoconnect Model#: PNM-S12NC Lot #: 20171110 Cat #: PNM-S12NC 	NEOMED, INC	A NeoConnect oral enteral syringe with EnFit connector was obtained in order to deliver oral/enteral medication to an infant. It was noted when the packaging was opened that it was not an EnFit connector that was in the package. It was a straight tip connector. Another syringe was obtained and it had an Enfit tip. The packaging of both of these syringes had the exact same reference and lot numbers and were labeled the same. The straight tip connector is not one that we use in our facility because it can inadvertently be connected to an IV catheter and increase the potential of an oral medication/feed being entered into an IV. Fortunately, this did not reach the patient and the nurse stopped when she noticed the catheter tip was not compatible with the EnFit system.

Device	Manufacturer	Problem
Tube Tracheostomy And Tube Cuff Brand: Shiley Model#: 4UN65H Lot #: 18B0754JZX Cat #: 4UN65H	Covidien LP	Insertion of a size 4 inner trach cannula - in metric it's listed as 6.5mm on the packaging and this was interpreted as US size 6 inner trach cannula
Warmer, Infant Radiant Brand: Giraffe Warmer Other #: 115995 	OHMEDA MEDICAL	Radiant warmer south wall was damaged and had the potential to fall open. This opens up the opportunity for the infant to fall from the warmer.
Monitor, Physiological, Patient(Without Arrhythmia Detection Or Alarms) Brand: Root Model#: RDS7A Other #: 14946; Vital Sign monitor	Masimo Corporation	Temperature module failing on multiple devices (at least 8 devices in the last 3 months). Replacing the probe well is not fixing the problem, because the module also fails to recognize any new well. When module overheats, it puts the temperature mode into "Continuous", which prevents the ability to spot check temperature of patients.
System, Imaging, Gastrointestinal Brand: Pillcam Sb3	Medtronic	Patient came in for gastrointestinal (GI) pill. Patient was given GI pill without any issues. All equipment was working properly before, during, and after GI pill was given. Patient had come back that evening as instructed and the pill recorder was downloaded by someone. As staff member was helping with another GI pill at another time, they noticed one of the GI pill recorders was not on. They turned the recorder on and it started working. The recorder was from the original patient's study and it stated that the video creation was unsuccessful. Staff attempted to create the video again. The video failed to create and Given/Medtronic technical support was called and informed of everything that happened. Staff followed technical support directions and attempted to create another video. This attempt failed and technical support was called again. Technical support asked staff to create another video which also failed. Staff received an email from technical support, which said support was able to see that the Pillcam recorder failed to copy data to the memory card, and that the study had been lost due to malfunction. Technical support said that they would be sending a replacement recorder to send the current malfunctioning recorder back so that they could look further into this.

Device	Manufacturer	Problem
Catheter, Intravascular, Diagnostic Brand: Cook Model#: G02089 Lot #: 8904123 Cat #: C-PMS-401J-FA	Cook Incorporated	Look alike packaging. While restocking the RN noticed that the packaging for the two catheter sets were identical with the exception of the name. The concern is that since the packaging looks the same the wrong catheter could be pulled and possibly used in an emergent situation. Please see picture below: 
Instrument, Ultrasonic Surgical Brand: Sonicision Model#: SCD48 Lot #: 82290092X Cat #: SCD48	Covidien LP	Three (3) different batteries were tried on the device and it would not work. Staff have to open new devices until they find batteries that work. This delays the patient's procedure. This is a repeating problem with the Sonicsision device at this facility. The facility has notified the manufacturer and returned product but the problem has continued.
Electrosurgical, Cutting Coagulation Accessories Brand: Vasoview Hemopro Model#: VH-3000 Lot #: 25138761 Cat #: VH-3000	MAQUET CARDIOVASCULAR LLC	A Maquet Vasoview Hemopro was used for vein harvest from the patient's right leg. The Physician Assistant saw the rubber tip of the Hemopro broke off on the camera/monitor, pulled it out from the patient's leg and the piece that broke off was retrieved. There was no patient harm. Note: The piece that broke off from the tip of the Hemopro was sent to Maquet together with the device. Please also note this is the third report since June 2018 that we have submitted re: defective Hemopro devices.

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 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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