MedSun
Medical Product Safety Network

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

May 2021

Volume 21, Issue 5

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 May 4, 2021

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

Pacific Medical Group (DBA Avante Health Solutions) Recalls Alaris Infusion Pump Module 8100 Bezel Due to Possible Cracked or Separated Bezel Repair Posts
April 30, 2021
Pacific Medical Group (DBA Avante Health Solutions) is recalling the affected products and devices because the front bezel components may crack or separate, leading to inaccurate delivery of fluids to patients. The separation of one or more bezel posts may result in free flow of fluids to patient, over delivery or under delivery of fluids delivered to a patient, and interruption of fluids delivered to a patient. This recall is related to Tenacore's recent recall of the Alaris pump bezel assembly and Alaris infusion pumps repaired with the bezel assembly.

Smisson-Cartledge Biomedical, LLC Recalls ThermaCor 1200 Disposable Sets for Risk of Patient Contact to Aluminum
April 12, 2021
Smisson-Cartledge Biomedical is recalling their ThermaCor 1200 Rapid Thermal Infusion System Disposable Sets because a part of the ThermaCor 1200 Disposable Set, the cassette (See Figure 1), which warms fluids directly with an aluminum plate may leak aluminum into the fluids and expose patients to high levels of the metal. The recall is specific to the disposable cassette portion of the device, not to the full pump. Use of the affected product could cause increase exposure to aluminum ions. Exposure to high levels of aluminum ions could cause serious patient harm such as bone or muscle pain and weakness, anemia, seizures, or coma.

Medtronic Recalls Evera, Viva, Brava, Claria, Amplia, Compia, and Visia Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy (CRT-Ds) Due to Risk of Shortened Battery Life
April 12, 2021
Medtronic is recalling the specified ICDs and CRT-Ds due to an unexpected and rapid decrease in battery life. The decrease in battery life is caused by a short circuit and will cause some devices to produce a "Recommended Replacement Time" (first warning that the battery is low) earlier than expected. Some devices may progress from "Recommended Replacement Time" to full battery depletion within as little as one day. If the user does not respond to the first warning, the device may stop functioning. The likelihood that this issue will occur is constant after approximately three years after device use.

FDA Recommends Transition from Use of Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities

FDA is recommending health care personnel and facilities transition away from crisis capacity conservation strategies, such as decontaminating or bioburden reducing disposable respirators for reuse. Based on the increased domestic supply of new respirators approved by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) currently available to facilitate this transition, the FDA and CDC believe there is adequate supply of respirators to transition away from use of decontamination and bioburden reduction systems.

The FDA recommends that health care personnel and facilities:

- Limit decontamination of disposable respirators. Decontaminated respirators and respirators that have undergone bioburden reduction should be used only when there are insufficient supplies of new FFRs or if you are unable to obtain any new respirators.

- Transition away from a crisis capacity strategy for respirators, such as decontamination of N95 and other FFRs.

- Increase inventory of available NIOSH-approved respirators—including N95s and other FFRs, elastomeric respirators, including new elastomeric respirators without an exhalation valve that can be used in the operating room, and powered air-purifying respirators (PAPRs). Even if you are unable to obtain the respirator model that you would prefer, the FDA recommends that you obtain and use a new respirator before decontaminating or bioburden reducing a preferred disposable respirator.

The FDA and CDC believe there is adequate supply of respirators to transition away from use of decontamination and bioburden reduction systems. However, the FDA is not revoking the EUAs for decontamination and bioburden reduction systems at this time. If there are insufficient supplies of FFRs resulting from the COVID-19 pandemic, health care personnel may continue to use currently-authorized decontamination and bioburden reduction systems, though such reuse of respirators should be limited to when no other respirators are available, including reusable respirators such as elastomeric respirators or PAPRs.

To read the full letter and all of FDA's recommendations for health care providers please visit FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during April 2021. 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.

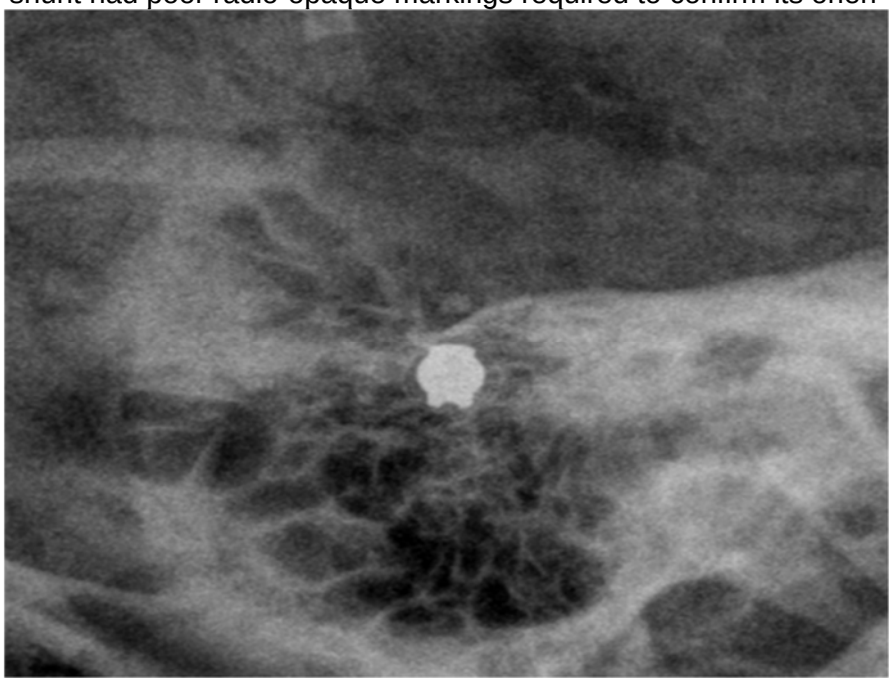
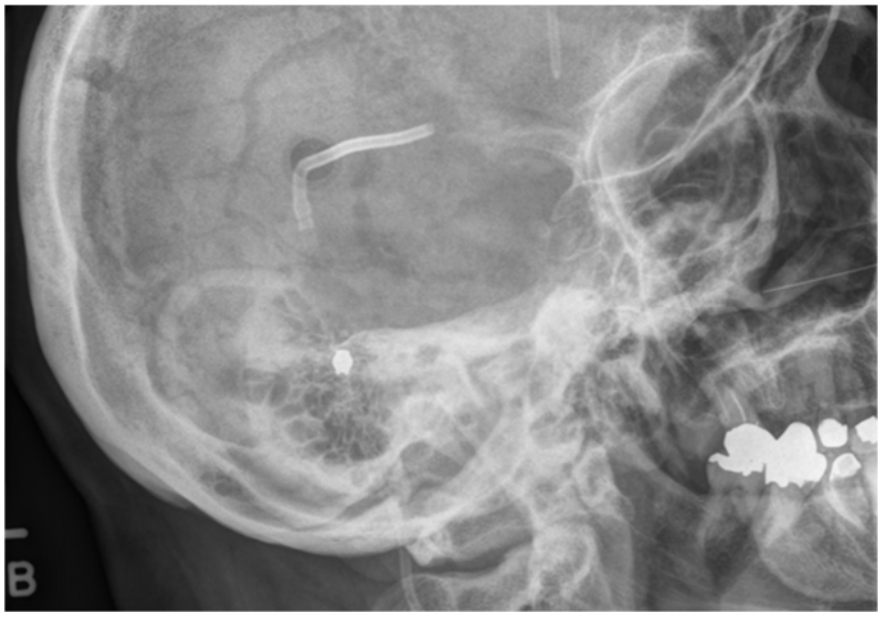
A database of all MedSun reports can be found at:

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


Special Note:

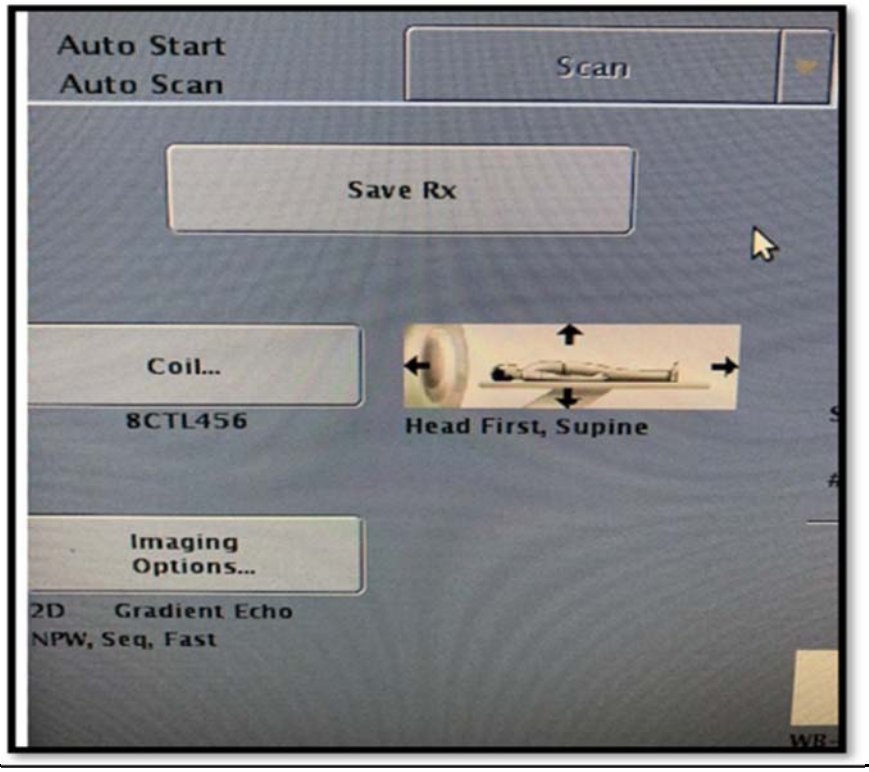
The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years 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.

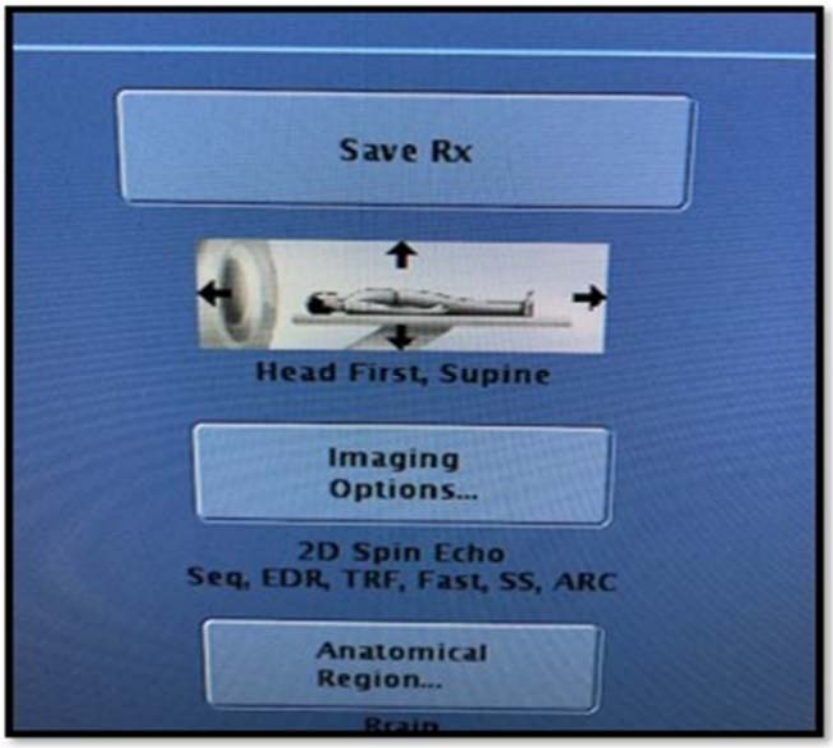
Device	Manufacturer	Problem
Electrode, Depth Brand: Anchor Bolt Lot #: 203868-26/20 Cat #: ACS-025SMS-10	Dixi Medical	The anchor bolt was being inserted into the skull when the bolt threads didn't catch and advanced into the patient's brain. Physician was able to retrieve the anchor bolt and an intra-operative CT was performed. Concern expressed that training and education was inadequate.

Device	Manufacturer	Problem
Device 1: Shunt, Central Nervous System And Components Brand: Strata™ Model#: 42866 Lot #: 0220812938 Other #: LOG 1507121721 **Device 2: Shunt, Central Nervous System And Components** Brand: Strata™ Model#: 42866 Lot #: 0219000135 Other #: TAG ID # W004010000916844	Medtronic PS Medical, Inc. Medtronic PS Medical, Inc.	A Medtronic ventriculo-peritoneal (VP) shunt was implanted into a patient. Post-operatively it was radiographically recognized that the shunt had poor radio-opaque markings required to confirm its orien-  

Device	Manufacturer	Problem
Splint, Extremity, Noninflatable, External, Sterile Brand: Dale Bendable Armboard Model#: 650 Cat #: 650	Dale Medical Products, Inc.	The middle-aged patient was having an MRI abdominal scan. Towards the end of the imaging exam, the patient squeezed the handheld alarm ball and stated that his hand was burning. The patient was removed from the MR bore. The patient stated it was his right hand that was burning. The patient had an MRI conditional arm board on his wrist. Upon taking the arm board off, the patient's skin was red, but he had no visible blistering at this time. An ice pack was applied and the patient's nurse, who escorted him to the study, was informed of the concern for a burn. The nurse assessed the patient and said she would reassess the area when the patient was back on the floor.
Accessories, Cleaning, For Endoscope Brand: Dsd Edge Endoscope Reprocessing System Model#: DSD Edge	Medivators, Inc.	Code orange called over head for chemical spill/leak in Medical Procedure Unit (MPU) scope room. Biomed Technician called as well. Found chemical was coming from underneath the Scope Disinfector (DSD). Biomed Technician ran a simulated scope run to find leak. Found a split in the internal tubing line on the back of the chemical tray. This line would leak when trying to pump disinfection to the basin and also drain the basin when the pump stopped. This is where the fluid on the ground came from. Biomed examined the tubing lines of our second DSD machine. Found these lines had deterioration as well. These lines are not called out to be replaced in the preventive maintenance instructions. We have replaced all tubing lines in both machines.
Coronary Drug -eluting Stent Brand: Synergy™ Model#: H7493926028300 Lot #: 26404846 Cat #: H7493926028300	Boston Scientific Corporation	A 74-years old patient with a history of hypertension, diabetes mellitus, a new onset of chest pain underwent a diagnostic cardiac catheterization. During the procedure, the Boston Scientific Everolimus-Eluting Platinum Chromium Coronary Stent System impacted a calcium buildup, prompting its retrieval from the patient. When attempting to reintroduce the Everolimus-Eluting Platinum Chromium Coronary Stent, the health care providers noticed that the device unraveled distally on the balloon with a fragment of the metal tubular mesh protruding from the device itself. Subsequently, a new device was used with no know harm to the patient.
Interventional Fluoroscopic X -ray System Brand: Interventional Angiography System Model#: INFX-8000C Cat #: INFX-8000C	Canon Medical Systems Corporation	Interventional Radiology patient positioned prone slipped laterally and suddenly fell from table to floor during conclusion of procedure though caregivers next to table. Patient was centered and mattress stayed in place. Patient needed serial CT scans. Small subarachnoid hemorrhage. No surgery needed. No straps that are attached to table for use in security patient. No straps that adhere to pad on top of table. Recommendations not found in Instructions for Use (IFU) of table. Reaching out to sales rep to see if they have some suggestions.

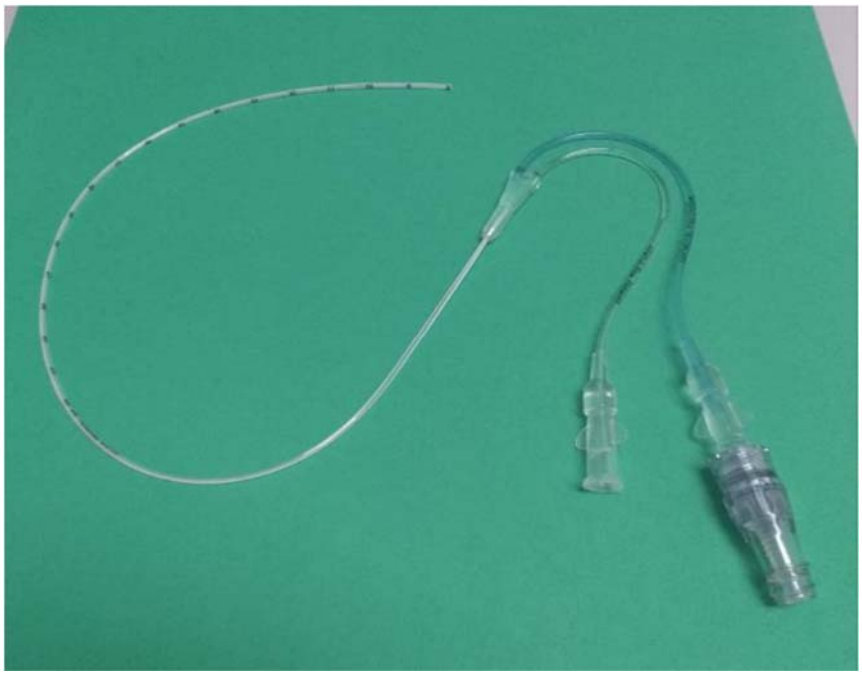
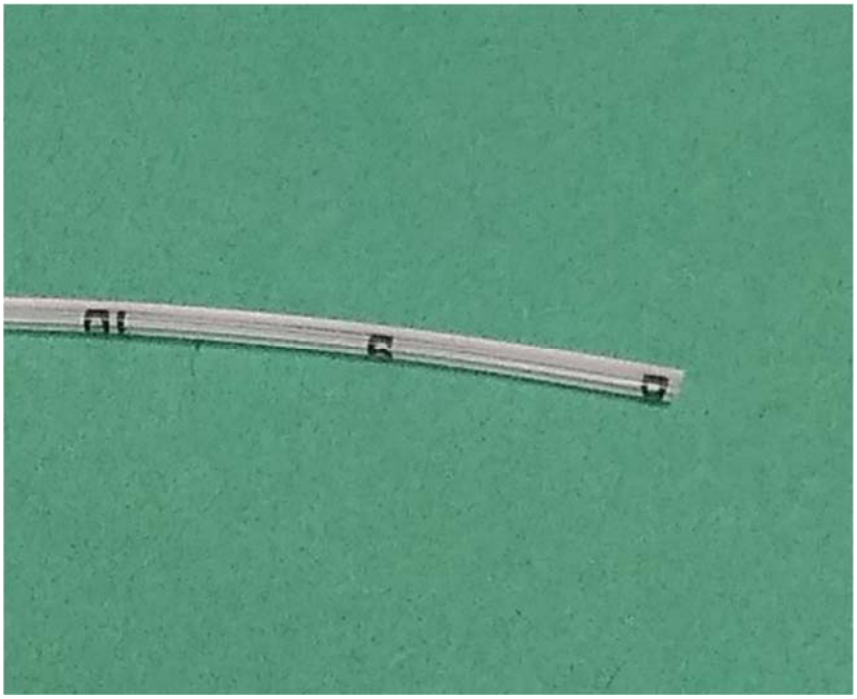
Device	Manufacturer	Problem
Device 1: Electrosurgical, Cutting Coagulation Accessories Brand: Barrx Model#: 64082-01 Lot #: F2514912X Cat #: 64082-01 **Device 2: Electrosurgical, Cutting Coagulation Accessories** Brand: Barrx Model#: 64082-01 Lot #: F2515693X Cat #: 64082-01	Covidien LP Covidien LP	Covidien Barrx 360 Express RFA Balloon Catheter would not inflate and reading faulty catheter, opened another catheter and it did the same. Code E73.
Leadless Pacemaker Brand: Micra™ Av Model#: MC1AVR1	Medtronic, Inc.	I implanted a leadless pacemaker one day. At the time, I was under the impression that the pacemaker was implanted in a standard location on the right ventricular septum. Pacemaker function was normal next day after implantation. After four and a half weeks I was informed by Nuclear Medicine MD that on Positron Emission Tomography–Computed Tomography (CT/ PET) report obtained for cancer follow-up, pacemaker appeared to be in the left ventricle. The patient was contacted and seen by me in the office next day. Pacemaker was no longer functional. I recommended admission for further work-up, which was done in a week time. After additional tests and multidisciplinary discussion, it was decided to manage conservatively with chronic anticoagulation, which the patient has had indications for prior to pacemaker implantation and dislodgement. I will follow-up with the patient as an outpatient with echocardiographic and radiographic interval testing.
System, Measurement, Blood-pressure, Non-invasive Brand: Omron 3Series Upper Arm Blood Pressure Monitor- Model#: BP7100 Cat #: BP7100 Other #: HEM-7121-Z2 (73796-71002)	Omron Healthcare, Inc.	Device is reading >10mmHg higher than actual blood pressure after checking against hospital monitor. Device taken out of service and new device given to patient.

Device	Manufacturer	Problem
System, Measurement, Blood-pressure, Non-invasive Brand: Good Neighbor Pharmacy Blood Pressure Monitor, Arm Auto Cuff Model#: 90-553	Veridian Healthcare LLC.	Device reading several mmHg higher than actual blood pressure.
System, Nuclear Magnetic Resonance Imaging Brand: Signa Artist Model#: SIGNA Artist Other #: Software DV28.1 R02 2002.a	General Electric Company	This is one of two recent events where RIGHT and LEFT (laterality) were reversed on the coronal MRI images performed on a GE. The neurosurgeon has been in contact with radiology/Imaging leadership about these laterality issues. The cause is evidently related to technologist's error in inputting data after a recent GE software upgrade, but the software allows this to happen with PATIENT ORIENTATION changes unknown to the technologist performing the study. This type of error obviously has significant risk of wrong sided surgery if the error is not caught. Even when the error is caught, there remains significant exposure for a patient error later because these images are included in the patient's electronic medical record and could be viewed by a surgeon in the future, who is unaware that this laterality issue impacted the views that she/he is seeing. Please see pictures below: Older GE 23.0 platform: 

Device	Manufacturer	Problem
System, Nuclear Magnetic Resonance Imaging Brand: Signa Artist Model#: SIGNA Artist Other #: Software DV28.1 R02 2002.a	General Electric Company	Newer 26 & 28.0 platform: 
Temporary Non-roller Type Left Heart Support Blood Pump Brand: Impella Model#: Impella 5.5 with SmartAssist Set, US Lot #: 21462313-34-36 Cat #: 0550-0008	Abiomed, Inc.	A potential heart transplant patient being maintained with the Impella 5.5 Left Ventricular Assist Device (LVAD). RN had found a clear collection of fluid on patient abdomen from an unknown source. Further investigation lead to the discovery that the fluid had been leaking from the Impella specifically from the "Red Impella Plug" component proximal to the patient. The fluid on abdomen likely was the Heparinized Impella purge solution. The Cardiothoracic Intensive Care Unit (CTICU) team, Ventricular Assist Device (VAD) team, and Impella Device representative had all been contacted regarding this finding. The Impella Device representative, explained how the leaking fluid would eventually lead to the total failure of the pump. This finding significantly alters the plan for patient care as the focus shifted to evaluating patient tolerance of imminent device removal. Furthermore, patient will likely go to OR and other therapies will have to be considered. The most concerning detail of this event is how there had been tegaderm (Transparent Film Dressing) wrapped around the "Red Impella Plug" component which was partially containing the leak from the device. It is not known who had initially placed the tegaderm but the leak from the device has likely been occurring for an indiscriminate amount of time.

Device	Manufacturer	Problem
Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms) Brand: Iacs W/ c500 Model#: MS25510 Cat #: MK31500 -13	Draeger Medical Systems, Inc.	An Infinity V500 Ventilation Unit was connected to the Infinity C500 Medical Cockpit when the hard drive on the Infinity C500 Medical Cockpit failed. The ventilator was in use on a critical care patient. Nursing staff were outside the patient's room when they heard an alarm from the ventilator they never heard before. When they entered the room, they discovered an error message on the screen. The staff could not tell if the ventilator was still functioning optimally for the patient, so they disconnected and started bagging. Respiratory was called and new ventilator was connected to the patient. Our clinical engineering team evaluated each component and found no errors with the Infinity V500 Ventilation Unit or the PS500 Power Supply Com Hub. The only error was a failed hard drive in the Infinity C500 Medical Cockpit. The error message was, "Reboot and select a proper boot device or insert boot media in selected boot device."
Accessories, Cleaning, For Endoscope Brand: Acecide-c High-level Disinfectant And Sterilant Lot #: 18176ACE,18299ACE, 20252ACE	Olympus Corporation of the Americas	On numerous occasions, we have received cases of Acecide-C a High-Level Disinfectant and Sterilant, from Olympus America that have been noted to be leaking. Acecide-C is used for high-level disinfection and/or sterilization of medical instruments. This chemical has a strong odor which may cause irritation the eyes, respiratory tract, and skin. On many occasions, there is no notable damage to the exterior packaging. The bottles arrive in a single large case with (6) individual boxes inside. Each of the small boxes contain a zip lock style bag with two bottles of Acecide-C; solutions 1 and 2. Upon closer inspection of the leaky bottles, some of the bottles appear to be firm and bulging.
Catheter, Biliary, Diagnostic Brand: Gore Viabil Biliary Endoprosthesis Model#: VH1006200 Cat #: VH1006200	W. L. Gore Associates, LLC.	The Gastrointestinal Laboratory (GI Lab) materials management employee placed an order for a Conmed / W. L. Gore Viabil stent VN1006200 that is a temporary stent. The stent that was received was VH1006200 that is a permanent stent. It was not noticed until stent deployment that a variance in the typical stent features was present. It was not realized until the materials management employee received a phone call from billing asking if the part numbers for the Conmed stents had been updated that we had erroneously received the wrong stent. When the materials management employee looked closely at the stent box, he noticed that the part number for the stent he ordered to refill the inventory varied by one letter from the part number on the stent box. The materials management employee began an investigation on the order he placed and reached out to a Conmed representative who stated that the stent we received was not the stent that was ordered AND that the received stent happened to be an irretrievable stent that is meant to remain in a patient. Our doctor was notified, and he talked to a doctor at Conmed that told him it would be fine to treat the patient the same and remove the stent at the scheduled date in the future with no impact to the patient. We suggest for a labeling change on the box that shows the product being PERMANENT or TEMPORARY. Right now, the only thing that lets you know the difference is in the REF# (Catalog Number) where one has a “H” in it and the other one has a “N” in it.

Device	Manufacturer	Problem
System, Dialysate Delivery, Central Multiple Patient Brand: Centrisol Part AAcid Concentrate Lot #: 489224	Medivators, Inc.	Solution used for dialysis tested highly positive for chloramine. 150 cases impacted, none reached patient directly, but 25 patient's dialysis impacted by delay. This contamination if infused would cause hemolytic anemia with high morbidity and mortality. Dialysate solution positive for chlorine, several containers in the lot number tested positive so the entire lot number sequestered. When the machines were checked for bleach residue should have tested negative but some tested positive.
Stapler, Surgical Brand: Justright 5mm Stapler Model#: JR-ST25-2.0 Cat #: JR-ST25-2.0	JustRight Surgical, LLC	The JustRight 5mm stapler was fired across the bronchus. All steps of the firing processes were followed, but after the JustRight 5mm stapler was fired it was noted that only a few staples were secured, there were some free floating staples, and the device did not appear to have fired correctly. A reload was then placed on the stapler handle and the stapler was fired again. A few staples held at the opposite end, there were still free floating staples, and the device did not appear to have fired correctly again. The stapler cut through bronchus and there was a [air] leak. It was decided to continue with procedure and suture the bronchus after the upper left lobe of lung was removed.
Device 1: Surgeons Gloves Brand: Protexis Model#: 2D72PT75X Lot #: TS20100210 Cat #: 2D72PT75X **Device 2: Surgeons Gloves** Brand: Protexis Model#: 2D72PT65X Lot #: TS20100108 Cat #: 2D72PT65X	Cardinal Health 200, LLC Cardinal Health 200, LLC	Two events have been reported with same issue. First event. Registered nurse (RN) put on a pair of the orange PROTEXIS PI Sterile Polyisoprene Powder-Free Surgical Gloves (Size 7 1/2), and the cuff of the glove ripped halfway off on the right side. There was not very much pressure used in putting the glove on, much less than normal as this has happened with this type of glove in the past. (Glove REF: 2D72PT75X Lot: TS20100210, Mfg: 2020-10-17 Use by Date: 2023-09-30) Second event. When RN opened a pair of Orange Protexis PI Sterile Polyisoprene Powder-Free Surgical Gloves (Size 6 1/2, REF# 2D72PT65X, Lot# TS20100108, Use by Date 2023-09-30), they ripped apart as RN was putting them on . We have had several of these [PROTEXIS PI Surgical Gloves] doing this.

Device	Manufacturer	Problem
Catheter, Umbilical Artery Brand: Argyle Model#: 8888160531 Lot #: 2011900052 Cat #: 8888160531	Cardinal Health, Inc.	While suturing a Umbilical Catheter Argyle™ Vessel 3.5 Fr. 15 Inch Dual Lumen, it inadvertently broke at 8 cm and was unable to be retrieved. A chest x-ray was immediately taken and the line fragment was in the inferior vena cava. The newborn patient was transferred via LifeFlight to a children's specialty hospital. The newborn patient was taken to Interventional Radiology where they were able to retrieve the fragment from the left pulmonary artery. Please see pictures below:  

Device	Manufacturer	Problem
Stand, Infusion Brand: Rotating IV Pole Lot #: LAU14256889 Cat #: 6600-0851-800 	Ohmeda Medical	Nurse reported she was putting an oxygen flow monitor on the wall behind an infant warmer in the well-baby nursery. She moved the Ohmeda Medical rotating IV pole out of the way (which is attached to the infant warmer) and it all snapped off and fell. Nurse checked the screws that secure the rotating IV pole to the warmer and the metal holding it together had broken. The weight limit for the pole is 9 kg. The two infusion devices on the rotating IV pole had a combined weight of 4.21 kg which is less than the weight limit. If there had been a baby in that warmer it could have severely injured the baby. Clinical Engineering completed an investigation of this event and found that the internal sleeve in which the bolt that secures clamping part to the pole was sheared off.

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: 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 Ill 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

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