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 December 2, 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

Baxter Healthcare Recalls Baxter SIGMA Spectrum Infusion Pumps with Master Drug Library (Versions 6 and 8) and Spectrum IQ Infusion Systems with Dose IQ Safety Software Due to Unplanned Shutdown Issues

December 1, 2020

Baxter Healthcare is recalling the Sigma Spectrum Infusion Pumps with Master Drug Library (V6, V8) and the Baxter Spectrum IQ Infusion Systems with Dose IQ Safety Software (V9) because improper cleaning of the devices may lead to residue build-up or corrosion on the device. If the device is running only on battery power, this may lead to an unplanned shutdown without alarming or alerting the user. This may cause an infusion delay or an interruption in treatment. There have been 17,493 complaints about this device issue and 16 reports of serious injuries. There have been no reported deaths.

Stryker Neurovascular Recalls Trevo XP ProVue Retriever Due to Core Wire That May Break or Separate During Use

November 9, 2020

Stryker Neurovascular is recalling the Trevo XP ProVue Retriever device because there is a risk the core wire may break or separate when the core wire is retracted during use. If this occurs, the device could be left inside the patient's blood vessel or tissue. The use of affected devices may cause serious adverse health consequences, including bleeding, additional blockage of blood vessels, disability, and death. There have been 11 reports of injury or illness related to this device issue and one death.

Medtronic Recalls Rashkind Balloon Septostomy Catheters for Quality Issues

November 3, 2020

Medtronic Inc. is recalling Rashkind Balloon Septostomy Catheters because of device quality issues that may lead to the device breaking, separating or failing during use. If this occurs, use of the affected product may cause serious adverse health consequences such as damage to blood vessels (vascular injury) and death. There have been two reported injuries and one death. Additionally, Medtronic has stopped the manufacturing and distribution of Rashkind Balloon Septostomy Catheters due to reasons unrelated to this recall.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during November 2020. 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

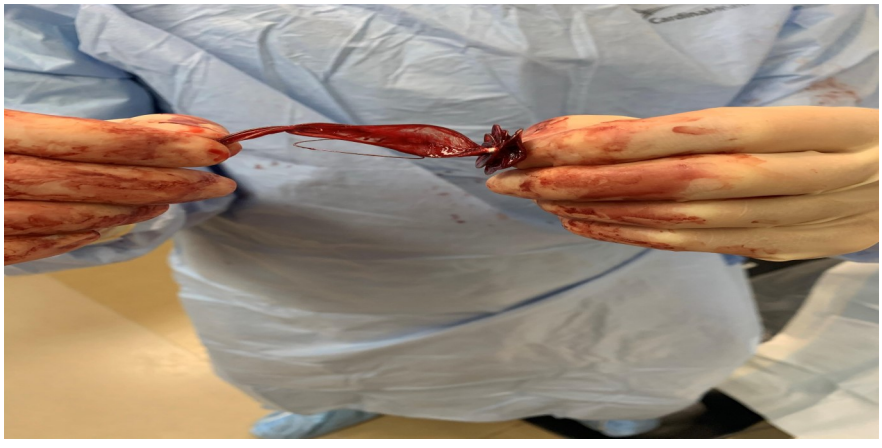

Special Note:

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
Dura Substitute Brand: Duraflex Model#: BP10405 Lot #: NZS18490018 Cat #: BP10405	Integra Lifesciences Corporation	Patient had a return to OR for CSF leak. Original surgery was for a pituitary tumor. Surgeon placed the Integra dural graft as an onlay graft along with fat. The patient developed a CSF leak postoperatively. Patient was taken back to the OR to repair the leak about 10 days later. Upon inspection, the edges of the graft along the suture lines had sealed, but there was a hole found in the center of the graft.

Device	Manufacturer	Problem
Catheter, Thrombus Retriever Brand: Penumbra System Model#: 5MAXJET7KIT-B Lot #: F95679 Cat #: 5MAXJET7KIT Other #: (17) 230121	PENUMBRA, INC.	Doctor noted that patient had a left middle cerebral artery (M1 segment) reocclusion demonstrated via cerebral angiography. Using the Penumbra JET™ 7 Reperfusion Catheter + Penumbra Hi-Flow Tubing (Model: 5MAXJET7KIT-B), doctor made 3 passes and was unable to open the artery. When doctor removed the catheter, he found that the catheter had unraveled. The internal metal of the catheter was unraveled near the end of the catheter and exposed, but the actual tip was intact. Using another catheter, he examined the artery and the unraveled catheter had caused a carotid cavernous fistula, and bleeding from the carotid artery. To stop the bleeding, he performed a left carotid take down with coils which essentially cut off blood flow to the left side of the brain. Left hemispheric ischemic stroke progressed and eventually caused a midline shift. Patient was given comfort care and allowed to pass peacefully. Patient died two days later.
Drills, Burrs, Trephines Accessories (Simple, Powered) Brand: Midas Rex Mr8 Model#: MR8-7TA11 Cat #: MR8-7TA11 Other #: EM800, CA800S	MEDTRONIC POWERED SURGICAL SOLUTIONS	C1 drill bit tip broke off from Medtronic Midas Rex™ MR8™ high-speed drill system, and lodged in the skull of the patient. Surgeon and scrub tech did not realized the tip broke off and left it inside the patient. The tip (foreign body) was retrieved a couple of days later. The C1 drill bit did not cause direct harm to the patient and it could have been left in place. However, following the surgical procedure, the patient required radiotherapy and the drill bit created MRI artifact that obscured the oncologists ability to accurately map the residual tumor. The patient was taken back to the OR to have the drill bit fragment removed. Please see pictures below: 

Device	Manufacturer	Problem
		
Orthopedic Stereotaxic Instrument Brand: Excelsius Gps Model#: Robotic arm control unit: GPS-0103 Cat #: 5163-1001 Other #: Camera CU SN: P7-14888	GLOBUS MEDICAL, INC.	The patient had a planned single position lateral decubitus surgery for pedicle screw fixation and interbody fusion from L4-S1. Robotic guidance was planned for placement of pedicle screws from L4-S1 (6 screws) using the Globus Excelsius GPS System. Two surgeons trained to use the Globus Excelsius GPS system, two Globus reps and a vascular surgeon were present during the procedure. The ICT (intra-operative registration device (reference frame)) is placed in the iliac crest to assist with image merge. A dynamic reference base (DRB (motion checker)) is also placed in the iliac crest and acts as surveillance marker for real-time intraoperative accuracy. The robotic software uses an algorithm to register intraoperative fluoroscopy scan images level by level (AP & Lateral) and performs a 2D-3D merge with a pre-operative CT scan. This registration is intended to ensure that the radiographic images indicating the intended location of surgery and the actual patient position in the O.R. matches, thus enabling the robot to guide screw placement. In this case, the software was having difficulty performing the initial image merge and registration. A software reset was advised by the rep. Following the system reset, they were able to complete image merge and registration. Once this was completed, registration scores were generated by the robot, which were reportedly adequate, indicating the images were matched. Palpation of landmarks was completed following registration and compared to the intraoperative images shown on the screen. However, palpation of landmarks as a secondary means of verifying system accuracy in the lateral position is more difficult. Following screw placement, an intra-operative CT scan showed sub-optimal positioning of 6/6 screws. The patient was then flipped onto a prone position for screw revision and replacement with decompression. One screw had penetrated the dura and a CSF leak repair was performed. Post-operatively the patient has new foot drop with 0/5 dorsiflexion. The patient has an altered gait and will require rehabilitation services.

Device	Manufacturer	Problem
Transcatheter Septal Occluder Brand: Gore Cardioform Septal Occluder Model#: GSX0030A Cat #: GSX0030A	W. L. Gore & Associates, Inc	Patient had an atrial septic defect that needed repair. The GORE CARDIOFORM septal occluder (Model GSX0030A) was deployed in the usual fashion using both fluoroscopic and intracardiac echocardiography guidance. However, once the device was in place, but before it was released it was felt that it was unstable and that a larger device would provide better closure. It was necessary to recapture the device. The catheter used for deploying the cardiac occluder was advanced in the inner catheter in an attempt to pull back device. The right atrial disc was recaptured, the left atrial disc would not release and the recapture cord broke. The cardiac occluder was therefore in an unstable position within the R heard with small amount of the left atrial disc still in. Attempts were made to snare it from the heart. This was done and it was pulled down into the right femoral vein however the left atrial disc still would not collapse or straighten out so that it could enter into the femoral venous sheath. Therefore, a vascular surgeon was consulted and a small cutdown was needed to remove the device. As per the WL Gore Structural Heart Clinical Specialist: The defect was a large functional patent foramen ovale, with a large aneurysmal primum. The physician opted to try a 30mm device and if it didn't work, he would bring the patient back and use an atrial septal defects occluder. The physician deployed the device and upon locking the device it fell off of the anterior rim and resulting in needed to remove the device. While attempting to recapture the device, the right disc unlocked properly but the left disc would not unlock from the deployed stage. Subsequently the retrieval cord broke, resulting in needing to snare the device from the right atrium. We were able to snare the device and bring it down to the femoral vein, but it would not exit the sheath due to the left disc still being fully formed. The physician consulted with vascular surgery and determined a femoral cutdown was the safest option to remove the device. After the cutdown, the surgeon was able to remove the device, still fully deployed on the left disc. Please see picture below: 

Device	Manufacturer	Problem
Ventilator, Continuous, Facility Use Brand: Hamilton-g5 Model#: 159002 Cat #: 159002	Hamilton Medical AG	This is one of 13 reports. In most cases, the ventilator was on a patient. The ventilator alarms and has a red banner on the top. I believe the ventilator still ventilates but not a hundred percent positive. Error code TF5507. I don't think there was any patient harm during any of these because the ventilator still ventilates. We do change out the ventilators when this occurrence happens. Manufacturer has been contacted and has stated possibly related to the mixer valves and in others it is the sensor board.
Implantable Cardioverter Defibrillator (Non-crt) Brand: Fortify Assura™ Model#: DR Cat #: CD2357-40Q Other #: Abbott Durata 7122Q-58cm, serial number BNY113216	ST. JUDE MEDICAL, INC.	Patient with implantable cardioverter defibrillator and ventricular lead implanted had a cardiac arrest. Rapid Ventricular tachycardia (~240 bpm) was changed to ventricular fibrillation with anti-tachycardia pacing (ATP) by the device. During 5 minutes of ventricular fibrillation, device did not appropriately shock (the device intermittently sensed V-tach / V-fib but then concluded a return to sinus rhythm due to small ventricular electrograms). Device ultimately successful with 800 J shock (two subsequent VF episodes lasted seconds immediately afterwards and were successful cardioverted with ICD shocks). In summary, there was a failure of device sensing during the prolonged V-fib episode.

Device	Manufacturer	Problem
Device 1: Tubes, Vials, Systems, Serum Separators, Blood Collection Brand: Bd Microtainer® Tubes With K2e (K2edta) Model#: 365974 Lot #: 9269005 Cat #: 365974	BECTON, DICKINSON AND COMPANY	Heel stick for blood specimen with good blood flow. Collected into microtainer. Reportedly clotted. Patient had to be re-drawn. Multiple lot numbers involved.
Device 2: Tubes, Vials, Systems, Serum Separators, Blood Collection Brand: Bd Microtainer® Tubes With K2e (K2edta) Model#: 365974 Lot #: 9291464 Cat #: 365974	BECTON, DICKINSON AND COMPANY	
Device 3: Tubes, Vials, Systems, Serum Separators, Blood Collection Brand: Bd Microtainer® Tubes With K2e (K2edta) Model#: 365974 Lot #: 0027887 Cat #: 365974	BECTON, DICKINSON AND COMPANY	

Device	Manufacturer	Problem
Device 1: Shunt, Central Nervous System And Components Brand: Strata Ii Lot #: 0219128329 **Device 2:** Shunt, Central Nervous System And Components Brand: Strata® Lot #: 0219081908 **Device 3:** Shunt, Central Nervous System And Components Brand: Strata® Lot #: 0218417810	Medtronic Medtronic PS Medical, Inc. Medtronic PS Medical, Inc.	A Medtronic Strata II ventriculo-peritoneal (VP) shunt was implanted into a patient. Post-operatively, it was radiographically recognized that the valve lacked the radio-opaque markings required to confirm its orientation and pressure settings. In addition to this patient, another patient was implanted with a defective Medtronic Strata II VP shunt valve on the same day [date redacted] at another hospital. After recognition of this implanted VP shunt valve defects, remaining Medtronic Strata II VP shunt valves in inventory were radiographically tested while remaining in their unopened packaging. The devices in inventory were also found to be defective for the same reason—no radiographic markings on the shunt valve. The lot numbers for these Medtronic Strata II VP shunt valve devices were 0219081908 and 0218417810.

Links to FDA/CDRH Databases and Other Information Sources

FDA U.S. FOOD & DRUG ADMINISTRATION
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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 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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