MedSun
Medical Product Safety Network

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

# October 2019

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## 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, 2019*

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

**The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication**
**August 29, 2019**
The FDA takes the risk of patient infection very seriously and continues to take steps to help improve the effectiveness of duodenoscope reprocessing. FDA is now recommending that hospitals and endoscopy facilities transition away from fixed endcap duodenoscopes to those with newer design features that facilitate or eliminate the need for reprocessing. Please note, we recognize that a full transition away from conventional duodenoscopes to the newer, innovative models will take time.

**Edwards Lifesciences, LLC, Recalls SAPIEN 3 Ultra Delivery System Due to Burst Balloons During Surgery**
**August 22, 2019**
Edwards Lifesciences has received reports of burst balloons during implantation procedures, which have resulted in significant difficulty retrieving the valve into the catheter and withdrawing the system from the patient, which may cause vascular injury, bleeding, or surgical intervention. The use of affected product may cause serious adverse health consequences, including death. Seventeen (17) injuries and one (1) death were reported at the time when Edwards initiated the Field Corrective Action in July 2019.

**Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality - UPDATE**
**August 7, 2019**
Earlier this year, FDA notified health care providers about a late mortality signal in patients treated for peripheral artery disease (PAD) in the femoropopliteal artery with paclitaxel-coated balloons and paclitaxel-eluting stents. This update is to provide the latest information on our analysis of long-term follow-up data from premarket trials and to provide summary information from our June 2019 advisory panel meeting. In addition, FDA is including recommendations to health care providers for assessing and treating patients with PAD using paclitaxel-coated devices.

## HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during September 2019. 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.**

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| Device | Manufacturer | Problem |
|---|---|---|
| **Catheter, Ultrasound, Intravascular**<br><br>Brand: Viewflex<br><br>Model#: Xtra<br>Lot #: 6996621<br>Cat #: D087031 | Irvine Biomedical, Inc. | EP study with ablation for atria tachycardia near SVC or possibly near right superior pulmonary vein. Rhythm continued post-procedure. Transeptal puncture was attempted and mapped in the left atrium. Shortly after the transeptal puncture was performed with the ablation catheter initiated, patient developed pericardial effusion. Patient required emergency pericardiocentesis with 1500 ml of blood removed from the pericardial space. After transfusions were completed, a pericardial drain catheter was placed. Patient was admitted to the MICU. He stabilized and did not require surgical intervention. The physician perceives that the tip of the ICE catheter is too rigid to perform properly. He feels the device caused the perforation to occur. |

| Device | Manufacturer | Problem |
|---|---|---|
| **Controller, Temperature, Cardiopulmonary Bypass**<br><br>Brand: Mch-1000<br><br>Model#: MCH-1000 | CardioQuip LLC | Patient alerted staff nurse there was a "pop" from the ECMO machine and the room smelled like smoke. The heater of the ECMO machine was extremely hot to the touch. Cardiac Perfusionist called to bedside to remove the heater and replace with another one. |
| **Needle, Hypodermic, Single Lumen**<br><br>Brand: Becton Dickinson And Company, Usa 22g X11/4<br><br>Model#: 368608<br>Lot #: 9157772<br>Cat #: 368608 | BECTON, DICKINSON AND COMPANY | Phlebotomists have reported an issue with the 22-gauge straight needles from BD. There have been at least 3 incidents where a phlebotomist went to screw a needle onto the Vacutainer barrel and the clear plastic part of the needle became detached from the black section where the threads are located. Staff reported the clear piece spins loosely, which is dangerous if this occurs during needle insertion and blood collection. The lab reported to this writer that this is a product number that was recalled in August due to missing bevels, however, this lot number was not part of that recall. |
| **Restraint, Protective**<br><br>Brand: Limb Holders<br><br>Cat #: 2510 | Posey Products LLC | Patient was in the pre-induction room awaiting surgery. Patient with known aggressive behavior was placed in four point restraints for patient and staff safety after attempting to kick several of the staff and removing lines/foley catheter. Lower extremity restraints were rechecked after 15 minutes of application and the left lower restraint was noted to be torn from the backing. The posey restraints are a fairly new product replacement at our facility and are deemed to be inferior to the previous product that utilized synthetic lamb wool. An old pair of synthetic lamb's wool soft restraints were obtained and placed on this patient and these restraints maintained their integrity for the duration of care until the patient was ready for surgery. Staff members have complained of the defects in the new product since it was introduced to our facility. Defects include a leash that is less compliant and therefore more prone to slipping even when a double half-hitch knot is used, and a tendency for the leash to tear off the backing resulting in increased risk of harm and/or skin breakdown for patients. |

| Device | Manufacturer | Problem |
|---|---|---|
| **System, Ultrasound, Intravascular**<br><br>Brand: Ilab Ultrasound Imaging System | Boston Scientific Corporation | Patient undergoing angiogram in cardiac catheterization laboratory. Cardiologist reported moderate lesion in the mid left anterior descending artery and attempted to perform fractional flow reserve (FFR)on the iLab Ultrasound Imaging System. The FFR would not connect. Attempts were made to reboot the equipment (it would reboot for a few seconds and then lose connection). A Biomedical Engineer was present and attempted to troubleshoot the equipment. The representative from company was contacted and came to facility. The rep also attempted to reboot the equipment. There was no sustainable solution so the FFR was not performed. Given that the FFR could not be performed, no stent was placed. Medical management and outpatient stress testing will occur. This patient may be required to have another angiogram done when the FFR is working, if the stress test shows concerns. The service rep placed a service call to manufacturer. Early August work order reports that the complaint was confirmed. Instead of repairing this V2 Polaris System, the hardware upgrade option was excised. iLab is to be upgraded from V2 hardware to V3 upgrade. On 8/7/19, the V3 hardware upgrade repaired the system complaint. |
| **Tubes, Gastrointestinal**<br><br>Brand: Kangaroo<br><br>Cat #: 461412 | Cardinal Health | For two weeks in mid-August we had several incidents were the feeding tube became disconnected/broke between the tube and the hub. Incident#1-Feeding tube disconnected/broke between the tube and the hub. The device was not saved. Incident#2-Feeding tube disconnected/broke between the tube and the hub. Not noted until feeding was found in bed. The tube was intact for about twenty-nine hours. The device was saved.<br><br>Incident#3 -When checking NG tube for placement, the RN noted excessive air removed from tube. As RN attempted to push aspirate back into tube it was noted that the aspirate was exiting the tube, just past the hub. The tube was noted to be bent at a 90-degree angle and tube was no longer fully attached. Tube was removed by RN and replaced with a new device. The tube was intact for about forty-eight hours. The device was saved.<br><br>Review: Since the packaging for these incidents was not saved we cannot say for sure what lot number was involved. Based on the location of these events, we suspect lot# 1919740164, but cannot confirm. We will continue to monitor. |
| **Pump, Infusion**<br><br>Brand: Alaris<br><br>Model#: 8100 | Carefusion 303, Inc. | During the OR case, BD Alaris pump module alarmed "channel error" message. The infusion was running lidocane. The end user proceeded to confirm error, the channel stopped delivering medication due to error, and end-user removed the tubing set out of the module. Approximately 20-30 min later it was discovered that the entire bag of the medication was delivered to the patient |

| Device | Manufacturer | Problem |
|---|---|---|
| **Device 1: Razor, Surgical**<br><br>Brand: Carefusion Surgical Clipper Blade<br><br>Model#: 4406<br>Lot #: 0918<br>Cat #: 4406<br><br>**Device 2: Razor, Surgical**<br><br>Brand: Carefusion Surgical Clippers Handheld Unit<br><br>Model#: 5513E<br>Lot #: 0918<br>Cat #: 5513E | Carefusion 2200, Inc.<br><br>Carefusion 2200, Inc. | While prepping a patient's groins for a cardiac procedure it was noted that multiple areas of bright red dot-like scratches/welts, the width of 1/2 of the razor clipper head, appeared- There 3 distinct tract lines in a width of half of the razor head noted in multiple sites along the groin and on the lower abdomen of the patient- Each set of 3 lines was 1 inch wide- The welted lines in sets of 3 continued to develop after the shaving was stopped- It looked painful but there were no lasting effects.<br><br>Upon closer examination of the clipper head, at least 6 out of the 20 u-shaped comb-like cutting point tips were missing - The razor's edge itself was also missing in that 1/2 inch section- It appears as if a bite of it was missing down to the gray plastic covering- It didn't appear broken off because the edges weren't bent. It appeared as if it was skipped over during the manufacturing process when the clipper head was made. |
| **Flowmeter, Tube, Thorpe, Back-pressure Compensated**<br><br>Brand: Amvex<br><br>Model#: FMAO#####XX<br>Cat #: FMAO | Ohio Medical | The clear hood, part# 7700-0010-500, on Amvex (Ohio Medical) Oxygen flowmeters are showing signs of plastic delamination and cracks. These flowmeters are within 1 and 3 years old. This report only covers a partial list of defective flowmeters (Qty 62) as we are continuing to replace this clear plastic hood across our facility. Here is the list of Oxygen flowmeters:<br><br>FMAO06403CQ, FMAO06407CQ, FMAO06416CQ, FMAO06420CQ, FMAO06422CQ, FMAO06423CQ, FMAO06424CQ, FMAO06425CQ, FMAO06432CQ, FMAO06439CQ, FMAO06444CQ, FMAO06446CQ, FMAO06447CQ, FMAO06448CQ, FMAO07266GQ, FMAO07318GO, FMAO07325GO, FMAO07329GO, FMAO07345GO, FMAO10069CP, FMAO10073CP, FMAO10091CP, FMAO10154CP, FMAO13926CP<br><br>FMAO13963CP, FMAO13966CP, FMAO13971CP, FMAO14005CP, FMAO14010CP, FMAO14023CP, FMAO14033CP, FMAO14036CP, FMAO14039CP, FMAO14045CP, FMAO14049CP, FMAO14063CP, FMAO14065CP, FMAO14113CP, FMAO14115CP, FMAO14117CP, FMAO14118CP, FMAO14119CP, FMAO14122CP, FMAO14123CP, FMAO14125CP, FMAO14127CP, FMAO14128CP, FMAO14130CP<br><br>FMAO14131CP, FMAO14134CP, FMAO14136CP, FMAO14137CP, FMAO14138CP, FMAO14140CP, FMAO14141CP, FMAO14144CP, FMAO14146CP, FMAO14150CP, FMAO14151CP, FMAO14152CP, FMAO14153CP, FMAO14157CP, FMAO14158CP, FMAO14160CP, FMAO14161CP, FMAO19556KL, FMAO19563KL, FMAO19593KL, FMAO20920CK, FMAO21955KL. |

| Device | Manufacturer | Problem |
|---|---|---|
| **Computer, Diagnostic, Programmable**<br><br>Brand: Hemosphere Advanced Monitor (Hem1)<br><br>Model#: HEM1<br>Other #: Multiple devices affected; 15467; 14567 | Edwards Lifesciences, LLC | It seems that every post-surgical heart patient I have received since we have gotten the new Edwards monitors has had an issue with monitoring Mixed venous oxygen saturation (SvO2). The SvO2 initially reads, but after a while, the monitor alarms and the error message, "Fault: Oximetry Cable Temperature" pops up. I have tried with this patient, as with others, to unplug and re-plug the cord for the SvO2. When you try to go into the "oximetry calibration" menu, all of the options are greyed out, so the monitor doesn't even give the user the option of recalling data or recalibrating. The issue has been in multiple rooms with multiple monitors. |
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## 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 October 2019 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