MedSun
Medical Product Safety Network

September 2026

Volume 26, Issue 9

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

- *Early Alert:* IV Start Kit Issue from Avid Medical (kits affected by the BD ChloraPrep Applicator Recall) **8/28/26**
- *Early Alert:* Angiographic Catheter Issue from Boston Scientific **8/28/26**
- AVID Medical Issues Correction for Kits Containing Medline Namic Star Off Handle Manifolds **8/27/26**
- *Early Alert:* Esophageal pH Monitoring Capsule Delivery Device Issue from Medtronic and Given Imaging **8/27/26**
- *Early Alert:* Heart Pump Controller Purge Cassette Issue from Abiomed **8/26/26**
- Boston Scientific Removes ENROUTE Transcarotid Neuroprotection System **8/26/26**
- *Early Alert:* Nitric Oxide Delivery System Issue from NOxBOX **8/24/26**
- *Early Alert:* Ventilator Issue from CooperSurgical **8/24/26**
- *Early Alert:* Convenience Kit Issue from AVID Medical (kits affected by the BD ChloraPrep Applicator Recall) **8/24/26**
- *Early Alert:* Convenience Kit Issue from Medline (kits affected by the BD ChloraPrep Applicator Recall) **8/24/26**
- *Early Alert:* Hudson RCI Neonatal/Infant Heated Wire Breathing Circuit Issue from Medline **8/21/26**
- *Early Alert*: Portrait Mobile Monitoring Software Issue from GE HealthCare **8/21/26**
- *Early Alert:* Epidural Kit Issue from Medical Action Industries (kits containing sodium chloride ampules manufactured by Huons Co., Ltd.) **8/21/26**
- Medline Issues Correction for Convenience Kits Containing B. Braun Bupivacaine Hydrochloride Components (kits containing Bupivacaine Hydrochloride manufactured by Huons Co., Ltd.) **8/20/26**
- *Early Alert:* Convenience Kit Issue from Becton Dickinson (kits containing sodium chloride ampules manufactured by Huons Co., Ltd.) **8/18/26**
- Becton Dickinson Removes Certain Intraosseous Vascular Access System Needle Sets **8/17/26**
- Baxter Removes Duo-Vent Solution Sets **8/13/26**
- Medline Issues Correction for Convenience Kits Containing ICU Medical Pain Management Components (kits containing Bupivacaine Hydrochloride manufactured by Huons Co., Ltd.) **8/12/26**
- Hamilton Medical Removes Breathing Circuit Set **8/11/26**
- Abiomed and Oscor Issue Correction for Catheter Introducer **8/10/26**
- Medline Issues Correction for Kits Containing Huons Lidocaine Hydrochloride and Bupivacaine Hydrochloride in Dextrose Injection **8/3/26**

- Medical Action Industries Issues Correction for Kits Containing Recalled Namic Manifolds **8/3/26**

Link to Device Recalls & Early Alerts

Announcements

FDA Seeks Public Feedback to Inform Regulatory Approach for Generative AI-Enabled Medical Devices

The FDA has issued a discussion paper on considerations for the regulation of generative artificial intelligence (GenAI)-enabled medical devices, seeking feedback from interested parties on risk assessment, premarket evaluation, postmarket monitoring, and other topics relevant to the regulation of GenAI-enabled medical devices. This discussion paper is intended to engage stakeholders on the challenges associated with GenAI-enabled medical devices and ways to advance regulatory approaches for these devices. The FDA encourages feedback on the discussion paper from device manufacturers, clinicians, consumers, researchers, the public, and other interested parties, to be submitted under the docket FDA-2026-N-7874 on Regulations.gov by **October 19, 2026**.

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FDA Weighs in on the Development and Use of Digitally Derived Measures for Clinical Investigations

The FDA's medical product centers have jointly published a white paper entitled: "Key Considerations for the Development and Use of Digitally Derived Measures for Clinical Investigations." The white paper highlights key considerations drawn from existing FDA guidances for the development and use of digitally derived measures (DDMs) as outcomes in clinical investigations.

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Public Meeting: Regulatory Science Innovations Catalyzing Medical Device Development – September 25, 2026

The FDA is announcing a public meeting entitled "Regulatory Science Innovations Catalyzing Medical Device Development." This meeting is co-sponsored with the Medical Device Innovation Consortium (MDIC). The purpose of the meeting is to advance regulatory science in support of breakthrough devices and disruptive medical device technologies by fostering meaningful, multi-stakeholder dialogue to help inform long-term research priorities and strategic planning for FDA's Center for Devices and Radiological Health (CDRH). The public meeting will take place on September 25th from 8:30 a.m. to 4:30 p.m. ET. In conjunction with this meeting, the FDA is opening a docket to receive comments from the public. Please submit all public comments to the docket [FDA-2026-N-8563, which will be available at regulations.gov].

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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: Tubes, vials, systems, serum separators, blood collection
Manufacturer: Greiner Bio-One **| Brand:** VACUETTE **| UDI-DI:** 29120017579032
Model/Cat: 454008P **| Lot:** B26043FM
Event: Several green/yellow lab tubes were used to collect blood throughout the network and labs at different campuses noticed alarming and confusing results. All tubes in the lot provided resulted in high potassium results and low calcium results. The lot number was identified, and all remaining unused tubes were removed from stock. When the tests were re-run using tubes from a different lot, the results were different and correlated to patients' conditions.

Type: Catheter and tip, suction
Manufacturer: Cook Inc. **| Brand:** Wayne Pneumothorax Set
Model: G56533 **| Cat:** C-UTPT-1400-WAYNE-IMH
Event: The pneumothorax catheter sets include a Heimlich valve which has been inserted backwards in multiple cases at multiple hospitals in our system, preventing air/fluid flow from the pleural space. This can contribute to development or worsening of a pneumothorax. The two ends of the valve are different colors but similarly shaped and it can be inserted in either direction when connecting the pigtail to the chest tube drainage system. The design of the valve can contribute to normal human error. Because the valve is not necessary for safe use of the catheter, our system supply chain has discussed with the manufacturer and requested removal of the valve from the kits; however, the manufacturer has declined to remove it. While training has been provided on correct use of the valve, the usability concerns with the design cannot be adequately mitigated with training alone.

Type: Monitor, extracellular fluid, lymphedema, extremity
Manufacturer: ImpediMed Limited **| Brand:** SOZOapp
Event: The SOZO was used to evaluate a patient for lymphedema. The patient demographics section in the SOZOapp was completed prior to patient arrival for workflow efficiency. The patient's dominant hand must be entered on the demographics screen; however, this information is not typically known until the patient arrives. As a workaround, the nurses enter right for all patients and must remember to go back to this screen if the patient is actually left-handed. In this case, the patient was left-handed, and the nurse forgot to change the demographics. The results showed that the patient did not have lymphedema. This error was identified months later. Once the correct hand dominance was entered, retrospectively the device noted that the patient would have been diagnosed with early lymphedema at the time of the initial evaluation. In the interim, she had developed swelling which was treated with a compression garment. While this event reflects normal human error, the team would like to recommend that the question of handedness be moved to a later screen in part of the workflow that is more likely to involve the patient. Moving this question and any others that may impact the assessment calculations, just before the assessment is started would increase the likelihood that the responses will be completed accurately with input from the patient.

Type: Cardiac ablation percutaneous catheter
Manufacturer: Biosense Webster **| Brand:** SmartAblate **| Model/Cat:** SAT001
Lot: 3015959, AC10285986
Event: The problem is the identification of particulate contamination in the SmartAblate irrigation tubing during cardiac ablation procedures, which is suspected to be linked to two cases of stroke in two patients. The patients were undergoing pulsed field ablation procedures for cardiac arrhythmias experienced confirmed cerebrovascular accidents (strokes) shortly after their procedures. During a follow-up quality review, staff noted unusual cloudiness and glitter-like particulates inside the SmartAblate irrigation tubing used during both procedures. This tubing, a single-use and pre-packaged component supplied by the manufacturer, is designed to irrigate ablation catheters and prevent clot formation. For both cases, staff observed repeated air notification alarms on the cooling pump. Troubleshooting steps were followed, but the abnormal appearance persisted, including cloudiness and discoloration, which was visually confirmed when held to the light. The presence of particulates in the tubing raised concerns that embolic material may have been introduced into the patients' circulation during the procedure, potentially causing or contributing to the post-procedural strokes. The temporally associated neurological events prompted immediate action including withdrawal of implicated pumps and tubing from service, notification and engagement of the manufacturer, consultation with clinical and engineering teams, and cancellation of pending procedures until further investigation can be completed.

Type: Screw, fixation, bone
Manufacturer: Biomet Microfixation **| Brand:** SternaLock EZ
Event: The SternaLock EZ 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, nonunion, 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 at the bottom of the sterilization caskets. In response, we 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, use of the plates was halted 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 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: Laparoscope, general plastic surgery
Manufacturer: Applied Medical Resources
Brand: Alexis Contained Extraction System With Kii Balloon Blunt Tip System
UDI-DI: 20607915134826 **| Model:** GTK17
Event: The patient underwent a planned total laparoscopic hysterectomy, bilateral

salpingectomy, and ovarian cystectomy of an enlarged fibroid uterus. The hysterectomy component was entirely uncomplicated. To extract the large uterus without intraoperative spill, the tissue was placed intact in the contained extraction system. The patient had largely central adiposity, so an abdominal morcellation was not optimal and a vaginal approach was planned. The white ring of the external soft bag was delivered through the vagina. The reps suggested placement of the small, ridged Alexis-O into the vagina within the specimen bag as an improvement feature to allow for adequate retraction of the vaginal walls. I placed the hard protective vaginal collar and was able to complete the morcellation of a small amount of distal tissue before I needed to rotate the specimen to establish a new plane. Once the next lobular component of the tissue emerged into the rotation, there was now redundancy on the entire system. I attempted to reactivate the outer containment bag ring, and in this process, the entire system suddenly burst free, leaving the specimen in the abdomen and resulting in what appeared to be a completely exploded extraction bag. There was a huge defect within the side opposite the ring. I was concerned there possibly was fecal material on this aspect of the bag and aborted any further attempts at vaginal morcellation. I conducted multiple exams from the pelvic region but could not feel any rectovaginal defects. I then returned to laparoscopy and conducted a very detailed exam of the deep pelvis, which seemed normal. I made the decision to close the vaginal cuff as usual and kept the specimen in the abdomen. No defect was immediately evident. We had to limit Trendelenburg slightly due to some ventilation concerns, and the omentum had fallen over the pelvic brim. Once the omentum was retracted backwards, we conducted an extensive evaluation, which ultimately required placement of extra-long sterile procto swabs in the abdomen. I then found (relatively high in the pelvis, quite cranially from the surgical site, and above the deep cul-de-sac) an explosive appearing defect in the anterior rectum. Ultimately general surgery was called and completed a colostomy with bowel resection as the damage was not amenable to a primary repair. I am concerned that the rigid ring within the smaller Alexis apparatus captured a component of the distal bowel, and when the back end of the bag broke, the entire system emerged forcefully and suddenly. I believe it is possible that in this moment, the firm ring shredded the anterior surface of the rectum.

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.

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