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/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM606672.pdf

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm603348.htm

In Brief

As of May 2, 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

Magnetic Resonance-guided Laser Interstitial Thermal Therapy (MRgLITT) Devices: Letter to Health Care Providers

April 25, 2018

FDA is currently evaluating data which suggests that potentially inaccurate MR thermometry information can be displayed during treatment. For example, MR parameters such as voxel size (measurement of the image resolution or detail) and MR image acquisition time (e.g., up to 8 seconds) may contribute to inaccurate MR thermometry readings and potential errors in the ablation assessment. In addition, MRgLITT devices may not account for the continued thermal spread of energy to the surrounding tissue (as the target ablation area returns to its baseline temperature), which may result in an underestimation of thermal damage.

24-Hour Multi-Patient Use Endoscope Connectors: Letter to HealthCare Providers and Healthcare Facilities - Risk of Cross-Contamination

April 18, 2018

The FDA is alerting health care providers and facilities about the risk of cross-contamination with certain connectors that are used in gastrointestinal endoscopy. Endoscope connectors that are labeled for use with multiple patients over the course of 24 hours without reprocessing are known as 24-hour multi-patient use endoscope connectors. To date, the FDA has not received acceptable testing to demonstrate the safe use of these products, and recommends against their use.

Certain Implantable Cardiac Devices by Abbott (formerly St. Jude Medical): FDA Safety Communication

April 17, 2018

FDA recently approved a firmware update that is now available and is intended as a corrective action (recall), to reduce the risk of patient harm due to premature battery depletion and potential exploitation of cybersecurity vulnerabilities for certain Abbott ICDs and CRT-Ds. This firmware update includes mitigations to addresses two separate issues: 1) a device-based Battery Performance Alert to detect rapid battery depletion in devices subject to the Battery Advisory from October 2016; and 2) updates to address cybersecurity vulnerabilities across Abbott's radio frequency (RF) enabled ICDs and CRT-Ds.

Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health

Providing patients with access to safe medical devices that meet their health care needs remains a top FDA priority. The Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health outlines how the agency will encourage innovation to improve safety, detect safety risks earlier, and keep doctors and patients better informed.

In the Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health, the FDA describes key actions it will take in the following areas:

- Establish a robust medical device patient safety net in the United States;
- Explore regulatory options to streamline and modernize timely implementation of postmarket mitigations;
- Spur innovation towards safer medical devices;
- Advance medical device cybersecurity;
- Integrate the Center for Devices and Radiological Health's (CDRH's) premarket and postmarket offices and activities to advance the use of a Total Product Life Cycle (TPLC) approach to device safety.

The FDA is modernizing measures to improve the safety of medical devices while continuing to create more efficient pathways to bring lifesaving devices to patients.

To submit formal comments on the Medical Device Safety Action Plan please click here: https://www.regulations.gov/comment?D=FDA-2018-N-1315-0001

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during April 2018 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
Cardiac/ peripheral Vascular Guidewire, Single-use Brand: Glidewire Cat #: GL3508	Terumo Corp.	When accessing the cephalic vein for a Pacemaker insertion, a Glidewire was inserted into the vein and the wire introducer was also advanced into the vein. Glidewire was removed from the vein but not the introducer. We were unable to visualize the introducer under fluoro. BASED ON PACKING LISTS FOR DEVICES PURCHASED FOR THE CATH LAB PRIOR TO PROCEDURE LOT# COULD BE 171113.

Device	Manufacturer	Problem
Catheter, Umbilical Artery Brand: Umbilicath Model#: Dual-Lumen Silicone Lot #: NA Cat #: 4273505	Utah Medical Products	The hub of an umbilical catheter (3.5) snapped off while the catheter was inside the baby. The nurse fortunately, was very observant and clamped the line before any air went into the baby or blood came out.
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: Bd Insyte Autoguard Model#: 382533 Lot #: 7339578 Cat #: 382533	Becton Dickinson and Company	A 20G IV catheter tip BROKE off into the adipose tissue of a patient when trying to withdraw the catheter. Surgical intervention was needed to remove the tip from the adipose tissue. The patient was discharged home the same day and did not face further complication from this event. Please see picture below: 

Device	Manufacturer	Problem
Computer, Diagnostic, Programmable Brand: Carescape Central Station V2 Model#: MP200 Other #: CSCS V2	GE Healthcare Systems	GE V2 CSCS Central Station may unexpectedly popup a drop down message saying "Please Contact your Biomedical or Service Department Immediately. The following Parameters are out of Range. Flash Disk Drive failure". The Popup warning window covers up a portion of the patient's vital sign screen and can only be removed from view by rebooting the V2. Rebooting the V2 Central Station potentially creates a 1) lapse in collecting disclosure data 2) In the case of telemetry monitoring, may lose monitored view of patients 3) If V2 is running 2.0.2 Wanna Cry patch software rebooting back to a NoComm. Critical alarm on all patients on the rebooted V2 Central Station.
Electrode, Electrocardiograph Brand: Kendall Model#: 533 Lot #: 735204X	Covidien LP	Multiple patients have had skin reaction to electrodes after wearing for twenty-four hour holter monitoring.
Electrode, Ph, Stomach Brand: Bravo Ph Capsule Delivery System Model#: 8956 Lot #: 37871q	Given Imaging, Inc.	The physician attempted to deploy the Bravo Device. The device failed to attached to the esophageal mucosa causing a small tear to the esophagus. A clip was applied and the bleeding was stopped. The capsule was still attached when the device was removed.
Incubator, Neonatal Transport Brand: Voyager Infant Transport Incubator Model#: Voyager 	International Biomedical, LTD	RISK: While on neonatal intensive care unit (NICU) transport, the ventilator in the transporter spontaneously went into system failure, which caused the respiratory therapist to have to bag the baby to keep her ventilated for the remainder of the transport. The Isolette then lost power in the ambulance causing the heat to turn off. The respiratory therapist also could not get the mechanism that heats/ humidifies the air for the ventilator to work.

Device	Manufacturer	Problem
Instrument, Surgical, Orthopedic, Ac-powered Motor And Accessory/attachment Brand: Coolcut Dissector, Sj Lot #: 10122143 Cat #: ar-7300ds Other #: SJ 3.0mm x 7cm	Arthrex, Inc.	The head of a small (ankle scope) shaver blade broke off in the patient's ankle shortly after being inserted. 54 minutes of mini fluoroscopy and an additional incision to the posterior aspect of the patient's ankle were required to locate and remove the shaver head.
Device 1: Motor, Drill, Pneumatic Brand: Midas Rex Perforator Driver Cat #: AD01 **Device 2: Drills, Burrs, Trephines Accessories (Compound, Powered)** Brand: Codman Model#: 26-1221 Lot #: HA5862 Cat #: 261221 Other #: CE0086	MEDTRONIC POWERED SURGICAL SOLUTIONS Codman Shurtleff, Inc.	Surgeon was utilizing the Midas Rex drill to enter skull for Craniotomy. When the perforator stopped, the regulator (Midas Rex drill) continued to spin, wrapping the cord around the device 4-5 times. Surgeons' hand was caught in the cord.

Device	Manufacturer	Problem
Pediatric Foley Catheter Brand: Rusch Pediatric Foley Catheter Cat #: 170003060 	Teleflex Medical, Inc.	Rusch Pediatric Foley Catheter was placed in an 18 month old patient. The Catheter was sutured to the Rusch Pediatric Foley Catheter was placed in an 18 month old patient. The Catheter was sutured to the patient's skin. When the child's diaper was removed it was noticed that the catheter was broken in half. Approximately 1" of the catheter was visualized coming out of the patient's penis by the patient's father. When the physician arrived to the patient's room the diaper was opened and the catheter could not be visualized. The catheter retracted back into the urethra. Patient showed no signs of distress or pain as a result. The non-retained half of the Foley was saved and measured to be approximately 12.8cm in length. The total length of the catheter is approximately 28.6cm. Meaning the patient retained approximately 15.8cm of the Foley catheter.
Retractor Brand: Sklar Richardson Retractor Other #: 60-1691	Sklar Corporation	Patient was scheduled for open right colectomy with on bloc resection of retroperitoneal mass, right ureterolysis. During the procedure, as the surgeon went to place the Richardson retractor to assist with exposure, he noted clear fluid coming from the handle attached to the retractor. it was removed and handed off the sterile field.
Set, Administration, Intravascular Brand: Codan Model#: BC 647 Lot #: 75390 Other #: 72.8130	Codan US Corporation	There were multiple episodes of the Codan bifuse sets with 1.2 micron filter in line breaking / leaking at the tubing insertion sites. When leak or break occurred the infusion was stopped and intravenous central line was changed out. 3 patients had their TPN interrupted with D10 hung to cover until new TPN could be prepared and delivered to the units. Devices were retained and reported to be returned to manufacturer for evaluation.
Spinal Anesthesia Kit Brand: Portex Pencil Point Spinal Anesthesia Trays Lot #: 3566332 Cat #: NEPI-NLD-15597C-20	Smiths Medical ASD, Inc.	Four reports of inadequate spinal anesthesia using the Smith Spinal Tray. Patients had diminished sensation and motor weakness, but could still feel and move their legs. General anesthesia required to proceed with surgical procedure. We have recently reported another manufacturer spinal trays as well, the medication in both trays is supplied by the same drug manufacturer. It is the same medication concentration, but they do have different numbers on them. We have only been using this tray for approximately 1 month and we have seen about 10 confirmed cases of inadequate spinals that have had to be converted to General Anesthesia. All of the patients had some motor weakness and some sensory deficit, but not enough to perform surgery on them.

Device	Manufacturer	Problem
Syringe, Piston Brand: Bd Luer-lok Lot #: 7282889/7282854 Cat #: 309653 Other #: 60 mL	BD (BECTON, DICKINSON AND COMPA-NY)	While the pharmacy person was "...batching iv medications there were three failures with 60ml syringes. While pushing medication into fluid bags three different syringes split down the side and medication spilled out. Please see pictures below:  

Device	Manufacturer	Problem
System, Image Processing, Radiological Brand: Cs-7 	Konica Minolta Healthcare Americas, Inc.	Chest x-ray was done with baby head down in a giraffe bed due to positioning for the endotracheal tube connected to oscillator at the foot of the bed and the baby could not be repositioned. Technologist rotated the image up/down on the machine for the doctor to be able to view the image in a head-up position on the portable screen. Tech verbalized that she was unsure but thought the laterality might be flipped due to the up/down flip. Because of a large tension pneumothorax, anatomic markers were not clear. Technologist left the NICU to return to imaging and annotate laterality with the assistance of her team lead. Meanwhile, the baby continues to decline and a code is initiated. The doctor determined a chest tube was needed emergently. Within a few minutes of the x-ray being taken, before the official radiology read, the NICU physician places a chest tube based on the image he viewed on the portable monitor. Routine confirmation x-ray of the chest tube shows it was placed on the opposite side than intended. A second chest tube is placed to address the original pneumothorax. Follow up simulation of the event determined a very complex software interface made it challenging for technologists to quickly select image adjustment options and clearly understand how the selection might impact the image in multiple directions. Human Factors engineer completed usability study of the Konica software involved in the event, see attachment.
Tubes, Vials, Systems, Serum Separators, Blood Collection Brand: Bd Vacutainer Luer-lok Access Device Holder Model#: 364902 Lot #: 7356752 Cat #: 364902	BECTON, DICKINSON AND COMPANY	A Luer-Lok was opened and found to have an oily substance inside the packaging. It was not used on a patient.

Device	Manufacturer	Problem
Mitral Valve Repair Devices Brand: Mitraclip Model#: CDS0501 Lot #: 71027U234 Cat #: CDS0501	ABBOTT VASCULAR INC.	Retained nitinol wire left in patient. Gripper line from Mitral Clip could not be withdrawn after the clip was deployed. Wire was cut at the femoral vein and retained. Dr. said the wire is stable. The risks of removing surgically outweigh the risks of having the wire retained. Physician said he could not pull out the wire. The rep was in the room and said on rare occasion this has been known to happen before. They called the Abbott clinical specialist and followed the known procedures for removing the wire and could not remove it. The retained item is a Nitinol wire ("like a metallic string"). It extends from the mitral valve down the inferior vena cava to the common femoral vein and was clipped at the right femoral vein. Dr said there was nothing particular about patient anatomy that lent itself to the this event, it was device issue (although known to happen before). Patient discharged with no sequelae.
Unit, Electrosurgical, Endoscopic (With Or Without Accessories) Brand: Hydratome Rx 44 Model#: M00583040 Lot #: 21361760	BOSTON SCIENTIFIC CORPORATION	An elderly patient underwent an ERCP (Endoscopic Retrograde Cholangio-Pancreatography) with sphincterotomy. During the procedure, the Hydratome RX44 would not bow to make the sphincterotomy cut. The cutting wire was noted to be loose at the tip of the Hydratome requiring the use of a second Hydratome. No harm to patient, no delay in surgery
Mask, Surgical Brand: Inst-gard Surgical Mask W/fog-free Adhesive Tape, Green Convertors Model#: AT73835 Lot #: 188EH394 Cat #: AT73835	CARDINAL HEALTH 200, LLC	Surgeon found black sticky residue on several of the masks inside the box. Per the surgeon, he found a mask like this last week and tossed the box but is now concerned because there is more than just minimal discoloration it has quite a bit more "it looks like mold but I'm not sure" and something clear and sticky on it. On one of the masks there are black spots and mucous looking residue and on another the black residue is less but appears to be coming from the inside pocket that encloses the metal bar that is used to pinch over the nose and hold the mask in place. The box nor the masks appear to have been contaminated with moisture or fluid.

Device	Manufacturer	Problem
Stapler, Surgical Brand: Justright 5mm Stapler Model#: JR-ST25-2.0 Lot #: 75IG1818 Cat #: JR-ST25-2.0	JUSTRIGHT SURGICAL, LLC	During a endoscopic surgical procedure while deploying a 5mm stapler the surgeon stated that the 5mm Stapler reload cartridge misfired. Reload removed and new reload inserted and stapler fired normally. Reload sequestered and sent to Biomedical for reporting. Packaging save to giver to manufacturer for analysis. Case proceeded without further incident
Device 1: Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 11171447 Lot #: 18015422 Cat #: 11171447 **Device 2: Set, Administration, Intravascular** Brand: Alaris, Smartsite Model#: 11171447 Lot #: 17125804 Cat #: 11171447	CAREFUSION 303, INC. CAREFUSION 303, INC.	We encountered a number of instances where the BD IV tubing was not priming appropriately. This occurred in multiple departments with multiple lot numbers. The manufacturer was contacted several times and it was disclosed that there was a known defect with the tubing. The problem is systemic so removing any one lot will not remedy the issue. At the beginning of April the manufacturer apprised us of a work around until the defect is permanently fixed.

Device	Manufacturer	Problem
Thermometer, Electronic, Clinical Brand: Arc Instatemp Non-touch Thermometer	ARC DEVICES USA INC	During patient assessment in the PACU the physician picked up a handheld infrared "touchless" thermometer to scan the patient's temperature. While holding the thermometer in her hand the thermometer burst apart in the physician's palm and emitted a large spark and smoke. The physician tossed the thermometer away from the patient and bed area. The thermometer was retrieved and sent to Biomedical for evaluation along with other thermometers of the same make for inspection. It was noted that the electronic thermometer had a one time use embedded battery which could not be replaced or exchanged. Biomedical performed a MAUDE database search on this model thermometer and noted frequent and similar events in which the battery failed and burst open the thermometer. Biomedical removed all thermometers of this type from the patient care areas. Biomedical to submit and report to mfg for analysis.

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 May 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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