MedSun
Medical Product Safety Network

February 2026

Volume 26, Issue 2

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

- Wound and Burn Dressing Issue from Integra LifeSciences **1/22/26**
- Insufflation Unit Issue from Olympus **1/22/26**
- Stent and Electrocautery-Enhanced Delivery System Issue from Boston Scientific **1/16/26**
- Draeger Removes Vapor 2000 and Vapor 3000 Vaporizers **1/16/26**
- Medline Removes Anesthesia Circuits and Anesthesia Circuit Kits **1/16/26**
- Broselow Rainbow Tape Issue from AirLife **1/16/26**
- Dialysis Tubing Set Issue from Vantive **1/14/26**
- AVID Medical Issues Correction for Medical Convenience and Organ Recovery Kits **1/9/26**
- Baxter Removes Sigma Spectrum Infusion System Platforms **1/5/26**
- Medtronic and Given Imaging Remove Bravo CF Capsule Delivery Devices **1/5/26**
- Conavi Removes Novasight Hybrid Catheters **1/5/26**
- Bard Removes PowerPICC Intravascular Catheters **1/5/26**
- Calyxo Updates Use Instructions for CVAC Aspiration Systems **1/5/26**
- Fresenius Kabi Removes Ivenix Large Volume Pumps **1/5/26**
- Alcon Removes Custom Pak Ophthalmic Procedure Packs **1/2/26**
- Quick Link to Medical Device Recalls

Announcements

FDA Hosts Rare Disease Day

FDA will host Rare Disease Day, a virtual public meeting, on Monday, February 23, 2026 in global observance of Rare Disease Week. The theme is: "Moving Forward. Looking Ahead. An Event for Patients." The goal of this year's Rare Disease Day is to explore ways to engage and collaborate with patients and their communities to support and accelerate the development of medical products for rare diseases.

Read More

Highlighted Reports

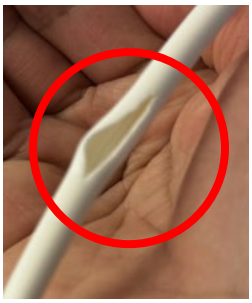
The reports that follow represent a cross section of device related events sent by MedSun Representatives during the prior month. The reports are presented as submitted by MedSun Representatives and in some instances, have been summarized and edited for clarity.

Search the MedSun Report Database

Type: Unit, cryosurgical, accessories
Manufacturer: Erbe Elektromedizin | **Brand:** Erbe | **Lot:** W0463400
Event: All equipment was functioning fine for all cases prior to the event. Using two hands, the provider advanced the cryoprobe into the target lung lesion and stepped on the cryoprobe pedal to start the first biopsy attempt. There was a split second of an audible gas leak but before anything could be done, the

cryoprobe catheter exploded. The explosion was verified by Erbe. The gas used to freeze is CO_2 (carbon dioxide); therefore, there was no heat or fire. Nonetheless, the cryoprobe whipped out of the patient. The provider involved had hyperextension to two fingers, and several staff members had hearing loss for around 30 minutes after the explosion. Two fingers of the proceduralist were hyperextended. There was no patient harm. The vendor has pulled the lot number for the product and will be replacing them. The damaged probe is with healthcare technology management. The vendor shared that three other institutions have had the same issue.

Type: Unit, cryosurgical, accessories
Manufacturer: Erbe Elektromedizin **| Brand:** Erbe **| UDI-DI:** 04050147021778
Model: 20402-401 **Lot:** W0462849 **| Cat:** 20402-401
Other: 1.1mm, length 1.15m, with over-sheath length 817mm



Event: During a robotic bronchoscopy, the surgeon was using a cryoprobe for a biopsy. The surgeon felt the cryoprobe inflate a little bit while inside the patient. Then the team heard a very loud hissing sound like pressure or gas building or inflating followed by an extremely loud bang. The surgeon froze in place and asked if everyone was okay. The team in the room paused to check that everyone was okay. The loud explosion disrupted the procedure and caused immediate pain and distress to the staff. The event was startling and occurred without any warning from the Erbe machine while the device was in use. The surgeon removed the probe from the patient. Anesthesia immediately confirmed there was no change in the patient's vital signs. The surgeon confirmed patient safety and no visible injury. Then the staff noted that the cryoprobe had a hole in it and was damaged. The team deduced that must have been the source of the explosion. The team members noted that no alarm from the Erbe machine went off during the incident. The team double checked the pressure within the Erbe machine and noted it to be 55 bar which is within normal limits. After confirming there was no visible patient injury, the cryoprobe was replaced and set aside. A new cryoprobe was then used to complete the procedure successfully. One technician reported immediate pain and discomfort in his ears from the incident but that they were okay to finish the rest of the day. One technician went to their medical provider for an appointment to check his ears as an urgent evaluation from the incident. The surgeon reports his ears are still sore the next day. One technician reports one ear is still sore the next day. One technician reports no impact.

Type: Unit, cryosurgical, accessories
Manufacturer: Erbe Elektromedizin **| Brand:** Erbe **| UDI-DI:** 04050147021778
Model/REF: 20402-401 **| Lot:** W0462849
Event: The device was tested per standard operating procedures outside the patient before being inserted into the airway. The cryoprobe catheter was dipped in the saline basin. I reached the foot pedal with my right foot while holding the catheter in my right hand. As soon as I pressed on the floor pedal, the cryoprobe exploded close to the right side of my face and right ear. The control unit and catheter were retrieved by Clinical Engineering for analysis. After inspection, no cause to the event was noted. The catheter and control unit were sent to the vendor for further analysis and the clinical sales representative was notified. We believe this is a manufacturing and/or lot issue.

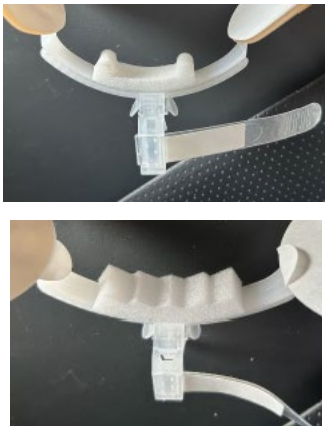
Type: Unit, cryosurgical, accessories
Manufacturer: Erbe Elektromedizin **| Brand:** Erbe **| UDI-DI:** 04050147021778
Model/REF: 20402-401 **| Lot:** W0462378
Event: During use, the disposable cryoprobe ruptured with a loud audible bang. The probe has a visible area where the rupture occurred, including a hole in the catheter. The tip of the probe was inside patient when the incident occurred but the part of the probe that ruptured was not.

Type: Analyzer, pacemaker generator function
Manufacturer: Medtronic Inc. **| Brand:** Carelink Common Application Platform
Event: *The description below represents multiple events reports from the user facility.*
Patients with an implantable device, are manually enrolled by the vendor and connected to the Medtronic Carelink site. Cardiac rhythm alerts not exporting or available for review for remote cardiac monitoring of patients at home as designed. Cases of incorrect vendor registration also have occurred. Failure to generate patient reports can result in harm, delays in care, and/or death.
Example 1: An alert was transmitted for abnormal cardiac rhythm. The data was exported on the same day but had missing information and the clinical team did not have the ability to review the alert. In another event, the alert was viewable on the Carelink site, but the data failed to export to the data aggregator automatically. It never transmitted as an alert but was on a summary report 24 days later.

Example 2: The patient manually sent a symptom transmission, which is viewable on the Carelink site, but the data failed to export to the data aggregator site automatically for the provider to see it. For this patient's specific episode, the backup manual process cannot be executed.
Example 3: A patient was not entered in Carelink by the vendor, which put the patient at risk for loss of follow up. Without being registered on the site, the patient's implanted cardiac device is not monitored. In another event, a patient had a functioning internal cardiac defibrillator, but the vendor manually registered the patient with the wrong date of birth. As a result, the patient went home without monitoring and needed an extra office visit to reprogram the device with the correct date of birth.

Type: Bed, AC-powered adjustable hospital
Manufacturer: Stryker Medical **| Brand:** ProCuity Series **| Model:** ProCuity
Event: A patient with delirium and confusion was able to turn off the bed alarm and wheel lock accidentally by pushing buttons on the handrails while wrapping their fingers around the edge of the bedrail (buttons are on the outside of the rail). Prior to the event, staff noted that the patient was in bed with gripper socks on and bed alarm set. The patient was able to get out of bed without the bed alarm sounding. Patient was found on the floor with the bed wheels unlocked and pushed across the room diagonally. The event highlights that patients can inadvertently push the correct sequence (head raise and flashing lock buttons) to turn off the alarm and bed wheel lock. Although unlikely to occur, this design has prompted the hospital to create workarounds to prevent inadvertent button pushes by patients with delirium and or confusion.

Type: Device, fixation, tracheal tube
Manufacturer: Hollister Inc. **| Brand:** AnchorFast **| Model/Cat:** 9799
Lot: all
Event: *The description below represents multiple events reports from the user facility.*
Multiple patients have experienced hospital acquired pressure injuries that were not present on admission. Reports were sent to the state's Department of Public Health. Injuries associated with the AnchorFast device are located on patients' philtrum and upper lip. The product is associated with an increase in pressure injuries including stage 3, unstageable, and a hole in the upper lip. The manufacturer has acknowledged an increase in pressure injury reports based on their design change but is not initiating a recall. They have returned to an old design but with a sub-par adhesive material. Staff report the devices are not as effective and have fallen off in some cases. There have been multiple communications with the manufacturer.



Top: Old design; Bottom: New design

Type: Endoscope, accessories, narrow band spectrum
Manufacturer: Olympus Medical Systems **| Brand:** Single Use Distal Cover **| Model:** MAJ-2315
Event: The patient was admitted from the post anesthesia care unit. In report, staff said the patient had coarse breathing and needed more oxygen due to noisy breathing and lower oxygen saturation. Upon arrival to the nursing unit, the patient had noisy breathing, which family members stated was not normal. The patient had discomfort and pain. While the patient was taking pills and drinking water, coughing started. The patient was upright and encouraged to cough again when a piece of plastic from the endoscope came out from the throat. The patient began breathing easier and no additional noise was heard. The patient had no more discomfort.

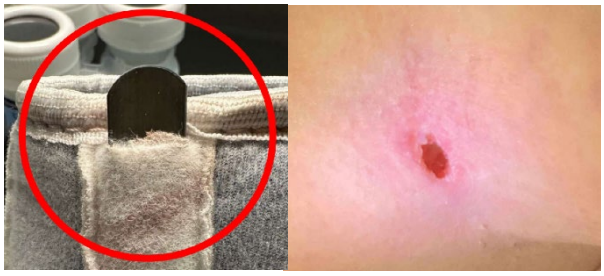
Type: Prosthesis, laryngeal (Taub design)
Manufacturer: Atos Medical **| Brand:** Provox Activalve Strong 6 mm **| UDI-DI:** 07331791000584
Model/Cat: 7161 **| Lot:** 2501098 **| Other:** 22.5 Fr
Event: This device is a voice prosthesis with a magnetic valve and is used in laryngectomy patients. The device was correctly placed in the patient. Four months later, the patient reported to the Speech Language Pathologist (SLP) that the small blue center piece came detached while drinking and was swallowed. The patient spit it back up and then choked on the next sip of liquid. Without the small blue center piece, the patient was choking and unable to speak. The SLP saw him as soon as possible in clinic, removed the faulty device and placed a new, different device. The manufacturer was notified. The patient is now able to eat, drink, and communicate. Device detachment put the patient at risk when it fell into the airway, leaving the patient susceptible to choking events. This facility reported a similar incident with this device approximately four years ago.

Type: System, endovascular graft, aortic aneurysm treatment
Manufacturer: Cook Medical Inc. **| Brand:** Zenith Alpha 2 Thoracic Endovascular Graft
Model: ZTA2-P-42-121-W **| Lot:** E4677112
Event: The sales representative provided the surgeon the thoracic endovascular graft to place inside the patient. The sales representative later notified the surgeon that the device implanted was voluntarily recalled 68 days ago due to the potential of scrapings of PTFE (polytetrafluoroethylene) coating from the nitinol release wire inside the graft, which may be released during deployment.

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: Humidifier, respiratory gas, (direct patient interface)
Manufacturer: Teleflex Inc. **| Brand:** Hudson RCI **| UDI-DI:** 14026704610317
Model: IPN046863 **| Cat:** 382-10
Event: The tubing circuit was attached incorrectly to a continuous positive airway pressure humidified heater which caused excess air inflow and lower circuit temperatures. It was determined that the heater intermittently heated the circuit and humidity to high temperatures to maintain the desired circuit temperatures. As a result, a newborn infant was sprayed with hot steam from circuit causing blisters and burns to the nose and face. We suggest the manufacturer add a heater alarm when the circuit cannot be warmed adequately so staff are alerted to high humidified air being cycled through the circuit.

Type: Restraint, protective
Manufacturer: DeRoyal Industries, Inc. **| Brand:** DeRoyal **| UDI-DI:** 00749756113427
Model/Cat: M7035-S **| Lot:** 62098955
Event: An elbow immobilizer was in place to provide protection for the intravenous peripherally inserted central catheter line and dressing. While repositioning the patient, the nurse noted that the metal rod had dislodged from its cloth covering and was digging into the patient's underarm, causing a puncture wound. There was report earlier of the same product dislodging from its cloth covering but no injury was noted at that time. The patient's left axilla injury site was assessed by the Pediatric Surgery Nurse Practitioner, cleansed with normal saline, packed and dressed.



Left: Exposed metal rod; Right: Axilla wound

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