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/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 February 25, 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: Vyaire Medical bellavista 1000 and 1000e Series Ventilators

February 17, 2022

Vyaire Medical is recalling the bellavista 1000 and 1000e Series Ventilators, with specific software versions and configurations, after reports of ventilators failing to ventilate and generating a technical failure alarm. Issues with the software version 6.0.1600.0 or higher installed can have a conflict in memory between software tasks when the data communication port is set to "HL7," which produces the technical failure alarm 305.

The use of affected ventilators may cause the ventilator to malfunction or stop, which may cause serious adverse events. There have been 18 complaints, seven injuries, and no reports of death.

Class I Recall: Arrow International, LLC (Subsidiary of Teleflex Inc.) Recalls the Arrow-Trerotola Percutaneous Thrombolytic Device Due to Risk of Tip Damage During Use

February 23, 2022

Arrow-International, LLC (a subsidiary of Teleflex Inc.) is recalling the Arrow-Trerotola Percutaneous Thrombolytic Device due to risk of tip damage during use, which may result in tip detachment from the basket. This could potentially lead to vascular injuries, including obstruction (blockage) of the vessel, additional thrombosis (blood clot), ischemia (inadequate blood supply), infarction (heart attack), infection or death.

As of December 2021, a total of 35 complaints reporting tip separation have been received. Of these 35 complaints, 14 reported injuries, and nine complaints involved use of a stent (support structure) to manage the separated tip. No deaths have been reported at this time.

Class I Recall: E25Bio Recalls COVID-19 Direct Antigen Rapid Tests That Are Not Authorized, Cleared, or Approved by the FDA and May Give False Results

February 18, 2022

E25Bio is recalling its COVID-19 Direct Antigen Response Tests (DART) for several reasons, including that these tests were marketed and distributed to U.S. customers without authorization, clearance, or approval from the FDA. Labeling distributed with some of the tests also includes inaccurate claims and instructions, including a statement that misrepresents the test as FDA-authorized. As this test was not authorized, cleared, or approved by the FDA, there is not sufficient data demonstrating that the test's performance is accurate. On February 4, 2022, the FDA issued a Safety Communication warning users to stop using these tests.

There have been no reports of injuries, adverse health consequences or death associated with the use of this product.

Potential Risk of Strangulation in Children who Use Enteral Feeding Delivery Sets – FDA Safety Communication

The FDA is warning health care providers, parents and caregivers of pediatric patients who receive enteral feeding that there is a risk of strangulation from the use of enteral feeding delivery sets. The feeding set tubing can become wrapped around a child's neck and cause strangulation or death. The FDA has received reports of two toddlers who died after being strangled by the tubing.

Recommendations for Parents and Caregivers of Children who Use Enteral Feeding Delivery Sets

- Be aware that the feeding set tubing can get wrapped around a child's neck, which can lead to strangulation or death.
- To the extent possible, avoid leaving the feeding set tubing where infants or children can become entangled.
- Discuss with your child's health care provider:
  - If your child has been tangled in their tubing before.
  - Steps you can take to help ensure that tubing does not get wrapped around your child's neck, such as keeping the tubing away from the child as much as possible.
  - Any other concerns you may have about the risk of strangulation from feeding set tubing.
- If your child is injured by feeding set tubing, please report the event to the FDA. Your report, along with information from other sources, can help improve patient safety.

Recommendations for Health Care Providers

- Review this topic and the information noted above with your colleagues, care teams, and caregivers of pediatric patients who use enteral feeding delivery sets, to ensure they are aware of the potential risk of strangulation with the associated tubing and are taking appropriate measures to keep the tubing away from the child as much as possible.
- When caring for pediatric patients who receive enteral feeding and as part of an individual risk assessment, be aware of the risk of strangulation from the feeding set tubing and follow protocols to monitor medical line safety.
- If a patient experiences an adverse event related to enteral feeding set tubing, you are encouraged to report the event to the FDA. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

To read the full Safety Communication, please visit FDA's website.

Baxter, Inc. Issues Urgent Safety Communication to Reinforce Important Safety Information Regarding Upstream Occlusion Alarms for all Spectrum V8 and Spectrum IQ Infusion Pumps – Safety Communication

Baxter International Inc. has issued an Urgent Safety Communication to reinforce important safety information regarding upstream occlusion alarms for all Spectrum V8 and Spectrum IQ infusion pumps. Incorrect administration set setup and/or incomplete resolution of upstream occlusion alarms may result in reduced delivery or non-delivery of medication, in some cases without alerting the user via pump alarm. Baxter previously communicated this information to customers via an Urgent Safety Communication notification on December 29, 2021.

Customers notified Baxter that the pump was not delivering medication at the programmed rate displayed on the screen, and in some cases was not alarming for upstream occlusions. After an upstream occlusion alarm, it is imperative to fully resolve any upstream occlusion before restarting the pump. Failure to do so may cause the pump not to re-alarm as expected, which can lead to interruption in therapy and/or under-infusion. The potential harm to the patient depends on several factors such as length of therapy delay, medication being infused, volume and rate of infusion, and the patient's underlying status and comorbidities. To date, Baxter has received 51 reports of serious injury and three reports of patient death over five years that may have resulted from incorrect administration set setup and/or incomplete resolution of upstream occlusion alarms.

Customers may continue to use Spectrum V8 and Spectrum IQ infusion pumps by following on-screen instructions and referencing the Operator's Manual for infusion setup instructions in the Preparing the Pump and IV Sets and Programming the Pump sections and upstream occlusion alarm troubleshooting in the Alarms section. To help prevent upstream occlusions, it is important to completely spike the IV container, remove the blue slide clamp completely from the keyhole, disengage the blue slide clamp completely from the IV tubing, check that the IV tubing is clear of any kinks or collapsed sections, ensure the roller clamp (if present) is released prior to infusion start, and ensure that rigid and semirigid containers are properly vented. After starting an infusion, it is important to verify that drips are flowing in the drip chamber, which may take several minutes when infusing at flow rates below 5 mL/hr. If an upstream occlusion remains after the RUN/STOP key is pressed, the pump may appear to be infusing normally but may be infusing below the programmed rate or not infusing at all. If a clinician suspects that they resumed an infusion without clearing an occlusion, they should stop the infusion by pressing the RUN/STOP key, clear the occlusion and restart the infusion.

Product Code	Product Description	Unique Device Identifier	Serial Number	Manufacturing Date	Release Date	Released Quantity (Units)
35700BAX2	SIGMA Spectrum Infusion System (V8 Platform)	GTIN 00085412498683	All	July 1, 2014 - June 8, 2021	February 5, 2015 - Present	140,674
3570009	Spectrum IQ Infusion System with Dose IQ Safety Software	00085412610900	All	June 29, 2017 - Present	December 6, 2017 - Present	175,028

To read the full Safety Communication, please visit FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during February 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
Gas-machine, Anesthesia Brand: Avance Model#: CS2 	Datex-Ohmeda, Inc.	Patient is toddler-aged female with multiple congenital conditions, including OEIS complex (omphalocele-exstrophy-imperforate anus-spinal defects), who presented for planned cloacal exstrophy closure. Intraoperatively, patient became hemodynamically unstable, and interventions performed to stabilize patient. During troubleshooting for cause of hemodynamic changes, it was discovered that the ventilator was alarming for high PEEP (positive end-expiratory pressure, 8-12 but was set to deliver at 5) and, after troubleshooting the anesthesia ventilator scavenge system, the scavenger bag was noted to be full/taut and the valve in a closed position. After fully opening the scavenger valve, PEEP decreased, and blood pressure improved. Approximately one hour later, patient sustained hyperkalemic cardiac arrest and was resuscitated. Period of increased intrathoracic pressure secondary to elevated PEEP suspected to be one of causal factors leading to metabolic derangements/hyperkalemia for this patient. The hospital recognized opportunities for design modifications to improve the safety of scavenging system on the anesthesia machine, as follows: 1. Scavenger valve is easy to manipulate and, if inadvertently bumped, can easily be switched into the closed position without intending to do so (there is no built-in mechanism to prevent accidental valve closure); 2. There is no alert to user if scavenger valve is closed/not scavenging effectively and building too much pressure (when there is a high PEEP alarm, the user must know to check the scavenger system, but high PEEP is a non-specific indicator and there are several other factors that could cause it, so a scavenger-specific alarm/alert would help the user narrow down the cause when troubleshooting high PEEP);

Device	Manufacturer	Problem
		3. The manufacturer recommends the user look at the fullness of the bag to determine whether the scavenging system is working but it is difficult for the user to see the scavenger bag when the anesthesia machine is in use because it is in a hard-to-reach place (i.e., underside/back of machine); 4. There is no way for the user to place the valve in a fixed, open position if desired (i.e., the manufacturer's adjustable valve design cannot be modified).
Catheter, Peritoneal Dialysis, Single Use Brand: Dialynate Set Cat #: 4000537 	Utah Medical Products, Inc.	Reporting as 4th occurrence in the past 6 months involving the Dialynate System. At approximately 0130, RN began to question the patient's ability to ultrafiltrate (UF) consistently throughout the shift with peritoneal dialysis (PD) flushes when patient wasn't undergoing any PD dwells. On average, patient had been UF'ing 5-15 mL every hour. Given previous instances of equipment malfunction with manual PD use recently, RN decided to perform a flush of dialysate from the Buretrol chamber to the collection bag, bypassing the patient. Three separate flushes were trialed (50mL, 70mL, and 100mL, respectively) directly into the collection bag, and all three outputs resulted in 10 mL above the instilled amount (60mL, 80mL, and 110mL, respectively). This discrepancy was clearly indicative of an equipment issue, likely having to do with inaccurate stamping of the measurement grid on the collection bag chamber. As a result, patient's intake and output documentation was inaccurately being reflected on the chart. Clinically, this meant that the patient was more fluid-positive that what our documentation up to this point had showed. This is a significant patient safety issue, particularly with a <10 kg dialysis patient whose daily intake and output continuously dictates daily therapies and clinical interventions.
Dialyzer, High Permeability With Or Without Sealed Dialysate System Brand: Prismaflex HF20 Model#: Prismaflex HF20 Lot #: 21a1203z	Baxter Healthcare	PrismaFlex HF-20 filter blood primed for CRRT. Approximately 30 minutes following initiation, effluent in bag was blood tinged. Nephrology & PICU team paged, all to bedside to monitor. Patient cell count sent to lab STAT: resulted in red blood cell (RBC) <2000. Circuit taken down. The patient was put onto a new CRRT circuit at 1056, and brand-new filter used. Team noticed pink tinged effluent in bag and pod around 1115, for a second time. CRRT Dialysis drew a cell count and sent it to lab STAT. No blood leak alarm on CRRT pump. Lab resulted RBC <2000. CRRT stopped, and Nephrology & PICU team paged back to bedside. Patient taken off CRRT at 1226. The filters with this lot number have been pulled from service, and the Prismaflex machine placed out of service. The concern with blood in the effluent line means there is a break in the filter, and the filter is compromised, allowing dialysate to get to the patient's blood freely. The patient's electrolytes and blood cultures were sent, and patient was on prophylactic antibiotics. The patient's labs were within this specific patient's norm, and the patient is currently not showing any signs of an infection.

Device	Manufacturer	Problem
Port Catheter, Implanted, Subcutaneous, Intravascular Brand: Vortex Model#: MP-P5SAT Lot #: 5128249 Cat #: MP-P5SAT 	Navilyst Medical, Inc.	When surgeon went to remove the Vortex MP titanium low-profile port system, the catheter portion broke apart. The breaking of the silicone catheter occurred as the surgeon attempted to pull it out. The surgeon's operative note describes the incident: "the three anchoring Prolene sutures were divided and removed. The port was taken out of its subcutaneous pocket. The catheter had rough surface. With traction the catheter came out of the tunnel but it fractured in the subclavicular area and only the portion from the tunnel came out. We had a retained intravascular catheter fragment. There was no bleeding from the site. C-arm was used, and the catheter was found to be fractured at the mid-clavicle level—too deep to explore from a subclavian approach. Catheter seemed to be in a stable position." The surgical wound was then closed. Surgeon then discussed the case with Interventional Radiologist (IR). IR agreed to take the child for endovascular retrieval of the fragment. Using right femoral artery approach, the foreign body was retrieved using a snare. Patient recovered and went home later that evening.
Pump, Infusion Brand: Plum 360 Model#: Plum 360	ICU Medical	While in use on a patient, the pump begins alarming "replace the battery" and continues to alarm until the pump is removed from the patient. Over 110 pumps have had this error and some of them multiple times even after the battery has been replaced. It does not matter what type of battery is in the device, all of the batteries from different manufactures have produced the same error.
Midline Catheter Brand: Midline Catheter Kit Model#: S4153108BP Lot#: REF-W1458 Cat#: S4153108BP	Bard Access Systems, Inc.	When the PICC line was being removed the guide wire became stuck, and when it was removed the wire was frayed and the Jtip had been lost. This fraying occurred distally along the guidewire very high up the humerus and the care provider did not feel that excessive force was used in advancing or retracting the guidewire. Radiology confirmed the retained guidewire fragment and determined that due to its small size, it was not clinically significant and risks inherent to attempted removal would outweigh any benefit.
System, Balloon, Intra-Aortic And Control Brand: Cardiosave Hybrid	Datascope, Corp.	The RN was just outside the door and heard an unusual sound. She entered the room and saw the screen had gone black, pump was off and a large puddle was on the floor. Anesthesia was close by to support the patient with medication until a replacement machine could be set up. About 450 of the 500 mL bag spilled onto the back of the machine where the ECG and pressure cables connect and then pooled on the floor. We are guessing that a connection in the transducer tubing came loose and since the heparin was inside a pressure bag at 300mmHg it likely suddenly gushed onto the back of the machine. Machine was brought to Clinical Engineering for evaluation. Manufacturer field service tech opened the machine and found traces of fluid in several spots inside the machine. It appears fluid reached the power supply board, causing the machine to shut down. The ingress protection rating of this machine is specified as IPX0 (No protection against ingress of water). Power supply board was replaced and unit returned to service.

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: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/human-factors-and-medical-devices
This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Medical Device Connection 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: https://www.fda.gov/medical-devices/medical-device-safety
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: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters 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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