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 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

- Insulet Removes Certain Omnipod 5 Pods **4/29/26**
- Trividia Health Issues Correction for TRUE METRIX Blood Glucose Monitoring Systems **4/28/26**
- Thoracic Stent Graft Issue from Bolton Medical **4/28/26**
- Arrow International Removes Dialysis Catheter Kits Containing Merit Medical Splittable Sheath Introducers **4/24/26**
- Automated Compounding System Issue from Omnicell **4/24/26**
- Convenience Kit Issue from Aligned Medical Solutions **4/23/26**
- Integra LifeSciences Recalls Codman Disposable Perforators Due to Risk of Device Disassembly **4/23/26**
- B. Braun Medical Issues Correction for Streamline Airless System Hemodialysis Bloodlines and B3 Low Volume Bloodlines **4/22/26**
- Tandem Diabetes Care Issues Correction for Tandem Mobi Insulin Pumps **4/22/26**
- Windstone Medical Packaging dba Aligned Medical Solutions Issues Nationwide Recall of Namic Angiographic Rotating Adapter 10cc Control Syringe Placed into Specific Packs **4/20/26**
- Convenience Kit Issue from American Contract Systems **4/16/26**
- Convenience Kit Issue from Medical Action Industries **4/16/26**
- Stryker Updates Use Instructions for Patient-Fitted TMJ Implants **4/15/26**
- Philips Issues Correction for Trilogy Evo Platform Ventilators **4/15/26**
- Percussionaire Corporation Updates Use Instructions for Phasitron In-Line Valve **4/15/26**
- Draeger Issues Correction for Atlan A350 and A350 XL **4/14/26**
- Merit Medical Removes 16F Dual-Valved Splittable Sheath Introducer **4/14/26**
- Convenience Kit Issue from AVID Medical **4/10/26**
- Baxter Updates Use Instructions for Volara Single-Patient Use Circuits **4/9/26**
- Medline Industries Removes Namic Angiographic Rotating Adaptor Control Syringes **4/9/26**
- Sizing Catheter Issue from Cook Medical **4/9/26**
- Abiomed Removes Impella Heart Pump Purge Cassettes **4/3/26**
- Abiomed Updates Use Instructions for Impella RP with SmartAssist Devices **4/3/26**
- Quick Link to Medical Device Recalls and Early Alerts

Safety Communications

- Risks of Using TRUE METRIX Blood Glucose Monitoring Systems by Trividia Health **4/28/26**

Announcements

FDA Announces READI-Home Innovation Challenge

The U.S. Food and Drug Administration (FDA) announced a new Innovation Challenge titled, "READI-Home: Reducing Readmissions through Device Innovation for the Home." The goal of this Innovation Challenge, which is part of the FDA's Home as a Health Care Hub Initiative, is to accelerate patient access to medical device technologies aimed at reducing hospital readmission. Innovation in this area has the potential to reduce morbidity and mortality associated with chronic conditions and significantly reduce the financial and logistical burden on the health care system.

Learn More About READI

CMS Proposed Rule Regarding Unique Device Identifiers (UDI)

The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would establish a Unique Device Identifier (UDI) measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability (PI) Program. Under this proposal, developed in partnership with the FDA, eligible hospitals would attest to whether or not they used certified electronic health record technology (CEHRT) to capture the complete UDI for each implantable medical device subject to UDI requirements.

Read the Proposed Rule

CMS and FDA Announced RAPID Coverage Pathway to Accelerate Patient Access to Life-Changing Medical Devices

The Centers for Medicare & Medicaid Services (CMS) and the U.S. Food and Drug Administration (FDA) announced the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway, a new pathway designed to expedite access to certain FDA-designated Class II and Class III Breakthrough Devices for people with Medicare. The RAPID coverage pathway allows CMS and the FDA to work together, with innovators, earlier in the technology development lifecycle so that evidence generated for FDA review can also support Medicare coverage decisions. By aligning regulatory and coverage expectations in advance, the RAPID coverage pathway is designed to significantly reduce delays that have historically occurred between FDA market authorization and Medicare national coverage determinations.

Read the News Release

FDA Updates Tips to Help Charge Medical Devices Safely and Avoid Overheating

The U.S. Food and Drug Administration (FDA) added a new safety tip for consumers to avoid spilling liquids on charging accessories for medical devices and to ensure such accessories are dry before plugging them into a device or to an electrical outlet. These safety tips can help reduce the risks of medical devices overheating, overheating related injuries, and fires.

Read the Update

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

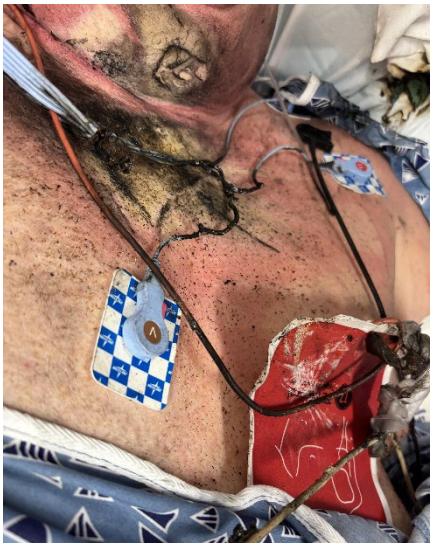
Type: Tubes, gastrointestinal (and accessories)
Manufacturer: Avanos Medical **| Brand:** Avanos **| UDI-DI:** 00350770460321
Model/Cat: 40-7431 **Lot:** 20136433
Event: There were two events where Corflow NG [nasogastric] tubing with guidewire stylets were left in post NG placement. The procedure is to place the tube using the guidewire, send patients to X-ray to confirm placement, and then remove the stylet before using the tube. The tube was utilized for feeding and medications for several days before staff realized the guidewire remained in place. Because the stylet and the ports are the same color, staff was not alerted to the fact that the stylet had not been removed post imaging.

Type: Distal transcutaneous electrical stimulator for treatment of acute migraine
Manufacturer: Theranica Bio-Electronics **| Brand:** Nerivio Infinity
Event: Our office received a patient safety report involving the Nerivio Infinity, which exploded while charging. The event caused damage to the patient's carpet but resulted in no injuries. Providers have been instructed not to order any Nerivio devices. The patient was using the device for headache relief.

Type: Table, operating-room, electrical
Manufacturer: Smith & Nephew **| Brand:** Spider2 Limb Positioner
UDI-DI: 00885554029673 **| Model/Cat:** 72203299S
Event: The operating room nurse was attempting to use the Spider2 Limb Positioner and used the foot pedal to move it with no luck. So, she changed the battery. She removed the battery that was in the equipment and replaced it with a battery that was on the charger. The battery that was on the charger was not hot to touch or swollen in any way. She plugged it into the machine and again attempted to move the limb positioner via the foot pedal, but it again did not move. She moved away to see if she could diagnose the problem. Approximately two seconds later, the battery that she had just plugged into the machine exploded and sent plastic shrapnel through the air. There was a patient on the bed at the time, but they were uninjured, along with staff in the room. The battery made a very loud and audible "pop" and startled all the staff in the room. The equipment was immediately taken out of service, and the manufacturer was contacted. Once it was safe, the battery was taken off the equipment, and the broken pieces of plastic were collected.

Device 1 **Type**: Pacemaker, cardiac, external transcutaneous (non-invasive)
Manufacturer: TZ Medical **| Brand:** Defibrillation Electrodes **| Model/Cat:** P-211-Z1
Lot: Y082525-02
Device 2 **Type:** Automated external defibrillators (non-wearable)

Manufacturer: Zoll Medical Corporation **| Brand:** R-Series ALS with AED
Device 3 **Type:** Analyzer, gas, carbon-dioxide, gaseous-phase
Manufacturer: Stryker Corporation **| Brand:** Pom Elite MM **Model/Cat:** 1001-MM **| Lot:** 121924
Event: A transesophageal echocardiogram (TEE) with cardioversion was performed on a patient. The TEE portion of the procedure was completed and TEE probe removed. The patient was receiving supplemental oxygen with a face mask. Cardioversion at 200 joules was performed. At this point, a spark was noted by the defibrillator pads. After the cardioversion, a yellow/orange glow was noted with rapid development of a flame emanating from the patient's chest and neck area. The sonographer heard a pop during the Cardioversion and saw a flash followed by flames coming out of the mask. The linens then caught fire. The oxygen was immediately removed by the anesthesiologist. The sonographer put the fire out with a towel. Water was poured onto the chest and neck region. The patient was assessed to have second degree burns on the chest and neck. The patient was sent to the Emergency Department followed by a transfer to a burn center for evaluation and treatment of the burns. This included admission to the burn unit and surgical preparation followed by an application of skin substitute to the neck and chest. The patient had no other areas of injury.



Type: Monitor, physiological, patient (without arrhythmia detection or alarms)
Manufacturer: Welch Allyn **| Brand:** Connex 6000 **| Model:** 68NTX
Event: Our facility currently has approximately 250 active units in service. Of those, 66 devices have been identified with cracked or damaged outer casings. This condition presents both an infection prevention concern and a potential safety risk. Compromised housing may allow fluid ingress during cleaning and disinfection, which could expose internal components and increase the risk of device malfunction or electrical hazard.

Type: Polymer patient examination glove
Manufacturer: American Nitrile Operations
Device 1 **Brand:** Opportunity Flex
Model/Cat: 72-50902, 72-50903, 72-50901, 72-50904 **| PMN/PMA:** K220825
Device 2 **Brand:** Opportunity Pro **| Model/Cat:** 72-50803, 72-50804, 72-50802, 72-50801
PMN/PMA: K220825
Device 3 **Brand:** Goodworks Performance Pro
Model/Cat: 72-50601, 72-50603, 72-50604, 72-50602 **| PMN/PMA:** K220825
Event: We received a minimum estimated 5,435 reports from 12/12/2025, to 2/28/2026 for failed nitrile examination gloves. The reported issues pertain to tears/rips, missing parts of gloves, foreign substances (dirt/mold), gloves stuck together, inconsistent glove thickness, size too small, reaction to material by staff, and size too large.

Type: Polymer patient examination glove
Manufacturer: Bosma Enterprises **| Brand:** Precision Touch Ice
Model/Cat: 73-20504,73-20501, 73-20502, 73-20503 **| PMN/PMA:** K233970
Event: We received a minimum estimated 7,500 reports from 12/12/2025 to 2/28/2026 for failed nitrile examination gloves. The reported issues pertain to tears/rips, missing parts of gloves, foreign substances (dirt/mold), gloves stuck together, inconsistent glove thickness, size too small, reaction to material by staff, and size too large.

Type: Polymer patient examination glove
Manufacturer: Nephron Nitrile **| Brand:** Huckleberry **| Model:** Huckleberry | **PMN/PMA:** K233970
Event: We received twenty-six reports from 11/13/2025 to 3/23/2026 about failed nitrile examination

gloves. This also includes reports related to anaphylactic events. The reported issues pertain to rips, tears, reaction to the material by staff and patients, and gloves stuck together.

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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