MedSun
Medical Product Safety Network

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The U.S. Food and Drug Administration's (FDA) MedSun program provides this monthly newsletter to inform patients and patient advocates about FDA information on medical device related topics. The MedSun program, launched in 2002 by the FDA's Center for Devices and Radiological Health (CDRH), uses a secure online reporting system to receive medical device adverse event reports from a network of over 300 clinical facilities across the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products and play a critical role in the FDA's postmarket surveillance efforts.

Learn More About MedSun

Safety Communications

- *Update:* FDA Encourages the Public to Follow Established Choking Rescue Protocols **11/13/25**

Highlighted Recalls

- Becton Dickinson Updates Use Instructions for BD Alaris Pump Issue **11/28/25**
- Baxter Permanently Removes Life2000 Ventilation System **11/26/25**
- BALT USA Removes MEGA Ballast Distal Access Platform **11/26/25**
- Max Mobility/Permobil Removes All SpeedControl Dials Used with SmartDrive MX2+ Power Assist Devices **11/25/25**
- Large Volume Pump Primary Administration Set Reverse Flow Issue from Fresenius Kabi **11/24/25**
- Correction Alert: Medline Industries Updates Use Instructions for Medline Kits Containing Flexicare BritePro Solo Fiber Optic Laryngoscope Handles **11/21/25**
- NOxBOX Ltd. Issues Correction for NOxBOXi Nitric Oxide Delivery System Due to Risk for Nitric Oxide Dosing Fluctuations **11/20/25**
- NOxBOX Ltd. Issues Correction for NOxBOXi Nitric Oxide Delivery System Due to Rapid Command Input Issue **11/20/25**
- Medline Industries Removes Certain Sterile Medline Convenience Kits **11/20/25**
- Siemens Healthineers Issues Correction for 3 Tesla MRI Systems **11/19/25**
- Update to Use Instructions for B Braun Hemodialysis Blood Tubing Set **11/19/25**
- Quick Link to Medical Device Recalls

Announcements

FDA Announces Circulatory System Devices Panel Advisory Committee Meeting

The FDA announced an upcoming virtual public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee (the Committee). On December 3, 2025, the Committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) sponsored by V-Wave, Inc. for the V-Wave Ventura Interatrial Shunt System, which is a first-of-a-kind device permanent implant designed to shunt blood from the left to the right atrium to improve symptoms in patients with advanced chronic heart failure.

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UPDATED: General Hospital and Personal Use Devices Panel Advisory Committee Meeting

The FDA announced an upcoming virtual public advisory committee meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee (the Committee). On December 10, 2025, the Advisory Committee will meet virtually to deliberate and make recommendations on issues related to an emerging technology in the context of medical devices and germicidal ultraviolet (UV) light as a mode of disinfection. The FDA is seeking to obtain feedback to improve the total product life cycle (TPLC) evaluation of UV disinfection devices. In addition, the Committee will meet to discuss and provide advice to the FDA on devices used in pandemic preparedness and response. This meeting was previously announced in the Federal Register and scheduled for October 8, 2025.

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Highlighted Reports

The reports that follow represent a cross section of device related events sent by MedSun Representatives during the prior month. The reports are presented as submitted by MedSun Representatives and in some instances, have been summarized and edited for clarity.

Search the MedSun Report Database

Type: Stimulator, autonomic nerve, implanted for epilepsy
Manufacturer: Livanova USA, Inc. **| Brand:** VNS Therapy AspireSR Generator
UDI-DI: 05425025750061 **| Model:**106 **| Lot:** 157067, 156654
Event: Our patient was scheduled for a generator exchange. The first generator was opened and presented to the field. Upon connection, an error was noted by the manufacturer's representative, and the generator was removed. A second generator was then opened, but the same error occurred once it was attached. The physician, nurse, and representative performed troubleshooting using manufacturer, vendor, and customer support instructions for both generators. A new lead was subsequently implanted with assistance from another physician; however, both AspireSR generators continued to display the same error when connected to the new lead. After further consultation with the onsite team, a different model generator was opened. This generator was successfully connected and implanted. We noted the patient's previous generator functioned without error when tested.

Type: Nebulizer (direct patient interface)
Manufacturer: Aerogen Limited **| Brand:** Aerogen Solo Continuous Nebulization Tube Set
UDI-DI: 05391517930405 **| Model:** AG-AS3085 **| Lot:** HM21502
Event: Aerogen syringe is a proprietary item that allows for delivery of continuous aerosolized medications. When operating, there are two events occurring. First, when delivering medications, medication is seeping above the syringe plunger. Second, while priming the syringe and tubing, after the tubing has been primed, the syringe continues to siphon all the medication (the syringe stopper moves independently). The manufacturer stated this is a known issue. Another customer in the Midwest had a similar issue and were able to move forward without further issues following a couple of tweaks to their practice. Their practice included pulling the plunger completely out of the back of the syringe to fill the syringe and refrigeration of the syringes after being filled. Once they started filling the syringes from the tip and ceased refrigeration, they no longer had any issues. None of the described practices are part of this process. Devices are used per IFU (Instructions For Use).

Type: Drills, burrs, trephines accessories (compound, powered)
Manufacturer: Micromar Indústria e Comércio LTDA **| Brand:** Easydrill Cranial Perforator
UDI-DI: 07898959543593 **| Model:** DM0010FAA **| Lot:** 1488/25 **| Cat:** DM0010FAA
Event: The physician was using the cranial perforator. During use, the device did not stop. This is a huge issue as it could have caused harm to the patient. He had to drill two holes in the skull and both times it did not stop. If he did not notice that it was not stopping, then he could have drilled a hole into the patient's dura causing more harm and injury to the patient. This is an ongoing issue with these drill perforators. This physician is not the only surgeon that has had this issue with the device.

Type: Set, tubing, blood, with and without anti-regurgitation valve
Manufacturer: B. Braun Medical Inc. **| Brand:** Hemodialysis Bloodlines
UDI-DI: 04046955674992 **| Model:** SL-2010M2096A **| Lot:** 0062000055 **| Cat:** SL-2010M2096A
Event: The Streamline Airless System sets (Hemodialysis Bloodlines) have bubbles accumulating in the arterial line, leading to even more bubbles and clotted blood in the dialyzers of several patients. This is the third lot number causing these issues. To date, no patient has been harmed by this issue, but it does harbor a large potential to put air into the patient. I removed this lot number from our floor and the supply room. This must stop; this is the third lot number to have the same problem.

These reports 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.
The 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.

Type: Catheter, intravascular, therapeutic, long-term greater than 30 days
Manufacturer: Argon Medical Devices, INC. **| Brand:** L-Cath S/L PICC S/L
UDI-DI: 00886333209934 **| Model:** 26GA (1.9F) x 30cm
Lot: 11603831, 11613894, 11600216 **| Cat:** 384539
Event: We are experiencing a trend involving several devices leaking or breaking at the hub. There have been ten recent events describing leaks, including devices that had been placed within a few days:

- The midline L-Cath was leaking around purple hub within hours of placement. It was removed.
- A PICC line was placed and the following day, it was leaking around the purple hub and repaired.
- A PICC line was leaking between the catheter and the purple hub.
- The PICC line was leaking, repaired, removed, and replaced.

Type: Pack, hot or cold, disposable
Manufacturer: Coopersurgical, Inc. | **Brand:** Transwarmer Infant Transport Mattress
UDI-DI: 00888937025767 **| Model:** 20421 **| Cat:** 20421
Event: The Transwarmer (an infant transport mattress with WarmGel) failed to adequately warm up when activated. The warmer in L&D (labor and delivery) was prepared for acceptance of 23+6-weeker born emergently. Upon admission to the NICU (neonatal intensive care unit), the baby's initial temperature was 36°C. It was determined that the Transwarmer had not warmed when activated. During the admission process, no less than four warmers were cracked and activated but did not warm. We need to ensure that these devices are correctly activated and warm to prevent a baby from getting cold.

Links to FDA CDRH Databases and Other Information Sources

- Database of Registered Medical Devices and Manufacturers
- Access Global Unique Device Identification Database (GUDID)
- Medical Device Safety
- MedSun: Medical Product Safety Network

- Medical Device Recalls

Contact Us

For questions about this newsletter or to request a copy of a previous edition, please email us.

Email: MedSun@fda.hhs.gov
Telephone: 800-859-9821

U.S. Food and Drug Administration
10903 New Hampshire Ave., Silver Spring, MD 20993