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/UCM561666.pdf

510(k)s Final Decisions:
https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM569547.pdf

In Brief

As of October 4, 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

Endovascular Graft Systems: Letter to Health Care Providers
September 28, 2017
The FDA is evaluating recent information regarding Type IIIa and IIIb endoleaks with the use of endovascular graft systems indicated for a procedure known as endovascular aneurysm repair (EVAR). EVAR treats abdominal aortic aneurysms (AAA) and aorto-iliac-aneurysms. FDA is bringing this potential complication to your attention to remind and encourage you to report Type IIIa and IIIb endoleak events to the manufacturer and the FDA. This may include reporting individual events as well as rates you may have experienced in your practice.

TAH-t Companion 2 Driver System (C2) and Freedom Driver System by SynCardia Systems: Letter to Health Care Providers
September 25, 2017
The FDA issued an update to the October 2016 letter to healthcare providers, to inform the health care community of the most recent, interim results from the ongoing SynCardia TAH-t post-approval study that is looking at mortality and neurological adverse events. These interim results continue to reflect a higher three-month mortality rate for the subgroup of patients requiring pre-implant circulatory rescue interventions when using the C2 Driver System compared to those using the CSS Console. The mortality rates for patients who did not require pre-implant circulatory rescue interventions continued to be similar for the C2 Driver System compared to the CSS Console.

Bridge Occlusion Balloon Catheter Model 590-001 by Spectranetics: Class I Recall
September 25, 2017
Spectranetics is recalling its Bridge Occlusion Balloon Catheter due to the possibility of a blocked guidewire lumen in some device units. If a device with a blocked guidewire lumen were to be used during the procedure, the device would not be positioned correctly and hemorrhage would not be controlled. This would delay life-saving treatment, which may result in immediate and serious adverse health consequences, including death.

Urogynecologic Surgical Mesh Implants by Boston Scientific: Notification
September 19, 2017
After extensive review of data and information from various sources available to the FDA, including data and information from Boston Scientific and results from the FDA's own testing of the finished product, the FDA has determined that the change in supplier of the polypropylene used to manufacture Boston Scientific's urogynecologic surgical mesh currently on the market does not raise new safety or effectiveness concerns.

AAMI Foundation Upcoming Events

The AAMI Foundation is hosting several upcoming events including the following:

FREE Seminar: Utilizing Lean Methodologies to Manage Telemetry Devices: October 20, 2017, 12-1pm EST

Learn how a 716-bed hospital that was struggling with managing the inventory of telemetry boxes and leads overcame these problems. Seminar discussion topics will include:

- Discuss the effects of poor telemetry device management in the acute care setting.
- Explain benefits of inventory control to improve patient safety and financial mitigation.
- Explain how to recognize key stakeholders required for telemetry inventory.

To register - https://register.gotowebinar.com/register/8481740833833565442

AAMI Foundation Annual Forum: Hot Topics in Patient Safety
November 18 and 19, 2017—San Diego, CA

This forum is intended for professionals who engage in pain management, alarm management, and infusion therapy, including nurses, pharmacists, physicians, clinical nurse specialists, respiratory therapists, and hospital senior leaders, as well as biomedical and clinical engineers, academics, and regulators. During this event AAMI will address several patient safety challenges including:

- Learn how to save patients from “failure to rescue’ events.”
- Decrease the number of nonactionable clinical alarms.
- Address key challenges to improving infusion therapy safety.

To register - http://my.aami.org/store/events/registration.aspx?event=FDARMN17

HIGHLIGHTED REPORTS

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

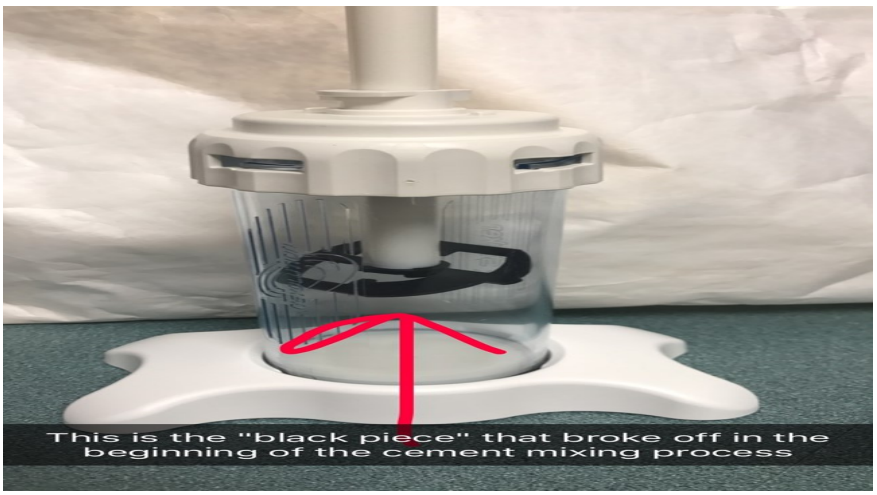

Special Note:

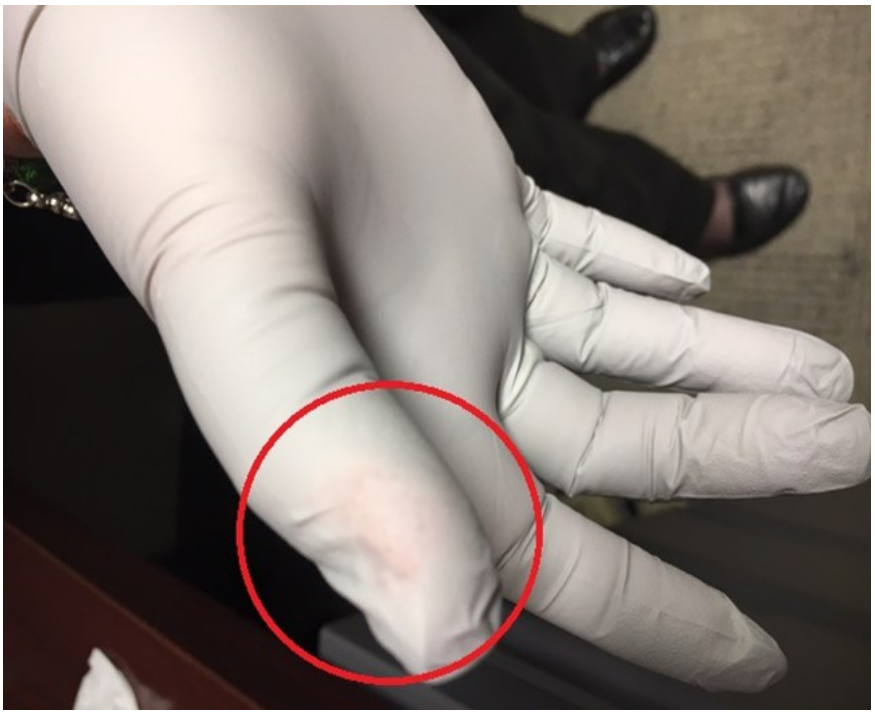
The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years 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
Bed, Flotation Therapy, Powered Brand: Versacare Model#: P3200K000500 Other #: M05093200K0005005	HILL-ROM, Inc.	Patient in bed and alarm was set by nurse on least sensitive setting to allow the patient to sit on the edge of the bed for breakfast. The patient had previously tried to get up and the alarm had alerted staff. This is a semiprivate room and the nurse was talking to the patient in the other bed when she saw the patient begin to walk around the curtain between the patients. The patient fell straight back striking the floor. The alarm did not activate when the patient stood up. The patient was recovering from a hip fracture. This fall resulted in a secondary fracture (non-surgical) to the right femur.

Device	Manufacturer	Problem
Epidural Anesthesia Kit Brand: Design Options® Model#: 552122 Lot #: 0061547772 Cat #: 552122 Other #: Spring-wound Catheter 19 Ga. Closed tip, Toughy 17 Ga x 4 in epidural needle	B. BRAUN MEDICAL INC.	The patient was undergoing bladder surgery and an epidural was requested. The catheter, once placed, resulted in leaking around the insertion site. When the provider attempted to remove the catheter, it broke with only a portion of the catheter being withdrawn. Neurosurgery was consulted and the patient required surgical removal of the catheter fragment and internal wire fragment. There were no complications from the removal and the patient went on to have surgery without an epidural being placed. Of note, on a placement attempt just prior to this insertion, a "wet tap" occurred. Upon review, after seeing a trend of wet taps, it was discovered that the wrong needle was placed in new epidural kits that were ordered from the manufacturer. The manufacturer was notified and the appropriate needles were taped to the epidural trays until new trays, with the correct needles, arrived to replace the current stock. Thus, the patient had two issues with the devices in the epidural tray kit during the same procedure.
Pump, Infusion Brand: Alaris Model#: 8015	Carefusion 303, Inc.	Code blue initiated on patient. During code, Alaris pump had three channels running, one with Neosynephrine infusing at 300 mcg/min, one with Levophed at 30 mcg/min, and Dobutamine at 7 mcg/min. All channels suddenly failed, flashed red and alarmed "channel disconnected." Attempted to turn channel off and reboot brain but it failed. All drugs were off in order to remove them and reprogram on another pump. Patient sent to Cath lab.
Shunt, Central Nervous System And Components Brand: Monitorr Csf External Drainage Syst Other #: Pole Mount Assembly	Integra Neurosciences PR	When the nurse entered room, pole-mounted external ventriculostomy drain (EVD) was noted to be at ~9cm BELOW External Auditory Meatus (EAM). That is well below the set and desired level for the Integra Neuroscience Drain. The EVD had 50cc drained from the lumbar drain. The physician was notified and examined the patient. The EVD was then raised to 10cm ABOVE the EAM and the device was immediately seen sliding down the lumbar drain pole. Multiple attempts were made to tighten the screw on the pole without success. The pole mount changed out. The Manufacturer was contacted by the clinical nurse specialist (CNS) assigned to this Neuroscience floor.

Device	Manufacturer	Problem
Light, Surgical, Ceiling Mounted Brand: Mira Led Series Minor Surgical Lights Model#: Mira 50 Cat #: L-MED50-CM-SC	Amico Lights Corporation	While adjusting the overhead LED exam light in the emergency department exam room, the LED light head separated from the ceiling mount arm and was caught by the Nurse before hitting the patient's gurney. The exam lamp cantilever arm sprang back towards the ceiling and could not be grabbed. Inspection of the separated light head noted cracking and separation of the plastic LED lamp shroud and deflector assembly right where the assembly attached to the ceiling mount arm. Engineering inspection of the remaining exam lamps in the department noted similar cracking at the light assembly and arm mounting section. Please see pictures below:  

Device	Manufacturer	Problem
Pump, Infusion Brand: Alaris Model#: 8100 Lot #: 12273911 	Carefusion 303, Inc.	The Alaris pump was infusing TPN on a NICU infant at 5.4 milliliters per hour. The TPN bag contained 130 ml and was hung at 16:43. Later that evening at the 21:30 check, the TPN bag was empty. The infant's blood sugar was elevated when checked.
Ventricular (Assisst) By-pass Brand: Heart-mate Ii	Thoratec Corpo-ration	The patient was found collapsed and unresponsive. Emergency Medical Services (EMS) was unable to resuscitate the patient. The EMS operator did note that the System Controller "lights were on and green."
Transducer, Ultrasonic, Di-agnostic Brand: Ec9-4 Transducer Model#: 10041225 Lot #: C4553580	Siemens Medical Solutions USA, Inc.	The probe was given to the Biomed department to repair cracked housing on the connector side.
System, Ce-ment Mixing Lot #: 17184022 Cat #: 0606-563 -000	Stryker	When beginning to mix the cement, the black missing piece broke off of the mixing arm, which caused mixer to malfunction and fall to bottom of the cement mixing vessel. The cement was unable to be mixed. New cement and mixer had to be retrieved. This extended OR time while new materials were retrieved, set up, and mixed. This was also a waste expense for the broken piece. Please see picture below: 

Device	Manufacturer	Problem
Specialty - tested For Use With Chemo-therapy - Patient Exami-nation Glove Brand: Halyard Sterling Lot #: SP7143ZZZ_08 AX Cat #: 50706	Halyard Health, Inc.	Halyard Sterling Nitrile powder free exam gloves, Size SMALL, Ref 50706 have visible 'weak' areas on one or more fingers of the gloves. Not every glove is affected although a majority of random gloves throughout the box have these 'weak' areas and several cre-ate holes or tear as user is inserting hand into the glove. Currently have (2) boxes of this same lot affected. Currently no issues report-ed with the other sizes of Halyard gloves. Please see pictures below:  

Device	Manufacturer	Problem
Tubes, Gastro-intestinal (And Accessories) Brand: Neomed Enteral Feeding Tube Model#: FTS8.0V-EO Lot #: 20160703 & 20160817 Cat #: FTS8.0V-EO 	Neomed, Inc.	NICU - Infants had to have feeding tubes removed and replaced unnecessarily. An infant had 8 Fr OG placed on 10 hours later the feeding tube hub/cap was found to be disconnected from the actual tube. It appears the hub slipped off the tube not that the tube was cracked or broken. Another event report on two days later described the same issue with this type feeding tube. Multiple product issues lead to further investigation. Two Lot numbers were identified, removed from hospital supplies and the distribution warehouse. The manufacture provided replacement product. Affected Lots #20160703 and #20160817. Three weeks later the NICU reports identified the same problem. The manufacture had never removed the two affected lot numbers from there distribution and those affected lot numbers were shipped to the distributor again. The product reported was the same lot number that had been removed before. For a second time the product was removed and replaced. Nearly 3 months later the same lot number has shown up in the hospital NICU supply and the same problems are reported. The orange hub detaches from the feeding tube. Feeding tube need to replace on infants due to the defective product. This is the third occasion in which the same lots of defective feeding tubes need to be removed.
Ventilator, Continuous, Facility Use Brand: Base Unit Servo-u	Maquet Critical Care AB	Patient on Maquet Servo-U became disconnected and ventilator did not alarm circuit disconnect.
Syringe, Piston Brand: Humapen Luxura Hd Model#: MS9673 Cat #: MS9673 	ELI LILLY AND COMPANY	Patient presented to emergency department (ED) in diabetic ketoacidosis and was admitted to intensive care unit. Patient responded quickly to treatment and was transferred to acute care unit the next day and discharged home. Parent reported that child had received a Luxura insulin pen at a prior clinic visit for use on insulin coverage, since it could administer insulin in 0.5 unit increments. Stated had not used it until 3 days prior to emergency department presentation, as was using Humalog Quick pens that they had an active script for. Had run out of the quick pens, so 3 days earlier started to use the Luxura insulin pen. It had a cartridge in it and was using that for insulin coverage. Prior to coming to emergency department, the parent looked closely at the Luxura pen and saw an expiration date of 2013 on the cartridge and thought she had been giving the child outdated insulin. Brought pen with her to ED and when hospital staff looked more closely at it and removed cartridge, realized it was the saline cartridge that is used for teaching/demonstration purposes (never used for injecting into patient). It was realized at that time that the saline cartridge had not been removed during the clinic visit to provide the Luxura pen home, and that the parents had never obtained the insulin cartridges that had been prescribed for use with the pen. Concern is that the saline cartridges provided by the company for teaching purposes are not well marked and are hard to read when in the Luxura pen. Staff wondered if it is possible to have better labeling of the saline cartridge that would make it easily distinguishable from the insulin cartridges. The fact that saline cartridge was expired is not an issue as this is what they supply for demonstration purposes of how to load the pen and dial the correct dose. Doctor had mentioned contacting company about the labeling, but I wanted to submit report as well. Unknown if Doctor contacted Eli Lilly. Unknown if doctor contacted manufacturer.

Device	Manufacturer	Problem
Ventilators Brand: Versa-med Ivent Model#: 201 Other #: Serial # 12487, 12308, 12567, 12368	GE	Clinical Engineering reports finding 70% of their ivent ventilators at one hospital and 20% at second site which inadvertently cycle power when the power switch cover is lifted and allowed to snap back into position

Links to FDA/CDRH Databases and Other Information Sources

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 October 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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