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 January 8 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

Cook Medical Recalls Flexor Check-Flo Introducers and Flexor Tuohy-Borst Side-Arm Introducers Due to Separation in Device
December 23, 2020

Device recall because of an increased chance of separation at a specific point (proximal bond site). If the device separates during use, this may lead to life-threatening adverse events. Use of the affected product may cause serious adverse events, including longer procedure time, another procedure to take out a separated piece, blocking blood flow to vital organs, vessel injury, and bleeding. There have been 57 complaints about this device issue and 14 reports of serious injuries. There have been no reported deaths.

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
December 4, 2020
FDA is updating the 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 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.

Baxter Healthcare Recalls Baxter SIGMA Spectrum Infusion Pumps with Master Drug Library (Versions 6 and 8) and Spectrum IQ Infusion Systems with Dose IQ Safety Software Due to Unplanned Shutdown Issues

December 1, 2020

Baxter Healthcare is recalling the Baxter Healthcare Sigma Spectrum Infusion Pumps with Master Drug Library (V6, V8) and the Baxter Spectrum IQ Infusion Systems with Dose IQ Safety Software (V9) because improper cleaning of the devices may lead to residue build-up or corrosion on the device. If the device is running only on battery power, this may lead to an unplanned shutdown without alarming or alerting the user. This may cause an infusion delay or an interruption in treatment. Use of the affected product may cause serious adverse events, including death. There have been 17,493 complaints about this device issue and 16 reports of serious injuries. There have been no reported deaths.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during December 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
Scalp Cooling System Brand: Dignicap Delta Model#: Delta	Dignitana Inc.	Patient was using the DigniCap Scalp Cooling system during chemotherapy treatment on visit day. Patient had been using the DigniCap for prevention of hair loss for several treatments. Patient reports nothing unusual with the treatment on visit day except that later they had rubbed her forehead and notice that skin had peeled off. They went in for a follow-up appointment with doctor on a later date and showed us the two areas temple and forehead that were affected. Patient reports no blistering just skin peeling and had put ointment on it at home.

Device	Manufacturer	Problem
Needle, Hypodermic, Single Lumen Brand: BD Vacutainer Eclipse Blood Collection Needle Lot #: 0135019 Cat #: 368607 Other #: (01) 30382903686071	Becton Dickinson and Company	Grey rubber stopper on the collection device is faulty and will not move back down when the blood collection tubes are put on and off, causing blood to spill into the vacutainer holder.
Blade Peak Plasma 3. 0s 3. 0Mm Cat #: PS210-030S	Medtronic	Plasmablad was not cutting or coagulating. had to open another blade to complete the case.
Device 1: Controller, Temperature, Cardiopulmonary Bypass Brand: Modular Cooler-heater (Mch)Model#: MCH-1000 Lot #: 537766 Other #: P/n-100-05-1131 **Device 2: Controller, Temperature, Cardiopulmonary Bypass** Brand: Modular Cooler-heater (Mch)Model#: MCH-1000 Lot #: 537763 Other #: p/n 1000 -05-1129m	CardioQuip CardioQuip	In Fall 2020, our facility was notified by the FDA that patients from one organization had experienced NTM infections (M abscessus) after heart surgery where the CardioQuip heater cooler devices were used. This prompted our organization to send samples from our machines to an outside lab for testing. 5/8 CardioQuip devices came back positive for NTM. Lab results available. We have not identified any related infections at this time. Upon receiving these results, a group convened and learned the following: Testing of our 8 devices revealed 5 of 8 machines contaminated with NTM, No known infections with ECMO patients and use of CardioQuip in the literature, Risk for infection is very low, but not zero. We only use the device to heat-not to cool. Standard Work for machine use and cleaning very rigorous, however design of machine is flawed. Next steps include: Continued use of the three machines that tested negative, since there is no acceptable substitute. All three will be re-tested, Report to FDA, Connect with the manufacturer, Potential retrospective review of ~ 200 ECMO patients.

Device	Manufacturer	Problem
Device 3: Controller, Temperature, Cardiopulmo-nary Bypass Brand: Modular Cooler-heater (Mch)Model#: MCH-1000 Lot #: 545354 Other #: p/n 1000-05-1136 c	CardioQuip	
Device 4: Controller, Temperature, Cardiopulmo-nary Bypass Brand: Modular Cooler-heater (Mch)Model#: MCH-1000 Lot #: 537761 Other #: pn/1000-05-1131	CardioQuip	
Device 5: Controller, Temperature, Cardiopulmo-nary Bypass Brand: Modular Cooler-heater (Mch) Model#: MCH-1000 Lot #: 545353 Other #: p/n 1000-05-1126 c	CardioQuip	
Device 6: Controller, Temperature, Cardiopulmo-nary Bypass Brand: Modular Cooler-heater (Mch) Model#: MCH-1000 Lot #: 537765 Other #: p/n 1000-05-1128-	CardioQuip	

Device	Manufacturer	Problem
Device 7: Controller, Temperature, Cardiopulmonary Bypass Brand: Modular Cooler-heater (Mch) Model#: MCH-1000 Lot #: 537762 Other #: p/n 1000-05-1129 m **Device 8: Controller, Temperature, Cardiopulmonary Bypass** Brand: Modular Cooler-heater (Mch) Model#: MCH-1000 Lot #: 537764 Other #: p/n 1000-05-1131	CardioQuip CardioQuip	
Instrument, Biopsy Brand: Bio-pince Ultra Full Core Biopsy Instrument Model#: 360-1080-02 Lot #: 11329588 Cat #: 360-1080-02	Argon Medical Devices	The handle (cockling lever) of a BioPince™ Ultra Full Core Biopsy Instrument 18ga x 10cm (use with optional Co-Axial Needle: MCXS1810BP) broke when the provider was cocking it to use to obtain a biopsy on the patient. This failure mode has happened at least three times over the last few months. This failure mode does delay the procedure time because a new gun needs to be retrieved and opened to complete the procedure. Our Materials Management Department has been in contact with the company's representative with this ongoing issue.

Device	Manufacturer	Problem
Pump, Infusion Brand: Medrad Intego Pet Infusion System	Bayer Healthcare	We have a piece of equipment in PET CT department 01017166 that was utilized outside of its quality control being performed. Linearity was required and we failed to recognize that and used the piece of equipment in November before it was noticed that we were acting outside of the quality control metrics being performed. Review of the event with several staff members, we have several backups in place that didn't fix or solve the problem. Actions to be taken, we need to review the equipment. The equipment does not notify us until the day that it is due. the reminders for staff didn't have the staff acting to fix it. We have things in place to remind staff that didn't work either but basically according to our radiation safety officers this should not be done and is a potential safety issue as we did not necessarily know the doses that patients were receiving. Does not flag the user before the QC is due. Think this should flag the user 7 days before it is due to plan and prepare for the linearity being performed. Current state is that no notification is done until no longer valid. Linearity is a must-be-done. We should not use this machine without valid linearity. Thinking about human factors items and how to make this a never event we feel a report on this device for a software block that could allow us to make dose delivery to patients have all QC up to date before the unit could deliver a dose.
Set, Administration, Intravascular Brand: Icu Medical 18 "Ext Set W/ 0.2Micron Filter, Clave, Spiros Model#: CH3556 Lot #: 4949284	ICU Medical, Inc.	Sitter notified RN pt line possibly leaking. Upon assessment, noted filter wet and appeared to have a small leak toward the top half of the filter. Disconnected line and primed new line.

Device	Manufacturer	Problem
Set, Administration, Intravascular Brand: Alaris Pump Module Smartsite Infusion Set Model#: 2426-0500 Cat #: 2426-0500	CareFusion 303, Inc.	There have been consistent reports of leaking Alaris infusion sets over the past few months. Leaking is often described to occurred at junction points or y sites. This is the second report to be submitted for this issue in the last three months. Health System was unable to produce a sample for failure analysis. We will work with the manufacturer moving forward on a solution to the persistent issues.
Set, Administration, Intravascular Set Brand: Tego Needlefree Connector Model#: D1005 Lot #: 4914659	ICU Medical, Inc.	Upon drawing blood from patient's central line, 2 small cracks noted in the Tego cap connected to the red lumen upon flushing the Tego cap. Small leakage did come out of Tego cap upon flushing, in which the 2 small cracks were noted. There have been a series of 5 Tego Connector D 1005 caps that broke at the site on the cap where the Tego cap connects to the Swabcap in a period of about 2-3 weeks.
Stopcock, I. V. Set Brand: Spinning Spiros® Closed Male Luer, Red Cap Model#: CH2000S-C Lot #: 4991021	ICU Medical, Inc.	Circle priming chemo and using Spiros cap. As I was priming the tubing through the pump, pump started beeping partial occlusion and as I traced the tubing, noticed a small drip between the connection end of tubing and the Spiros cap. Gauze applied to site and wet spot noted.
Ventilator, Continuous, Facility Use Brand: Bellavista Model#: 1000	Imtmedical AG	The Carefusion Bellavista BV1000 Ventilator shut down on a patient in the middle of the night. There were no issues with the electrical outlets or power issues which could have attributed to this issue. The nurse automatically switched out the ventilator for one that was working at the time of the failure.

Device	Manufacturer	Problem
Ventilator, Continuous, Facility Use Brand: Bel-lavista Model#: 1000	Imtmedical AG	We have a series of issues with 9 Bellavista Ventilators. These issues have been on-going since we purchased these ventilators and they all had a software upgrade which further made the issues worse. Here are the issues: The ventilator constantly alarming "occlusion" with no kink. On occasion high Positive End Expiratory Pressure alarms for no reason. Power button to do normal shut down procedures doesn't work (screen locks). One ventilator inadvertently shut down during transport, needs a battery check. Pressure line on flow valve easily gets occluded. Patient's in non-invasive fraction of inspired oxygen (NIV-Fi02) can't go above 70%. Low pressure alarm – can't decrease below 7.

Links to FDA/CDRH Databases and Other Information Sources

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

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 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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