MedSun
Medical Product Safety Network

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

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

Premarket Approval Final Decisions:
http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM532485.pdf

510(k)s Final Decisions:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm531617.htm

In Brief

As of December 21st, 2016

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

Patient Safety Alert: Contaminated Organ Preservation Solution (December 21, 2016)
The CDC, Healthcare Resources and Services Administration (HRSA), FDA, and Iowa Department of Public Health (IDPH) are investigating a report of bacterial contamination of the organ preservation solution SPS-1, manufactured by Organ Recovery Systems (ORS). Do not use SPS-1 from the following lots: PBR-0074-330, expiration 07/01/2018 and PBR-0060-392, expiration 06/01/2018.

Standard Offset Cup Impactor with POM-C Handle by Greatbatch Medical: Class I Recall
(December 20, 2016)
The Standard Offset Cup Impactors are reusable handheld devices used during hip joint replacement surgeries to implant cups in the hip socket (acetabulum). Greatbatch Medical is recalling the Standard Offset Cup Impactor with a POM-C handle that failed sterility testing when sterilized in a dedicated instrument case. Non-sterile surgical devices can lead to infections, and other serious adverse health consequences.

FDA Bans Powdered Surgeon Gloves, Powdered Patient Examination Gloves and Absorbable Powder for Surgeon's Gloves
(December 16, 2016)
FDA displayed the final rule to ban powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove because these products present unreasonable and substantial risk to health care providers, patients and other individuals. The act of banning a device is an important decision, and the FDA only takes this action on rare occasions when necessary to protect the health of the public.

Convenience Kits containing Multi-Med Single Lumen Catheters by Centurion: Class I Recall
(December 9, 2016)
Centurion is recalling the Centurion Convenience Kits containing Multi-Med Single Lumen Catheters. The catheters have a potential for excess material to remain at the tip of the catheter from the manufacturing process. If this occurs, the excess material may separate from the catheter during use and could enter the patient's bloodstream. This can result in serious adverse health consequences.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during December 2016. 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
Bandage, Cast Brand: Tcc Ez Cast Lot #: 1115013	DERMA SCIENCES, INC	Patient was seen a couple of months ago and casted (cast called TCC EZ). The patient returned today for a follow up appointment and his RN reported that prior to removal of cast, patient complained the cast was "soft." The patient proceeded to say that he did not call to report it because he did not want to "bother us." The cast was removed and 2 injuries/new wounds located to the right lower leg. It was determined that our lot of casts were defective. Derma Sciences was notified immediately and remaining casts were collected and swapped for a new batch. The manager from Derma Sciences will be issuing a product complaint report.

Anesthesia Conduction Kit Brand: Perifix Fx Model#: CE17TKFCS Lot #: 0061519932 Cat #: 332097 Other #: PERIFIX FX Continuous Epidural Anesthesia Tray with PERIFIX 1 Ga x 3-1/2 in (9cm) Tuohy Epidural Needle winged and Springwound Epidural Catheter 19 Ga Closed Tip	B. Braun Medical, Inc.	Anesthesiologist called to labor and delivery for the placement of an Epidural catheter. After threading the epidural catheter into the patient, the anesthesiologist was unable to administer any medicine, the catheter lumen and distal ports were not patent. The epidural catheter was removed, and the MD provider opened a second epidural kit (with presumably the same lot #), and discovered the second catheter had the same defect. The MD provider accessed a third kit with presumably a different lot # from the anesthesia supplies cabinet in labor and delivery, and this time was able to re-access the patient's epidural space and administered epidural medicine with good effect and without further issues. All epidural catheter kits with the same lot # as the defective non patent kits, were removed and sequestered pending manufacturer notification. Manufacturer response for Epidural Catheter, PERIFIX FX Continuous Epidural Anesthesia Tray with PERIFIX 1 Ga x 3-1/2 in (9cm) Tuohy Epidural Needle winged and Springwound Epidural Catheter 19 Ga Closed Tip (per site reporter) ========== Not known
Light Source, Fiberoptic, Routine Brand: Luxtec	INTEGRA LUXTEC, INC.	While using the lighted breast retractor staff could smell something burning. Surgical team stopped operating and everyone in the suite searched for fire/burning. Smoke was noticed coming out of the light box where the lighted breast retractor was plugged in. The lighted breast retractor was unplugged and removed from the surgical field due to causing the small fire.
Device 1: System, Perfusion, Kidney Brand: Sps-1 Static Preservation Solution Lot #: PBR0074330 **Device 2: System, Perfusion, Kidney** Brand: Sps-1 Static Preservation Solution Lot #: PBR0060392	Organ Recovery Systems, Inc. Organ Recovery Systems, Inc.	A liver transplant recipient anesthetized on table. When the sterile bag containing the liver was opened, the transplant surgeon immediately noted a foul odor (later became even more potent) and the case was ceased until the source of the odor could be determined. Case subsequently cancelled as cause odor determined to be coming from at least two bags of organ preservation fluid. Samples of fluid were taken and sent to Microbiology; results came back positive for a number of organisms. Preliminary results showed the following: Sample [1] is original sample, directly out of bag perfusing one of the kidneys. Growth is abundant. Preliminary identifications so far are for Enterococcus casseliflavus and Pantoea agglomerans. Sample [2] is "sps straight out of bag into jar", and it looks clean by Gram stain. Sample [3] is "sps from jar w/lt kidney" and has a Gram stain similar to the original one from yesterday (mixed organisms, abundant). Sample [4] is "sps lot pbr 0060 392". Gram-positive cocci that are similar to those previously; for whatever reason they're more sparse and the Gram negative organisms are not here but may appear later in culture. Sample [5]is "sps lot pbr 0074 330". This appeared clean by Gram stain at the time.

Flexible Endoscopic Ultrasound Scope Brand: Eus Scope	Olympus Corporation of the Americas	During procedure, the physician had problems with inflate and flush functionality. The techs tried different buttons which appeared to help initially. Post procedure, the scope was sent for evaluation to an independent repair vendor. The vendor reported that the air/water channel had a partial blockage with unknown material. This was cleared and the scope was completely evaluated and found to be functioning properly. A single unrelated repair was completed during the evaluation. The repair vendor recommended review of reprocessing procedures take place with Olympus, which was scheduled and completed. Additional information is included in the mfr response and the purpose of this report is to point out the potential for the air/water channel to become blocked partially and the operator not realize it has occurred. ========== Manufacturer response for Flexible Endoscopic Ultrasound Scope, EUS Scope (per site reporter) ========== The local Olympus reprocessing specialist was contacted. Once the endoscope was returned to our facility, he evaluated the scope. He also provided additional in-service for staff on reprocessing this scope as well as cleaning the air/water channel. He corresponded with a colleague in another territory and they indicated this has occurred only one other time to their knowledge. It is unclear as to how this could have occurred. The reprocessing specialist provided additional information, such as there are no brushes that can reach this portion of the air/water channel. Irrigating water through this channel upon removal of the scope from the patient is considered best practice, since this scope is commonly removed and reinserted during the procedure. During the time the scope is removed, materials can dry out, potentially causing a source of blockage. This procedure is recommended regardless of whether the scope is going back in, or if the procedure is completed. These steps have been implemented.
Humidifier, Respiratory Gas Brand: Precision Flow	Vapotherm, Inc.	Yellow triangle with exclamation point error occured on Vapotherm while on patient. The error cleared when restarted, but FiO2 unstable and drifting to 21% when set at 100%. The Vapotherm technical support indicated failure of main board.
Automated External Defibrillators (Non-wearable) Brand: Onestep Cpr Aa Model#: 8900-0225-01 Lot #: 4016 Cat #: 8900-0225-01	BIO-DETEK INCORPORATED	Staff attempted to remove Zoll One Step AA pads from the package and when they removed the pads, the bottom of the pad stuck to the packaging causing damage to the pad. The pad tore. This error has occurred with multiple pads of the same lot number. Error has not occurred in pads with different lot number. Manufacturer response for Zoll One Step AA Pads, Zoll (per site reporter) Zoll reached out to me and asked about the incident. They asked if the pads could be returned to Zoll so they could conduct a full investigation with regards to how this situation occurred.

Dialyzer, High Permeability Brand: Nxstage Cartridge Express Lot #: 60878011 Cat #: CAR-505 Other #: $$0318608780117/	NxStage Medical, Inc.	A continuous renal replacement therapy cartridge was reported by surgical ICU staff to be sucking in air through the effluent filter located on the venous line. They have reported that this has happened on numerous cartridges from this lot number. SICU staff discarded the filter before clinical engineering was notified of the situation, but they did report the event to the manufacturer, NxStage. No harm came to the patients while this lot number of cartridges were being used. The SICU staff notified the manufacturer. Since the cartridge was discarded, the manufacturer encouraged staff to follow up if/when this occurs again so that they can actively investigate the issue. The manufacturer has also reached out to identify more information on the NxStage unit that this cartridge was being used on. They are also sending us a return kit so that they can investigate a cartridge of the same lot number being reported.

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/PostmarketRequirements/HumanFactors/ucm119185.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/cdrh/medicaldevicesafety/
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.accessdata.fda.gov/scripts/wlcfm/recentfiles.cfm
This database contains the most recent manufacturer warning letters.

To access additional January 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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