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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.

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Highlighted Recalls and Early Alerts

- [Draeger Removes VentStar Resus Neo Hoses](#) **10/2/26**
- [Boston Scientific Removes Imager II Angiographic Catheters](#) **9/25/26**
- [Abiomed Removes Automated Impella Controllers](#) **9/24/26**
- [Becton Dickinson Issues Correction for Kits and Procedure Trays Containing Recalled Sodium Chloride Ampules](#) (removal of sodium chloride ampules manufactured by Huons Co., Ltd.) **9/24/26**
- [Early Alert: VOCSN Ventilator Issue from React Health](#) **9/23/26**
- [Early Alert: Heart Pump Controller Issue from Abiomed](#) **9/23/26**
- [AVID Medical Issues Correction for Kits Containing Huons Sodium Chloride Ampules](#) (removal of sodium chloride ampules manufactured by Huons Co., Ltd.) **9/21/26**
- [CooperSurgical Removes INCA Infant Nasal CPAP Sets](#) **9/21/26**
- [Spectra Medical Removes Sodium Chloride Injection USP Ampules](#) (removal of sodium chloride ampules manufactured by Huons Co., Ltd.) **9/18/26**
- [NOxBOX Updates Use Instructions for NOxBOXi Nitric Oxide Delivery System](#) **9/18/26**
- [Medtronic and Given Imaging Remove Esophageal pH Monitoring Capsule Delivery Device](#) **9/15/26**
- [Medical Action Industries Issues Correction for Epidural Kits Containing Spectra Medical Devices Lidocaine Ampules](#) (removal of sodium chloride ampules manufactured by Huons Co., Ltd.) **9/10/26**
- [Boston Scientific Removes Infinion CX Leads](#) **9/3/26**
- [GE HealthCare Updates Use Instructions for Portrait Core Services Software](#) **9/3/26**
- [Medline Issues Correction for Convenience Kits Containing BD ChloraPrep Applicators](#) (removal of BD ChloraPrep applicators affected by the [BD ChloraPrep Applicator Recall](#)) **9/2/26**
- [Recall Expansion: Medline Industries Removes Reprocessed Electrophysiology and Ultrasound Catheters](#) **9/2/26**
- [Medline Removes Neonatal and Infant Heated Wire Breathing Circuits](#) **9/1/26**

[Link to Device Recalls & Early Alerts](#)

Announcements

FDA Issues Frequently Asked Questions (FAQs) on PFAS in Medical Devices

The FDA has updated its webpage about PFAS (per- and polyfluoroalkyl substances) in medical devices to include new Frequently Asked Questions (FAQs) to help consumers understand what these materials are, why they are used, and how the FDA evaluates the safety and effectiveness of devices that contain these materials.

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CDRH Launches Rare Disease Impact Initiative

The FDA's Center for Devices and Radiological Health (CDRH) has launched the **CDRH Rare Disease Impact Initiative** to help address challenges associated with rare disease device development - such as small patient populations and the complex nature of many rare diseases – and facilitate the advancement of medical devices for people with rare diseases. The initiative's new webpage provides tools and resources that may help advance rare disease medical devices.

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FDA Announces Draft Guidance on Robotically Assisted Surgical Devices and Upcoming Public Workshop on Medical Devices with Autonomous and/or Remote Teleoperation Capabilities

The FDA announced a draft guidance, [Robotically-Assisted Surgical Devices — Premarket Submissions](#). This draft guidance, when finalized, provides recommendations on non-clinical testing, clinical data, and labeling to support premarket submissions for certain robotically assisted surgical devices (RASDs). This guidance does not address remotely teleoperated RASDs, or autonomous robots that perform significant aspects of operative procedures independent of qualified practitioners.

The FDA is also hosting a public workshop on [Evaluating Benefit-Risk in Robotic Medical Devices with Autonomous or Remote Teleoperation Capabilities](#) on December 2–3, 2026. The workshop is open to all and will explore a broad range of robotic medical devices both inside and outside the operating room, including those with autonomous and remote teleoperation capabilities, with the goal of deepening the FDA's understanding of user experience and fostering an exchange of ideas that can support the evaluation of benefits and risks to promote patient safety and device effectiveness.

Submit comments on this draft guidance

Submit comments under [docket number FDA-2026-N-9505](#) at www.regulations.gov by November 24, 2026 to ensure the FDA considers comments on this draft guidance before it begins work on the final version of the guidance.

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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](#)

Device 1

Type: Helmet, surgical

Manufacturer: THI Total Healthcare Innovation

Brand: ViVi Helmet

Device 2

Type: Hood, surgical

Manufacturer: THI Total Healthcare Innovation

Brand: ViVi Peel-Off Hood

Model/Cat: 80500V

Event: There have been several events involving the Zimmer Helmet. We have identified the following major issues:

- The light should be stronger - in some cases it has been too dim for deep wounds.
- The bottom portion of the clear plastic hood is cutting staff's hands when the hood is removed. This might seem like a small issue, except that it is a very concerning issue if a clinician gets cut after treating a patient who has a blood born pathogen.
- The side Velcro tabs need to be re-designed given the trouble people are having with the hoods popping off the helmets.
- Natural head movements during surgery can cause the fan or the light to shut off, creating a distraction for the surgeon.

The manufacturer has implemented design changes to address those issues, and they are having us return all our product and replacing them with "new" ones over the next month.



Type: Screw, fixation, bone

Manufacturer: Biomet Microfixation | **Brand:** SternaLock EZ

Event: These plates are used in cardiothoracic surgery for closing and stabilizing the sternum after it has been opened or fractured. The system provides rigid fixation, helping the sternum heal properly and reducing complications such as instability, non-union, or infection. We have experienced ongoing issues with the sternal plates that were first identified after the heart team reported multiple defects related to rust observed in the bottom of the sterilization caskets. In response, our team began inspecting the pans and discovered that multiple instruments across all pans exhibited visible pitting, which was initially believed to be the source of the rust. The vendor was contacted and promptly replaced all affected instruments. However, despite replacing the instruments, rust continued to appear in the bottoms of the caskets, and the newly supplied instruments also demonstrated the same pitting. As a precaution, we halted use of these plates while further investigation was conducted. Over the course of several weeks, we collaborated closely with the vendor representative to determine the cause of the issue. Multiple corrective efforts were attempted, including reprocessing the trays using different sterilization methods, replacing outer trays, adding trays to caskets, removing instruments from the tray, and fully replacing all instruments. Despite these efforts, the issue persisted.

The vendor subsequently sent engineers to the department to directly observe our reprocessing workflow. To rule out issues related to Sterile Processing Department equipment or practices, we sterilized other instruments using the same processes. The issue could not be replicated with any other instrument sets, indicating that the concern appears specific to the SternaLock

EZ system. We believe this issue poses a potential patient safety risk. Given the persistence of rust and pitting despite instrument replacement and verified reprocessing practices, we believe this concern may extend beyond our facility. We feel these implants represent a broader safety concern that warrants external reporting and investigation.

Type: Tubes, gastrointestinal (and accessories)

Manufacturer: Avanos Medical | **Brand:** Avanos | **UDI-DI:** [00350770460321](#)

Model/Cat: 40-7431

Event: We identified a potential human factors/design concern. An enteral feeding tube was inserted overnight with the stylet left in place following insertion. It is unknown whether the retained stylet was recognized during subsequent nursing assessments. The issue was identified the following day when the patient underwent an MRI examination. After completion of the scout image and first imaging sequence, the MRI technologists noted image artifact and questioned whether the patient had any metal associated with the feeding tube. An additional sequence was attempted; however, due to continued artifact, the patient was slowly removed from the scanner for further assessment. The patient denied having any implanted facial metal or other internal metallic objects. The MRI team asked the patient's nurse to inspect the feeding tube. Upon examination, the nurse discovered that the stylet remained in the feeding tube. The stylet was immediately removed and discarded in a sharps container. The patient had been in the MRI scanner approximately 3 to 5 minutes before the retained stylet was identified. The radiologist was notified and confirmed that imaging could proceed following stylet removal. The patient reported no discomfort, injury, or adverse symptoms. No evidence of harm was identified. A potential contributing factor identified during event review was the design of the feeding tube assembly. The stylet port and feeding tube port are the same color and appear similar, making it difficult to visually identify when the stylet remains in place. This may be especially challenging when different staff members are involved in tube insertion, x-ray confirmation, and subsequent patient care. The retained stylet was not recognized until MRI image artifact prompted further investigation. This raises a potential usability concern related to visual differentiation of components and detection of retained stylets during care handoffs.

Device 1

Type: Reprocessed blood pressure cuff

Manufacturer: Hygia Health Services | **Brand:** Welch Allyn | **Model/Cat:** SOFT-11

Device 2

Type: Monitor, physiological, patient (with arrhythmia detection or alarms)

Manufacturer: Philips Medizin Systeme Bøblingen | **Brand:** IntelliVue X3

Model: MX100/X3

Event: Upon removal of surgical drapes at the end of an eight-hour surgical case, the blood pressure cuff hose was found kinked, and the cuff on the right arm was inflated for an unknown length of time. The hose was disconnected, and the cuff was subsequently deflated. An assessment revealed right upper extremity ischemia secondary to an iatrogenic blood pressure cuff injury. Due to prolonged potential ischemia time and concern for reperfusion injury, the decision was made to take the patient to the OR for a right forearm and hand compartment release.

Device 1

Type: Defibrillator, automatic implantable cardioverter, with cardiac resynchronization

Manufacturer: Medtronic | **Brand:** Cobalt XT HF CRT-D MRI SureScan | **Model:** DTPA2D1

Device 2

Type: Analyzer, pacemaker generator function

Manufacturer: Medtronic | **Brand:** CareLink SmartSync

Event: *This facility has submitted multiple reports about this type of problem.* At the time of implant, the vendor representative enrolled the patient's implantable cardioverter defibrillator into the wrong CareLink clinic. Failure to register a patient correctly into remote monitoring

eliminates the provider's ability to monitor the patient's heart condition for which the device was implanted. Reliance on a manual registration process poses a risk.

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