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 July 2, 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

Becton Dickinson & Company (BD) Recalls SmartSite Syringe Administration Set Due to Risk of Leaks

July 1, 2019

BD is recalling its SmartSite Syringe Administration Sets due to leaking of the sets which may result in under□infusion of critical medications, delay or interruption of infusions, contamination of the fluid paths and/or health care provider exposures to hazardous medications. Delayed infusion or under-infusion of life-sustaining medications could result in serious adverse health consequences, particularly for very low birth-weight babies (micro-preemies). Additionally, contamination of the fluid path could result in an increased risk of infection for patients.To date, BD has not received any reports of serious injury or death due to the malfunction of this device.

Edwards Lifesciences Recalls the IntraClude Intra-Aortic Occlusion Device Due to Risk of Balloon Rupture

July 1, 2019

Edwards LifeSciences is recalling the IntraClude Intra-Aortic Occlusion Device due to a risk of balloon rupture during use, which may add time to the procedure and compromises the safety of the patient. The IntraClude balloon bursting may cause serious adverse health consequences related to increased time the patient is on cardiopulmonary bypass, including neurological damage, embolism, stroke and death.

Certain Medtronic MiniMed Insulin Pumps Have Potential Cybersecurity Risks: FDA Safety Communication

June 27, 2019

The FDA is warning patients and health care providers that certain Medtronic MiniMed™ insulin pumps have potential cybersecurity risks. Patients with diabetes using these models should switch their insulin pump to models that are better equipped to protect against these potential risks. Check to see if the model and software version of your insulin pump is affected. Read the Medtronic Patient Letter to learn how to identify your pump's software version. If you live outside the United States, Medtronic will send you a notification letter with instructions based on the country where you live. Talk to your health care provider about a prescription to switch to a model with more cybersecurity protection.

Artificial Intelligence and Machine Learning in Software as a Medical Device

The FDA is considering a total product lifecycle-based regulatory framework for these technologies that would allow for modifications to be made from real-world learning and adaptation, while still ensuring that the safety and effectiveness of the software as a medical device is maintained. The FDA's traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies. Under the FDA's current approach to software modifications, the FDA anticipates that many of these artificial intelligence and machine learning-driven software changes to a device may need a premarket review.

On April 2, 2019, the FDA published a discussion paper "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback" that describes the FDA's foundation for a potential approach to premarket review for artificial intelligence and machine learning-driven software modifications. The ideas described in the discussion paper leverage practices from our current premarket programs and rely on IMDRF's risk categorization principles, the FDA's benefit-risk framework, risk management principles described in the software modifications guidance, and the organization-based total product lifecycle approach (also envisioned in the Digital Health Software Precertification (Pre-Cert) Program).

In this framework, the FDA introduces a "predetermined change control plan" in premarket submissions. This plan would include the types of anticipated modifications—referred to as the "Software as a Medical Device Pre-Specifications"—and the associated methodology being used to implement those changes in a controlled manner that manages risks to patients —referred to as the "Algorithm Change Protocol." In this approach, the FDA would expect a commitment from manufacturers on transparency and real-world performance monitoring for artificial intelligence and machine learning-based software as a medical device, as well as periodic updates to the FDA on what changes were implemented as part of the approved pre-specifications and the algorithm change protocol. The proposed regulatory framework could enable the FDA and manufacturers to evaluate and monitor a software product from its premarket development to postmarket performance. This potential framework allows for the FDA's regulatory oversight to embrace the iterative improvement power of artificial intelligence and machine learning-based software as a medical device, while assuring patient safety

For more information and to read other resources on this topic please **click here**.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during June 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
Biliary Catheter, Drainage Brand: Exodus Biliary Drainage Catheter Model#: M001465231 Lot #: 23213365	AngioDynamics, Inc.	Patient was undergoing routine biliary catheter exchange. When the existing drain (initially placed approximately three months ago) was wired during the procedure, the pigtail portion of the catheter broke off in the small bowel. External portion of catheter was removed and new catheter placed. No apparent harm to patient.

Device	Manufacturer	Problem
Transfer, Patient, Manual Brand: Comfort Glide Lt Sheet Model#: MSC600LT Lot #: 29819010003 Cat #: MSC600LT	Medline Industries, Inc.	Patient was being repositioned in ICCU bed when the handle ripped off of the inflatable mattress. Mattress was immediately deflated to avoid potential patient injury. Per RN "this has happened to us five times now". Other problems reported: 1. During inflation, patient's spine does not remain in neutral posture on the Comfort Glide Air LT. In some instances, cervical extension past neutral occurred during inflation phase (when the body elevates with the head lagging behind, this simulates the feeling of falling). With most body types, volunteers' posture became more flexed during inflation and while inflated, with the pelvis being the lowest part of their body. Reports have been received that the mat does not inflate evenly on narrow surfaces, and rocks the patient in a vulnerable position. 2. Medline Comfort Glide Air LT has a slippery underside. Medline rep reported that the mat features a 30% assist when mat is not inflated, serving the caregiver even if the power is not turned on during a lateral transfer. While volunteers sat on the Comfort Glide at the edge of the bed (after transfer was completed), many were observed slipping down off the edge. The slippery nature of the LT mat may be a safety hazard when patients are transferred to narrow surfaces (i.e. OR/procedure tables, CT surface, gurneys), propped in sitting (i.e. cardiac chairs), or when transferring to sitting at the edge of the bed (should be removed before ICU mobility). Sitting on a reduced friction transfer surface at the edge of an ICU bed will accelerate a fall. Further research is needed to determine if either mat would cause a patient to slip down/off a cardiac chair. 3. The technique trained to move the mat requires pulling from an outstretched position. The Comfort Glide LT offers 75% assistance w/lateral transfer, but the side collapses when the caregiver tries to push the mat and it doesn't move well. The caregiver on the receiving side needs to bend over the transfer surface to reach for the handles and pull from this outstretched position. Pushing is less effective in moving the Medline product and results in more pulling. Pelvic contact with the transfer surface is suspected of contributing to this lag. 4. The Medline Comfort Glide Air LT commonly gets stuck in the gap between surfaces. It occurred several times during product testing, and has since been reported commonly with transfers that do not meet closely (i.e. bed – gurney). In order to free the mat, extra pulling force is required. 5.The Medline Comfort Glide LT showed artifact in some Xray exams. No radiological evidence was provided to prove absence of artifact, so independent testing was initiated. Initially, Medline's mat showed a great deal of interference, producing a gray cast over the image, and significantly reducing contrast. Upon further testing, it was found that it was due to the hygiene sheet, and not the mat. This will prevent the hygiene sheet from being present when patients are in an X-ray exam. The use of different scanning techniques revealed differences in the Medline mat's images. The Medline mat's seams were present using the "hand" technique in 2 departments, and present using the "chest" technique in 1 department (but not the other). The seams were not present using the 3rd technique. 6. Pulling forces used to move a 280lb volunteer on the Medline mat were significantly greater than those needed to move the same volunteer on two other competitor's products.

Device	Manufacturer	Problem
Gas-machine, Anesthesia Brand: Ge Advance Cs2 Model#: CS2 Other #: G1500213	GE Healthcare, Inc.	During surgery, the anesthesia machine shutdown unexpectedly. The anesthesia group quickly had the patient ventilating with an ambu bag and oxygen tank. Hooked patient up to transport monitor for vitals. Machine swapped out to a different anesthesia machine that was working appropriately. Approximately 25 minutes all together. Patient remained stable with vitals never changing.
Hot Pack Brand: Accutherm Hot Pack Lot #: CN19080	Medline Industries, Inc.	Patient requested hot pack and Accu-Therm hot pack provided. Staff was going to activate pack, but patient stated she would do it. Upon patient squeezing the pack, it busted open spilling contents on patient's hands. Patient sustained redness and pain to hands as a result.
Implant, Intragastric For Morbid Obesity Brand: Orbera Intragastric Balloon	Apollo Endosurgery, Inc.	Orbera balloon was removed from pt just short of the 6 month intended duration due to episodes of vomiting. Removal was initiated the request by the patient to have it removed. There was 580ml of fluid was removed from the balloon. The rep that was on site during the procedure said that the balloon looked bigger than usual.
Prosthesis, Hip, Femoral Component, Cemented, Metal Brand: R3 Variable Angle Drill Guide Model#: 7136-4477 Cat #: 7136-4477 Other #: instrument part number: 08HMO3487	Smith and Nephew, Inc.	Cannot disassemble this instrument and unable to adequately clean for use despite following the instructions for use (IFU). Bioburden present with first and the replacement after cleaning but not after second replacement. Did not reach pt so no harm.

Device	Manufacturer	Problem
Device 1: Pump, Infusion Brand: Alaris Pump Module Model#: 8100Lot #: 10720782 **Device 2: Pump, Infusion** Brand: Alaris Model 8100 Model#: 8100 Lot #: 10720547	Carefusion 303, Inc. Carefusion 303, Inc.	Pt receiving Injectafer 750mg. Medication given within appropriate time frame however the Pump continued to pump the remaining medication in tube even when air had passed beyond the pump air sensor. No harm to patient as pumped was stopped by RN before any air delivered to patient. Pump brain #10720782, pump #10720547.
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 2426-0500 Cat #: 2426-0500	Carefusion 303, Inc.	IV tubing snapped at the most distal port site. This has been frequently occurring. Unfortunately, the packaging is discarded before the failure occurs, so lot information has not been recorded.
System, Thermal Regulating Brand: Blanketrol® LII Model#: 233 Cat #: 86107	Cincinatti Sub-Zero Products, Inc.	Blanketrol III found to be leaking current. Medical Engineering reported three Blanketrols having a problem with the current leakage to ground. When the Blanketrols are first turned on, the current leakage is about 18-19 milliamps. When a relay in the Blanketrol closes, the current leakage jumps to about 50 milli-amps, setting off the alarms in the intensive care units with isolated ground (power). After the Blanketrols are running, the current leakage to ground sometimes exceeds the limit of the tester. Medical Engineering believes the spike in the current leakage to ground is what sets the alarms off, even though it is within the acceptable limits.
Electrosurgical, Cutting Coagulation Accessories Brand: Vasoview Hemopro Model#: VH-3000 Lot #: 25145463 Cat #: VH-3000	Maquet Cardiovascular, LLC	Vasoview Hemopro Endoscopic Vessel Harvesting System Harvesting Tool tip broke off during vein harvesting in the left leg. The physician's assistant searched with a scope to find the pieces. Five pieces were found but we believe there may be retained fragments in the patient's leg.

Device	Manufacturer	Problem
Unit, Electrosurgical, Endoscopic (With Or Without Accessories) Brand: Redfield Irc 2100 Infrared Coagulator Model#: IRC-HS1 Lot #: Cat #: IRC 2100	CooperSurgical, Inc.	Device IFU conflicts with manufacturer's instructions and best practices for disinfection. Concern for potential infection transmission in patients. A physician who practices at our healthcare facility has indicated he/she will begin to use the IRC 2100 Coagulator manufactured by Redfield Coporation. The manufacturer's website is www.redfieldcorp.com and is advertised for use in multiple healthcare settings. The IRC 2100 is a device that comes into contact with mucous membranes (anus) and would be considered a semi-critical instrument, requiring high level disinfection (HLD). The product's instructions for use (IFU) state a number of disinfectants are acceptable to use such as Cidex, Methracide, etc.--all of these are high level disinfectants. However, the IFU further states that the device cannot be washed, soaked or rinsed, and directs the users to wipe clean with the HLDs above. In following this IFU, it directly conflicts with manufacturer IFUs of disinfectants which work by soaking for a certain amount of time, temperature, etc. This appears to be a recognized problem, and Dr. William Rutala acknowledged this in a study he published in 2012 where he developed a different cleaning method for this device. The Redfield 2100 IFUs are not consistent with the Spaulding scale. If this method has indeed been validated, the company should update their IFU manual to reflect this. Because we have no other option available, we are adopting the Rutala method/procedure in the interim.
Pump, Infusion, Enteral Brand: Kangaroo Epump Enplus Spike With Flush Bag Model#: 775100 Lot #: 190250079 Cat #: 775100	Cardinal Health, LLC	During assessment of an enteral feeding line the clinician noted leaking of feeding solution from the safety spiked section of the tubing where the spike connected with the feeding bag. Leaking was noted from the section where the clear tubing connects to the safety spike barb. Feeding set replaced with new feeding circuit and flush bag. Package inset sent to Biomedical for reporting and evaluation. This is an on-going issue with these feeding sets developing leaks at the safety spike and tubing interface. Biomedical noted that this is a different lot number than the previous reported events.
Sterilization Wrap Containers, Trays, Cassettes &Other Accessories Brand: One Tray	Innovative Sterilization Technologies, LLC	The OR department has been experiencing issues involving the One Trays. The trays have been flaking off and divots from the silicone seal around the bracket which holds the filter in place during the sterilization process. There is also noted rust starting to appear on the bottom of the trays prior to use. These trays are newly purchased and have never been used. The OR team opened an entire container of the One Trays and noted all of them were compromised with rust and/or failure of the silicone seal. We have had a water-soluble test completed with results pending. The manufacturer is unsure what is causing the discoloration. Our OR team did provide one of these trays to a local rep with no information as to their internal evaluation. The rep did bring a new tray, but it also showed signs of discoloration. No patients have been harmed from these

Device	Manufacturer	Problem
Device 1: Orthopedic Stereotaxic Instrument Brand: Pin Perc Reference Model#: 9733235 Lot #: 2018090333 **Device 2: Orthopedic Stereotaxic Instrument** Brand: Pin Perc Reference Model#: 9733235 Lot #: 2018090333	Medtronic Navigation, Inc.	Surgeon performing spinal surgery. Stated that when he tried to put pins in array they would not fit. Opened another package and these also had issues with fit but he was able to get them in but he stated they were really tight.

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 July 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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