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 29, 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

Class I Recall: Ellume Recalls COVID-19 Home Test for Potential False Positive SARS-CoV-2 Test Results

November 10, 2021

Ellume is recalling certain lots of the COVID-19 Home Test because they have higher-than-acceptable false positive test results for SARS-CoV-2. The reliability of negative test results is not affected. For these tests, a false positive test result shows that a person has the virus when they do not have it and could lead to:

- Delayed diagnosis or treatment for the actual cause of the person's illness, which could be another life-threatening disease that is not COVID-19.
- Further spread of the SARS-CoV-2 virus when presumed positive people are grouped into cohorts (that is, they are housed together) based on false test results.
- The person receiving unnecessary COVID-19 treatment from a health care provider, such as antiviral treatment, convalescent plasma, or monoclonal antibody treatment, which can result in side effects.
- Disregard for the recommended precautions against COVID-19, including vaccination.
- Isolation, including monitoring household or close contacts for symptoms, limiting contact with family or friends, and missing school or work.

There have been 35 reports of false positive results sent to the FDA and no deaths reported.

Class I Recall: Datascope/Getinge/Maquet Recalls Cardiosave Hybrid/Rescue Intra-Aortic Balloon Pump Battery Packs Due to Risk of Battery Failure

October 29, 2021

Datascope/Getinge/Maquet is recalling this product due to the risk of the battery failing and having a shortened run-time due to substandard batteries not meeting performance specifications being released to customers, which may cause the device to stop working when operated by battery only.

The firm has received 3 global complaints related to the issue. An incorrect trajectory could result in serious injury or death if undetected during surgery.

Datascope/Getting/Maquet reports receiving six complaints, and no reports of injuries or deaths related to this issue. However, there is a potential for underreporting since the end user reporting a failed battery or short battery-run time cannot be aware that they originally received a substandard battery.

Leadless Pacing Systems: Risk of Major Complications Related to Cardiac Perforation During Implantation – Letter to Healthcare Providers

The FDA is reminding providers about the risk of major complications if cardiac perforation occurs during leadless pacemaker implantation. Cardiac perforation is a rare complication of any pacemaker system implant. Cardiac perforation can lead to major complications or even death.

The overall risk of cardiac perforation associated with leadless pacemaker implantation appears similar to the risk associated with traditional transvenous pacing systems. However, the Medtronic Micra leadless pacemaker premarket clinical studies suggested major complications related to cardiac perforation appeared to be more severe for patients who received a leadless pacing system compared to patients who received a transvenous pacemaker. The FDA continues to evaluate outcomes in patients who receive leadless pacing systems. Information from real-world use suggests that cardiac perforations associated with Micra leadless pacemakers are more likely to be associated with serious complications, such as cardiac tamponade or death, than with traditional pacemakers.

The FDA is bringing this information to your attention as a reminder and to encourage you to report leadless pacemaker cardiac perforations and complications related to perforation to the manufacturer and the FDA. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. The FDA is working with the manufacturer to evaluate information from all available sources, including post-market studies and real-world data, to provide additional information on this issue.

Recommendations for Health Care Providers

- Discuss the risks and benefits of available pacemaker system options with patients as part of shared clinical decision-making.
- The benefit-risk profile of leadless pacing systems compared to transvenous systems or alternative treatment options should be considered for each patient.
- Be aware that although cardiac perforation is a rare complication following pacemaker system implant procedures, the risk of major complications following cardiac perforation may be higher in patients who receive leadless pacing systems vs. traditional transvenous pacemakers.
- Implanting physicians should be prepared to emergently manage patients experiencing perforation during leadless pacemaker implantation. In some cases, urgent cardiac surgical intervention may be necessary.
- Read and carefully follow the Instructions for Use and training for the Medtronic leadless Micra Transcatheter Pacing System.
- Report any adverse events or suspected adverse events experienced with the Micra Transcatheter Pacing System or other pacemaker systems.

To read the full letter, please visit FDA's website.

November 2-3, 2021: Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting

The Circulatory System Devices Panel of the Medical Device Advisory Committee met on November 2, 2021 to discuss and make recommendations on the benefit-risk profile of the Endologix AFX endovascular graft system with regards to the risk of Type III endoleaks. The FDA also requested panel input on the totality of data on AFX devices and whether further actions are necessary.

QUESTION #1. Totality of Data - Considering the totality of the available information, please discuss the Type III endoleak concern associated with the AFX family of devices, focusing on the currently available AFX product (AFX2):

A. Please discuss the strength of the evidence that the AFX family of devices (and the AFX2 device in particular) is associated with a clinically meaningful increased rate of Type III endoleaks (all Type III endoleaks and Types IIIa and IIIb).

   Panel Consensus: The data show a clinically meaningful increased risk of Type III endoleaks associated with the AFX with Strata device. For the AFX2 device, data were insufficient to show that the Type III endoleak risk has been adequately addressed.

B. Please discuss the effectiveness of the sponsor's mitigation strategies (including device design/manufacturing changes and updated instructions for use) to lower the Type III endoleak risk.

   Panel Consensus: The sponsor's mitigation strategies, including labeling updates, did not adequately lower the Type III endoleak risk and failed to identify patients at increased risk.

C. Considering your responses to Questions 1A and 1B, please discuss additional strategies (such as such as instructions for use or other labeling changes) that could prevent, mitigate, or treat Type III endoleaks that may be associated with the AFX family of devices, particularly the AFX2 device.

   Panel Consensus: Patients should be informed of the Type III endoleak risk and the importance of annual follow-up. A shared decision-making process should be included in treatment decisions regarding the AFX2 device.

To read all of the questions to and recommendations from the panel, please visit FDA's website.

HIGHLIGHTED REPORTS

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

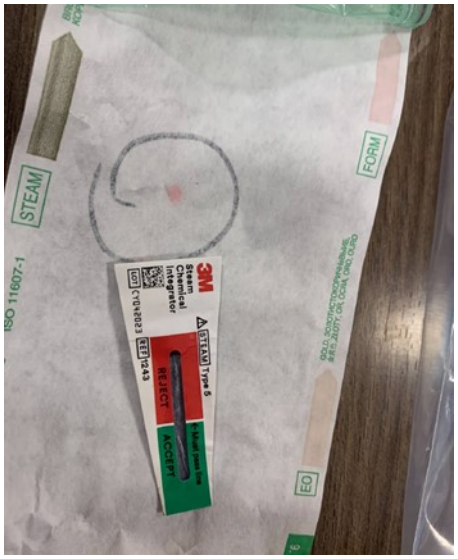
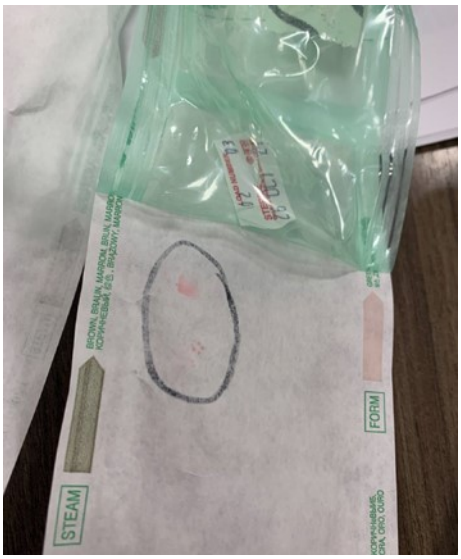
The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years 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
Dialyzer, High Permeability With Or Without Sealed Dialysate System Brand: Tablo Hemodialysis System Model#: PN-0006000 Cat #: PN-0006000	Outset Medical, Inc.	Home dialysis patient dialyzing in-center on a trial basis with a new home dialysis machine. The last 10 minutes of therapy, dialysis machine alarmed due to hypotension. RN went to check on the patient. He was unresponsive to verbal touch. 100-200 ml of blood noted on floor. There appeared to be a leak at the junction of the arterial line and the dialyzer. There had not been a leak during the priming. Patient was placed in Trendelenburg, blood returned to patient and 300 ml saline bolus was given. Code team was called and patient was transported to the emergency department by emergency medical services. Electrolytes were normal. Hemoglobin was down to 9.4 mg/dl, from > 10 mg/dl earlier that month. He was kept overnight and discharged the next day. The company is investigating the defect.
Needle, Catheter Brand: Yueh Centesis Disposable Catheter Needle Model#: G09489 Lot #: 14083164 Cat #: DTVN-5.0-19-7.0-YUEH	Cook, Inc.	Patient undergoing image-guided paracentesis. The disposable centesis catheter needle that was placed in the patient came apart. The hub broke off from the catheter and needed to be removed and replaced with a new one. The second was successfully placed with no immediate complications to the patient. Ascities drained. The broken centesis catheter and packaging was saved and will be returned to the representative.

Device	Manufacturer	Problem
Ventilator, Continuous, Facility Use Device #1 Brand: Astral 150 Ventilator Model#: 150 Cat #: 27003 Device #2 Brand: Astral 150 Ventilator Model#: 150 Cat #: 27003 	Resmed Pty Ltd	The ventilator we chose to evaluate was the Resmed Astral. After initial evaluation and department education, we began trialing the ventilator on two of our pediatric patients. We discovered circuit configuration for these pediatric patients required the use of a dual limb circuit to obtain flow triggering. The single-limb set up on the Astral ventilator will not allow for flow triggering. In a dual-limb circuit configuration, this requires the use of an "exhale block". Exhaled flow returns to the expiratory block, then past the expiratory flow sensor chip. The circuit required heated humidification, set temperature at 37 degrees Celsius per department policy. On multiple occasions, water rain-out at the expiratory block led to the expiratory flow sensor chip failing due to excessive moisture. This caused the ventilator to malfunction. During this event the ventilator read no minute ventilation and high respiratory rate. The patient decompensated. This required replacing the expiratory flow sensor chip and exhalation block. This also required interruption of mechanical ventilator to remedy the issue. When the expiratory chip was replaced it only temporarily fixed the problem. On two separate occasions, the patient was placed on a different mechanical ventilator because of Astral ventilator malfunction. To date, our team has replaced a total of 12 expiratory flow sensor chips. We contacted Resmed for direction on how to remedy this issue. Their recommendations were as follows: place a water trap and hydrophobic filter proximal to the expiratory block, decrease the humidifier temperature. We followed Resmed's recommendations. This did not solve the problem. The ventilator did alarm low minute ventilation and high respiratory rate, but did not give any indication that the chip was wet and the ventilator was malfunctioning. Patient #1 Went home with the Astral vent and that night she became limp and blue while on the ventilator. Parents decannulated the patient and began resuscitative measures. She was brought back to the hospital from an outside facility on a different vent. Two days later, we switched her back to the home Astral vent and that continued to work well until eight days later when respiratory noted. Patient remains trached with 4.5 Peds Bivona Flex x52mm. Cuff is typically deflated, however last night her cuff had to be inflated to minimal seal to get her home ventilator to stop alarming circuit disconnect. She has 2 home ventilators, one for transport and one for stationary use. Her vent for stationary use is currently not working properly due to possible water in the circuit board. Her transport vent was used over night. Four days later, the patient was switched to another manufacturer's ventilator due to concerns for the Astral vent malfunctions. Patient #2 Respiratory was paged to patient's bedside due to respiratory distress. Patient had severe retractions and was diaphoretic. Respiratory found patient's Astral filter saturated with water, and water reached the ventilator. Patient was hand-ventilated and a sensor was changed on the Astral. Respiratory attempted to recalibrate the circuit, but it failed. Additional respiratory therapy support was present to help troubleshoot patient's Astral. Patient was switched to another manufacturer's ventilator at this time. Patient's ventilator settings were discussed with provider.

Device	Manufacturer	Problem
Circuit, Breathing (w/ Connector, Adaptor, Y-Piece) Brand: Universal F2 Anesthesia Breathing Circuit Model#: LC395-6121Z Lot #: 100057004 Cat #: LC395-6121Z	King Systems Corp.	Elbow gas sampling port on the King/Ambu universal breathing circuit came loose after 4-hour procedure and we were unable to re-seat the cap. Previously, this was a luer-lock cap, but it has recently changed by the manufacturer to be a push-on cap.
System, Balloon, Intra-aortic And Control Device #1: Brand: Cardiosave Hybrid, Type BPlug Model#: 0998-00-0800-53 Lot #: 3000141070 Cat #: 0998-00-0800-53 Device #2: Brand: Sensation Plus 8fr. 50cc Intra-aortic Balloon With Accessories Lot #: 3000141070 Other #: 14000635	Datascope Corp.	Registered nurse noted intra-aortic balloon pump was not augmenting or filling appropriately, contacted nurse practitioner from cardiovascular Intensive Care Unit who confirmed finding at bedside. Upon inspection of tubing, found blood indicating balloon rupture. Pressor requirements quickly escalated with mean arterial pressure 40-50 eventually requiring norepinephrine, neosynephrine and epinephrine. Additional providers notified and cardiologist, fellow and cardiovascular intensivist came to bedside to exchange balloon and pump. Patient experienced oxygen desaturation during procedure and disorientation requiring intubation and ventricular tachycardia requiring cardioversion that return to rhythm; however patient was pulseless electrical activity as there was no palpable pulse. Cardiopulmonary resuscitation began, CODE team called and return of spontaneous circulation achieved. Unfortunately balloon was not saved; however pump and tubing connected to balloon were and turned over to biomed.
Catheter, Coude Brand: Surestep Foley Tray System Bard Lubricath Foley	C. R. Bard, Inc.	Situation resulted in patient requiring surgical airway due to allergic reaction. A recent safety event in our health system has highlighted the risk of using latex urinary catheters in patients with latex allergies.

Device	Manufacturer	Problem
Model#: A800365 Cat #: A800365		Background: Our hospital is not a latex-free organization. Vigilance is required when checking patient records for latex allergies and ensuring all equipment and supplies are latex free as latex allergies can be serious and life threatening. Assessment: Bard SureStep Foley Catheter trays Contain latex. Upon review of our current materials, it is apparent that labeling of Foley kits and individual catheters, with respect to latex-status has not been as effective as we had wished. The latex caution label is not easily visible, and it can be difficult to tell the difference between latex and latex-free kits. Individual urinary catheter items may also contain latex.
Drape, Surgical Brand: Deroyal Model#: 63-101 Lot #: 10210526	Deroyal Industries, Inc.	The linting from the blue towels is possibly leading to increased risk of surgical site infections. The contact person at the company said the process and/or blue towels are the same.
Laparoscope, General Plastic Surgery Brand: Versaone Model#: NON-B12STF Lot #: J1D2884Y Cat #: NON-B12STF	Covidien LP	The patient underwent laparoscopic appendectomy for perforated acute appendicitis. When the surgeon advanced the trocar through the peritoneum, a loud crunching sound was heard. The trocar was inspected, and found to be in good position; however, there were small blue flecks of plastic embedded in the peritoneum. The trocar was withdrawn, further inspected, and noted to have linear defects on both sides of the trocar tip where some of the plastic appeared to be shorn off. The operation proceeded and prior to closure, a variety of techniques were utilized to remove the plastic pieces. Approximately half of the plastic pieces were able to be removed.
Indicator, Physical/ chemical Sterilization Process Brand: Comply Sterigage Model#: 1243A, 1243B, 1243RE	3M Company	Upon steam sterilization of surgical instruments, the 3M chemical integrator (product numbers 1243A, 1243B, 1243RE) did not maintain integrity of the packaging, resulting in red dye staining surgical instruments during sterilization. Manufacturer instructions and sterilization parameters were followed. Twenty-five lots have been reported at 6 separate facilities within the health care system. The dye staining presents a risk of introducing foreign substances into the sterile field and/or body during surgical procedures if unnoticed. Dye staining also introduced a delay in care if alternative instruments need to be found or sterilized. The manufacturer was contacted and determined not to issue a product recall but agreed to replace defective product when identified.

Device	Manufacturer	Problem
		 

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:
https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/medical-device-connectors
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 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 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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