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 October 1, 2020

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

Recommendations About the Use of Dental Amalgam in Certain High-Risk Populations: FDA Safety Communication

September 24, 2020

The U.S. Food and Drug Administration (FDA) is providing recommendations about the use of dental amalgam in certain groups of people who may be at greater risk to the potential adverse health effects of mercury exposure. The FDA does not recommend anyone remove or replace existing amalgam fillings in good condition unless it is considered medically necessary by a health care professional (for example, a documented hypersensitivity to the amalgam material).

Becton Dickinson (BD) CareFusion 303 Inc. Recalls Alaris Syringe and Alaris PCA Modules Due to Potential Incorrect Display of Syringe Types and/or Sizes

September 16, 2020

BD/Carefusion 303 is recalling the Alaris™ Syringe Module and Alaris™ PCA Module because the Alaris PC units may display the incorrect syringe types and/or sizes. This could potentially result in delays in infusion, under-infusion, or over-infusion. If this occurs, this could lead to serious adverse events, including death. There have been no reported injuries or deaths.

FDA Reminds Users about the Importance of Following Instructions for the Cold-Therapy Mode of Water-Circulating Hot/Cold Therapy Devices: FDA Safety Communication

September 9, 2020

FDA wants patients and health care providers to know about the risk of injury that may happen to patients if the cold-therapy mode of water-circulating hot/cold therapy devices is not used correctly. Patients who use these devices may get injuries from the cold, such as temporary (transient) numbness or discoloration, or frostbite and cell death (necrosis), which may require skin grafts, muscle/skin flap reconstruction, or amputation. The FDA issued this safety communication to help remind health care providers and patients of important instructions for use, warnings, and precautions.

FDA Letter to Health Care Providers - Potential Risk of Infection during Cardiac Surgery When Using the CardioQuip Modular Cooler-Heater Device

FDA continues to monitor the risk of Nontuberculous mycobacteria (NTM) infections in patients who have undergone cardiothoracic surgery using heater-cooler devices, and to collaborate with stakeholders including public health partners, manufacturers, and experts to evaluate additional strategies to reduce the risk of infection from using these devices during cardiac surgery.

This letter provides new information from FDA's ongoing evaluation. We have recently become aware of three U.S. patients from one facility who were infected with Mycobacterium abscessus (a type of NTM) after undergoing cardiothoracic surgery involving the use of a CardioQuip Modular Cooler-Heater (MCH). Previously, the FDA had not received reports of NTM patient infection or NTM device contamination with use of the CardioQuip MCH device. At this time, the root cause of NTM patient infection and device contamination with use of this device is not known.

Health care providers and staff should review FDA's current recommendations for the use of any heater-cooler device to help reduce the risk of NTM infections in patients when using these devices during cardiothoracic surgeries:

- Be aware that heater-cooler devices are important in patient care. In appropriately selected patients, the benefits of temperature control during open chest cardiothoracic procedures generally outweigh the risk of infection transmission associated with the use of these devices.

- Strictly adhere to the cleaning and disinfection instructions provided in the manufacturer's heater-cooler device labeling. Ensure you have the most current version of the manufacturer's instructions for use readily available for staff who interact with these devices.

- DO NOT use tap water to rinse, fill, refill, or top-off heater-cooler water tanks since this may introduce NTM organisms. Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. When making ice needed for use in the heater-cooler, use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. Deionized water and reverse osmosis-treated water are not recommended because they may promote corrosion of the metal components of the system.

The complete letter to health care providers and recommendations can be found on FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during September 2020. 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
Automated External Defibrillators (Non-wearable) Brand: Pacer Pads Cat #: R2018-33 Other #: 195091074	Zoll Medical Corporation	Patient arrived to emergency department (ED) via EMS with external transcutaneous pacing in progress. Patient appears to have been paced x12 hours. Upon removal of pacer pads, 4 small burns were noted on the upper chest on the skin where the anterior pacer pad had been placed. No burns noted on patient's back where posterior pad had been in place. No concerns or issues reported by EMS with the defibrillator/pacing device. No concerns or issues reported by ED with the Zoll defibrillator/pacing device. This reporter is unable to determine the milli-amp amount that was set for pacing.

Device	Manufacturer	Problem
Apparatus, Nitric Oxide Delivery Brand: Aeronox Nitric Oxide Delivery Device Model#: AeroNOx Lot #: X-143 Cat #: 731-9148 	INTERNATIONAL BIOMEDICAL, LTD.	Life flight RN Note: Nitric 2.0 would not charge plugged into the isolette. This was not noticed until we were in the air and the other cord was in the tail. Roughly 5 minutes from landing, the nitric machine stopped reading. Bagger was set up and ready to go. Patient bagged and tolerated bagging well. Once helicopter landed at the hospital, grabbed plug from tail and attempted to use that, but it would not charge either. Patient bagged to NICU and placed on their equipment. Clinical Engineering came to NICU and looked at the equipment. They found that the middle part of the normal plug was loose and that is why it would not charge with that. The isolette plug had power, but would only charge when held it just right. Patient was already very sick so it is unknown if the malfunction caused more harm to the patient due to alternative measures. Clinical Engineering Note: DC input jack on rear of Aeronox does not hold cable connector tightly, the cable can fall out. The charger was carried on the transport and the power cord was not connected tightly to the charger so that when the attempt was made to power the Aeronox from the charger after the battery failed, there was no power from the charger. The connector on the cable that powers the Aeronox from the incubator also failed due to problems of fit and looseness. This caused the Aeronox to be running on its internal battery even though the connector was connected. Clinical Engineer made temporary resolution to DC power input configuration to assure connection. There have been similar events in the past.
Container, I. V. Brand: Microtek Model#: 1 Lot #: 200318 Cat #: 2006S	Microtek Medical, Inc.	Microtek vial decanters have a cap on the spike that is inserted into the glass vial. The cap often comes off the spike while in the package therefore compromising the ability to aseptically decant IV fluids from glass vials.

Device	Manufacturer	Problem
Device, Vein Location, Liquid Crystal Brand: Accuvein Av400 Model#: AV400	Accuvein, Inc.	Our HTM (Healthcare Technology Management) received a service call to inspect a broken Accuvein Finder. The complaint was the "Arm is snapped off the machine, wand is working". Technician inspected the device and ordered a replacement arm. Once received, the arm was replaced and device was returned to service. This type of repair has happened numerous occasions and could potentially harm the health care staff member. Manufacturer was made aware when replacement arm was sent out.
Dura Substitute Brand: Lyoplant Model#: 1066064 Lot #: 220125 Cat #: 1066064	Aesculap, AG	The patient had a craniectomy with a closure of the dura utilizing a Aesculap AG Lyoplant (Model/Catalog # 1066064, Lot # 220125) dural graft on [date redacted]. The patient returned to surgery 13 days later for a repair of a CSF leak. During this surgery, the surgeon identified that the dural graft had "disappeared". There were no signs of infection of the surgical site. The cause of the graft failure is unknown.
Electrosurgical, Cutting &Coagulation &Accessories Brand: Ligasure Model#: LF1837 Lot #: 01500222X Cat #: LF1837	Covidien LP	During a surgical procedure the Covidien Ligasure persistently created error codes and would not initiate a burn. It was unplugged and plugged back in five times, this did not resolve the issue. A second Ligasure was brought into the case with the same results. A third Ligasure was finally brought into the case and worked. This seems to have become more prevalent following a software upgrade to the ValleyLab FT10 Electrosurgical Generator which powers the Ligasures. Representative from the company seems to think that the persistent issues could be the result of consumable devices that were manufactured before the software update was available for the ESU. The devices will be returned to the manufacturer for failure analysis.
Implanted Brain Stimulator For Epilepsy Brand: Rns Neurostimulator Kit	Neuropace	Recently, patient admitted to hospital with stroke symptoms. Subsequent, imaging revealed brain hemorrhage at the site of one of the electrodes originally placed at another facility.

Device	Manufacturer	Problem
Laparoscope, General Plastic Surgery Brand: Genistrong Model#: 550-000-003 Lot #: J0865-A Cat #: 550-000-003	Genicon, Inc.	GENICON Single-Use Specimen Retrieval Bag ripped open at the bottom of the bag while pulling the bag with specimen (gallbladder) out of the abdomen through the port hole. There were no injuries to the patient, or leaking into the abdomen. The surgery team (surgeon, scrub and assistant) claim this is a frequent issue with these particular GENICON Single-Use Specimen Retrieval Bags.
Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms) Brand: Apexpro Model#: FH Transceiver Cat #: 2025064-004 Other #: ID: 270413, TTX 0590 FH (60590)	GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.	A patient was a Code Blue last evening. The RN 1 reported that she went into the room three minutes earlier, and the patient was lying on his side with agonal breathing and his O2 was off. She yelled to a nurse to grab a vital signs (VS) machine and pulse oximeter. She then rolled the patient onto his back, he was not responsive to verbal commands or a sternal rub. RN 1 and RN 2 verified he initially had a "dull pulse", but once turned he did not have a pulse. A Code Blue was called and doctor was present for the code. When the monitor station was called to ask what the telemetry was showing, RN 3 stated that the patient was not on telemetry. During the code it was noted that the patient was shocked once, give 1mg of Epinephrine and was intubated at bedside. Doctor wanted to the monitor station to confirm when the patient went off of telemetry and it was confirmed that telemetry was lost 40 minutes earlier. RN3 denied knowing that the patient was off telemetry "I was not aware". "There were no alarms going off". "I did not make the RN 1 or NT aware, because I didn't realize it." RN 1 confirmed that she was not aware that the patient was off telemetry and the NT was also not aware. Clinical Engineering sequestered the telemetry box and are doing their own investigation. An alert report was sent, but will need to be analyzed by Clinical Engineering. Manager, Risk Management, Patient Experience Director and AVP were made aware of the situation. Also spoke with Nurse Manager in CCU where the patient is now being cared for.

Device	Manufacturer	Problem
Pump, Infusion Brand: Caddsolis	Smiths Medical MD, Inc	The patient's PCA pump was found to be empty unexpectedly. The equipment was checked, and it was believed that the patient was able to draw from the cassette. The latching mechanism is prone to failure from overuse/ improper use and makes the pump vulnerable to manipulation as the gate on the tubing does not completely close (too much of a gap between the cassette and the gate), leaving it open and possible for someone to draw from the cassette. There is opportunity for improvement on the latching mechanism design to prevent manipulation that could result in overdose if a patient were to draw from it.
System, Image Processing, Radiological Brand: Intellispace Pacs Breast Suite	Philips Healthcare Informatics, Inc.	In the PACS suite for mammography images, in the diagnostic view (LM View)the PACS will read and label the LEFT 3D Tomo indicator bar as reversed in orientation on PACS on Breast TOMOs (i.e. lateral breast registers as "M" for medial, and vice versa) for the Hologic Affirm Prone Biopsy System and the GE Essential with SenoClaire. This has been recognized by the Radiologists and they are aware of its occurrence. Philips was first contacted about this observation in May 2020.
Thermometer Kit Brand: Dikang Hbg01 Model#: HGB01 Cat #: DIKANG HGB01	HUNAN HONGGAO ELECTRONIC TECHNOLOGY CO., LTD	The Hospital in part of its process had purchased a number of Electronic Infrared Skin Thermometers. The purpose of these Skin Thermometers were to provide a 1st level of temperature screening of Staff and Visitors. Since these have been purchased, there has been many repairs performed on these devices including broken triggers, taking a low temp, and not reading accurately. With this being a critical scanning tool/ process there is a risk potential in failing to properly screen staff and visitors.
Ventilator, Continuous, Minimal Ventilatory Support, Facility Use Brand: Philips Respironics Cat #: 1121065	Respironics California, Inc.	Stage II pressure ulcer idientified to bridge of nose under bi-level positive airway pressure (BiPAP) mask.

Device	Manufacturer	Problem
Ventilator, Continuous, Minimal Ventilatory Support, Facility Brand: Philips Respironics V60 Ventilator Model#: V60	RESPIRONICS CALIFORNIA, LLC	In March 2020, we received recall letter entitled "Philips V60 Ventilators May Shut Down Unexpectedly Due to a Premature Component Failure." We notified Philips that we had four affected V60 ventilators that required replacement of the Power Management PCBA part. In April, Philips send a second letter in regards to the "Philips V60 Ventilators May Shut Down Unexpectedly Due to a Premature Component Failure" informing us that they are experiencing a delay in the production of the components necessary to correct/repair the ventilators. This facility did not remove any of the four devices from service per Philips original analysis that concluded it is not necessary to remove affected Philips V60s from service due to the rarity of the failure. Philips maintained that the public health is best protected by leaving non-failed V60s in the field for critical life-sustaining therapeutic use. Biomed Follow up: Biomed requested a service person to come to facility and repair this vent. Philips has indicated that they will remediate the recall on the vent at that time. Philips explained that they do not have the inventory of parts to remediate all of our vents affected, but because this one failed relative to the recall, they will repair it.
Ventilator, Continuous, Minimal Ventilatory Support, Facility Use Brand: Philips Respironics Cat #: REF1021165	Respironics California, Inc.	Pressure-induced injury to the nose when using a Bilevel Positive Airway Pressure (BiPAP) mask.
Wire, Guide, Catheter Brand: Lunderquist Lot #: 3842965	William Cook Europe ApS	Patient was undergoing non-surgical aortic valve replacement (AVR) with a 26mm CoreValve. Using a retrograde percutaneous approach, for a transcatheter aortic valve. A .035/180cm Lunderquist Extra Stiff wire was advanced retrograde across the aortic valve to the left ventricular apex. After the delivery of the balloon aortic valvuloplasty, the Lunderquist wire was noted to have an abnormal band approximately 40mm from the distal tip at the segment of the wire that is generally bonded. At this point the physician became concerned given the abnormal appearance of the wire for trauma to the left ventricle. A straight pigtail was delivered and the wire was exchanged for a new one. The initial wire was examined and there was no evidence of disruption of the outer core, it just simple appeared to have bent slightly. In caution, an ECHO was performed and it was noted for a pericardial effusion, patient was stable during procedure, consult placed to CV surgeon patient brought to OR for Subxiphoid pericardial window followed by sternotomy, cardiopulmonary bypass, and repair left ventricular perforation. Per OR report, there was a 1cm laceration near the distal end of the circumflex near the apex.

Device	Manufacturer	Problem
Mask, Surgical Brand: Halyard Model#: 46828 Cat #: 46828	OM HALYARD, INC.	5-10 n95 duckbill masks elastic broke when putting mask on. Halyard fluidsheild n95 particulate filter respirator ref#4682
Respirator, Surgical Brand: Kimberly-clark® N95 Particulate Filter Respirator And Surgical Mask Model#: 46827	KIMBERLY-CLARK GLOBAL SALES, LLC	RN put on a brand new N 95 mask at start of shift. After doing vitals and assessment, RN doffed PPE including N95 mask. When taking bottom strap off, the elastic bands snapped off. RN threw out N95 mask. The next time this RN needed to go into the patient room, I grabbed a new N 95 mask. After two uses, the same thing happened where the elastic band snapped when taking off the mask.

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 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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