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):

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 April 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

Cybersecurity Vulnerabilities Affecting Medtronic Implantable Cardiac Devices, Programmers, and Home Monitors: FDA Safety Communication

March 21, 2019

FDA is issuing this safety communication to alert health care providers and patients about cybersecurity vulnerabilities identified in a wireless telemetry technology used for communication between Medtronic's implantable cardiac devices, clinic programmers, and home monitors. The FDA recommends that health care providers and patients continue to use these devices as intended and follow device labeling. Although the system's overall design features help safeguard patients, Medtronic is developing updates to further mitigate these cybersecurity vulnerabilities. To date, the FDA is not aware of any reports of patient harm related to these cybersecurity vulnerabilities.

UPDATE: Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality - Letter to Health Care Providers

March 15, 2019

Several weeks ago, FDA notified health care providers about the potential for increased long-term mortality after use of paclitaxel-coated balloons and paclitaxel-eluting stents (collectively "paclitaxel-coated products") to treat peripheral arterial disease (PAD) in the femoropopliteal artery, as identified in a recent meta-analysis of randomized trials published in the Journal of the American Heart Association. Because of concerns regarding this issue, the FDA will convene an Advisory Committee meeting of the Circulatory System Devices Panel. The date will be announced in the coming weeks.

Safe Use of Surgical Staplers and Staples – Letter to Health Care Providers

March 8, 2019

FDA is concerned by the increasing number of adverse events associated with surgical staplers and staples for internal use and is providing additional recommendations for health care providers to help protect patient safety and reduce the risk of adverse events associated with these devices. In addition, we are announcing new actions we intend to take to help ensure the safe use of these devices. To further promote the safe and effective use of surgical staplers and staples for internal use, the FDA intends to issue a draft guidance for public comment in 2019, which will describe proposed recommendations to manufacturers of surgical staplers and staples for internal use about information to include in their product labeling.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during March 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
Mesh, Surgical, Collagen Lot #: RC2AN18K4 Cat #: 2169-2	Rotation Medical	Patient underwent arthroscopic repair of glutea tendon with a Regeneten patch (bioinductive collagen implant). Patch successfully placed, anchored, and deployment instrument removed. Surgical procedure completed and patient discharged to home the same day. Patient returned for two week follow up with orthopedist at which time imaging was completed and showed a retained foreign body suspected to be in subcutaneous tissue or IT band. The patient was returned to the OR and the foreign body location was confirmed with fluoroscopy and retrieved. Foreign body identified to be in the subcutaneous tissue between the IT band and the skin. The removed foreign body was identified as the spring mechanism of the delivery system for the Regenten patch and a small plastic piece attached to it. Fluoroscopy confirmed no further retained foreign body. The patient was discharged to home on the same day. The manufacturer was notified of the event by Materials Management.

Device	Manufacturer	Problem
Bariatric Bed, Ac-powered Adjustable Hospital Brand: Citadel Plus Model#: FX811B8B4AM ABB Cat #: FX811B8B4AM ABB	ArjoHuntleigh	Patient transferred from ICU to MedSurg room on a bariatric bed during the night. At 01:20 RN heard Bed alarm going off in one of the rooms. RN ran into the room and found the patient on his side facing the window with the lower left side rail completely separated from the bed. No visible injury noted but patient complained of side pain until he was placed in bed. RN deployed a patient lift to place patient back in same bed and RN provided sitter until replacement bed arrived. Patient transferred to replacement bed and failed bed was sequestered for follow up and reporting to Risk Mgt and Biomedical Engineering. Inspection of bed by Biomedical noted complete separation of side rail panel from mounting and locking frame. The mounting assembly still had 4 each mounting screws which were still attached to the side rail attachment rivets. Biomedical's MAUDE database search noted recent events involving loose and detached side rails with this model bed. Biomedical suspected that patient may have tried to kick side rail free in effort to exit bed, but determined cause may be different based on recent reported failures reviewed in the MAUDE database. Bed transferred to the Manufacturer for return and analysis. Biomedical to monitor and report any additional side rail failures and inform the rental agency not to move or position bed by the use of raised side rails. Please see pictures below: 

Device	Manufacturer	Problem
		 

Device	Manufacturer	Problem
Pump, Infusion Model#: 8110 	BD	•Summary of issue: When changing out a medication syringe and restoring the infusion; a discrepancy may occur between the volume infused value indicated on the Alaris Syringe module and what is documented in the Electronic Medical Record (EMR). Due to the fact that the Alaris Syringe module can detect the exact volume in the syringe, this may have been caused by the Volume to be Infused (VTBI) value not revised to reflect the volume in the new installed syringe. This affects all syringes and all library profiles. •How many times occurred: How many times it has occurred is being assessed with an audit this week, but that will only be a subset of all of our patients who are treated via the pump. It is very difficult to know for sure how often it has occurred/occurs due to low event reporting by nursing (and/or they don't even catch it). We have four recent known events. The three most recent reports are from an audit of pump messages only, found in a time span of less than 48 hours. Both patient safety events and non-medical events have occurred. Our belief is that many unidentified patient safety events have occurred as nursing does not often catch the erroneous volume that has charted on the patient from the pump. I suppose if they catch it, and correct the value manually in the EMR, these might be considered non-medical events. Clinical care of our smallest patients is being compromised because when wrong intake values are being sent to the EMR via the pump, decisions about how to manage fluid balance are impacted. Examples of the safety consequences are: 1) Nutrition (could result in less calories being supplied) in NICU babies and small infants and 2) Decisions about the need (and dose needed) for diuretics in cardiac patients are impacted if the chart makes it appear the patient has a positive fluid balance. Overall, it is fundamentally unsafe for a very common critical care nursing workflow to result in the pump sending incorrect data to our EMR. The values sent to our EMR did not infuse into the patient through the pump. • Work with BD: Two years ago several months of email communication and meetings occurred with the pump team leaders and BD. At the end, due to a slow response from the manufacturer, Risk and Executive leadership became involved. Our understanding at that time was that promises were made that this would be fixed by early 2018. BD sent a tip sheet for the interim. The email response from BD two weeks ago seems to indicate that they believe this "tip sheet" was the fix. It is not. The bad data is still being sent to our EMR.
Restraint, Protective Brand: Peek ABoo Mitts Lot #: 8212T001 Cat #: 2811	Posey Products LLC	We have had 15 Unplanned Extubations over the past year where the root cause involved patient's being able to remove their mitts and self-extubate. We have also noted that patients were able to remove their mitts and remove other devices (Keo-feeds, Chest-tubes).

Device	Manufacturer	Problem
Device 1: System, Thermal Regulating Brand: Mistral Air Warming Unit Model#: MA1100-pm Cat #: MA1100-pm **Device 2: System, Thermal Regulating** Brand: Mistral Air Adult Reflective Lot #: 1609216 Cat #: MA0320-PM Other #: ET37MAO320PM0/ $$7L16092165	THE SURGICAL COMPANY INTERNATIONAL BV Stryker Medical	During a surgical case, a Stryker Mistral air unit was in use warming the patient. The Mistral Air Reflective Drape was on the patient, under the surgical drapes. A portion of the Mistral Air Reflective Drape was hanging over and touching the Mistral Air Unit. When the electrosurgical pencil was deployed at the field, the Mistral Air unit would alarm. Biomed was brought to the room to investigate and when the Mistral Air Unit was pulled out and the Mistral Reflective Drape no longer was touching the Unit the alarm ceased. At the end of the case, the Biomed set up the same blanket on an empty OR bed to investigate if there were any electrical issues with the electrosurgical unit (ESU) or the Mistral Unit. He could not identify any biomedical issues with either device. However, he was able to produce the following serious issue: The Mistral Reflective Drape was placed on an empty OR bed, with the unit on and warm air circulating through the device. He placed a grounding pad for the ESU on himself and plugged in a ESU pencil and turned the ESU on. He deployed the pencil into the air (he was attempting to see if the unit would alarm) While doing this he touched the reflective coating on the Mistral reflective drape and his finger was immediately burned as if cauterized. The ESU pencil was NOT in contact with his body at all, just deployed into the air. We changed out the ESU, The ESU pencil, the ESU grounding pad, the Mistral Air unit and the Mistral Air Reflective drape and the burn was reproducible every time.
Tube, Tracheostomy (W/wo Connector) Brand: Shiley Model#: 8PERC Lot #: 18A0559JZX Cat #: 8PERC	Covidien LP	Patient with tracheostomy placed. Eight days later, the registered nurse noted that a piece of the patient's tracheostomy tube was broken off of the main tracheostomy front plate. It was described as the end of the tracheostomy tube where the inner cannula locks into the tracheostomy - this end piece separated from the tracheostomy tube. The patient had been up in the chair and recently was moved back to bed without incident. There were no reports of the patient pulling at the device or other difficulties with the device. There was not apparent injury. The patient continued to pull appropriate volumes on the ventilator. Please see picture below: 

Device	Manufacturer	Problem
Ventilator, Continuous, Exhalation Valve Model#: 260170/01 Lot #: 201005970	Hamilton Medical, Inc.	Background: Earlier this month, it was identified that two lot numbers of Hamilton neonatal circuits had white debris surrounding and within the locking collar on the valve. These lots were pulled from service, Hamilton notified, and Life Flight notified of need to remove locking collar on the neonatal expiratory valve to clean it prior to use if white debris was seen upon visual inspection. Alternatively, we could replace the original valve with an individually-wrapped expiratory valve. About a week ago, the pediatric/neonatal team was dispatched to pick up a intubated patient by Life Flight and placed on conventional ventilation using the Hamilton ventilator, neonatal circuit, and expiratory valve (unknown lot number). Prior to use, the Hamilton neonatal circuit/valve passed tests. No alarms initially, but after departing facility, started to get occasional "disconnection on ventilator side" alarms. All connections double checked and they were all feeling well-seated. Return tidal volumes all within normal limits. The patient's transcutaneous monitoring (TCM) responded to titrations well. When not being jiggled, the Hamilton would not alarm. Roughly ten minutes out from airport, the alarm became more frequent. Still with good return tidal volume, good saturations, and TCM. Once in ambulance and in route to hospital the alarm was non-stop. The patient's PEEP titrated up to keep saturations greater than 90% and to assist in re-expanding previously-known collapsed right upper lung and bilateral areas of atelectasis with good result in TCM. One "Loss of PEEP" alarm seen at this time as well and one episode of loss of tidal volume associated with patient bearing down, which quickly returned to normal exhaled tidal volumes. A PEEP of 10 and sixty percent oxygen upon arrival to hospital. Receiving PICU team notified of technical ventilator concerns during sign out. Clinical Engineering contacted upon completion of flight to look at Hamilton, circuit, and valve. It was discovered that the circuit and valve had the white debris inside the locking collar as seen in previous lot numbers. Visual inspection of valve had been completed prior to placing the circuit on the ventilator and no debris was seen. Staff member also reported that it was easy to turn when she placed it in the Hamilton. When examined by Clinical Engineering, it would no longer turn at all. Clinical Engineering cleaned it out and it was easier to turn, but still did not move as freely as the peds/adult valves do, but did seat into valve lock. Circuit and valve left with night team. It was reported in the morning that "circuit ran for 30 minutes". It never failed the tightness tests or gave any alarms when running on the test lung with different settings. A locking collar that progressed from not having visible debris and being easily placed in valve lock to having visible white debris and no longer turning at all, combined with alarms that initially did not appear, then progressively became worse speaks to hidden debris. Clinical Engineering demonstrated how to remove back portion of valve to clean off and then replace…..

Device	Manufacturer	Problem
		Concern for known patient harm: possible that these alarms meant that our patient was not receiving the intended PEEP, which was likely true according to Clinical Engineering. Prior to going home, I returned to the PICU to deliver chart, evaluate patient, and ventilator settings. Patient had been weaned to PEEP of 8, but was now pressure-limiting with peak inspiratory pressures in the 31-32 range and saturations intermittently in the high 70's. It is possible that low saturations towards the end of the trip were probably a combination of the ventilator problems and the patient's inherent disease process. Concern for potential patient harm: if the white debris is in the expiratory valve; could it be in other parts of the circuit? i.e on the inspiratory side where it could potentially be forced into patients' lungs? Concern for potential patient harm: cleaning method of using non-sterile water to clean a ventilator circuit could present a risk of contamination to the patient. Lots involved: 201005970, 2022669(valve only), 201009251 and 201003740(full circuit). Seven sets have been identified. Six found prior to use and one on the above patient. Per site reporter, the rep has been very responsive. She overnighted a different product in that can be used. We will be returning the sets that weren't used on patients for further investigation. The rep also reported that a couple of other facilities have reported this issue. Please see picture below: 

Device	Manufacturer	Problem
Epidural Anesthesia Kit Brand: Design Options® Perifix Fx Epidural Tray Model#: 555296 Lot #: 61640693 Cat #: 555296	B. BRAUN MEDICAL, INC.	Patient had epidural with breakthrough contraction pain and was instructed to use epidural bolus button. After hitting button 2 times with no relief, anesthesia was called. Doctor assessed patient and noted that epidural cath had become disconnected where it clips to filter.
Tube, Tracheal (W/wo Connector) Brand: Hudson Rci Model#: IP-N046760 Cat #: V5-10316	Teleflex Incorporated	Pt. was admitted to ICU with diagnosis of pneumonia, NSTEMI, Sepsis and altered mental status. Pt. intubated in Cath Lab with Sheridan ET tube size 8. Two hours post-intubation, ET tube was exchanged due to cuff leak. Pt. condition declined. After prolonged resuscitation, family requested DNR and patient expired. This facility has reported several devices with this problem within the last month to the manufacturer. Different device sizes are involved. Product has been returned to the manufacturer.
Ventilator, Emergency, Manual (Resuscitator) Brand: Hudson Rci Lifesaver Adult Manual Resuscitator Model#: IP-N044941 Cat #: 5374	Teleflex Incorporated	During resuscitation efforts, right around bag valve mask did not inflate when placed around the patient's mouth, preventing a seal therefore decreasing the effectiveness of the air being pushed into the lungs. The reservoir bag did not inflate. Bag was replaced.
Introducer, Catheter Brand: Micropuncture Model#: G48008 Cat #: MPIS-501-10.0-SC-NT-U-SST	Cook Incorporated	During PICC line insertion, the guidewire became knotted at the tip. MD was unable to successfully reduce the knot. Upon attempt to remove, a fragment of the guide wire broke off and was retained within the soft tissues potentially intravascular and tiny peripheral arm vein. CT scan was completed and verified metallic foreign body 16mm in length outside the brachial artery and vein and posteromedial to these vessels. A portion extended along the posterior periphery of the biceps muscle. Foreign body was removed via small incision over the radiodense foreign body. Following blunt dissection under fluoroscopic guidance, the wire fragment was removed. Dermabond was used at the skin surface.

Device	Manufacturer	Problem
Lithotriptor, Extracorporeal Shock-wave, Urological Brand: Modu-lith® Model#: SLX-F2	Storz Medical AG	Patient underwent a left extracorporeal shock wave lithotripsy w/ general surgery. Discharged. The following day, patient was admit-ted with recto-peritoneal bleed.

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 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 April 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:

Telephone: 800-859-9821
Fax: 800-859-1292
E-mail: medsun@fda.hhs.gov

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993