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):

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 May 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

FDA takes action to protect women's health, orders manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse to stop selling all devices
April 16, 2019
FDA ordered the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse (POP) to stop selling and distributing their products in the U.S. immediately. The order is the latest in a series of escalating safety actions related to protecting the health of the thousands of women each year who undergo surgery transvaginally to repair POP. The FDA has determined that the manufacturers, Boston Scientific and Coloplast, have not demonstrated a reasonable assurance of safety and effectiveness for these devices, which is the premarket review standard that now applies to them since the agency reclassified them in class III (high risk) in 2016.

Use of the Stryker Wingspan Stent System Outside of Approved Indications Leads to an Increased Risk of Stroke or Death: FDA Safety Communication
April 25, 2019
The WEAVE study was recently completed and showed a higher incidence of stroke or death when the Wingspan was used outside of the FDA-approved indications for use. The study obtained Institutional Review Board approval and was conducted at 24 clinical sites in the United States to further assess the rates of stroke or death within 72 hours of the Wingspan Stent placement procedure. A total of 198 patients were treated using Wingspan in the study. Of the 198 patients treated, 152 patients met the FDA-approved indications for use criteria, and 46 patients did not meet the approved indications for use criteria. There was a higher incidence of stroke or death within 72 hours of the procedure when the Wingspan was used in patients outside of the FDA-approved indications for use.

FDA Alerts Providers and Patients to Check for Premature Battery Depletion in Certain Medtronic Pacemakers: FDA Safety Communication
May 7, 2019
FDA is alerting health care providers and patients about issues that may cause batteries in certain Medtronic implantable pacemakers or cardiac resynchronization therapy pacemakers (CRT-Ps) to drain more quickly than expected without warning patients or health care providers. The FDA is aware of three medical device reports in which a Medtronic implantable pacemaker or CRT-P battery had fully drained because of a crack in the device's capacitor, without any warning to the patient or health care provider. If a capacitor in an implanted pacemaker or CRT-P is cracked, it can create an electric short, which can cause a battery to drain earlier than expected. If the battery is completely drained, the device will no longer deliver pacing therapy.

ECRI 2019 Top 10 Patient Safety Concerns

Organizations across the continuum of care are striving to become high-reliability organizations, and part of being highly reliable means staying vigilant and identifying problems proactively. This annual top 10 list helps organizations identify looming patient safety challenges and offers suggestions and resources for addressing them.

In selecting this year's list, ECRI Institute relied both on data regarding events and concerns and on expert judgment. Since 2009, when their patient safety organization (PSO), ECRI Institute PSO, began collecting patient safety events, they and their partner PSOs have received more than 2.8 million event reports. That means that the 10 patient safety concerns on this list are very real.

This year's list includes the following concerns:

1. Diagnostic Stewardship and Test Result Management Using EHRs

2. Antimicrobial Stewardship in Physician Practices and Aging Services

3. Burnout and Its Impact on Patient Safety

4. Patient Safety Concerns Involving Mobile Health

5. Reducing Discomfort with Behavioral Health

6. Detecting Changes in a Patient's Condition

7. Developing and Maintaining Skills

8. Early Recognition of Sepsis across the Continuum

9. Infections from Peripherally Inserted IV Lines

10. Standardizing Safety Efforts across Large Health Systems

CDC: 2017 National and State Healthcare-Associated Infections Progress Report

The Centers for Disease Control and Prevention (CDC) is committed to protecting patients and healthcare personnel from adverse healthcare events and promoting safety, quality, and value in healthcare delivery. Preventing healthcare-associated infections (HAIs) is a top priority for CDC and its partners in public health and healthcare. The 2017 National and State Healthcare-Associated Infections (HAI) Progress Report provides a summary of select HAIs across four healthcare settings; acute care hospitals (ACHs), critical access hospitals (CAHs), inpatient rehabilitation facilities (IRFs) and long-term acute care hospitals (LTACHs). Data from CAHs are provided in the detailed technical tables but not in the report itself.

The 2017 National and State HAI Progress Report provides data on central line-associated bloodstream infections (CLABSIs), catheter-associated urinary tract infections (CAUTIs), ventilator-associated events (VAEs), surgical site infections (SSIs), methicillin-resistant Staphylococcus aureus (MRSA) bloodstream events, and Clostridioides difficile (C. difficile) events. For each of the four healthcare settings, the report consists of national factsheets and detailed technical tables; the national factsheets provide a high-level view of HAIs at a national level, while the technical tables include additional statistics about HAIs, reporting mandates, and data validation efforts in each state and select US territories. The report's national factsheets, as well as the detailed technical tables, include infection-specific standardized infection ratios (SIRs), which measure progress in reducing HAIs compared to the 2015 baseline time period. The SIR is the ratio of the observed number of infections (events) to the number of predicted infections (events) for a summarized time period. In addition to the SIRs, the report includes the standardized utilization ratios (SURs), which measure device use by comparing the number of observed device days to the number of predicted device days. The SIR and SUR metrics are calculated using the 2015 national baseline and risk adjustment methodology.

HIGHLIGHTED REPORTS

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

Device	Manufacturer	Problem
Accessories, Cleaning, Pad Brand: Draco Model#: HY0305Z Cat #: HY0305Z	Cygnus Medical, LLC	Deep cleaning pads were found with mold inside sealed package. Expiration date 12/31/2020. Box was thrown away so we are unsure of the lot number.

Device	Manufacturer	Problem
Catheter, Hemodialysis, Triple Lumen, Non-implanted Brand: Mahurkar Model#: 8888102004HP Lot #: 1814300160 Cat #: 8888102004HP	Covidien LLC	Pt required Continuous renal replacement therapy (CRRT). Used Mahurkar acute high pressure triple lumen catheter tray, 12F x 24cm. line placed without incident, confirmed wire placement with US. However, when tried to remove the wire, unable to remove. Called vascular surgery for assistance who was ultimately able to remove the wire, which was quite kinked. The issue is that the wire in this kit is too flimsy to place a line, especially a dialysis line, which requires multiple dilations. The wire in this kit is different, as is the plastic sheath holding the wire, from the Mahurkar kits that do not have the third port (the wire in that kit is more sturdy). I have had issues with the quality of the wire in this kit while placing other HD lines as well. The vascular surgeon also felt that the original wire was not suitable for line placement.
Defibrillator Brand: Zoll XSeries Difibrillator Model#: X Series	Zoll Medical Corporation	We have had three separate instances of Zoll defibrillator malfunctions. This is the 3rd of three Zoll defibrillator malfunctions. This event occurred approximately four months ago with a Zoll X Series defibrillator. The unit was not recognizing the USB device flash drive so we could not transfer data from the device. This is the second time this has happened with this machine. The device was again returned to Zoll and this time they replaced the CP board to correct the issue. The device is only a few months old.
Electrocardiograph, Ambulatory (Without Analysis) Brand: Digitrak Xt Holter Recorder W/ leadwires Model#: Digitrak XT	PHILIPS MEDICAL SYSTEMS, INC.	24 hour Holter monitor was applied to the patient. Before patient left the office, name and ECG tracings were recording as usual. Upon Holter return and downloading, no ECG tracings were noted on the monitor.
Extracorporeal Dialysis System Brand: Baxter Prismaflex Extracorporeal Dialysis System (Crrt) Model#: Prismaflex Cat #: 107493	Gambro AB	During Continuous Renal Replacement Therapy the RN responded to the CRRT machine error for Effluent Bag full the CRRT machine gave an additional "Flow protection3" caution message. During troubleshooting the clinician received additional WARNING and MALFUNCTION messages including a Malfunction "Communication Error" message that locked up the CRRT not allowing any additional input from the user. The user contacted manufacturer and was informed that they would have to use hand pump to draw back blood in order to exchange CRRT filter set with new CRRT machine. There was also an additional previous event with this same malfunction error. Machine exchanged and sent to Biomedical to evaluation and repair. All machines in CRRT fleet recently had major software upgrade performed.

Device	Manufacturer	Problem
Device 1: Pouch, Colostomy Brand: Esteem Plus One-piece Drainable Pouch Lot #: 8B00773 Cat #: 416718 Other #: (DRN 1 PC Cut to fit 60/70 MM)	Convatec	Multiple colostomy bags found to have adhesive that does not stick. The part of the device that is supposed to be sticky is not sticky or tacky at all. It is immediately apparent that something is wrong with the product. We have notified the manufacturer and are returning multiple boxes. Multiple lots are affected. Lot 8B00773, 8K01707, 8G01414, 8J01719, 8K04961, 8G01414
Device 2: Pouch, Colostomy Brand: Esteem Plus One-piece Drainable Pouch Lot #: 8K01707 Cat #: 416718 Other #: (DRN 1 PC Cut to fit 60/70 MM)	Convatec	
Device 3: Pouch, Colostomy Brand: Esteem Plus One-piece Drainable Pouch Lot #: 8G01414 Cat #: 416718 Other #: (DRN 1 PC Cut to fit 60/70 MM)	Convatec	
Device 4: Pouch, Colostomy Brand: Esteem Plus One-piece Drainable Pouch Lot #: 8J01719 Cat #: 416718 Other #: (DRN 1 PC Cut to fit 60/70 MM)	Convatec	

Device	Manufacturer	Problem
Device 5: Pouch, Colostomy Brand: Esteem Plus One-piece Drainable Pouch Lot #: 8K04961 Cat #: 416718 Other #: (DRN 1 PC Cut to fit 60/70 MM) **Device 6: Pouch, Colostomy** Brand: Esteem Plus One-piece Drainable Pouch Lot #: 8G01414 Cat #: 416718 Other #: (DRN 1 PC Cut to fit 60/70 MM)	Convatec Convatec	Multiple colostomy bags found to have adhesive that does not stick. The part of the device that is supposed to be sticky is not sticky or tacky at all. It is immediately apparent that something is wrong with the product. We have notified the manufacturer and are returning multiple boxes. Multiple lots are affected. Lot 8B00773, 8K01707, 8G01414, 8J01719, 8K04961, 8G01414
Stapler, Implantable Model#: PVE35A,PCEE60A,PLEE60A,PSEE45A,PSEE60A,PSEE60A Lot #: R94D8T	Ethicon Endo-Surgery, Inc.	While opening supplies for surgeon's gastric bypass procedure the scrub technician noticed several black flecks on the stapler. Staff decided not to use the stapler and opened a new one. In the process of opening another stapler staff noticed black flecks in numerous other packages. The charge nurse, OR director and Materials Management staff was notified. The rep was called because the majority of our stapler stock was found to have the black flecks. Product was found that we were able to use to finish the cases for the day.
Sterilization Wrap Containers, Trays, Cassettes &Other Accessories Brand: Aesculap Steam Ster Locks Orange Model#: US906 Lot #: 585854-01 Cat #: US906	AESCULAP, INC.	We had nine sets with the Aesculap USA orange locks becoming un-locked after sterilization, cooling, and storage. The locks are designed to tolerate steam sterilization. This has happened before. Different instrument processors and supervisor assembled those sets. Steris, our sterilizer vendor, has checked the sterilizers and the sterilizers are staying within the required cycle parameters. This could hamper patient care and delay surgeries. The locks that failed have a slightly different color and feel thinner than those from batches or lot numbers that work properly.

Device	Manufacturer	Problem
Monitor, Vital Signs Brand: Suresigns Vs4 Cat #: 863283	Philips Medical Systems, Inc.	While connecting and setting the patient on a vital signs monitor with NBP, SPO2, and Temp, the RN set the alarm limits for SPO2 SAT, and Pulse Rate for the patient. While the clinician was attending to the patient, the monitor alarmed Low Pulse and reverted back to the programmed default values. For example, when SPO2 is set and saved for a low Sat of 85 and the low pulse rate set for 65, the patient is monitor at 95 SAT and a pulse rate of 70-72. The monitor suddenly alarms "Pulse Low" and reverts back to default setting of Low Sat 90 and Low Pulse 75. This alert occurs between 18 and 120 seconds. This issue is occurring on all recently purchased (95 each) Vital Signs monitors place into service in the last 4 months. Biomedical is unable to determine what is causing the default reverts which should only occur when monitor powered off, changing patient population profile, or physically changing each measurement limit. Biomedical tried to change the alarm limit after default reset but the same alert and default reset occurred. Biomedical advising clinical team to select safe default parameters and provide additional patient monitoring until issue is resolved by manufacturer. The monitor still gives accurate SPO2 and NBP readings. Manufacturer notified id defaulting issues and Biomedical to open work request with mfg.
Shunt, Central Nervous System And Components Brand: Codman Lumbar External Drainage Catheter Model#: 82-1706 Lot #: 211738 Cat #: 821706	CODMAN & SHURTLEFF, INC.	Lumbar drain was attempted to be placed in IR (Interventional Radiology). After second attempt of placing catheter, it was noted by that the end of the catheter was frayed. After looking closer, it was determined that a portion of the drain was no longer attached. Multiple images including a DynaCT in the room discovered a retained foreign body from the catheter. Catheter was removed and a new one placed.

Device	Manufacturer	Problem
Device 1: Set, Administration, Intravascular Brand: Plum Lifeshield Model#: 1233605 Lot #: 936405H Cat #: 1233605 **Device 2: Set, Administration, Intravascular** Brand: Plum Lifeshield Model#: 1233605 Lot #: 936405H Cat #: 1233605 **Device 3: Set, Administration, Intravascular** Brand: Plum Lifeshield Model#: 1233605 Lot #: 936405H Cat #: 1233605 **Device 4: Set, Administration, Intravascular** Brand: Plum Lifeshield Model#: 1233605 Lot #: 936405H Cat #: 1233605	Hospira, Inc. Hospira Inc. Hospira, Inc. Hospira, Inc.	During our NICU patients parenteral feedings and primary IV line assessments, the clinicians found leaking at the inline 0.2 micron filter assembly at the air vent valve section of the filter. This filter is located approx. 35cm proximal of the primary sets infusion cassettes. Leaking at the 0.2 micron filter has been reported in previous MedWatch reports from this facility. In this current MedWatch there were 5 reported incidents of leaking filters. All reported primary sets were of the same reference and LOT number. As our policy the sets were removed intact along with the product labeling cover to identify by Ref and lot number for manufacturer analysis. The sets were sequestered and set to Biomedical for reporting. Biomedical has 26 reports logged identifying these events with leaking 0.2 micron filters. biomedical is also awaiting the manufacturer report of the recent events that go back to 10/2018. The manufacturer has provided our facility the same product in different lot number to determine if additional failures occur. All 5 of primary sets involved in this report has occurred within the last 21 days.

Device	Manufacturer	Problem
Device 5: Set, Administration, Intravascular Brand: Plum Lifeshield Model#: 1233605 Lot #: 936405H Cat #: 1233605 	Hospira, Inc.	During our NICU patients parenteral feedings and primary IV line assessments, the clinicians found leaking at the inline 0.2 micron filter assembly at the air vent valve section of the filter. This filter is located approx. 35cm proximal of the primary sets infusion cassettes. Leaking at the 0.2 micron filter has been reported in previous MedWatch reports from this facility. In this current MedWatch there were 5 reported incidents of leaking filters. All reported primary sets were of the same reference and LOT number. As our policy the sets were removed intact along with the product labeling cover to identify by Ref and lot number for manufacturer analysis. The sets were sequestered and set to Biomedical for reporting. Biomedical has 26 reports logged identifying these events with leaking 0.2 micron filters. biomedical is also awaiting the manufacturer report of the recent events that go back to 10/2018. The manufacturer has provided our facility the same product in different lot number to determine if additional failures occur. All 5 of primary sets involved in this report has occurred within the last 21 days.
System, Tomography, Computed, Emission Brand: Discovery Nm/ct 670 Model#: Discovery NM/CT 670 Other #: nuc med gamma camera	GE MEDICAL SYSTEMS ISRAEL, FUNCTIONAL IMAGING	Two nurses rolled a patient bed into a nuclear medicine room. In an attempt to raise the bed to the level of the nuclear medicine bed, a part of the bed raised up into the camera cover, causing damage to the cover of the camera. The area around the camera is limited. The bed is large and takes up much of the space. There is a lack of space to properly see around the bed while it is being raised. Because of this, the nurses did not realize the bed was rising into the cover. GE came out to inspect the camera and damage was limited to the cover. The GE tech stated that they see this happen all the time. No harm to patient or staff, but the potential is there. The question was raised, "If it happens so often, why doesn't GE put a sensor on the camera when it senses the stress on the cover?"
Monitor, Vital Signs Brand: Suresigns Vs4 Cat #: 863283	Philips Medical Systems, Inc.	While connecting and setting the patient on a vital signs monitor with NBP, SPO2, and Temp, the RN set the alarm limits for SPO2 SAT, and Pulse Rate for the patient. While the clinician was attending to the patient, the monitor alarmed Low Pulse and reverted back to the programmed default values. For example, when SPO2 is set and saved for a low Sat of 85 and the low pulse rate set for 65, the patient is monitor at 95 SAT and a pulse rate of 70-72. The monitor suddenly alarms "Pulse Low" and reverts back to default setting of Low Sat 90 and Low Pulse 75. This alert occurs between 18 and 120 seconds. This issue is occurring on all recently purchased (95 each) Vital Signs monitors place into service in the last 4 months. Biomedical is unable to determine what is causing the default reverts which should only occur when monitor powered off, changing patient population profile, or physically changing each measurement limit. Biomedical tried to change the alarm limit after default reset but the same alert and default reset occurred. Biomedical advising clinical team to select safe default parameters and provide additional patient monitoring until issue is resolved by manufacturer. The monitor still gives accurate SPO2 and NBP readings. Manufacturer notified id defaulting issues and Biomedical to open work request with mfg. Please see pictures below:

Device	Manufacturer	Problem
Monitor, Vital Signs Brand: Suresigns Vs4 Cat #: 863283	Philips Medical Systems, Inc.	  

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 May 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:

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Food and Drug Administration
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