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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 information from FDA 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](#)

Highlighted Recalls

- [Dexcom Uncovers Theft of Scrapped Product, Notifies Potentially Impacted Users](#) 5/29/26
- [KayserBetten Issues Correction for KayserBett IDA Beds](#) 5/29/26
- [Erbe USA Removes Flexible Cryoprobes](#) 5/28/26
- [Philips Issues Correction for Trilogy Evo Platform Ventilators](#) 5/28/26
- [IV Tubing Set Issue from ICU Medical](#) 5/27/26
- [Heart Pump Issue from Abiomed](#) 5/27/26
- [Insulet Initiates Voluntary Medical Device Correction for Certain Omnipod Pods](#) 5/26/26
- [Medline Removes Namic Star Off Handle Manifolds](#) 5/26/26
- [Arrow International Removes Dialysis Catheter Kits Containing Merit Medical Splittable Sheath Introducers](#) 5/26/26
- [Heart Pump Controller Issue from Abiomed](#) 5/21/26
- [React Health Removes VOCSN V+Pro Ventilators](#) 5/21/26
- [Omniceil Removes Syringe Labels Used with the i.v.STATION Automated Compounding System](#) 5/21/26
- [Bolton Medical Removes Relay Pro System](#) 5/20/26
- Updated: [Trividia Health Issues Correction for TRUE METRIX Blood Glucose Monitoring Systems](#) 5/19/26
- [Anesthesia Machine Issue from Draeger](#) 5/15/26
- [AVID Medical Removes Convenience Kits Containing Namic RA Syringes](#) 5/12/26
- [Aligned Medical Solutions Removes Convenience Kits Containing Namic RA Syringes](#) 5/11/26
- [Medical Action Industries Removes Convenience Kits Containing Namic RA Syringes](#) 5/7/26
- [American Contract Systems Removes Convenience Kits Containing Namic RA Syringes](#) 5/7/26
- [Boston Scientific Issues Correction for ACCOLADE Pacemakers and CRT-Ps](#) 5/7/26
- [Intuitive Surgical Removes 8mm SureForm 30 Gray Reloads](#) 5/5/26
- [Cook Medical Removes Various Centimeter Sizing Catheters](#) 5/5/26
- [Quick Link to Medical Device Recalls and Early Alerts](#)

Letters to Health Care Providers

- [Disruptions in Availability of Neurosurgical Patties, Sponges, and Strips](#) 5/6/26

Announcements

Proposal Submission Period for the 2026 Experiential Learning Program (ELP) is Now Open

The Center for Devices and Radiological Health's (CDRH) Experiential Learning Program (ELP) is an innovative learning opportunity for new and experienced CDRH staff. Proposals are being accepted through June 18, 2026. Through ELP, CDRH staff participate in training visits to help close knowledge gaps between emerging and innovative technology and the pre-market review of the resulting medical device. These visits are not intended for the FDA to inspect, assess, judge, or perform a regulatory function (for example, compliance inspections).

CDRH encourages participation from:

- Companies
- Academia
- Clinical facilities
- Medical device incubators and accelerators
- Health insurers
- Health technology assessment groups

[Read More About the ELP](#)

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](#)

Device 1: Type: Catheter, percutaneous, cardiac ablation, for treatment of atrial flutter

Manufacturer: Medtronic | **Brand:** Sphere-9 Catheter | **Model:** AFR-00001

Device 2: Type: Implantable cardioverter defibrillator (non-CRT)

Manufacturer: Biotronik | **Brand:** Rivacor 7VR-T

Event: During radiofrequency ablation, the electrical output of the Sphere-9 ablation catheter interacted with a previously implanted Biotronik implantable cardioverter-defibrillator device. The energy caused the patient to go into ventricular fibrillation twice. The patient was successfully shocked out of this rhythm.

Type: Set, administration, intravascular

Manufacturer: ICU Medical | **Brands:** Lifeshield, Plum

Model/REF: 1266228, 1423028, 1422928, 1468728

Event: *This facility submitted multiple reports for these devices.*

Event 1: In the Emergency Department, black spots and debris were noted in the drip chamber of the IV tubing by the RN who immediately removed and sequestered it. The contaminant is suspected to have originated in the IV tubing. All IV tubing with that lot was pulled from our stock and the product was returned to ICU Medical. Since that time, we have identified multiple tubing lots that are affected by the problem. We continue to inspect and monitor additional supply issues.



Event 2: A frontline team member discovered mobile and immobile debris floating in the drip chamber of the IV tubing after spiking a normal saline bag. The IV bag and tubing were sequestered, our supply chain was notified, and they pulled the lot. Infection prevention was notified and during their investigation, they discovered another single report of a similar event where the tubing was discarded. After this second discovery, out of an abundance of caution, the lot was removed from supply across our hospital system. We then expanded the evaluation to include inspection of all ICU Medical product and over a few hours discovered 20 affected lots. We reported the event to the CDC (Center for Disease Control). The local CDC has requested frozen samples for transmission to their offices. In most cases, there seems to be a single brown or black spot within the same area in the drip chamber. All these affected lots were removed from supply, and we are working with ICU Medical to get additional supply to allow for smooth internal operations. Our laboratory team has started to analyze the product. They received three samples of different lots and have concluded their visual inspection. In each case the drip chamber was opened, and attempts were made to retrieve the sample. It was determined that the sample is encased in the plastic wall of the drip chamber. Aggressive attempts were made to retrieve the sample from the inside surface of the drip chamber with a scalpel. The item was magnified and visually inspected. So far, they have found that one speck is a black spot, and the other is a brown spot with spikes all around. In each case, the specimen seems to be embedded in the plastic of the drip chamber in almost identical locations. The team tried to remove the speck and was unable to do so. Even with aggressive scraping from a scalpel, the speck could not be removed from the plastic inner surface of the drip chamber. Additional testing is in progress. Our frontline care team remains vigilant and will continue visually inspecting these devices for any additional concerns.

Type: Set, administration, intravascular

Manufacturer: ICU Medical | **Brand:** Lifeshield | **Model/Cat:** 1422928

Event: Our facility was notified by the Department of Public Health of contaminated IV tubing sets from the manufacturer. Per the alert received, "The Department of Public Health has been made aware of reports in other states of contaminated IV tubing sets from a single manufacturer with national distribution and is alerting health care facilities to inspect their supplies. The contamination is reported as small black dots on the internal walls of the drip chambers and has been reported in numerous lots across three product types from ICU Medical. In some products, particulate matter appears in the lumen or chamber of the tubing. In most, particulate matter appears embedded in the plastic material but not within the lumen or chamber. Preliminary reports of similar findings in a second state suggest this may be a widespread issue with one or more nationally distributed product lines. The presence of foreign material in infusion materials may pose a health risk to patients. It is unknown whether the particulates contain biological material. No information is available at this time about the dates when these lots were shipped or used. No adverse events have been linked to the contaminated products. The manufacturer, the U.S. Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) have been notified and are investigating." At our facility, a primary tubing set was identified with the black specks. Other secondary tubing included in the identified lot numbers are not known to be impacted. At our facility, instructions are provided for continued enhanced visual inspection by Materials Management and the frontline team of all the IV tubing sets prior to use. A concise one-pager is being finalized for frontline staff at potentially impacted sites. A web version is being created to support version control. Inbound inventory is being

inspected ahead of the scheduled ICU Medical pump go-live with contingency planning in place should the risk or scope change. We are continuing coordination with the manufacturers as testing results become available.

Type: Stimulator, hypoglossal nerve, implanted, apnea

Manufacturer: Inspire Medical Systems | **Brand:** Inspire | **Cat:** 3028

Event: Patients presented to the MRI suite for a scan. The Inspire implant and safety guidelines were followed. The implanted medical devices were acting in an incorrect manner.

Patient 1: Shortly after an MRI was performed, the patient stated the Inspire device was independently turned on (without use of the remote that was stored in a secure locker). The implant may need to be tested to validate its functionality and performance.

Patient 2: Per Inspire implant specifications; MRI scan duration is not to exceed scan times of 30 minutes within any 90-minute period. The patient was scheduled for two MRI examinations, one of the brain and the other of the C-spine. The MRI of the brain was performed first with the C-spine to follow. After waiting the full 90 minutes between scans, the patient was brought back into the MRI room (zone 4), but the patient stated the device turned on again without the use of the remote. To ensure the safety of the patient, the MRI C-spine was not performed.

Patient 3: A patient reported the implant turning on by itself and stimulating the patient's tongue. This caused an inability to breathe so the MRI scan was stopped immediately.

Type: Neurosurgical paddle

Manufacturer: Medline Industries | **Brand:** Medline

Event: Our organization received notification from Medline regarding a recall of Medline-branded neuro sponges due to higher-than-expected endotoxin levels identified in certain sponge lots. These neuro sponges are routinely used across multiple surgical specialties, including neurosurgical intracranial and spinal procedures and orthopedic spine surgeries, where they are considered critical surgical adjuncts. At the time of notification, current inventory of alternative products was limited to approximately ten days of supply on hand, and ongoing nationwide demand for substitutes has raised concerns about imminent shortages or unavailability of functionally equivalent products. Peer discussions with other healthcare organizations indicate widespread concern regarding the ability to safely proceed with urgent and emergent surgeries should these neuro sponges or comparable alternatives remain unavailable. Within our health system, surgeons who routinely use these products have expressed concern that lack of availability or substitution with less effective alternatives may increase the risk of adverse surgical events, particularly in high-risk neurosurgical and spinal procedures. Medline's recall communication indicated the risk of patient harm related to endotoxin exposure was considered "very low," and no adverse patient outcomes have been reported to our organization to date related to prior use of the affected neuro sponges. This report is submitted to inform the FDA of the potential patient safety impact associated not only with the recalled device, but also with the resulting supply disruption, which may pose a secondary risk to patient care should access to critical surgical materials remain limited. Our organization remains available to provide additional clinical context or participate in discussions to support safe resolution of this issue.

Type: System, ablation, microwave and accessories

Manufacturer: NeuWave Medical | **Brand:** NeuWave | **Model/Cat:** PR20 | **Lot:** ML23068340

Event: The single-use ablation probe broke/exploded during its active cycle during the actual ablation. The probe appeared to be in good, normal operating condition prior to use. There was no visible damage to the probe or the packaging. The probe was tested as per protocol, passing the bubble test. The probe was successfully used during the tissue lock phase. However, upon initiating the ablation phase, the probe ruptured after approximately 30 seconds into a 7 min 65W ablation cycle (ablation mode). There was an audible pop followed immediately by the ablation machine self-terminating the cycle. There was an error message reflecting a question of whether the probe was in an air pocket or not. The probe was gently repositioned 1-2mm fore and aft as per typical practice; however, it would not successfully reactivate. The probe channel was switched but similarly would not activate. A new probe was placed into the lesion to complete the procedure. This was accomplished successfully with the assistance of aligning the new probe with the broken one. It was

during the imaging of the second probe's placement that the fragmentation was noted. The broken probe hub was removed, intentionally leaving the probe tip at the site of the target lesion to act as a lesion fiducial marker. This fiducial marker was used during the procedure for localization and can be used in the future for triangulation purposes. The fragment was lodged solidly within the liver parenchyma and should not migrate or cause harm to the patient. Any attempt to remove it would significantly increase risk of injury or complication. The ablation was completed successfully. The patient tolerated the procedure, recovered without incident, and subsequently was discharged four hours later.



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: Ventilator, continuous, facility use

Manufacturer: Bio-Med Devices | **Brand:** Bio-Med Devices | **Model:** TV-100

Other: current software version TV100_220629-1

Event: *This facility has submitted multiple reports for these devices. Affected patient populations include neonates, infants, children, and adults.*

Event 1: In the OR, the patient was placed on a TV-100. The patient was not ventilating properly and began to desaturate relatively quickly. The anesthesiologist began to question the ventilator; ventilator settings were the same as what the patient had been on. The patient was placed back on the OR ventilator, the TV-100 was checked, and everything was appropriate. The patient was placed back on the TV-100 and ventilation was noted. The patient desaturated again, so the anesthesiologist decided to bag the patient during transport without attempting the TV-100 again or waiting for a backup. The patient required manual bagging while the ventilator was failing.

Event 2: Staff were called to the delivery room for assistance needed for a full-term baby with a slow start. The full-term baby had poor respiratory effort requiring positive pressure ventilation (PPV), continuous positive airway pressure (CPAP), and oxygen. The patient was resuscitated initially with PPV via mask and T-piece resuscitator using 60-100% oxygen to achieve target saturation. Once the patient began breathing, the provider switched to CPAP via mask and temperature, pulse, and respiration (TPR) monitoring. At this time, the patient required 100% oxygen to maintain a target saturation. I converted the patient to the transport ventilator with settings of CPAP 7, 100% oxygen via nasal mask. The patient desaturated to 59% on the transport ventilator. The patient had fair air entry bilaterally and the mask had a good seal. When I went to troubleshoot the ventilator, I found that although the ventilator was set to deliver 100%, the inhaled gas was analyzed at 21%. We immediately removed the patient from the transport ventilator and placed them back on TPR monitoring with return of oxygen saturation to 96%. The TV-100 ventilator was pulled from service.

Event 3: The patient was placed on the TV-100 upon arrival in the Emergency Department. Shortly after, respiratory care was called to the bedside because the ventilator powered off on its own. The RN was in the room when it happened and was able to remove the patient from the ventilator, manually ventilating with the bag valve mask. The patient was placed on a different brand ventilator, and the TV-100 was removed from use.

Event 4: A TV-100 ventilator was being used on a patient. The touch screen stopped responding to input but otherwise, the ventilator remained functional. I switched the ventilator out for a different brand. When the TV-100 was removed from the patient, I was unable to put it into standby and could only turn it off with a hard reset. Per the manufacturer, we are the only customer reporting this issue.

Event 5: I responded to an adult medical emergency. The transport ventilator had a battery that was not charged. The device was sent to the office to be charged. Although it should charge, the battery life did not improve. I retrieved a proper functional machine. This caused a delay in placing a patient on a ventilator.

[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