MedSun
Medical Product Safety Network

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

July 2017

Volume 17, Issue 7

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):
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/mda/mda-list.cfm?list=1

Premarket Approval Final Decisions:
https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM561666.pdf

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm561793.htm

In Brief

As of June 23rd, 2017

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

System CS100, CS100i and CS300 Intra-Aortic Balloon Pumps by Datascope: Field Correction
June 19, 2017
Datascope Corp. is voluntarily performing a worldwide field correction of certain Intra-Aortic Balloon Pumps (IABPs) sold by Datascope Corp. for a potential electrical test failure code. This field correction also applies to any System 98 or System 98XT IABP that was converted to a CS100i or CS300 IABP.

Frameless Stereotaxic Navigation Systems: FDA Safety Communication
June 15, 2017
The FDA is aware that some health care providers have experienced navigational accuracy errors during surgical procedures when using frameless stereotaxic navigation systems. Some of these errors have led to patient deaths, serious or life-threatening injuries, and inaccurate, aborted, or prolonged medical procedures.

SpF PLUS-Mini and SpF XL IIB Implantable Spinal Fusion Stimulators by Zimmer Biomet: Class I Recall
May 30, 2017
Recall due to higher than allowed levels of potential harmful chemicals, which may be toxic to tissues and organs (cytotoxicity) and that were found during the company's routine monitoring procedure.

LeadCare Testing Systems (with Blood Obtained from a Vein) by Magellan Diagnostics: FDA Safety Communication
May 25, 2017
Affected devices may underestimate the blood lead levels (BLL) and give inaccurate results when processing venous blood samples. Falsely lower test results may lead to improper patient management and treatment for lead exposure or poisoning.

HeartMate II LVAS Pocket System Controller by Abbott-Thoratec: Class I Recall
May 23, 2017
Patients may sometimes need to change to their backup back-up system controller during the course of ventricular assist therapy. The change should be done quickly and in the hospital, because it can present a significant challenge to patients that are elderly and/or untrained. For these patients, a slow or improper driveline changeover places them at risk of serious injury or death.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during June 2017. 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

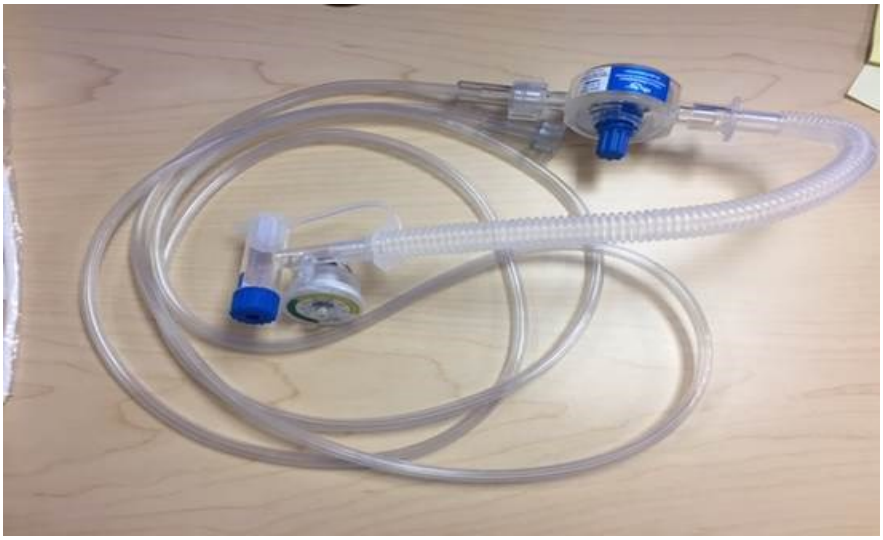

Special Note:

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: Edge Electrodes With Redi-pak™ Preconnect System Model#: 11996 Lot #: 705531 Cat #: 11996-000017	Physio-Control, Inc.	Physio-Control electrode defibrillation pads are not being recognized by the defibrillator when connected, resulting in the inability to emergency pace or defibrillate the patient if needed. This has been a recurrent event in the EP labs with this specific electrode model. Staff has been encouraged to save the device and record all events. Several packages were saved, but only 1 pair of electrodes was retained from the date and patient specified in this report. It was observed that these electrodes come from the same lot #. In addition, multiple Lifepak 20 machines have been used when the electrodes failed, indicating that the defibrillator machine is not responsible. In this particular event, a different model of electrodes were placed on the patient and worked successfully. No harm came to the patient and the procedure was carried out as planned. Both the electrodes and the lifepak 20 from this event are currently being tested by the Biomed Department. All electrodes on site with the same lot number are being exchanged with the manufacturer. The manufacturer has requested the failed electrodes that were saved from this event, as well as the Lifepak machine that was in use. These items will be given to the manufacturer when Biomed has completed testing. It is still unclear why the electrodes could not be sensed by the defibrillator, but any testing results will be shared when they are made available to Clinical Engineering.

Device	Manufacturer	Problem
Ceiling Lift Brand: Ceiling Lift 625 (Lifts Up To 625 Lbs.) Model#: 323120 Cat #: 323120	Medcare Products	The nurse used the hand remote to lower the sling of the ceiling lift and then to raise the patient from the bed. When she tried to lower the patient to the wheelchair the lift did not move. At that point she pulled the emergency cord to lower the patient and it failed to do so. Later investigation indicated that the lift had been compromised previously in the way it was operated. What can happen is that when the lift is lowered all the way down the motor will reverse and then spool backwards. The hook mechanism spools up into the motor housing. Then the lift can get stuck in the up position. It was found that the ceiling lift was operating according to instructions. However, the possibility of the spooling backwards creates a high potential for patient harm. This is the second time there has been an incident with the ceiling lift. The point of reporting is to make others aware of the possibility of a similar event. This could be life threatening or create an incident.
Implant, Auditory Brainstem Brand: Nucleus Profile Model#: CI512 Cat #: CI512	COCHLEAR LIMITED	Patient with a cochlear implant scheduled for MRI unrelated to implant. The patient informed technologist via MRI screening form and verbally of the make and model of the implant. Technologist visited manufacturer's website for MRI safety guidelines for the specific implant. Technologist found an informational page titled " Cochlear implants and MRI". Information on this site was misleading and incomplete regarding necessary technical parameters needed to safely scan. Information was general and not specific to make and model of the implant. Throughout the website, the term "removable" is used without clarification that only the external component can be removed without surgery. This lack of clarity suggested that by removing the "removable" external component of the implant the patient was now safe to scan. Upon later investigation by the MRI scientist was able to find the Magnetic Resonance Imaging (MRI) Guidelines handbook but at the time of the event the web page visited did not provide a link to this professional resource.
Implantable Infusion Pump Brand: Synchromed Ii Model#: 8637-20 	Medtronic	Patient had an infusion pump with baclofen implanted. The patient experienced alternating periods of apparent underdosing and overdosing of his baclofen, in spite of a stable programmed infusion rate. When the device was refilled on two separate occasions, the amount of drug remaining in the reservoir was substantially different than the expected remaining volume. The patient underwent surgical exploration of the device as well as a contrast study of the catheter, which revealed no external accumulation or leakage from the device or catheter, leading to the conclusion that there was a defect in the device itself. The pump was explanted and a replacement pump was implanted. The patient is now progressing as expected.

Device	Manufacturer	Problem
Device 1: Mattress, Air Flotation, Alternating Pressure Brand: Protevo Model#: 1VAKS-B00000M0 **Device 2: Mattress, Air Flotation, Alternating Pressure** Brand: Protevo Model#: 1VAKS-B00000M0	LINET LLC LINET LLC	Staff attempted to disconnect the CPR release and the hose connector breaks. This is the 3rd hose connector that has broken on one of these pumps. We only have 11 of these pumps and every bed requires one so when one goes down we have to remove a bed from service. Also we have only been using these beds and pumps for about 6 months so in 6 months almost 30% of our pumps have failed.
Umbilical Vessel Catheter Brand: Argyle Model#: 888816033 Cat #: 888816033	Covidien LLC	The umbilical artery catheter (UAC) was noted to be spontaneously leaking at the distal portion of the thinnest part of the catheter, prior to the hub. The leakage was noted after a fluid change. The line was not pinched or clamped at all prior to leaking. It was later found that the prior RN had bent the line back upon itself, which led to a micro crack. Per RN, packaging of this product states that it should not be bent; so I understand that use error contributed to this leak; but I have submitted this report to indicate the difficulty with using this delicate product. The RN manager also told me that the RNs occasionally have difficulty unattaching IV tubing from the UAC, and cannot use traditional methods to get it unattached because of the delicacy of the catheter.
Ventilator, Continuous, Minimal Ventilatory Support, Facility Use Brand: Philips Respironics Model#: V60 Cat #: 1053616	Respironics California, Inc.	Patient was placed on V60. Patient started to desat on way to elevator. Verified that O2 tank full, connected and turned on. V60 appeared to be functioning correctly prior to leaving room. Check completed by RRT. When we arrived at elevator on floor patient sat was dropping. After getting off elevator on floor and heading to ICU the BIPAP screen went black and shut off. Message displayed was, "Vent Inoperative" below that says "100A" then "Data Acquisition PCBA ADC Reference Failed." Once machine turned off patient taken off BIPAP and placed on NC from tank on BIPAP. Continued to room and new BIPAP obtained.

Device	Manufacturer	Problem
Ventilator, Emergency, Powered (Resuscitator) Brand: Neo-tee T-piece Resuscitator Model#: 10-50811 Lot #: 1711950811 Cat #: 10-50811	MERCURY ENTERPRISES, INC.	The inline manometer will not read. It is getting stuck and the manometer hand will only move when banged on to free the dial hand. Please see pictures below:  
Circuit, Breathing (WConnector, Adaptor, YPiece) Brand: Portex Model#: C49291785D-NL Lot #: 3360701 Cat #: C49291785D-NL	SMITHS MEDICAL ASD, INC	The elbow connection of the circuit is cracking and causing a large leak intra-operatively. Our facility has experienced several similar issues with this particular device. Also, we are experiencing numerous disconnects (from the looser fittings) and persistent leaks around the swivel connector at the gas sampling line connector. Note: the device is manufactured by Portex, distributed by Smiths Medical, and packaged in Mexico

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 2017 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