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 November 1, 2019

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

Update on Risk of Type III Endoleaks with Use of Endologix AFX Endovascular AAA Graft Systems: FDA Safety Communication
October 28, 2019

FDA is evaluating new information about the risk of blood continuing to leak into the aneurysm (Type III endoleak) when Endologix AFX endovascular grafts (AFX with Strata, AFX with Duraply, or AFX2) are used for the treatment of abdominal aortic aneurysms (AAA). We've previously communicated about the greater risk of Type III endoleaks occurring with the Endologix AFX with Strata device compared to other endovascular graft systems, which can result in serious injury. It is important for patients and health care providers to be aware that data from an integrated healthcare system, published in a recent conference abstract, suggest there also may be a higher than expected risk of Type III endoleaks occurring with the use of AFX with Duraply and AFX2 endovascular grafts. FDA recommends lifelong follow-up for patients treated with any endovascular graft.

ICU Medical Issues a Voluntary Nationwide Recall of Certain Lots of Plum and Sapphire Microbore Infusion Sets with Inline Filters
October 8, 2019
ICU Medical, Inc. announced a voluntary recall on 29 July 2019 of certain lots of Plum and Sapphire Microbore Infusion Sets with inline filters due to the potential for small amounts of fluid leaking out of the air vents on the inline filters. To date, ICU Medical is not aware of adverse events related to this matter and is issuing this notification out of an abundance of caution.

Medtronic Recalls 6 French Sherpa NX Active Guide Catheters Due to Separation and Fragmentation Issue
October 8, 2019
Medtronic is recalling the 6 French Sherpa NX Active Guide Catheter due to a risk of the outer material separating from the device resulting in detached fragments that could result in the underlying stainless-steel braid wires being exposed. These fragments could be left inside the patient's bloodstream, and this or the attempts made to retrieve the fractured pieces, can cause other serious adverse health consequences such as continued blockage of blood vessels, injury to blood vessel walls, development of blood clots, embolism, heart attack or death. Medtronic received five customer complaints. No serious injuries or deaths were reported.

FDA has recently released the draft guidance, Breast Implants - Certain Labeling Recommendations to Improve Patient Communication. This draft guidance, when finalized, will provide manufacturers of breast implants with certain labeling recommendations to help ensure that patients receive and understand the benefits and risks of saline and silicone-gel filled breast implants, including the risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and systemic symptoms commonly referred to as breast implant illness (BII). Specifically, the draft guidance provides recommendations for the content and format of product labeling, including:

- Boxed warning;
- Patient decision checklist;
- Materials/device descriptions, including types and quantities of chemicals and heavy metals found in or released by breast implants;
- Silicone gel-filled breast implant rupture screening recommendations;
- Patient device card.

Another recommendation described in the draft guidance focuses on revising the rupture screening recommendations for patients with silicone gel-filled breast implants. Previously, the FDA recommended that labeling include the method(s) and frequency of screening for rupture, and current approved labeling recommends magnetic resonance imaging (MRI) screenings for patients beginning three years following implantation and every other year thereafter. The new recommendations issued in draft propose that patients without symptoms be screened using either ultrasound or MRI at five to six years following implantation and then every two years thereafter.

This draft guidance will be open for public comments through December 23, 2019, at www.regulations.gov under docket number FDA-2019-D-4467.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during October 2019. 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, Suction, Operating-room Brand: Presource Standard Thora Para Catheter Model#: 30-CE8SF Lot #: 474169 Cat #: 30-CE8SF	Cardinal Health 200, LLC	Sealed Thora Para Catheter drainage tray from cardinal Health had two empty lidocaine vials inside. Clearly visible that the tops of the glass vials had been opened and the vials were empty. No fluid inside vials or inside the tray. The clear plastic wrapper around the tray was sealed and intact. The vials were Lidocaine 1%, 5ml. The contents of the tray was not used on any patient. Tray was returned to central supply department for return to the manufacturer.

Device	Manufacturer	Problem
Automated External Defibrillators (Non-wearable) Brand: Onestep Adult Electrode Model#: 8900-0224-01 Other #: OneStep CPR Complete	Zoll Medical Corporation	There have been multiple complaints about OneStep Zoll pads failing self tests. After inspecting these pads, the packaging was very "distressed". As we found out, these pads are being folded, squished and otherwise manhandled before being shoved into Pyxis machine bins. There is a small gauge wire attached to each pad that is apparently very fragile and this bending/creasing and rough handling is fracturing these wires. In the best-case scenario, the wire is sufficiently severed that the defibrillator will fail the automated self-test and alert the user via bold messaging on the display and a red X on the ready for use (RFU) display. In the worst case, the wire fractures but will have enough contact to pass the self-test and appear to be good, up until when the pad is flexed such as when applying the pad to a patient, at which time the defibrillator will flash the message and audibly announce alarm "check pads" with a "poor connection" error message. Obviously, this would create a potentially disastrous delay in resuscitation efforts. A similar condition was noted on the second set of pads reported to have the same problem (although nowhere near as mangled). Additionally, we were able to create/duplicate this situation on a new set of pads. Pads have no warning not to bent it.
Catheter, Angioplasty, Peripheral, Transluminal Brand: Armada Model#: B1120-040 Lot #: 81023G1 Cat #: B1120-040	Abbott Vascular	Physician was advancing Armada 35 PTA Catheter 12 mm x 40 mm x 80 cm; inflated in the superior vena cava all the way out. In the superior vena cava and innominate vein; inflated to 16 atmospheres and then in the subclavian vein inflated to about 9 atmospheres. This showed a residual stenosis in the subclavian vein; right before the origin of the jugular vein as well as a severe stenosis in the innominate vein and right before it joined the left innominate. He advanced the Armada 35 PTA Catheter 12 mm x 40 mm x 80 cm; inflated this right at the tight stenosis in the innominate vein. He inflated this to 20 atmospheres for two minutes. The balloon burst. He removed the balloon, which was difficult because it stuck to the wire. He had to remove the sheath, most of the wire, and the balloon all together. He inspected the balloon and it had come out in its entirety. He cut the wire and placed a 6-French sheath back in place. He then exchanged this for a longer 6-French sheath. A venogram showed no extravasation, but there was still severe stenosis. He advanced an angle taper into the subclavian vein to the thoracic outlet and performed a venogram. This showed that there was residual stenosis in the innominate vein. He then removed the sheath and wire, and pressure was held for hemostasis. The patient was taken in good condition back to the intensive care unit. Per hospital, the manufacturer has requested the balloon.
Diathermy, Ultrasonic, For Use In Applying Therapeutic Deep Heat Brand: Solaris Plus D719 Model#: D719 Other #: 230626; 23805	Dynatronics, Corp.	Patient was on Electrical Stimulation (Interferential current (IFC)), set up was over right upper trapezius. Reports feeling a sudden surge of electricity which was painful and then a few seconds later felt a second stronger surge of electricity. Then reports feeling as if machine then died and no longer was putting out electricity. At that time he activated call button and the rehabilitation aide came over. Stated that the surges were painful but he was fine and not in pain, but wanted to alert us that he believed the machine to be malfunctioning. Patient was immediately removed from the machine.

Device	Manufacturer	Problem
Image-intensified Fluoroscopic X-ray System, Mobile Brand: O-arm Model#: BI70002000	Medtronic Navigation, Inc.	The BI-700-02000 model of the Medtronic O-Arm has been in use at this facility since March 2019, and is replacing another Medtronic unit. Employees are complaining about a significant difference in the amount of force needed to maneuver the O-Arm. This particular maneuvering action is what is called "jacking" or "lift and shift" in order to move the O-Arm laterally. After the O-Arm is "jacked up", the technologist has to lift the base by the handle to get the front wheels back on the ground in order to move it. This ends up causing a great amount of strain on the technologist's neck, shoulders, and/ or back. Facility Action: Contacted Medtronic and only given suggestions by Medtronic on how to properly use O-Arm and explanation given of "that's just how it is made." A video of the exact same model that's being used at another user facility was viewed. It appears this same move seems to require little effort in this video. Contacted an Ergonomic Specialist. Report follows: The Medtronic O-Arm has been in use at this facility since March 2019, and is replacing another Medtronic unit. Employees have noted a significant amount of force needed to maneuver the unit. The unit is placed into an alcove when not in use, and must be pushed laterally in order to put it into the alcove. In order for the unit to fit the O-Arm unit must be retracted fully into a C-position. This action takes away the forward counter weight, and results in the unit being loaded to the rear of the O-arm. The employee then must apply a pulling force, whilst pushing down on the back area to get it to move. The unit has an automated drive when moving forward, and with enough room present, can be manipulated into the correct space. Often, the employees note that there is not enough room in the OR to use this function and manual methods of moving must be implemented. When the arm is in the open position downward force must be applied on the handle while the employee must move the unit laterally. Up to 50 pounds of push force was needed to move the unit laterally. A downward force of up to 42 pounds was needed to counter the lack of weight on the front end between the O-Arm being closed or open. For comparison, the previous O-Arm required 14 to 18 pounds of force to move laterally with no downward force required. After the Ergonomist evaluated the equipment, his three recommendations were: 1. Counter Weight - Biomed tech to contact the Medtronic O-Arm representative to discuss our issues. One option that was discussed was to have a counter weight available to apply to the base of the unit near the front (which would eliminate the need to push down on the handle area) in order to aid in reducing the push force needed to move the unit manually. 2. Storage Space - The alcove area where the unit has been historically kept is a limiting factor. Identification of an area where the O-Arm can be closed and to not have to move the unit laterally in order to recharge and store is recommended. 3. Staff Orientation - Orientation of the OR staff to better understand the space requirements of the new O-Arm may be beneficial. This would especially apply to the OR technicians who set up the surgical suite and sterile field so that they understand the need for increased space for operation of the new O-Arm. A Biomed Tech did follow up with Medtronic field service engineer (FSE) regarding counter weight, and the FSE reported that the tipping is normal and they are safeguards so it doesn't tip and crush a user's foot. Biomed had this discussion with the FSE early on, and we had not had too much experience with the unit, yet. The Biomed Tech did add a 20 lb weight inside the front cover with no luck. The weight fit inside the cover, but was too large and would have been in the path of the extending assembly when moving the O-Arm out. The tech did place the weight at the end of the bottom frame and when he extended the O-Arm and jacked it up, 20 lbs was not enough to make a difference.

Device	Manufacturer	Problem
Introducer, Catheter Brand: Oscor Adelante Breezeway Delivery Sheath Model#: AB081045 Lot #: C1-16755 Cat #: AB081045	Oscor, Inc.	Manufacturing Defect – Internal dilator was too short for the sheath. Caused a stepdown from the opening in the sheath to the dilator that could have caused harm to the patient at the time of the procedure. Oscor Delivery Sheath was manufactured with a defect. Dilator that was paired with the sheath was too short for the sheath and is used in a patient may have caused vascular injury to the patient. Defect was discovered during prep of the device and never entered into the patient body.
Set, Tubing, Blood Model#: SL-2010M2096 Lot #: 90554009 Cat #: SL-2010M2096	NXSTAGE MEDICAL, INC.	During dialysis, when rinsing back, the arterial line would not secure to priming hub. It would not stay on or screw. It started to pull air into the line. Staff noticed this was occurring quite quickly and held it physically together so it wouldn't pull air into the system and cause air to enter into the dialysis tubing. Upon inspection the tubing didn't have the threads to secure it in place. Issue identified with more than one of these lines.
Tubes, Gastrointestinal (And Accessories) Brand: Corflo Nasogastric/ nasointestinal Feeding Tube/ with Stylet Model#: 20-9432 Cat #: 20-9432	Avanos Medical, Inc.	In the past several months there have been a total of 20 Haylard Corflo keofeeds inserted into a patient's lung. 16 of the 20 resulted in pneumothoraces with most requiring chest tube placement. 4 of the 20 were removed from the lung without evidence of a pneumothorax.
Uterine Manipulator, Single-use Brand: Advincula Delineator Uterine Manipulator Model#: AD750SC-KE40 Lot #: 269507 Other #: Delineator Uterine Manipulator	Cooper Surgical, Inc.	The equipment cup melted into the patient's vagina during routine use during a robotic hysterectomy. It melted during colpostomy using monopolar current at 30 watts.

Device	Manufacturer	Problem
Device 1: Surgeon's Gloves Brand: Medichoice Polyisoprene Micro Surgical Gloves Lot #: 1809054405 Cat #: 270-SPL Other #: size 71/2, 3oz	Ansell Healthcare Products, LLC	Our surgical departments switched to a new sterile glove earlier this year. We have had multiple reports where holes were found in the gloves right out of the package, easy tearing of the glove when being donned and the glove stretching out of shape after being worn for a period of time during a surgical case. Multiple lot numbers are involved. The manufacturer is aware and the sales representative have taken several packages of the defective gloves with them from our facility. All events occurred prior to procedures being started, no patient harm occurred.
Device 2: Surgeon's Gloves Brand: Medichoice Latex Micro Surgical Gloves Lot #: 1811031005 Cat #: 312-SPL Other #: Size 6, 2oz	Ansell Healthcare Products, LLC	
Device 3: Surgeon's Gloves Brand: Medichoice Polyisoprene Surgical Gloves Lot #: 1906470304 Cat #: 171-63005 Other #: size 7	Ansell Healthcare Products, LLC	
Device 4: Surgeon's Gloves Brand: Medichoice Polyisoprene Micro Surgical Gloves Lot #: 1807001905 Cat #: 183-SPL Other #: size 8, 3 oz	Ansell Healthcare Products, LLC	

Device	Manufacturer	Problem
System, Tomography, Computed, Emission Brand: Discovery Pet Ct Model#: 690 Other #: 202476D690 	GE Medical Systems, Inc.	A teenager was undergoing an outpatient gated-cardiac CT scan triggered by a power injection. The scan was completed in typical fashion; technologists completing every step of the setup and scan selection process in the usual way. No error messages were generated from the scanner during the setup and image acquisition. After the exam, the images acquired were ungated, had entire sections that were included in the planning, but missing from the image stack, and overall were non-diagnostic for the referring physician. The patient was exposed to meaningless radiation and contrast. The scan will need to be repeated. However, the scan could not be repeated at that time because the reasons for the malfunction of the CT scanner were unclear to the technologists and the supervising physician. Therefore, it was believed to have been unethical to administer more radiation and contrast without understanding why the malfunction occurred. GE service and application teams were contacted immediately with the patient on the table. In further investigation, it was found that the GE scanner was serviced two weeks prior to the scan. However, in completion of service, it did not have the necessary cardiac software reloaded and tested on the unit. This was due to an incomplete database belonging to GE called ELicense, in which all existing versions of software on imaging equipment are supposed to be stored. Due to the malfunction of the equipment, a second pediatric patient scheduled for a cardiac angiogram in preparation for open heart surgery the next day had to be rescheduled due to the CT scan being non-operational. This also resulted in the open-heart surgery being rescheduled as well. GE service engineers responded to the service order opened on the Discovery PET 690, and troubleshooting of the reported problem resulted in the reloading of the appropriate cardiac scan options. With the appropriate software loaded, the unit was tested successfully. Per manufacturer's response to the user facility, the device use was discontinued two days for software resolution for all cardiac angiograms using this piece of equipment. The software issue was corrected by GE and the correct software was reloaded to the unit. The canceled case was rescheduled for the following week. GE agreed to have resources available to ensure that the gated-cardiac angiogram ran successfully.

Device	Manufacturer	Problem
Ventilator, Continuous, Facility Use Brand: Hamilton -g5 Model#: G5		Ventilator started alarming red alarm Error message TF:5507 while in use. Although everything else seem to be functioning well, I decided to switch this ventilator and red tag it to ensure patient safety. This device was brought down by RT staff to RCS Biomed department on 09-21-2019 with a red tag that stated "TF 5507 alarm". This is a newly purchased device deployed for patient use about a month ago. Hamilton medical technical support was contacted. TF 5507 is a technical fault which relates to either a defective AIR MIXER VALVE or a DEFECTIVE PRESSURE SENSOR BOARD as per Hamilton medical G5 Service manual version en. 624093.06 and version en. 624093.07. There was no interruption in ventilation with this error code and the ventilator did not fail to deliver the ordered ventilation. There was no patient harm associated with this incident.
Catheter, Nephrostomy, General Plastic Surgery Brand: Gp General Purpose Drainage Catheter Model#: GPL2-1230H Lot #: 9E440 Cat #: GPL2-1230H	Uresil, LLC	The drain placed and hooked to JP bulb- bulb unable to hold air, disconnected and hub was cracked.
Device 1: Syringe, Irrigating (Non Dental) Brand: Nico Fluid System Model#: NN-8015 **Device 2: Syringe, Irrigating (Non Dental)** Brand: Nico Fluid System Model#: NN-8015	Nico Corporation Nico Corporation	After priming the fluid irrigation NICO system, several holes were discovered after water began to spray around the room soaking the surgeon scrub nurse and surgical field. After disposing of the FIRST disposable of this, a second one was opened up to the surgical field and this second one had holes in the fluid irrigation system spraying and soaking the surgeon scrub nurse and surgical field. This is a disposable that we have had for quite some time and use it a couple times a month at least. The scrub in the case has used this supply/disposable before and even after opening a second one it happened once again and saturated the field, surgeon and scrub.

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 November 2019 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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