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 January 7, 2020

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

LivaNova Recalls VNS Therapy SenTiva Generator Due to Reset Error

January 2, 2020

LivaNova is recalling the VNS Therapy SenTiva Generator System due to an unintended reset error that causes the system to stop delivering VNS therapy. If device replacement is needed, there is a risk associated with additional surgery to replace the generator. LivaNova has received 14 reports of unexpected reset errors. 4 patients have required early revision surgery for failed devices. No deaths related to this issue have been reported.

Smiths Medical ASD, Inc. Recalls Medfusion® 4000 Syringe Pumps Due to Malfunctioning Alarms and Potential Interruption of Therapy

December 19, 2019

Smiths Medical has become aware of a software issue in the most recently updated Medfusion® 4000 Syringe Pump Firmware, Version 1.7.0, that could potentially cause the low battery alarms to stop working. If the battery alarms do not work, the healthcare provider using the pump will not receive audible or visual notification that the battery is shutting down. This may lead to an interruption of therapy which may lead to serious injury, adverse events, or death. Smiths Medical has received 74 complaints related to the software update. No injuries or deaths have been reported.

Cook Medical Recalls CrossCath® Support Catheters Due to a Manufacturing Error Which May Cause the Marker Bands to Dislodge or Cause Buckling

December 17, 2019

Cook Medical has identified that an error occurred during manufacturing which may cause the radiopaque marker bands to be too loose on certain CXC3.0 CrossCath® Support Catheters (compatible with 0.014” wire guides) and too tight on certain CXC3.4 CrossCath® Support Catheters (compatible with 0.018” wire guides). Marker bands that are too loose can dislodge from their original position and marker bands that are too tight can cause buckling.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during December 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
Device 1: Battery, Replacement, Rechargeable Brand: Molicel Lithium Ion Battery 11. 1vdc, 7. 8ah Model#: ME202EK Lot #: 1813 Other #: 453564509341 **Device 2: Monitor, Physiological, Patient Arrhythmia Detection Or Alarms** Brand: Suresigns Vs4	Philips Medical Systems Philips Medical Systems	While attempting to take a scheduled blood pressure reading for the patient the bedside monitor displayed a "Replace Battery Immediately" error message and would not allow the clinician to take a blood pressure. The monitor was plugged into AC power, but the error message caused the BP monitor to freeze and not allow any user interface action. Monitor was removed from service and sent to Biomedical for evaluation. Biomedical removed the rechargeable battery pack and pressed the self check key and noted that the battery charge indicator showed 100% charge. Re-insertion of the battery back into the monitor created the "Remove Battery Immediately" message. A new battery replacement was inserted into the monitor with no additional error messages. This was the second incident of this type of failure in the last two weeks on the same model and age of monitor about 11 months into service. The battery lot numbers were the same on both batteries. These LiIon batteries were to have a 36 month service life.

Device	Manufacturer	Problem
Bed, Pediatric Open Hospital Brand: Cub Pediatric Crib Model#: REF-FL19 Other #: Crib canopy FA64183; Crib and crib canopy 	Stryker Medical	Crib canopy in retracted position, toddler placed thumb in the hole that is used to lock the crib top in place when it is drawn down. Crib had to be manually cut to free the patient's thumb from this hole.
Interventional Fluoroscopic X-ray System Nederland B.V. Brand: Allura Xper Fd Model#: Allura Xper FD10/10 Cat #: 722011	Philips Medical Systems	A converter within the Philips XRay generator had an internal short and smoked. The concern for fire caused a procedure to be delayed; no harm to patient.
Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms) Brand: Philips Intellivue Mx400 Patient Monitor Model#: 866060 Cat #: 866060	Philips Medizin Systeme Böblingen GmbH	A patient, with continuous telemetry monitoring, was found unresponsive in the patient's room. Review of the monitor strips showed that the patient's heart rate was decreasing over a period of time prior to being found unresponsive. It is unclear at this time if the monitoring system alerted staff to the heart rate changes. HealthAlliance leadership immediately consulted with Philips to try to identify if the monitoring equipment contributed to this event. Analysis is ongoing.
Scope Model#: ENF-V3	Olympus	Scope was used recently with no signs of damage. It was sent out to SPD and then returned from SPD a few days later with a label that stated, "Scope failed the leak test" We have all witnessed different carriers handling the scopes in a very careless manner. The scopes leave clinic in good condition and return damaged. Too many scopes have failed a leak test this year (6?). This is a concern regarding both the care, transportation, and possible sterile processing of equipment. We recently had another scope, that was not used, not had not failed a leak test, go out to be cleaned and failed the leak test. Also, based upon this, the scope was sent in on an afternoon but didn't get processed by SPD until more than 24

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System, Peritoneal, Automatic Delivery Brand: Low Recirculation Volume Apd Set With Cassette Lot #: H19G12058 	Baxter Healthcare Corporation	Patient on Continuous cycling peritoneal dialysis (CCPD) in PICU. Standard treatment. Was on cycle 7 of 12. Leak was noticed at Drain line on BAXTER Low Recirculation Volume Automated Peritoneal Dialysis (APD) set with Cassette by PICU RN. Dialysis nurse was paged and arrived to PICU. Noted kink in cassette and visible leakage from line patient line was clamped immediately. Nephrology was also notified and made aware. Cell culture and intraperitoneal (IP) Antibiotics started prophylactically. Cell count resulted fluid clear, 1 white blood cell (WBC) and 19 Neutrophils. Pt afebrile. Pt mother was updated. On-call nurse inspected supply of Low recirculation cassettes that remained on the unit. Some were also noted to be defective. Entire Case was pulled and will be sent back to Baxter LOT # H19G12058 EXP# 2024-07-12.
Tray, Surgical, Instrument Brand: Genesis Container Lot #: 3201016D19, 3213043F19	CareFusion 2200, LLC	Genesis sterilization container opened for instrument tray access in OR case to find black debris on solid bottom of container. Containment measures for patient safety were completed and continue as needs are identified. Root Cause Analysis was conducted to determine Genesis container lid gasket material to be consistent with the debris material. 37 instances of black debris in Genesis containers were reported between a two-month timeframe. This has occurred on multiple occasions and involves multiple lot numbers: 3201016D19, 3213043F19, 3193383C19, 3205231E19, 3205233E19, 3205233E19, 3203317D19, 3193884C19, 3206144E19, 3207744E19, 3203316D19, 3205232E19, 3207311E19, 3206146E19, 3206143E19, 3208300E19, 3204536E19, 3203319D19, 3207308E19, 3203318D19, 3212249F19, 3210142E, 3204537E19, 3204357E19, 3206152E19, 3205046E19, 3209810E19, 3210142E19, 3205045E19, 3202119D19, 3212249F19, 320153E19, 3204539E19, 3208658E19, 3206155319, 3202642D19, 3209808E19, 3202401D19, 3202641D19, 3206147E19, 3204065E19, 3205121E19, 317769L18, 3176589L18, 3177768L18, 208093E19, 3207314E19, 3204899E19, 3208680E19, 3181841A19, 3177770L18, 2954560C17, 3209803E19, 3174427L18, 3200546D19
Table, Operating-room Brand: Steris 5085 Srt Surgical Table Model#: 5085	Steris Corp.	During a laparoscopic appendectomy the patient was tilted less than ten degrees to the left. As surgeon was finishing the procedure, staff heard a loud metal "snap/pop". Staff saw patient began to shift to his left as the physicians began to brace and hold the patient. Staff assisted and braced patient from sliding further. Patient unharmed, sterility maintained and patient placed on new bed. There was discussion about the loud noise heard prior to the patient falling and this noise was able to be recreated with adding some pressure to the sliding pads as it hit the bed frame. After investigation of how the patient could have started to slide off the bed frame from the OR table, it was concluded most likely the table pad was not secured in the pegs initially, prior to the patient getting on the bed. If the pegs were engaged in the frame we could not recreate a way for the pads to slide off the frame. There are 4 pegs on each of the plates, 2 of which snap into an opening to receive them and 2 which we believe caused the patient to slide.

Device	Manufacturer	Problem
Treadmill, Powered Brand: Ge T2100 Treadmill Model#: T2100 Cat #: T2100-ST2	GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.	Patient was having exercise stress test. After 12:02 minutes the stop button was accidentally deployed on patient's Left grab bar as RN was taking BP while patient was walking on TM (Tread Mill). The Left grab bar has an automatic stop button in addition to a pull cord from underneath the bar. This caused treadmill to suddenly stop which did not cause patient harm. This caused the treatment portion of the test to be reordered and restarted. This design appears to be a poor design when staff approach patient from the patient's Left side. Clinical Engineering staff attached a plastic button cover with Velcro to prevent the automatic stop button from accidentally being pushed while nurses are attending to the patient. Please see picture below: 
Ventilator, Continuous, Facility Use Brand: Hamilton -g5 Model#: G5 Other #: Control no. M038182	Hamilton Medical AG	Ventilator was delivered to Biomed department for repair of displayed error code TF:5507 and displayed alarm messages of "Air and Oxygen Supplies Failed". Problem was confirmed during testing. Ventilator was still under warranty, and vendor performed repairs on-site. Vendor replaced "Sensor Board 2", part no. 155699. Old sensor board was serial no. 24591. Proper operation was confirmed, and ventilator was returned to clinical use.

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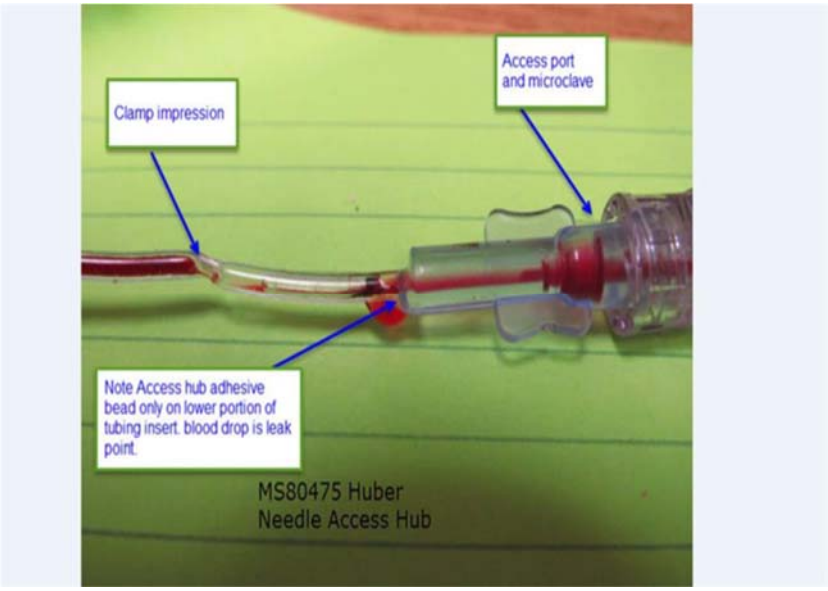
Ventilator, Continuous, Facility Use Brand: Hamilton G5 Model#: G5	Hamilton Medical AG	Registered Respiratory Therapist (RRT) responded to ventilator alarm. Patient's mechanical ventilator alarming a Technical Fault (TF) code. Pt was not being ventilated at that time. Pt immediately removed from mechanical ventilator and hand bag ventilated. Mechanical ventilator then shut off completely. Vent was removed from use and tagged for service.
Ventilator, Continuous, Minimal Ventilatory Support, Facility Use Brand: V60 Other #: BIPAP	Philips North America, LLC	While adjusting patient's bipap mask, a strange noise was heard from the mask. Patient began to complain that they could not breath and immediately desaturated. Fogging occurred in the mask and an alert on the bipap stated the patient was rebreathing their CO2 and there was no leak. Patient quickly desaturated to the low 60%. Got a new mask and placed the patient on a heated high flow at 100% O2 and 601pm. Elbow on the mask was changed because exhalation could not be felt. Placed patient back on the bipap and was able to ventilate the patient and O2 saturations recovered.
Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms Brand: Intellivue Model#: MP70 Other #: MV-9737	Philips Medizin Systeme Boeblingen GmbH	Intermittent incorrect beat per minutes on the numerical readout. The numerical readout changes do not reflect the displayed waveform and are inconsistent with the pulse oximetry numerical readout. New software was placed on the system approximately 6 months ago. Problems began occurring at that time. Philips was notified and troubleshooting began but all attempts to resolve the issues have been unsuccessful (such as changing leads). We placed another call to Philips last week and today and are still waiting for a service technician to contact us.
Dialyzer, High Permeability With Or Without Sealed Dialysate System Brand: Nxstage Cartridge Express Model#: CAR-505 Lot #: 90678002 Cat #: CAR 505	NXSTAGE MEDICAL, INC	Faulty CRRT (Continuous Renal Replacement Therapy) cartridge sent to hospital by manufacturer with floaters in cartridge that prohibited use. RN noted floaters when preparing pt for CRRT but did not use it when problem was identified.
Endoscope Channel Accessory Brand: Rx Locking Device And Biopsy Cap Model#: M00545260 Lot #: 22346749 Cat #:	Boston Scientific Corporation	Pt. was undergoing ERCP for bile leak. A biopsy cap with locking device with a foam piece to prevent back flow of bile out of the cap was utilized during procedure. A blunt needle was used to puncture a hole in this cap to allow the ERCP supplies to pass through. Physician had difficulty passing dreamtome through the biopsy channel. Physician used blunt end to puncture cap again along with NS flush which was unsuccessful. Biopsy forceps allowed the dreamtome to be advanced although with difficulty. Physician pulled dreamtome out and attempted to place stent. During threading of the stent through the scope, the piece of foam from the ERCP biopsy came out of the end of the scope into the small intestine. Several attempts were unsuccessful in trying to retrieve the foam piece. Physician felt the patient could pass the foam piece on own with no problem. Pt. family were notified of retained foam piece by physician and documented in the medical record.

Device	Manufacturer	Problem
Snare, Flexible Brand: Rescuenet Model#: DGN-538 Cat #: DGN-538	Boston Scientific Corporation	Patient presented to emergency room with complaint of feeling of food stuck in esophagus. Pt underwent endoscopic procedure to remove foreign body. Per the manager of the unit, during an esophageal foreign body removal, the basket shredded off the probe after one use. Four in total were used, all devices failed prematurely.
Set, Administration, Intravascular Brand: Safestep Port Access Needle Model#: LH-0031 Lot #: ASDV051 Cat #: LH-0031		Port-a-cath line (PAC), which was hep-locked, was entered in order to draw scheduled AM labs. The line flushed well without resistance and appeared intact at the insertion site. When blood was attempted to be drawn from the line, the syringe filled with air and the line began to leak blood below the clave. The RN clamped the line above the perceived line break and de-accessed the PAC. The CVC was re-accessed and blood cultures were drawn prior to drawing labs. Huber needle assembly brought to Biomedical for reporting and assessment. Biomedical confirmed line was leaking at the junction where the tubing entered the female luer hub. BME noted adhesive/sealant may have leaking from bonding point resulting in tubing leak. Line saved for mfg. evaluation. Please see picture below: 
Closed Drug Transfer System Brand: Spinning Spiros Closed Male Luer Cat #: CH2000S Other #: 00840619026615	ICU Medical, Inc.	Chemotherapy leak due to closed system transfer device syringe attachment (Spiros syringe cap). Adriamycin leaked in bag sent from Pharmacy and around the patient in the Cancer Center. Adriamycin syringe received from pharmacy and RN noticed that the cap (spinning spiros closed male luer red cap) was not on the adriamycin and there was some chemo noted on the bag. The luer cap was applied to the syringe and it was verified it was on correctly. RN attached syringe to patient and started to inject, but the Adriamycin syringe came apart from the luer cap and the luer cap started leaking saline from it onto the blue drop cloth which was changed. Adriamycin was then given without the luer cap. Spill was cleaned up per protocol and employee and patient were not exposed

Device	Manufacturer	Problem
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 11607704 Lot #: (10) 19087420 Cat #: 11607704	CAREFUSION 303, INC.	While hanging new bag of Propofol infusion and tubing in Alaris pump, tubing came apart at connection site. Nurse reprimed a new set of tubing, placed in IV Pump and infusing without difficulty.
Syringe, Piston Brand: Bd Luer-lok Model#: 309653 Cat #: 309653	BECTON DICKINSON AND COMPANY	Received notification of concerns related to BD 60ml syringes are no longer going to be manufactured and BD 50ml syringes are being replaced from Central Supply. Letter was received from Manufacturer. Both syringes have same catalog REF number (309653). Instead of removing 60ml syringes from use, both 50ml and 60 ml syringes are still available for use by staff. Both types are stocked and may pose risk if staff not aware of 10ml difference while meds are prepared. IV pump guard rails would need to be changed manually to accommodate the appropriate quantity of fluid (60ml vs 50ml). This hospital system is removing all 60 ml syringes from the stock.

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/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 Ill 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 2020 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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