MedSun
Medical Product Safety Network

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

February 2021

Volume 21, Issue 2

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 February 6, 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

Boston Scientific Recalls EMBLEM S-ICD Subcutaneous Electrode (Model 3501) Due to Risk of Fractures

February 2, 2021

Boston Scientific is recalling the EMBLEM S-ICD Subcutaneous Electrode because of increased risk of fractures at a specific point (distal to the proximal sense ring) shown in Figure 1. If the device fractures during use, it could become unable to deliver therapy to slow very fast heartbeats from cardiac arrest (tachycardia). A failed device may cause serious adverse events. Examples include injury or death if cardiac arrest cannot be treated or need for additional surgery to replace failed devices. There have been 27 complaints about this device issue and 26 reports of serious injuries. One death has been reported.

Penumbra's Recall of the JET 7 Reperfusion Catheter Due to Distal Tip Damage

January 29, 2021

Penumbra recalled the Penumbra JET 7 Xtra Flex because the catheter may become susceptible to distal tip damage during use. The FDA has received over 200 medical device reports (MDRs) associated with the JET 7 Xtra Flex catheter, including deaths, serious injuries, and malfunctions. Twenty of these MDRs describe 14 unique patient deaths, which include reports from different reporting sources for a single adverse event. Other MDRs describe serious patient injury, such as vessel damage, hemorrhage, and cerebral infarction. Device failure modes reported in the MDRs include ballooning, expansion, rupture, breakage or complete separation, and exposure of internal support coils near the distal tip region of the JET 7 Xtra Flex catheter.

Safety Recall for Deluxe Heat Therapy Massager

January 28, 2021

Wahl Clipper Corporation is voluntarily recalling all Deluxe Heat Therapy Massagers, Model 4212. Discontinue use immediately. The connection between the massager and heat attachment can overheat causing smoke or spark, which may pose a fire hazard.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during January 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
Balloon Aortic Valvuloplasty Brand: True Dilatation Model#: 0284514 Cat #: 0284514	Bard Peripheral Vascular, Inc.	Patient had a transcatheter aortic valve replacement. Patient had a history of known peripheral artery disease. During the procedure, right intravascular iliac artery lithotripsy was done. During deployment, Edwards SAPIEN 3 transcatheter heart valve migrated, and Edwards balloon catheter ruptured. A vascular attempt to remove the Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System was unsuccessful. The transcatheter heart valve, balloon, and guidewire were retained in patient. Patient required a femoral bypass procedure.

Device	Manufacturer	Problem
Ventilator, Emergency, Manual (Resuscitator) Brand: Mercury Medical - Child Cpr-2 Bag Model#: 10-56153 Lot #: 2001656153 	MERCURY ENTERPRISES, INC.	Staff removed pediatric ambu-bag with bag-valve-mask (BVM) - mask immediately noted to be misshapen at the base which led to difficulty attaching the mask to the ambu-bag.
Electrosurgical, Cutting & Coagulation & Accessories Brand: Argonenh (System 7500) Model#: SYSTEM 7500 Cat #: SYSTEM 7500	ConMed Corporation	Level one trauma to OR. surgeon requested Argon Beam Coagulator (ABC). Brought into room, usual settings selected and did not work when surgeon attempted to use it. Pt continued to hemorrhage from liver laceration while we switched hand piece, grounding pad and argon tank to resolve problem to no avail. As surgeon was unable to control bleeding with cauterization she was forced to use fibrillar, surgi-cel and avitene. Pt eventually packed with 28 lap sponges and left open with abthera wound vac instead of a closed abdomen.
Catheter And Tip, Suction Brand: Medline Model#: MDS096513 Lot #: 20-211 Cat #: MDS096513	MEDLINE INDUSTRIES, INC.	This is a recurring issue with the Medline Industries Standard Suction Swab Kits (oral swabs) with Biotene. The sponge part has broken off the handle, thus drastically increasing the risk of aspiration or swallowing. These Medline oral swabs are used on confused or comatose patients who may not be able to spit or cough the sponge out once it is dislodged from the handle.

Device	Manufacturer	Problem
Prosthesis, Mitral Valve, Percutaneously Delivered Brand: Edwards Sapien 3Transcatheter Heart Valve (Thv) Model#: 9600TFX Cat #: 9600TFX29A Other #: 14FR-SHEATH 0.035IN-GW	Edwards Lifesciences LLC	Patient had a transcatheter aortic valve replacement. Patient had a history of known peripheral artery disease. During the procedure, right intravascular iliac artery lithotripsy was done. During deployment, Edwards SAPIEN 3 transcatheter heart valve migrated, and Edwards balloon catheter ruptured. A vascular attempt to remove the Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System was unsuccessful. The transcatheter heart valve, balloon, and guidewire were retained in patient. Patient required a femoral bypass procedure.
Pump, Infusion Brand: Alaris Model#: 8015 Other #: 5613	CAREFUSION 303, INC.	IV pump stopped functioning and was reading "communication error". The brain had stopped, and pumps were flashing red lights. Found multiple issues of: Code=800.8000.0; Failure=PCU15_GENERAL_OS_FAILURE; in the event Log of Alaris PCU 8015
Headlamp, Operating, Battery-operated Brand: Ronin X6 Model#: X6	Ronin Surgical Corp.	During a laminectomy procedure, the surgeon noted burning at the surgical incision site while using a portable high intensity LED surgical headlamp system. The surgeon discontinued use of headlamp and proceeded with completion of surgery without additional complications. Follow up with patient occurred to note progress of skin healing. No additional interventions required. During discussion with another surgeon it was discover that an additional surgeon noted burning at the incision site on their unrelated procedure. Two headlamp assemblies sent to Biomedical engineering department for evaluation and reporting. Biomedical engineering testing of the headlamp assemblies noted significant warming and heating of a target area when measured with an electronic thermistor-based thermometer. Biomedical engineering also was able to burn and singe a non-reflective surface during testing of the lamp system. Biomedical engineering to contact manufacturer for follow up.
Device, Fixation, Tracheal Tube Brand: Hudson Rci Gentle-lock Model#: IP-N914324 Lot #: 35063 Cat #: 81801	Teleflex Incorporated	We had two intubated patients whose endotracheal tubes were secured using the device. Both patients were prone. When the therapist turned the first patient's head, the device broke. In the case of the second patient, the holders slid off the track. Respiratory therapy reported incidentally there were multiple instances over the weekend of the tube holders breaking while in use.

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

Contact the MedSun Program Staff:

Telephone: 800-859-9821
Fax: 800-859-1292
E-mail: medsun@fda.hhs.gov

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993