MedSun
Medical Product Safety Network

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

April 2021

Volume 21, Issue 4

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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 April 5, 2021

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

Acellular Dermal Matrix (ADM) Products Used in Implant-Based Breast Reconstruction Differ in Complication Rates: FDA Safety Communication
March 31, 2021

FDA is informing patients, caregivers, and health care providers that certain acellular dermal matrix (ADM) products used in implant-based breast reconstruction may have a higher chance for complications or problems. There are several methods for reconstructing the breast following mastectomy (surgical removal of the breast). For patients who will have breast reconstruction using implants, the surgeon may use a breast implant alone, or both a breast implant and ADM. The FDA has not cleared or approved ADM or mesh for use in breast reconstruction. The FDA is informing health care providers and patients of our recent analysis, and requesting prompt reporting of adverse events to help us better understand the risks.

UPDATE: The FDA Reminds Patients and Health Care Providers of the Importance of At Least Yearly, Lifelong Follow-Up with Use of Endologix AFX Endovascular AAA Graft Systems: FDA Safety Communication
March 29, 2021
FDA is updating our October 28, 2019 safety communication on the use of AFX endovascular grafts with Duraply material (AFX with Duraply or AFX2) to provide new data, review current recommendations, and announce the FDA's intention to convene an Advisory Committee meeting in 2021. The FDA recommendations from our October 2019 safety communication have not changed. The FDA is reminding patients and health care providers of the importance of at least yearly, lifelong follow-up for all patients who have any type of Endologix AFX endovascular graft (AFX with Strata, AFX with Duraply, or AFX2) in order to monitor for Type III endoleaks. The FDA continues to evaluate new information which suggests the risk of Type III endoleaks occurring with the use of AFX endovascular grafts with Duraply graft material (AFX with Duraply or AFX2) may be higher than expected.

Medtronic Recalls Affinity Pixie™ Oxygenator and Cardiotomy/Venous Reservoir with Balance™ Biosurface for Possible High Levels of Endotoxins
March 24, 2021
Medtronic is recalling the specified device due to potentially elevated levels of harmful bacteria called endotoxins. The use of a device with high endotoxin level may result in fever, infection, acute systemic toxic reaction, or death. There have been no complaints, reports of injuries, or deaths related to this device issue.

Infections Associated with Reprocessed Urological Endoscopes - Letter to Health Care Providers

The U.S. Food and Drug Administration (FDA) wants to raise awareness among health care providers, including those working in reprocessing units in health care facilities, about the risk of infections associated with reprocessed urological endoscopes, including cystoscopes, ureteroscopes, and cystourethroscopes, used for viewing and accessing the urinary tract. The FDA has received numerous Medical Device Reports (MDRs) which describe patient infections post procedure or other possible contamination issues associated with reprocessing these devices.

The FDA is currently investigating the potential causes and contributing factors associated with the reported infections and contamination issues. While some reports indicate possible inadequate reprocessing or maintenance issues (for example, device failed leak testing) as a potential cause, the FDA is also evaluating other potential issues including reprocessing instructions in the labeling and device design. Although the FDA is early in our evaluation, based on the available data we believe the risk of infection is low. The FDA is emphasizing the importance of following the manufacturer's labeling and reprocessing instructions for these devices, including accessory components, for cleaning and subsequent processing to minimize the risk of infection.

The FDA recommends that health care providers:

- Carefully follow the reprocessing instructions described in the manufacturer's instructions for use.
- Do not use damaged devices or those that have failed a leak test, as they could be a potential source of contamination.
- Develop schedules for routine inspection and periodic maintenance in accordance with the manufacturer's instructions.
- Discuss the benefits and risks associated with procedures involving reprocessed urological endoscopes with your patients.

To read the full letter and all of FDA's recommendations for health care providers please visit FDA's website.

Are There "FDA Registered" or "FDA Certified" Medical Devices? How Do I Know What Is FDA Approved?

You may have seen words like this on a website selling a medical device in the United States, sometimes even with an FDA logo:

- FDA Registered
- FDA Certified
- FDA Registration Certificate

Such words may be used to mislead you. Is that the same thing as FDA approved, FDA cleared, or FDA authorized? The short answer is NO. Here's why.

FDA Registration:

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States are generally required to register annually with the FDA. It's important to understand, when a facility registers its establishment and lists its devices, the resulting entry in the FDA's registration and listing database does not denote approval, clearance, or authorization of that facility or its medical devices.

Are there FDA Certificates?

When a business involved in the production and distribution of medical devices intended for use in the United States registers with the FDA, they do not receive a certificate from the FDA. It's important to understand, the FDA does not issue any type of device registration certificates to medical device facilities. In addition, the FDA does not "certify" registration information for businesses that have registered and listed.

How Do You Know if the FDA Approved, Cleared, or Authorized a Medical Device?

The FDA provides several ways for you to check if the FDA approved or cleared a medical device or, as described below, if the FDA authorized the device to be used during a public health emergency.

Check for Approved and Cleared Products in the Devices@FDA Database: Devices@FDA is a catalog of approved and cleared medical device information from the FDA. To search for FDA-approved or FDA-cleared products by device name or company name: Go to the Devices@FDA Database. In the Enter a search term in the space below field, type the name of the device or the company name. You can type the exact name of a specific device or a generic name for a category of devices (such as pacemaker). Click Search. You can also check if a device has an Emergency Use Authorization (EUA) here. To read the full communication and to read all of FDA's information on this topic, please visit FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during March 2021. 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, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: BD Insyte-n Autoguard Model#: 381511 Lot #: 0195143, 0080379, 0119474 Cat #: 381511 	Becton Dickinson and Company	Multiple complaints from nursing staff of BD intravascular catheters splintering or splitting. Upon single attempt, the plastic sheath of catheter splinters when needle is re-introduced. On initial insertion, there have been complaints of needle not cannulating the skin/vein easily and resistance is met. IV infiltrates appear to be trending up. Below is some of the descriptions that have been shared: • The catheter is hard to cannulate the skin – "almost as the skin is tough and I know it is not" • "I meet resistance if I need to reintroduce the needle into the catheter" • "It doesn't seem to thread right" • "It doesn't feel right when I puncture the skin" • "When I pull it out the catheter is splintered or torn" (after IV attempt was unsuccessful)

Device	Manufacturer	Problem
Defibrillator, Automatic Implantable Cardioverter, W. Cardiac Resynchronization Brand: Acticor 7Hf-t Model#: 429523 Cat #: 429523	BIOTRONIK SE & Co. KG	BIOTRONIK SE & Co. KG Acticor 7 HF-T implantable cardioverter defibrillator (ICD) malfunctioned two days after being implanted on the patient. Patient experienced episodes of ventricular tachycardia (v-tach), and reported that the Acticor 7 HF-T ICD did not fire appropriately and failed to pace. Manual cardioversion was required due to the malfunctioning of the ICD. BIOTRONIK SE & Co. KG technical support was unable to interrogate or reprogram device. As a result, patient required a 2nd procedure to replace the malfunctional ICD pulse generator.
Lift, Patient Transfer Brand: Golvo Mobile Lift Model#: Golvo 8008	Hill-Rom Inc.	Patient fell / was dropped from mobile patient lift (Liko Golvo 8008). Quick investigation found that the clips on the ends of the slingbar were broken or taken off, which caused the patient sling to slip off the slingbar.
Device 1: Neurosurgical Paddie Brand: Codman Model#: 80-1400 Lot #: J8118Y Cat #: 801400 **Device 2: Neurosurgical Paddie** Brand: Codman Model#: 80-1400 Lot #: J8985X Cat #: 801400	CODMAN SHURTLEFF, INC. CODMAN SHURTLEFF, INC.	Mid case during a lumbar laminectomy, scrub noted half a string missing from a CODMAN Surgical Patty 1/2 Inch x 1/2 Inch (1.27cm x 1.27cm). Scrub immediately notified registered nurse (RN) and surgeon. Extensive search performed by several RNs, tech, and surgeon. CODMAN surgical patty (radiopaque part of cottonoid) was found with partial string attached. No intentional alterations performed to cottonoid. Cottonoid (CODMAN) patty was inside "working tube" while surgeon used Burr and Kerrisons. No flat plate performed after surgery because radiopaque part of patty (cotton part) was located and the non-radiopaque part (string) was the item missing.
Polymer Patient Examination Glove Brand: Queen Disposable Nitrile Gloves Other #: Ysxb No. 20200731	GUANGDONG JUNAN MEDICAL TECHNOLOGY CO.,LTD	The "Queen" brand of blue gloves are very poor quality. They stick to the glue on the EKG electrodes and makes it difficult to apply to the patient. This incident did not cause delay as she was brought in via EMS but the patient was in afib w/RVR and any delay in applying our tools to monitor the cardiac rhythm poses a higher risk of harm.

Device	Manufacturer	Problem
Port &Catheter, Implanted, Subcutaneous, Intravascular Brand: Power-port Lot #: REEV2356	Bard Access Systems, Inc.	Patient had RIJ (Right Internal Jugular) dual lumen power port implanted two months ago. Lot # REEV2356. Patient reports after recent CT scan she felt a pop and had issues using her port. Was booked for a port check. Physical exam demonstrated port raised on lateral lumen, patient stated this was a change from when it was placed.
Powered Laser Surgical Instrument Brand: Light-sheer Duet	Lumeinis LTD.	Patient arrived for laser hair reduction treatment for Brazilian area. Patient called approximately 3 hours later stating she had some tenderness on upper thighs and in the buttock region. When she examined area, there were small pink squares that were tender to touch. Discussed with patient whether or not she has been taking any medication, has any medical conditions, had previous sun exposure, tanning lotions on the area. Patient denied all. Offered patient to return to clinic for provider to examine and provide post care instructions. I asked if I could have a provider review the photos she sent and follow-up with her with more information. FNP advised for the client to take benedryl nightly and keep area moisturized and nothing else on the skin, as we do not want irritation. I recommended for the patient to ice off and on for comfort. Settings were appropriate for patient's skin type, and patient tolerated same settings used previously, as well as settings higher. Following patient encounter, I did talk with the Lumenis engineer, as a maintenance was scheduled to be completed. Engineer did confirm laser had caused the burn as there was not enough coolant in the laser and the suction/seal was not working properly during patient's treatment. There was no indication from the laser or the patient's tolerance of treatment that it was not working properly. Engineer stated the laser was causing superficial heat to target the skin. Laser maintenance and issue resolved. Patient informed 24 hours later the cause of the laser burn was due to the malfunction of the suction in the handpiece. Patient stated skin appeared the same although it did not hurt anymore. Patient instructed to continue keeping area moisturized and taking benedryl nightly until area is fully healed. Patient informed area is a mild superficial burn, similar to a sunburn. I informed patient I would follow-up with her to reassess healing process. Manufacturer response for LightSheer Duet Laser, Lumenis (per site reporter) Customer reported chill tip errors and issues with temp too high. Found coolant level to be extremely low and fans dusty. Thoroughly cleaned components and fan intakes. Filled unit to recommended level of coolant. Calibrated handpieces. Preventative maintenance performed per Lumenis specifications. Unit meets specifications and is within recommended tolerances. Unit tested and operational. Ready for customer utilization. Staff indicated no errors were present on the equipment to indicate a problem (E26, P3, P4, or P5--System temperature is to hot). OEM recommends room temperature be between 60F and 80F and cooling perforations not be obstructed. Also recommends inspecting umbilical for bends or kinks as this prevents proper exchange of cooling liquids. No bends or kinks visible in umbilical cords. Room temperature set at 78F. Requested FSE answer the questions: 1. Is there an alarm for low coolant levels the end user can see? 2. Was there any leaks found that would explain the low coolant level? 3. If no leaks could the temperature in the room cause the equipment to run hot? 4. Are there alarm logs stored on the equipment? If so did he see any alarms associated with cooling/overtemp failures.

Device	Manufacturer	Problem
Device 1: Shunt, Central Nervous System And Components Brand: Strata™ Model#: 42866 Lot #: 0220812938 Other #: LOG 1507121721 **Device 2: Shunt, Central Nervous System And Components** Brand: Strata™ Model#: 42866 Lot #: 0219000135 Other #: TAG ID # W004010000916844	MEDTRONIC PS MEDICAL, INC. MEDTRONIC PS MEDICAL, INC.	A Medtronic ventriculo-peritoneal (VP) shunt was implanted into a patient. Post-operatively it was radiographically recognized that the shunt had poor radio-opaque markings required to confirm its orientation after implantation and pressure settings. The lot number for this device is 0220812938 and the LOG number is 1507121721. In addition to this implanted device, another Medtronic Strata II valve shunt which was not implanted was found to have poor radiographic markings as well. The lot number for this defective device is 0219000135; the model number is 42866; the tag ID number is W004010000916844.
System, Surgical, Computer Controlled Instrument Brand: Sureform Model#: 480460 Lot #: K91201006 Cat #: 480460	Intuitive Surgical, Inc.	Stapler load of da Vinci Xi SureForm 60 blue stapler misfire on the gastric pouch during a robotic Roux-en-Y gastric bypass. An additional staple load was placed medially on the gastric pouch. Return to surgery was needed a few days after the original procedure due to abdominal pain and peritonitis.
Ventricular (Assist) Bypass Brand: Medtronic Hvad Pump Implant Kits Model#: HVAD-LVAD	Medtronic, Inc.	Heartware Left Ventricular Assist Device (LVAD) was implanted in spring of 2019. The patient was admitted almost a year later for a controller change with a LVAD pump involved in an urgent device communication from December 2020 with the potential (< 1% chance) to not restart with a controller exchange. The patient controller exchange occurred in the pre-operative area by the cardiovascular operating room (CVOR). The patient was prepped for emergency pump exchange in the event the LVAD didn't restart. The LVAD did not restart with controller exchange. Epinephrine (EPI gtt) started and patient was taken emergently to CVOR for a LVAD pump exchange. Patient did require additional surgery and remains hospitalized for rehabilitation, but did not suffer serious, long term injury.

Device	Manufacturer	Problem
Defibrillator, Automatic Implantable Cardioverter (Crt-d) Brand: Amplia Mri™ Quad Crt-d Surescan™ Model#: DTMB1QQ	Medtronic, Inc.	Patient's Implantable Cardioverter Defibrillator generator noted to suddenly lose output. Device was interrogated and was unable to be communicated. Emergent generator change procedure was performed while inpatient and device was returned to manufacturer who was able to confirm device performance malfunction consistent with current premature battery depletion advisory.
Needle, Hypodermic, Single Lumen Brand: Monoject Model#: 8881202017 Cat #: 8881202017	Cardinal Health, Inc.	Covidien Monoject substitute blunt needles- Ref 8881202017. RN called supervisor with complaints that new substitute needles were leaving tiny pieces of rubber in syringe. I examined the syringe and found a tiny piece of the rubber seal floating inside of the syringe. RN stated that she was double checking her medication when she noticed a small piece of the rubber seal floating in the medication. RN noticed that the substitute needles were flat not beveled, causing a punch out of the rubber seal each time they were used. stated that the punch out is logged into the needle and gets sucked into the syringe with the medication. If the rubber can get sucked thru the needle into the syringe, certainly the tiny piece of rubber can get injected thru an IV site in to the patient. RN immediately went to all floors, ER, ICU, CT, Pharmacy and advised the Supervisor to remove these substitute needles from their stock. RN advised staff to search for any place where blunt needles are used to make sure that none are missed. Advised to collect all the unused needles and the syringe with the rubber in it and keep in Supervisor office. Also went to stock room and spoke about not restocking this product. Was advised that there were no more needles like that, all of the supply they had was already distributed to the units. I advised him to inform next shift and all staff to not restock this item if any more were found. No harm to any patient.
Needle, Hypodermic, Single Lumen Brand: Monoject Model#: 8881202017 Cat #: 8881202017	Cardinal Health, Inc.	On the Med-Surg floor, a night shift nurse reported to the manager that the 18 gauge black blunt needles that were being supplied to draw up medications were faulty and actually allowed pieces of the medication vial rubber top to get into the syringe itself, causing a risk of embolus. The Supervisor was made aware of this (representing a 2nd incident of this occurring on a different campus at our affiliate). Pictures were taken which show an orange colored piece of the vial tip floating in the solutions within the syringe. No harm to any patient since it was noticed BEFORE the syringe was used.

Device	Manufacturer	Problem
Needle, Hypo-dermic, Single Lumen Brand: Monoject Model#: 8881202017 Cat #: 8881202017	Cardinal Health, Inc.	Elderly female was being treated for Chronic Obstructive Pulmonary Disease (COPD) on the inpatient medical floor. When the RN was drawing up Solu-medrol using a blunt needle (18 gauge, gray, Monojet), a piece of the rubber stopper was able to be drawn into the syringe. The Supervisor was notified. No harm to patient be-cause it was discovered by the nurse prior to administering the medication. (This is the 3rd reported event in the month of February at our affiliates. Each on a different campus).

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: https://medsun.fda.gov/
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 Ill 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 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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Food and Drug Administration
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