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 26, 2022

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

Class I Recall: Medtronic Recalls HawkOne Directional Atherectomy System Due to Risk of Tip Damage During Use

January 21, 2022

Medtronic is recalling the HawkOne Directional Atherectomy System (i.e., Catalog numbers H1-S and H1-S-INT) due to the risk of the guidewire within the catheter moving downward or prolapsing when force is applied during use. If this happens, the catheter tip may break off or separate and this could lead to serious adverse events including a tear along the inside wall of an artery (arterial dissection), a rupture or breakage of an artery (arterial rupture), decrease in blood flow to a part of the body because of a blocked artery (ischemia), and/or blood vessel complications that could require surgical repair and additional procedures to capture and remove the detached and/or migrated (embolized) tip.

There have been 163 complaints about this device issue. There have been 55 injuries and no deaths reported about this device issue.

Class I Recall: Medtronic Recalls Synergy Cranial and StealthStation S7 Cranial Software Due to Potential Risk of Inaccurate Biopsy Depth Gauge Cycle View

January 6, 2022

Medtronic is recalling its Synergy Cranial and StealthStation S7 Cranial software due to the potential inaccuracies caused by the Biopsy Depth Gauge Cycle View. If the user encounters the software issue where the graphical Biopsy Depth Gauge is no longer synchronized with other navigation views, it may result in a prolonged procedure, the need for an additional surgical procedure, aborted procedure, tissue injury, including potential for life-threatening injury (such as hemorrhage, unintended tissue damage, or permanent neurological injury), which could lead to death.

There have been four complaints regarding this device issue. There have been no reported injuries or deaths.

Class I Recall: Getinge, LLC Recalls the Vaporizer Sevoflurane Maquet Filling for Flow Family Anesthesia Systems Due to a Risk of Harmful Chemical Exposure

January 19, 2022

Getinge is recalling the Vaporizer Sevoflurane Maquet filling due to the potential chemical breakdown of Sevoflurane, a general surgical anesthetic, that may result in inhalation and/or skin exposure to harmful chemicals. If this occurs, this may cause serious patient harms including irritation of the respiratory tract, lung edema (swelling caused by excess fluid), and severe hypocalcemia (condition in which the blood has too little calcium).

There have been eight complaints regarding this device issue. There have been no reported deaths or injuries.

UPDATE: Blood Specimen Collection Tube Conservation Strategies - Letter to Health Care and Laboratory Personnel

The FDA is aware the United States is experiencing significant interruptions in the supply of several blood specimen collection (blood draw) tubes because of an increase in demand during the COVID-19 public health emergency and recent vendor supply challenges. The FDA is expanding the medical device shortage list to include **all** blood specimen collection tubes. The FDA previously issued a letter to health care and laboratory personnel on June 10, 2021, about a shortage of sodium citrate blood specimen collection (light blue top) tubes.

Recommendations

The FDA recommends that health care providers, laboratory directors, phlebotomists, and other personnel consider the following conservation strategies to minimize blood collection tube use and maintain quality and safety of patient care:

- Only perform blood draws considered medically necessary.
    - Remove duplicate test orders to avoid unnecessary blood draws.
    - Avoid testing too frequently or extend time intervals between tests whenever possible.
- Reduce tests at routine wellness visits and allergy testing only to those that target specific disease states or where it will change patient treatment.
- Consider add-on testing or sharing samples between laboratory departments if previously collected specimens are available.
- If you need a discard tube, use a tube type that has a greater quantity available at your facility.
- Consider point of care testing that does not require using blood specimen collection tubes (lateral flow tests).

FDA Actions

On January 19, 2022, the FDA updated the medical device shortage list to include all blood specimen collection tubes (product codes GIM and JKA). Section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires the FDA to maintain a publicly-available, up-to-date list of the devices the FDA has determined to be in shortage.

The FDA continues to monitor the current situation to help ensure blood testing remains available for patients where testing is medically necessary. The FDA will inform the public if significant new information becomes available.

To read the full updated letter, please visit FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during January 2022. 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:

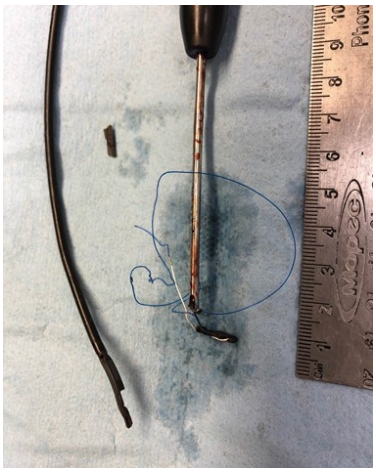
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm

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
Analyzer, Gas, Carbon-dioxide, Gaseous-phase Brand: Capnostream 35 Model#: Capnostream 35 Cat #: PM35MN	Medtronic	RN responded to EtCO2 monitor alarming. The monitor was alarming 'Battery Low". The clinician noted that the charging cord was plugged into the unit, but alarm was still occurring. RN contacted Respiratory Therapy to have monitor replaced. Respiratory informed the RN that they would have to locate a replacement due to several units in repair for the same failure. Respiratory exchanged with legacy monitor and patient monitoring continued without additional actions. Monitor removed from service and sent to Biomedical engineering for repair and reporting. Biomedical engineering confirmed that when known good charger connector inserted into monitor the Battery Charge icon on the monitor front panel would not illuminate. This report is a re-occurring event with the same failure. Unit in service for less than 4 months and was actually a replacement for a monitor with the same failure issue.
Device, Fixation, Tracheal Tube Brand: Dale 240 Blue Tracheostomy Tube Holder Model#: 240 Blue Lot #: 21H2318 Cat #: 240	Dale Medical Products	Adolescent patient with tracheostomy tube and mechanical ventilation. Velcro part of the trach holder/strap was found to be completely detached/broken off from the soft part of the strap that encircles the neck. There was no actual patient harm -- trach tube did not become dislodged because the vent holder (which is also secured with Velcro) was attached. Trach holder/strap was replaced upon discovery of breakage. 

Device	Manufacturer	Problem
Catheters, Transluminal Coronary Angioplasty, Percutaneous Brand: NC Emerge Model#: H7493926708400 Lot #: 28317304 Cat #: H7493926708400	Boston Scientific Corporation	The tip of the balloon NC Emerge PTCA 4mm x 8mm dilatation catheter broke off in right radial artery after it was inflated with high pressures during a percutaneous transluminal coronary angioplasty. The patient had to go to the operating room for an open procedure to remove the broken piece of balloon. The broken tip was found using fluoroscopy and was easily removed.
Device, Hemostasis, Vascular Brand: Manta Model#: 2115 Lot #: MN2101402 Cat #: 2115	Essential Medical, Inc.	18 Fr. MANTA vascular closure device failed to close the femoral arterial access site at the conclusion of the original surgical intended procedure. Right femoral artery bleed, FemoStop femoral compression system was placed, no pulse felt or dopplered in right foot. Vascular surgeon consulted. Femoral cut down performed. Artery was sutured, no bleeding was noted. MANTA collagen plug found in tissue right groin and subsequently extracted. Pulse in right foot was felt. Femoral cut down was sutured closed.
Device, Hemostasis, Vascular Brand: Perclose Proglide Model#: 12673-03 Lot #: 1102941 Cat #: 12673-03	Abbott Vascular, Inc.	Per the cardiologist note: "under ultrasonic guidance, with the use of micropuncture needle, an access was made in left common femoral artery, and a Perclose ProGlide suture was attempted but did not take, thereafter there was difficulty removing the device. A cut down was then performed (by vascular surgeon) and Perclose ProGlide device removed." Site of open arteriotomy was used for access for the valve replacement. Then after valve replaced and function confirmed with fluoroscopy, the arteriotomy was surgically patched by the vascular surgeon. MD described complication of surgery: "left groin access site Perclose ProGlide device fracture needing open arteriotomy." Per surgeon note: "using ultrasound guidance, placed wire into the left femoral artery. Then placed one Perclose ProGlide device without difficulty. Went to place a second Perclose ProGlide device for later closure and the device became stuck in the artery and the plastic part became separated from the metal part. Pressure was held on the groin; however, there was bleeding without direct pressure. Therefore, I did an emergent left femoral artery cutdown with pressure held at the bleeding site. This was carried down through the subcutaneous tissues until we could identify the left common femoral artery." Then vessel loops were placed on the left common femoral artery, the profunda artery, and the superficial femoral artery to control the bleeding. "There were sutures attached to the end of the Perclose ProGlide device, which was in the artery, which we could not see. We therefore did a longitudinal arteriotomy and were able to identify the retained portion of the Perclose device and remove this. With this complete removal and now controlled artery, we decided to proceed with the Transcatheter Aortic Valve Replacement (TAVR) procedure. Once the TAVR procedure was completed, the femoral sheath was removed. Then to repair the artery, we used a pericardial patch to place a longitudinal oval patch repairing the artery. The wound was then closed in 4 layers." Surgeon described this complication of surgery: "the Perclose percutaneous device separating in the left femoral artery."

Device	Manufacturer	Problem
		Patient required one unit of packed red blood cells and then went home the following day. 
Electrocardiograph Brand: Mac Model#: VU360	GE Medical Systems Information Technologies, Inc.	The MacVu360 EKG machines have been documented to not keep time accurately and it is posing a problem with time documentation such as STEMIs (ST-elevation myocardial infarction) where the EKG to balloon time is measured. We currently have 46 machines and the manufacturer has been contacted over the last couple of months to be notified and to correct the situation by our Clinical Engineering (CE) team. The discrepancy in the time reported by the EKG machine and actual time is currently being addressed by CE team rounding on the entire hospital to manually address the time issues. Couple of months ago, communication was received from GE Healthcare acknowledging that the time sync on their devices is not working and that a manual sync is required. The time synch function does not work as intended. Communication was later received from GE Healthcare regarding the MAC VU360 not properly syncing to the Network Time Protocol (NTP) server informing CE that there had been a partial fix with the last software release. The key information was that the carts cannot be turned off which only makes the fix a partial fix. GE Healthcare communicated that a software release will be coming out in quarter four to fix the issue. The current recommendation is to use the manual time on the EKG machines.
Heart Valve, More Than Minimally Manipulated Allograft Model#: SGPV00 Cat #: SGPV00	Cryolife, Inc.	The pulmonary homograft initially implanted may have been defective in some way. A pulmonary homograft was needed for the surgery to replace the patient's native valve. It was selected based on the size that was appropriate for the patient. There were no deviations noted in the way the graft was stored, or in the standard procedures of thawing and rinsing the graft in preparation for its use. The graft was implanted in the usual way with a running suture. After the patient was off the cardiopulmonary bypass machine and anticoagulation had been reversed, there was still some significant bleeding around the suture lines. As surgeon was trying to place repair stitches, the graft kept tearing in multiple places. It was determined that the patient urgently needed to be placed back on the bypass machine for adequate cardiopulmonary support. The pulmonary homograft initially implanted was not of sufficient quality and the tissue was friable and kept tearing as repair stitches were being placed. A new homograft of similar size was thawed and implanted in its place.

Device	Manufacturer	Problem
		The Cryolife sales/clinical representative was contacted. Representative is working on paperwork on his end. A request was made to save the tissue and return it to the company so it can be tested to see if they can identify what went wrong with the graft. The tissue is set aside in a specimen jar, suspended in room temperature normal saline irrigation. Company's representative will get the appropriate paperwork and shipping products from his company and pick up the defective tissue to be returned.
Needle, Hypodermic, Single Lumen Brand: Jelco Model#: 402510 Lot #: 4133093 Cat #: 402510	Smiths Medical, Inc.	While preparing to administer flu vaccine, I had put the needle on the syringe just before administering the vaccine. I did not notice anything unusual when attaching the needle to the syringe. When I administered the vaccine, the fluid squirted out from the needle hub and did not go into the patient.
Duodenoscope and Accessories, Flexible/Rigid Brand: Evis Exera Duodenovideoscope Model#: TJF-Q180V	Olympus Medical Systems Corp.	The state health department notified our facility of an NDM (New Delhi metallo-beta-lactamase 1) producing *E.coli* strain in one of our inpatients that matched the strain of another patient tested at different facility ~2 months prior. After investigating, it was found that the other patient was a previous patient at our facility, as well. Our team worked with the lab to see if this organism was identified in any other patients at our facility, and three other patients were identified to have NDM producing *E.coli*. Chart reviews were began to find any commonalities between the five patients. One of the commonalities discovered was that all patients had an endoscopic retrograde cholangiopancreatography (ERCP). One ERCP scope appeared to be in common. The scope was sequestered. Updated the state health department and requested that the other three isolates be sequenced by the State.

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:
https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/medical-device-connectors
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: https://medsun.fda.gov/
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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