MedSun
Medical Product Safety Network

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

August 2022

Volume 22, Issue 8

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/medical-devices/device-approvals-denials-and-clearances/recently-approved-devices

Premarket Approval Final Decisions:
https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals

510(k)s Final Decisions:
https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances

In Brief

As of August 1, 2022

The FDA Enforcement Report containing the most recent Class I, II and III recalls can be found here. If you see 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--Covidien, LLC (Medtronic) Recalls Palindrome and Mahurkar Hemodialysis Catheters Due to Catheter Hub Defect

July 28, 2022

Covidien, LLC (Medtronic) is recalling the Palindrome and Mahurkar catheters due to a catheter hub defect that will connect both extension catheters. There is a potential leaking condition within the hub of specific chronic dialysis catheters. This may be noticed when flushing one extension tube and the flow of fluid through the tip of the catheter returns unanticipated fluid through the adjacent extension tube. During treatment, this leak could result in mixing of the arterial and venous blood and lead to increased recirculation and poor dialysis, and the development of thrombi and emboli.

Use of the defective catheter may cause serious adverse health outcomes, including bleeding, surgical removal and replacement of the affected catheter. There have been no reports of death or injury.

A complete list of affected devices is available in the Medical Device Recalls database.

For Monkeypox Testing, Use Lesion Swab Samples to Avoid False Results: FDA Safety Communication

July 15, 2022

FDA is advising people to use swab samples taken directly from a lesion (rash or growth) when testing for the monkeypox virus. FDA is not aware of clinical data supporting the use of other sample types, such as blood or saliva, for monkeypox virus testing. Testing samples not taken from a lesion may lead to false test results.

Recommendations include:

- Use lesion swab samples when testing for the monkeypox virus.
- Be aware of the CDC's Information for Health Care Professionals, including clinician FAQs and preparing and collecting specimens for monkeypox virus testing.
- If your patient was tested for the monkeypox virus using an alternate sample type and you suspect an inaccurate result, consider retesting your patient using a lesion swab sample.
- Be aware of the CDC's Information for Laboratory Personnel that includes information about procedures, testing, preparing and collecting specimens, and recommendations for clinicians.
- Contact the FDA at MPXDx@fda.hhs.gov to discuss new test development and alternate testing approaches, and to share validation data from saliva, blood, or any other sample types.
- **Report any problems you experience with monkeypox virus tests to the FDA, including suspected false results**.

The CDC's FDA-cleared non-variola orthopoxvirus test can detect monkeypox from a lesion sample. This test is performed in many laboratories included in the CDC's public health Laboratory Response Network (LRN) as well as additional large reference laboratories to facilitate monkeypox testing capacity and access.

Refer to the FDA Safety Communication for further details.

Patient Safety Input Requested: Software Functions Excluded from Device Definition by 21st Century Cures Act

Comment period closes: August 15, 2022

The U.S. Food and Drug Administration (FDA) requests input on patient safety, including best practices to promote patient safety, education, and competency, associated with medical software functions that are excluded from the medical device definition by the 21st Century Cures Act. This input will help the FDA develop a report on the risks and health benefits of non-device software functions, which include certain software functions intended for:

- Administrative support of health care facilities;
- Encouraging a healthy lifestyle;
- Serving as electronic patient records;
- Transferring, storing, converting formats, or displaying data; and
- Providing limited clinical decision support.

Who should comment: Patients and other health care consumers, health care providers, startup companies, health plans or other third-party payors, venture capital investors, information technology vendors, health information technology vendors, small business purchasers, employers, and any other interested stakeholders.

Read: Development of 21st Century Cures Act Section 3060 Required Report: Request for Input.

The comment period is open until 8/15/22 at www.Regulations.gov under docket number FDA-2018-N-1910-0047.

Discovery Workshop on eConsent: From Birth to End of Life

August 16, 2022, 12:00PM--4:30PM ET

The use of technology to enable electronic consent (eConsent) for how and when a person's electronic health information is shared is central to placing patients in control of decisions regarding their data. On August 16th, from 12:00-4:30pm ET, the Office of the National Coordinator for Health Information Technology (ONC) will present a workshop exploring technical standards and approaches to enable capturing, maintaining, and communicating a patient's consent decision for sharing electronic health information throughout different life stages, within the context of applicable law. Participants will also explore capturing consent decisions to share EHI between healthcare providers and other non-HIPAA covered entities. An agenda and registration are available here.

Smiths Medical Recalls Certain Medfusion 3500 and 4000 Syringe Infusion Pumps for Software Issues That May Impact Infusion Delivery

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

Medfusion Syringe Infusion Pumps
Models, Product Codes, and Software Versions:

- Medfusion Syringe Infusion Pumps 4000
- Medfusion Syringe Infusion Pumps 3500

Device Use:

Smiths Medical Medfusion 4000 and 3500 Syringe Infusion Pumps are used to give fluids to patients in precisely controlled amounts. They deliver blood or blood products, lipids, drugs, antibiotics, enteral feedings and other therapeutic fluids through infusion tubing into a vein or through other cleared routes of administration. Syringe pumps are primarily used in the neonatal and pediatric populations or in operating rooms and ICUs for the adult population.

Reason for Recall:

Smiths Medical is recalling Medfusion 3500 and 4000 Syringe Infusion Pumps for eight software malfunctions that affect different serial numbers and software versions. These malfunctions may cause serious harm or death to patients from under- or over-infusion, or delays in the delivery of critical medications to patients.

The eight software issues are as follows:

(1) False alarm for Primary Audible Alarm (PAA) system failure
(2) Unanticipated Depleted Battery Alarms
(3) Abnormal circuit board behavior, which may cause internal clock system failure
(4) Intermittent Volume Over Time (IVOT) delivery mode where the infusion continues after system failure
(5) Unanticipated clearance of Program Volume Delivered (PVD)
(6) False alarm for Rate Below Recommended Minimum for Syringe Size
(7) Incorrect bolus or loading dose time display
(8) Network configuration may affect pump communications.

Smiths Medical states there have been a total of 7 serious injuries and one death reported related to these issues. The Customer Notification identifies the injuries and/or deaths associated with each software issue.

For more information on this recall, including instructions from Smiths Medical for customers, contact information, and additional resources, go to FDA's website for this recall.

HIGHLIGHTED REPORTS

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

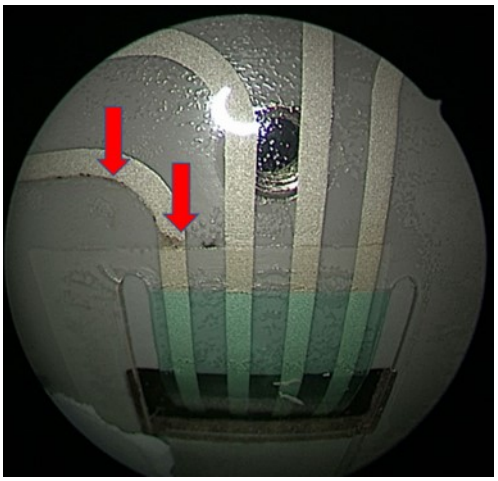
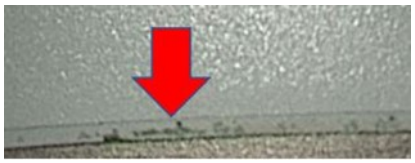
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm

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: **Type: Staple, Implantable** Brand: Ethicon Flex Gst Model #: PSEE60A Lot #: V94X33 Cat #: PSEE60A **Device 2**: **Type: Staple, Implantable** Brand: Ethicon Flex Gst Model #: PSEE60A Lot #: V95A85 Cat #: PSEE60A	**Device 1:** ETHICON ENDO-SURGERY, LLC **Device 2:** ETHICON ENDO-SURGERY, LLC	Echelon 60 failed to fire causing pulmonary artery bleeding leading to hypovolemic arrest and death. Patient scheduled for a right lower lobe (RLL) lobectomy. During the procedure, the Physician fired the Echelon 60 and it did not deploy. Another Echelon 60 with blue load was given to replace the defective one. The second stapler was deployed. Bleeding was seen by Medical Doctor (MD). The MD tried to control the bleeding then eventually patient became hypovolemic, then arrested. After a period of time patient expired in the OR. Total of two Echelon 60 open but Registered Nurse (RN) could not identify which box the defective stapler was from. Lot V94X33 EXP 2024-04-30 REF PSEE60A and LotV95A85 EXP 2024-06-30 REF PSEE60A were the two boxes. An RN saw the stapler did not fire and asked for a new stapler. A new stapler was given to the MD. The team did ACLS for the hypovolemia and arrest. Root cause analysis (RCA) is in progress.

Device	Manufacturer	Problem
Device 1: **Type: Automated External Defibrillators (Non-wearable)** Brand: Onestep Complete, Single, RSeries, Electrodes Model #: 8900-0224-01 Lot #: 3821 Cat #: 8900-0224-01 **Device 2**: **Type: Automated External Defibrillators (Non-wearable)** Brand: Onestep Complete, Single, RSeries, Electrodes Model #: 8900-0224-01 Lot #: 1122C Cat #: 8900-0224-01	**Device 1**: Zoll Medical Corporation **Device 2**: Zoll Medical Corporation	2 devices with same defect: Patient arrested. First set of One Step CPR complete pads had gel adhesive roll up off of pad within first two minutes of CPR (anterior set). Second set was applied, adhesive began to roll and separate from pads during next round, (also anterior set) team repositioned gel and pad during pulse checks for duration of CODE BLUE (35min). The hospital service will be returning to manufacturer through representative.
Type: Endoscopic Grasping/cutting Instrument, Non-powered Brand: Karl Storz Model #: 27074B Lot #: FL01	Karl Storz GmbH Co. KG	From what the doctor states, the stone was very solid/hard. This is a very uncommon procedure and the stone crushing forceps are seldom used (1-2 times a year). It looks like the pin that holds the top jaw together snapped and the jaw cleanly broke off the main instrument housing. No retained metal. An evaluation of the remaining forceps will be done by our surgical instrument company and replacements purchased for any faulty or old forceps. ========== Manufacturer response for Stone Crusher, Stone Crusher (per site reporter) ========== Not sure at this time

Device	Manufacturer	Problem
Type: Endoscope, Neurological Brand: Image1 SConnect Model #: TC201US	Karl Storz Endoscopy-America, Inc.	The Endoscopy equipment TC 201 and TC 304 models were having issues where the power would not shut off and the units occasionally overheated. The manufacturer identified a fix to insulate the front cover of the equipment, ultimately reducing water intrusion. It seemed as though the design of the device was not made to handle the cleaning fluid, and when fluid came into the front panel, the power button malfunctioned. ========== Manufacturer response for Endoscopy camera control unit, Image1 S Connect II (per site reporter) ========== The manufacturer did a full evaluation, and found that additional insulation was necessary to reduce water intrusion on the power buttons and electrical networks.   

Device	Manufacturer	Problem
Type: Ventilator, Continuous, Facility Use Brand: Hamilton-mr1 Model #: MR1	Hamilton Medical AG	Hamilton had recently released software upgrade v3.0.3 that requires a full calibration after the completion of the upgrade. The software provided a new graphical user interface, new waveform layout, and an added audiovisual alarm to Tesla spy. BioMed reached out to the RT manager for approval of software upgrade and scheduled to have it completed during preventative maintenance. While performing preventative maintenance BioMed attempted to install software upgrade v3.0.3 with fault. An error occurred while verifying the file "Verify manifest file failed" BioMed called Hamilton technical support and was told to try the file again. After the second failed attempt, the technician sent us an older file (v3.0.1migration file) that successfully loaded. We then proceeded to load the second file (v3.0.3). After the unit rebooted, the tesla spy alarmed indicating it had lost communication to the gauss meter. While in service mode, the technical state was highlighted red with the Tesla Spy board missing technical information (part number, serial, etc.). The technician instructed us on how to add the information however oddly, we were not able to key in the correct Tesla Spy board part number due to no keyboard pop-up and limited selection of available known part numbers. The tech had us reset the tesla spy alarm but that did not clear the error. We attempted to update the firmware of the Tesla Spy board but, the graphic user interface did not show a selectable tab. We were then told that the technician had seen a similar issue and it would require either the ESM board or Tesla Spy board needing to be replaced due to a communication error caused by a line-of-code of the new software. Hamilton technicians had knowledge of similar issues, but a statement was not disclosed clarifying software compatibility. The aftermath has put our facility in a position where we cannot serve a critically ill population and will require emergent transfer out to lateral care facility affecting customer care and impacting patient safety as Hamilton does not offer a loaner program for a known issue. Also, we will be charged service fees for a known fault that is result of a manufacturer upgrade.

Device	Manufacturer	Problem
Type: Pump, Infusion Brand: Plum 360 Model #: 300100407 Cat #: 30010	ICU MEDICAL, INC.	The patient experienced a Cardiac Arrest and the patient successfully regained a pulse. Prior to the cardiac arrest, the patient had a Hospira Plum 360 infusion pump infusing Levophed. When the patient was resuscitated, the patient's blood pressure required a significant increase in the Levophed dose to 1mcg/kg/min. This medication is weight-based and 1 mcg/kg/min is a significant amount of medication. As the RN increased the infusion rate and started the infusion pump, the pump alarmed "Turn off and turn back on" If the alarm persists after the pump is turned on, schedule maintenance. The patient required the medication and the IV pump could not be turned off and on. The staff had to retrieve a second IV pump. The 2nd pump had to be programed with the medication and patient information and this task requires a brief pause in the medication. The Hospira pumps can only be programmed with Infusion set cassette in the pump. Due to brief pause in medication to program a new pump, the patient cardiac arrested again. The patient did survive the second cardiac arrest.
Type: Pump, Infusion Brand: Plum 360 Model #: 30010 Cat #: 30010	ICU MEDICAL, INC.	Plum pump malfunction. The pump would alarm for door closure even when the door was closed. It would not start.
Type: System, Xray, Tomography, Computed Model #: CT-Sensation 64 400-185419	Siemens AG/Siemens Healthcare GmbH	Manufacturer was here to replace the MCU on this scanner, which is what was determined to be the culprit for why the scanner keeps cutting off mid-scan randomly. They replaced it and left; I went to scan an adrenal protocol on a patient that begins with a non-contrast scan of the abdomen and pelvis and the machine stopped after trying to acquire 1 image. I reloaded the scan and the machine stopped after a short series of images were acquired that only made it to the top of the patient's kidneys. At this time, I had to relocate the patient to our other scanner and call the manufacturer to come back to reevaluate this scanner as the problem is not fixed. At this moment they are here saying a controller is bad. The same area of interest/anatomy on this patient was irradiated 3 times in an effort to complete this scan.

Device	Manufacturer	Problem
Type: Ventricular (Assist) Bypass Brand: Hvad Pump Implant Kit Model #: 1103	Heartware Inc.	LVAD patient developed pump thrombus, leading to death. Detail of note: Pump analysis says 'external factors' deformed the pump, causing the impeller to make contact with rear housing. Treatment Summary: The patient was admitted for Ventricular Assist Device (VAD) high power and suspected thrombus. In addition, the patient was showing signs and symptoms of heart failure and their International Normalized Ratio (INR) was 2.6. The patient was given 2 doses of Tissue Plasminogen Activator (tPA) to treat the thrombus. After the tPA treatment, the patient experienced changes in mental status and a hemorrhagic stroke. The patient continued to decline neurologically, and an electroencephalogram (EEG) showed continuous seizing. The decision was made to withdraw care and the patient subsequently passed away. Device Analysis: Analysis of the pump revealed the device did not pass visual inspection or dimensional verification. Visual examination revealed abrasions on the lower housing ceramic surface and on the inferior surface of the impeller. These mechanical abrasions of the lower housing ceramic surface and matching surface of the impeller are indicative that an external factor may have forced the impeller against the rear housing which led to scoring marks observed during visual inspection. Dimensional verification revealed the front and rear housing disc curvatures were found to be deviating from specifications.

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Links to FDA/CDRH Databases and Other Information Sources

Establishment Registration & Device Listing:
This database includes medical device manufacturers registered with FDA and medical devices listed with FDA. It is updated monthly and contains multiple links to other FDA databases.

Global Unique Device Identification Database (GUDID):

A searchable database administered by the FDA which serves as a reference catalog for every device with a unique device identifier (UDI) and contains additional GUDID specific resources.

Human Factors Website:

A site providing information about human factors design, testing and use considerations. Other links include information about the CDRH Human Factors Team activities, including their contact information.

Medical Device Connectors Website:

A site providing information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other. Examples of misconnections, additional resources, and other links reside on this site.

MAUDE (Manufacturer and User Facility Device Experience):
The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters [1] (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. This site also contains links to other FDA databases.

Medical Device Safety Website

One-stop for safety information with links to FDA medical device safety communications, recent letters to healthcare providers, recent medical device recalls, and more device safety related links.

MedSun Website:
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)]:
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 web interface for more recent records. It is updated monthly and contains multiple links to other FDA databases.

Premarket Approvals (PMA):
The Premarket Approval (PMA) database of premarket approvals of Class III devices may be searched by a variety of fields and is updated monthly. This site contains multiple links to other FDA databases.

Product Classification:
This database can be used to determine the classification of a device and the regulations it is subject to. It has a list of all medical devices with their associated classifications, product codes, FDA Premarket Review organizations, and other regulatory information. Multiple links to other FDA databases are included on this site.

Warning Letters:

This database contains the most recent manufacturer warning letters. Site is searchable.

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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