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/UCM591257.pdf

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm587897.htm

In Brief

As of January 5, 2018

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

Reprocessed Agilis Steerable Introducer Sheath by Sterilmed: Class I Recall

January 2, 2018

The Agilis Steerable Introducer Sheath's hemostatic valve, which prevents blood from flowing back through the valve, may fail due to an improper seal of the sheath hub. Improper seals can allow blood to leak through the hub, cause the cap to fall off during the procedure, or can create a difference in pressure that allows air into the circulatory system (air embolism).

Defibrillation Electrodes for Lifepak AEDs by Physio-Control: Class I Recall

December 19, 2017

Physio-Control Inc. is recalling infant/child defibrillation electrodes because the artwork on the pads within the packaging shows incorrect placement instructions for infants. There is no issue with the performance or function of the defibrillation electrodes. However, incorrect placement of the electrodes on an infant may result in failure to deliver an effective shock to an infant in cardiac arrest.

Injectable Silicone for Body Contouring and Enhancement: FDA Safety Communication

November 14, 2017

The FDA is alerting the public and health care providers that injectable silicone is not approved to enhance or augment the body. Such use can lead to ongoing pain, infections, and serious injuries, such as scarring and permanent disfigurement, embolism (blockage of a blood vessel), stroke, and death. The FDA is aware of cases where patients have received injectable silicone for body contouring purposes, such as gluteal or breast enhancement ("butt fillers" or "breast fillers"), by unqualified providers posing as doctors or licensed healthcare practitioners in non-clinical settings such as residential homes or hotels. The FDA is aware that some injectors have falsely told consumers they were receiving an FDA-approved dermal filler, but consumers were instead injected with silicone. Injectable silicone is permanent, with side effects that can occur right after the injection and up to years after treatment. Silicone spreads and migrates easily inside the body, which may worsen adverse events and make surgical attempts to remove the silicone oil more difficult or impossible.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during December 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
Adapter, Nebulizer Brand: Aeroneb Lot #: 170615 Cat #: AAA-1 	Vapotherm, Inc.	The Vapotherm aeroneb adapter for the precision flow vapotherm was being used with an aerogen nebulizer. The adapter pops out of place if an occlusion occurs or if not securely fit in place. These two items are provided and validated as being able to be used together by Vapotherm. Currently this combination has only been used in the NICU due to its higher efficiency. If the system pops off it can potentially be dangerous to the patient or the staff. In this case, it was reported as occurring, but no patient was identified. The biomed department was able to reproduce the event. Since the event the Vapotherm adapter and Aerogen nebulizer are no longer used together. Per manufacturer's response to the site, the manufacturer recommended reducing the flow rate when securing the adapter and noted the issue would not occur if the adapter is on and properly secured.

Device	Manufacturer	Problem
Bed, Ac-powered Adjustable Hospital Brand: Secure S3 Model#: 3005S3EX Other #: Order No. 4252067	Stryker Medical	Clinical Engineering was informed about Truss Head Screws becoming unfastened on the Litter Assembly (Head Assembly) of a new Secure S3 bed. The patient noticed a rocking motion on this part of the assembly, and notified staff. A second Secure S3 bed, on the same floor, was tested by our Biomed Technician and found the same problem.
Cable, Electrode Brand: Intellivue M1669a Ecg Trunk Cable Model#: M1669A Cat #: M1669A Other #: 989803145071	Philips Medical Systems	While inspecting the bedside monitors, the clinician noted excessive deterioration of the ECG trunk cable near the ECG lead connection point. RN noted that the insulating cover was "melting" and separation of the connector body covering. Biomedical contacted and also confirmed that the connector body was being dissolved by some cleaning agent. Biomedical inspected additional ECG trunk cables and noted the same plastic breakdown occurring. Biomedical contacted EVS and the manufacturer for advise on cleaning agents allowed. Biomedical substituted with an alternative ECG trunk cable that could be used without deteriorating effects until cleaning issue/ substance resolved.
Device 1:Clip, Implantable Brand: Lapra-ty Model#: XC200 Lot #: JC2048 Cat #: XC200 **Device 2: Clip, Implantable** Brand: Lapra-ty Model#: XC200 Lot #: KC2110 Cat #: XC200 **Device 3: Clip, Implantable** Brand: Lapra-ty Model#: XC200 Lot #: JE7143 Cat #: XC200	Johnson & Johnson International, Inc. Johnson & Johnson International, Inc. Johnson & Johnson International, Inc.	OR staff pulls operative sterile supply items required for the next day's cases, into disposable plastic bags as a daily task. It was reported by one RN that the packaging of the LapraTy foil packaging contained several creases and appeared damaged. The RN opened the package and was able to spot pin-prick holes in the packaging. Upon follow up by Clinical Engineering, it was reported that this is a regular occurrence, and 3 samples were saved: one from the above event and two that were also noted during unknown case set-ups. The foil packaging is very fragile and can easily become kinked, bent, or crumpled. Although there are no easily noticeable holes, when each package is held in front of a light, several pin prick holes can be observed, indicating compromised sterility of the product. Images of the 3 packages positioned in front of a light can be viewed under the attachments tab.

Device	Manufacturer	Problem
Gauze/sponge, Internal, X-ray Detectable Brand: Vistec X-ray Detectable Sponges Model#: 7317 Lot #: 17H197562 Cat #: 7317	Covidien	Circulating Nurse setting up for a case. When opening a single pack of Raytec sponges, the circulator noticed two extra sponges on top of the 10 sponges with tape band.
Implantable Pacemaker Pulse-generator Brand: Allure Rf Model#: PM3222	St. Jude Medical	The patient was undergoing a pacemaker generator change. The existing leads were used. The provider swapped the ventricular leads. The existing leads were greater than 10 years old and the serial numbers were worn out. The model being replaced was an upgraded model, one that had moved the RV lead and LV lead from the current model. The leads were swapped. The patient returned the following day to the EP Lab and the leads were swapped back to the correct position.
Needle, Hypo-dermic, Single Lumen Brand: Jelco Model#: 982312 Lot #: 3491835 Cat #: 982312		On the same day, two needle sticks occurred, which involved the same device and two different users. Event #1: Blood was drawn with a butterfly needle. The safety component was pulled closed and a piece of the needle was still exposed even after closed as far as it would go. As the needle was disposed of, the user didn't realize the needle was still exposed and received a needle stick in the palm of hand. Event #2: After drawing blood from a patient, the user withdrew the needle. It failed to lock as the user was turning to dispose of the needle. The user stuck himself with the needle.
Pediatric Crib Brand: Cub Pediatric Crib Model#: FL19H Cat #: FL19F/H (190) 	Stryker Corp.	The primary nurse and NA left the patient's room. All side rails on the crib were up. The patient's parents were not in the room. The primary nurse started her rounds approximately 15 minutes later and saw that the patient was not in her crib. Patient was found standing at the foot of the crib. The foot of the bed railing was partially down. The patient had a bump on her head. CT scan was completed and was negative. Two bags belonging to the parents were hanging on the foot rail handle. They had been hanging dirty clothes there, as they had been staying in the room with the patient, but on this day the parent's had hung other personal belongings, one of which was a heavy bag of books. We believe we recreated the event by hanging a 25 pound weight from one of the crib handles. The handle rotated and likely decreased the locked position security. We are not certain at what minimum weight this inadvertent rotation can occur, or how potentially having bag straps or closure ropes wedged down behind the handle mechanism affects functionality of the locking mechanism. We will no longer allow use of the bed handles as hanging places.

Device	Manufacturer	Problem
Port Introducer Kit Lot #: 435984 Cat #: 03-4038A	Cardinal Health	Patient connected to elastomeric pump containing 5FU for continuous home infusion. Patient reported to the chemo infusion center around 11 am to have his fanny pack replaced as the zipper had broken. At that time, everything was working properly. Around 2pm the patient reported back at the infusion department because the tubing from the 5FU pump had become disconnected from the tubing on the Huber needle. Upon examining the patient and the equipment, the clave connector had become loosened to the point it came disconnected from the Huber needling tubing. Subsequently the patient had chemotherapy on his clothing. Because the vascular access was compromised, the huber needle was removed.
Set, Administration, Intravascular Brand: IV Administration Set Model#: 490368 Cat #: 490368	B. Braun Medical, Inc.	When Pitocin bag was spiked with tubing, the medication leaked out around the spike. When staff tried to remove the tubing from the bag, the spike broke.
Spinal Epidural Anesthesia Kit Brand: Espocan® Model#: ES1827KDS Cat #: 333194	B. Braun Medical, Inc.	The saline in the epidural kit which should be PF and for epidural use is labeled "FOR IV USE ONLY" with no mention of being PF. B. Braun's ESPOCAN combined spinal and epidural anesthesia tray has saline in the kit which should be PF (for epidural administration) but is listed as NON PF and for IV USE ONLY. This could be detrimental to many patients if given epidural route.
Surgical Pack, Custom Pack Brand: Dynj Custom Pack Model#: DYNJ54802B Lot #: 17HD2663 Cat #: DYNJ54802B	Medline Industries, Inc.	While setting up for the case and counting sponges, a sponge was opened and what appeared to be animal fecal material fell out from the sponge. The sponge and pack were removed from service and replaced. The procedure was completed as planned with no delay or further issues. The sponge will be returned to the Medline representative.
Syringe, Piston Brand: Bd Luer-lok Lot #: 7122994 Cat #: 309657	BD	LPN drew up Rocephin and immediately noted the syringe to have fluid behind the plunger prior to injection. LPN then had an additional failure in the same lot number and was able to replicate the problem with up to 3 syringes. There was no patient contact with defective syringes. All other syringes by same lot number isolated. Interpretation by Practice Manager: It appears the plunger turns sideways just a little bit, allowing fluid to escape behind the plunger into the barrel of the syringe above the plunger.

Device	Manufacturer	Problem
System, Thermal Regulating Brand: Blanketrol Iii	Cincinnati Sub-Zero Products, Inc.	The Cincinnati Sub-Zero Blanketrol III system was being used to cool body temperature to 33.5. The body temperature never got below 34.0. The nurse noticed that there was no water in the cooling blanket. The Cincinnati Sub-Zero Blanketrol III system was switched out. No untoward patient effects.
System, Surgical, Computer Controlled Instrument Brand: Hot Shears (Monopolar Curved Scissors) Model#: 400180 Lot #: M10170912	Intuitive Surgical, Inc.	During a robotic case, staff noticed the Tip Cover Accessory for Monopolar Curved Scissors are splitting at the seam. Staff went through 5 tips during the one case. One of them is missing a very small piece that became detached during the procedure. This piece was likely removed from the surgical site via suction. Without complete coverage on the Monopolar Scissors, patients are at risk for burns. The patient was not harmed as the covers were replaced when defects were noted. The procedure was completed as planned. Clinical Engineering received 4 of these tip covers, all from the same lot #. Microscope images were obtained and demonstrate that the origin of each split is at the seam of the material. All pieces will be returned to Intuitive Surgical for failure analysis.
Vinyl Patient Examination Glove Brand: Sensicare Ice Model#: MDS6801 Lot #: AN709540946 Cat #: MDS6801 Other #: SensiCare Ice Blue Nitrile Exam Gloves,Dark Blue, Small	Medline Industries, Inc.	While donning nitrile exam gloves, the clinicians noticed some type of material in the gloves. Upon inspection of the glove, the clinician removed a foreign object from the glove. The glove and object were retrieved and sent to Biomedical, along with the original glove container to be sent to the manufacturer for analysis and reporting. The clinician ordered a new box of exam gloves. No apparent patient harm from this event.
System, Nuclear Magnetic Resonance Imaging Brand: Oasis Other #: 1.2T MRI system	HITACHI LTD., MEDICAL SYSTEM OPERATIONS GROUP	A male patient had an MRI scan completed several days ago. During his scan, he felt warmth in his mid-abdomen. He did not report that to the MRI technologists at the time of his visit. The patient telephoned the MRI manager a few days after the scan to report that he has an area of blistered burn that developed on his abdomen where it was in contact with the MRI magnet bore. The MRI manager and Radiology/Imaging quality leader for that area telephoned the patient the next day to learn more about how this happened. The patient had a scheduled appointment with his primary care physician (PCP) that same day. The PCP confirmed the small area (1.5 cm by 0.5cm) of second degree burn and prescribed topical silvadene cream to be applied to the area twice daily. PCP documents that there is no evidence of surrounding cellulitis.

Device	Manufacturer	Problem
Ventilator, Emergency, Manual (Resuscitator) Brand: Airlife Lot #: 0001145284 Cat #: 5404L 		Respiratory Therapist reported, "Patient in CICU intubated called to the bedside by RN because the patient was not oxygenating and SPO2 was falling. When I came in the room the RN had reached for our resuscitation bag and it had gotten hung up and pulled apart and fallen on the floor. I had another RT go get a new resuscitation bag. When I got the bag I checked the PEEP/exhalation valve to make sure I was delivering the appropriate amount of PEEP (Positive end-expiratory pressure) to the patient. When I put the bag on the patients ET tube I could not manage to keep appropriate pressures or deliver an appropriate volume to help recover her SpO2. I asked for a 2nd resuscitation bag to be brought in and continued to struggle to ventilate and oxygenate with the bag I had. When the next replacement bag arrived I again checked the PEEP/exhalation valve and was then able to effectively bag my patient so they were able to recover their SpO2 and be placed back on the ventilator. After my patient was stable we examined the first replacement bag and found that the PEEP/exhalation bag was cracked and that it was causing the bag to malfunction". The inventory at our hospital had been checked with the initial lot # concern of a critical airway may be compromised. A report was filed previously for multiple cracked valves. After the above incident with patient's critical airway compromised it was discovered that continued shipments and different lot numbers also contained defective peep valves from Vyaire. At that time all stock was pulled from crash carts, OR, ICU, and storage areas that the product was kept and all lots were checked for cracked peep valves. We found a significant amount of peep valves on all three products -the Vyaire product, Air life baby resuscitation flow bags, and anesthesia circuits have been reported to Vyaire as early as this summer and to FDA since the fall with additional addendum. While working with Vyaire about this problem they have still continued to ship in product containing a 11-12% inventory with cracked peep valves to our hospital. Our hospital has established the extra work at each shipment checking inventory when it arrives because of poor response from the company to be responsible for their inventory. Looking at alternative product is being addressed. The following are the lots # that are involved since discovery. 1L bags: 0001130873. Manufacturer date 8/4/17 0001105358. Date 6/1/17 0001145275. Date 8/30/17 0001139399. Date 8/17/17 0001130873. Date 8/4/17 0001030004. Date not logged 0001127073 Date not logged ½ L bags: 0001108624. Date 6/22/17 0001145284. Date 8/31/17 Anesthesia Tubing: 0001151137. Date 9/11/17; 0001133164. Date not logged; 0001136108. Date not logged; 0001110875. Date not logged

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 January 2018 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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