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):
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/UCM544411.pdf

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm541137.htm

In Brief

As of March 1st, 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

Comprehensive Reverse Shoulder by Zimmer Biomet: Class I Recall

February 16, 2017

Zimmer Biomet is recalling the Comprehensive Reverse Shoulder because these devices are fracturing at a higher rate than is stated in the labeling. Fractures may result in revision surgeries which could cause serious adverse health consequences such as permanent loss of shoulder function, infection, or rarely, death.

Alaris Syringe Pump Module (Large Volume Pump), Model 8100 and AIL Sensor Kits by CareFusion: Class I Recall

February 9, 2017

CareFusion is recalling the Alaris Syringe Pump because of a faulty Air-In-Line (AIL) sensor which may generate a false alarm, and cause the syringe pump to stop supplying the infusion to the patient. If the AIL sensor is faulty, the false alarm may be repeated and require the health care provider to clear the alarm to restart the infusion.

Halo One Thin-Walled Guiding Sheath by Bard Peripheral Vascular Inc.: Class I Recall

January 30, 2017

Bard Peripheral Vascular Inc. is recalling the Halo One Thin-Walled Guiding Sheath because the sheath body may separate from the sheath hub while removing the device from the patient's leg. The company also reports that the sheath may kink, and that its tip may become damaged during the procedure. The use of affected sheaths may result in prolonged procedure times and on additional surgical intervention to remove detached components from the patient.

HIGHLIGHTED REPORTS

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

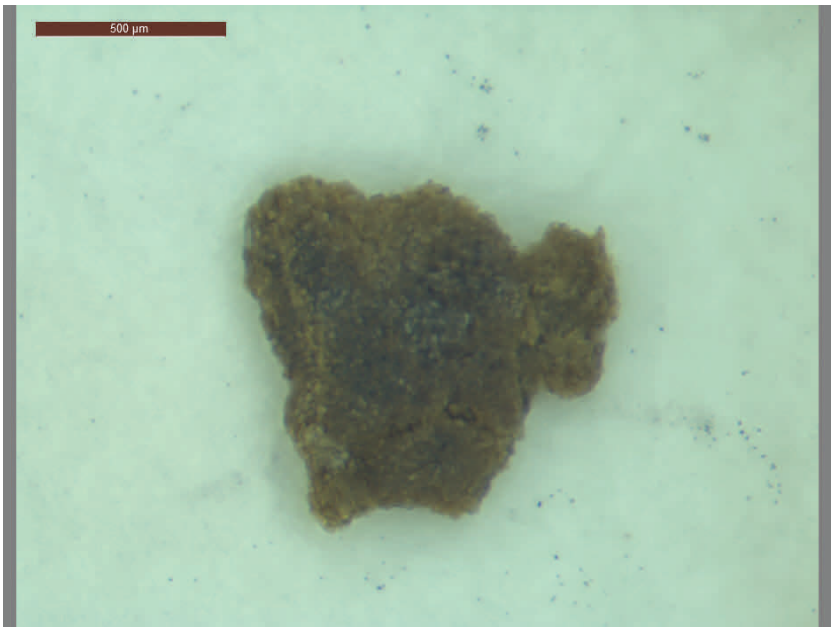
A database of all MedSun reports can be found at:

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
Ventilator, Continuous, Minimal Ventilatory Support, Facility Use Brand: Philips Respironics Model#: V60 Cat #: 1053617	Respironics California, LLC	Patient on BiPAP, and machine shut off, flashing error code 100E. The nurse was in the room and noticed the machine had turned off. The patient began to reach for the mask but the nurse was able to turn the BiPAP back on before anything happened to the patient. This is the third event we have experienced in the last six weeks since purchasing these BiPAP machines five months ago. Once Biomedical Engineering was notified, they reported it to Phillips. According to Phillips, the 100E error code is what is causing the v60's to shut down and Phillips' solution, at this time, is to downgrade the software to an earlier version.

Device	Manufacturer	Problem
Cannula, Manipulator/ injector, Uterine Brand: Vcare Lot #: 201609121 Cat #: 60-6085-201A	Conmed Corporation	Small white screw on the top of the handle kept screwing into the handle piece crooked. The piece needed to screw in flush in order for the product to be used. The device was not used on the patient. No patient harm occurred. The physician obtained a different device for the procedure. The device and wrapper were saved for the manufacturer. They did obtain another VCare device that worked with no issues. Manufacturer response for Uterine manipulator, VCare medium vaginal-cervical-Ahluwalia's- retractor- elevator (per site reporter) ========== They will file a complaint and will examine the product once they receive it.
General Surgery Tray Brand: Medline Industries, Inc. Model#: DYNJ51804A Lot #: 16SB8811 Cat #: DYNJ51804A		Two A V Fistula Packs were discovered to have contaminants in the pack upon opening them. These events were not necessarily from the same surgical case. They were reported to Clinical Engineering from an OSF (Outside Facility). The packaging was saved from each of the packs and a new pack was opened to complete the procedure. Please see picture below: 
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: Jelco Lot #: 3312336 Other #: GTIN# 1035168807744	Smiths Medical ASD, INC.	A nurse attempted to insert a catheter and the patient complained of extreme pain at attempt so the nurse stopped. A second nurse also attempted an IV start with the same lot number of product. Again, the patient complained the IV needle hurt more than normal. The remainder of the lot number of this product was removed from stock. Nurse indicated that the catheter tip seemed "blunt ended." Sales representative contacted and will pick up the specific lot supply that was removed from inventory and manufacturer will conduct an investigation.

Device	Manufacturer	Problem
Catheter, Intravascular, Diagnostic Brand: Torcon Nb Model#: G08895 Lot #: 6957601 Cat #: HNB5.0-38-100-P-NS-DAV	Cook Incorporated	Hair found inside sterile packaging. Please see picture below: 
Device 1: Device, Vein Location, Liquid Crystal Brand: Accuvein Model#: AV400 1.0 Cat #: AV 400 **Device 2: Device, Vein Location, Liquid Crystal** Brand: Accuvein Model#: HF470-1	AccuVein, Inc. AccuVein Inc	The Accuvein is composed of two Major pieces: Unit and the roll-stand. The stands are falling apart and continue to fail on regular basis at an unacceptable high rate. Once the stand breaks, it causes the main unit to dislodge and potentially fall and gets cracked and fall apart. Currently we have in our Biomed workshop about 5 broken stands with at least 3 broken units. The rate of these units being broken is affecting the hospital's ability to provide proper and timely care to our patients, those who need the Accuvien for care. Manufacturer response for Vein Finder, AccuVein (per site reporter): We met with the manufacturer more than once, we discussed our concerns and we showed them what is happening. This has been going on for more than a year. The manufacturer reported that the units are breaking because the hospital uses bleach to contain cross contamination and reduce hospital associated infections (HAIs). The hospital reviewed that comment, and we found out that even the containers used to hold the cleaning products is made of plastic material that does not fail or crack even when left for months and months with the solution in it. Now, the only option for the hospital to get the devices repaired and working, is: - Send the broken unit back to OEM and get replacement for $1600 each with 90 days warranty, and $1950 with a 1 year warranty. Anyhow, Warranty does not cover broken units/stands, and they do not consider what we are experiencing as manufacturer defect. - Send the stands back to the OEM and get a replacement for $400 for a refurbished stand and $750 for a new one. - Sign a contractual agreement that will cover the units and the stand, but we still pay a copay for the stand, even with the highest tier agreement level. Bottom line, we are expected to pay not less than $2000 per each unit, for multiple units, multiple times a year. With the OEM still considering the failures we have are not ordinary, with no serious steps to resolve.

Device	Manufacturer	Problem
Device 1: Attachment, For Endoscope Brand: Bridge Model#: 27033F **Device 2: Cystoscope And Accessories, Flexible/ rigid** Model#: 27033A **Device 3: Electrosurgical, Cutting &Coagulation &Accessories** Brand: Bugbee Model#: 27770AA **Device 4: Handle, Resectoscope** Brand: Slender Model#: 27033E **Device 5: Sheath, Urethrotome** Model#: 27033U 	Karl Storz Endoscopy-America, Inc, Karl Storz Endoscopy-America, Inc. Karl Storz Endoscopy-America, Inc. Karl Storz Endoscopy-America, Inc. Karl Storz Endoscopy-America, Inc.	Patient was scheduled for a cystoscopy with transurethral incision of posterior urethral valves and a circumcision. During the cystoscopy, the patient became hemodynamically unstable and the procedure was stopped. The patient was stabilized and transferred to the Pediatric Intensive Care Unit (PICU) where he continued to decompensate. After approximately three hours, he returned to the operating room for a STAT exploratory laparotomy and it was discovered that the left iliac vein and artery were lacerated. The vessels were immediately clamped to control bleeding. The vascular team was contacted, and the artery was repaired without difficulty. The patient improved immediately and was readmitted to the PICU for four days. He was later transferred to an inpatient room and discharged eleven days after admission.
Cesarean Section Tray Brand: Medline Industries, Inc. Lot #: 16WB5000	Medline Industries, Inc.	Medline C-section pack missing blades. Pack is supposed to have 2 blades but no blades were in the new pack when opened.

Device	Manufacturer	Problem
Bed, Pediatric Open Hospital Brand: Springfield Crib Model#: E1843-CGP 	HARD MANUFACTURING CO., INC.	Infant patient was in the crib and as the child leaned against the railing it dropped and the patient fell out of the crib. Parents were in the room and stated that it happened so fast. Parents immediately picked up the child with no apparent harm. The crib was evaluated with no apparent malfunction. The nurse felt the bed malfunctioned as the rail apparently did not lock. When I examined several similar cribs and raised the side rail, I noted that several times the right side did not latch. Is this an issue elsewhere? Do the rails need some way to identify that both sides are secure?
Extracorporeal Photopheresis Kit (Ecp) Brand: Therakos Extracorporeal Photopheresis Kit Lot #: E354	Therakos	Patient was started on the extracorporeal photopheresis machine after a 2 person machine/kit setup validation check. About 15-20 minutes into the procedure the nurse noticed a leak in the tubing of the apheresis kit and what is supposed to be a closed system (apheresis/one piece kit). The nurse immediately put the machine on pause called over a second nurse and called the Therakos hotline where she was transferred to help in the EU. She was instructed to stop the procedure and "abort treatment". She was then instructed by this Therakos EU representative to return the red blood cells that had been removed from the patient that were in the bowl and return bag. One hour and a half after the incident, the nurse received a call from Therakos company representative in the US stating that you should consult with a physician before reinfusing the blood when you have a leak in the kit. This technician requested picture and the kit back.
Instrument, Ligature Passing And Knot Tying Brand: Corknot® Quick Load® Model#: 030850 Cat #: 030850 Other #: 31350	LSI Solutions, Inc.	Aortic valve surgery using a bovine valve was completed a few years prior. During that surgery the core knot device was used to place valve. Within one year valve insufficiencies were noted with the patient. The patient required another aortic valve replacement and during that procedure it was noted that the core knot fasteners had damaged (perforated) the bovine valve placed previously.

Device	Manufacturer	Problem
Device 1: Intraocular Lens Brand: Acrysof® Model#: SA60WF Cat #: SA60WF.235 **Device 2: Iol Cartridge** Brand: Monarch Iii "d" Cartridge Model#: 8065977763 Lot #: 32511809	Alcon Laboratories, Inc. Alcon Laboratories, Inc.	During the procedure, an intraocular lens was passed to the surgical field and inspected by the surgeon under the microscope. The lens was then loaded into the cartridge. After inserting the lens, the surgeon noticed a scratch on the lens and removed it from the patient. A different lens was successfully inserted into the patient's left eye and the procedure was continued as planned. No harm came to the patient. The IOL, cartridge, and inserter were saved for inspection. Several similar occurrences of scratched IOLs have been reported internally at this site. In the majority of the cases, the lens was left in place as the scratch was located on the periphery of the lens and would not affect patient vision. We have been encouraging surgeons to save the devices and report them on our hospital's internal system so that we can provide product specific information to the FDA. This was the first scratch in which we received enough product information to investigate and report the event. In many cases, it appears that the cartridge tips might be responsible for the scratches. We confirmed that surgeons are using the proper cartridge for the IOL size and will continue to monitor the issue and report lot numbers of cartridges that potentially have defects on their inner edge.
IV Tubing Extension Brand: Lifeshield Lot #: 66132NS	Hospira, Inc.	IV therapy nurse reports that patient was being assessed for new PIV site in the right arm. No current peripheral IV's or medications infusing in the right upper extremity. Accessed vein in right forearm without difficulty with #22 gauge angio. Attached newly opened saline lock, aspirated blood and flushed with 10mL NS. Saline lock was in sealed package prior to connection with no obvious abnormalities. Post flush and clamping of saline lock, there was a gray particulate matter that appeared internally within the saline lock tubing. Site was assessed by another RN and the saline lock was promptly removed and replaced with new saline lock, aspirated, and flushed with 10mL NS without incident.
Needle, Hypodermic, Single Lumen Brand: BD Precisionglide Needle Lot #: 5148847 Cat #: 305106 Other #: 3038290305 1060	BD	While attempting to inject Botox for routine migraine treatments, it was noted that the glide needles where not penetrating the skin due to apparent "dullness". This occurred on two different dates and with two separate providers. In each case additional needles from the same box were opened and attempted to be used, again with the same difficulty. Needles from another box were subsequently used with successful treatment to the patients. The manager was notified and two boxes of needles, from the same lot were pulled off the shelf.
Plate, Fixation, Bone Brand: Stratos Model#: 014-01001 Lot #: 2013003201 Cat #: 014-01001	MedXpert GmbH	Healthy very active man was found to have a chest wall mass and underwent incisional biopsy followed by a complex chest wall resection approximately 6 months ago. His pathology demonstrated a chondrosarcoma. He required resection of three ribs and a reconstruction was performed with the Stratos system. A portion of the diaphragm was resected and replaced with a vicryl mesh. He did well after surgery noted persistent pain in the area of the surgery. He had a recent CT scan about a month ago followed by a chest x-ray which showed there was a migration of the lower Stratos rib fixation element.

Device	Manufacturer	Problem
Portable Cardiology Monitoring Brand: Lifewatch	LifeWatch Services, Inc.	Late last year, we discovered that we were having data integrity issues with LifeWatch's portable cardiology monitoring system. This particular patient's cardiology information was "merged" with another patient and as such the patient was believed to have A-Fib when in fact he did not. The patient was given medication that was not needed, but there was no other harm to him. However we are concerned that this data integrity issue is not isolated to this case. Our IT (Information Technology) Department was able to recreate this issue. We also have concerns that this may go all the way back to 2012. To date, we have not heard back from the manufacturer on this issue, they cancelled our meeting last week. Manufacturer response for LifeWatch Portable Cardiology Monitoring, LifeWatch (per site reporter) ========== The manufacturer is not being as helpful in resolving this issue as we would like. We have had this software in place since 2008 and there were documented issues back in 2012 that we are not sure have been resolved. We are also concerned that the vendor does not have the raw data in order to review other patients to make sure their data is correct.
Pump, Infusion Brand: Alaris Model#: 8100	CAREFUSION 303, INC.	Medication infused in 2 hours instead of 16 hours. RN concern there was an issue with Alaris cassette and/or IV tubing.

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 March 2017 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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