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

- ICU Medical Removes IV Gravity Burette Set **12/30/25**
- Dexcom Issues Correction for Dexcom G6 and G6 Pro Software **12/29/25**
- GE HealthCare Updates Use Instructions for CareStation Anesthesia Systems **12/29/25**
- Draeger Removes ErgoStar Catheter Mounts **12/23/25**
- Cook Medical Removes Zenith Alpha 2 Thoracic Endovascular Graft **12/23/25**
- IMPRIS Imaging Inc Issues Correction for IMRIS Neuro III-SV **12/23/25**
- Convenience Kit Needle Issue from Integra LifeSciences **12/23/25**
- Siemens Healthineers Issues Correction for 3 Tesla MRI Systems **12/23/25**
- Medtronic Removes DLP Left Heart Vent Catheter **12/22/25**
- Baxter Issues Correction for Novum IQ Large Volume Pumps **12/22/25**
- B. Braun Medical Inc. Removes Microbore Extension Sets **12/22/25**
- Abiomed Updates Use Instructions for Automated Impella Controllers **12/22/25**
- Anesthesia System Issue from GE HealthCare **12/10/25**
- Olympus Updates Use Instructions for Ligating Device **12/3/25**
- Glucose Monitor Sensor Issue from Abbott Diabetes Care **12/2/25**
- Glycar SA Removes Pericardial Patch **12/1/25**
- Quick Link to Medical Device Recalls

Announcements

FDA Updates Lists of Medical Devices that Incorporate Digital Health Technology

The FDA has updated its searchable lists of medical devices that incorporate digital health technology authorized for marketing in the United States including artificial intelligence, augmented reality and virtual reality, and sensor-based digital health technology. The lists include medical devices that have been identified primarily based on information provided in the summary descriptions of their marketing authorization documents.

FDA Launches TEMPO: A First-of-Its-Kind Digital Health Pilot to Expand Access to Chronic Disease Technologies

The FDA announced the Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot, a voluntary pilot designed to promote access to certain digital health devices

while safeguarding patient safety. The pilot will evaluate a new, risk-based enforcement approach that supports digital health devices intended for use to improve patient outcomes in cardio-kidney-metabolic, musculoskeletal, and behavioral health conditions.

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Request for Public Comment: Identifying Accessories Suitable for Distinct Classification as Class I Devices

The FDA announced a "Request for Public Comment: Identifying Accessories Suitable for Distinct Classification as Class I Devices." The FDA is seeking information from interested parties regarding existing medical device accessories that may or may not be suitable for distinct classification in Class I. The agency considers an accessory to be a finished device that is intended to support, supplement, and/or augment the performance of another device (also known as a "parent device"), or as part of a device system. This request for public comment is a preliminary step to help the FDA identify suitable accessories for distinct classification into Class I and is intended to seek early feedback from groups and individuals outside the Agency. The FDA intends to consider all relevant comments submitted within 60 days, on or before February 3, 2026, to develop a proposal for the distinct classification action.

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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: Gauze/sponge, internal, X-ray detectable
Manufacturer: Covidien LP **| Brand:** Situate **| UDI-DI:** 10884521700604 | **Model/Cat:** G0404-16P01C-1
Event: Two Situate RF and X-ray detectable gauzes were introduced through laparoscopic ports to achieve hemostasis during a laparoscopic adrenalectomy. After hemostasis, the two gauzes were gently removed/pulled back out through the lap ports. After gauze counts were correct, the laparoscopic incisions were closed and then a scan performed, which alarmed detection. A recount was done, and again, confirmed that the two gauzes were accounted for. A hand-held wand was used to verify/confirm and it, too, alarmed. After a closer inspection of the two gauzes removed from the patient, it was noted that the green pocket that contains the RF tag/capsule was torn, and the tag/capsule was missing. The decision was made to proceed with re-entry through a 10 mm laparoscopic port to search for and retrieve the capsule. Vascular Surgery was consulted. Using fluoroscopy with a C-arm, the capsule was visualized beneath a loop of small bowel. It was successfully retrieved and removed from the abdomen. The port site was then re-closed.

Type: System, imaging, pulsed echo, ultrasonic
Manufacturer: GE Healthcare **| Brand:** IC5-9-D transvaginal probes **| UDI-DI:** 00840682108584
Model: IC5-9-D
Event: Sterile Processing Services (SPS) is cleaning the IC5-9-D transvaginal probes per GE's instructions. They have required many repairs on these probes and biomed/GE believe it's due to oversaturation of fluid. GE points to another part of the manual to refer to for cleaning the probes, however the SPS department is cleaning the specific probe per the exact recommendations.
Sterile Processing stated they will not change their process because it matches the manual. The hospital requested GE update their manual. The local GE representative points SPS to portion of manual marked

"example of probe immersion level" Sterile Processing is referring to the portion of manual specifically noted as probe immersion level for IC5-9-D probes. An update to the IFU is needed.

Type: Indicator, biological sterilization process
Manufacturer: 3M Company **| Brand:** 3m Attest Steam Integrators **| Model/Cat:** 1243 **| Lot:** GF092028
Event: We ran into several issues with our steam integrators. They are exploding while going through the sterilization process. They all appear to be the same lot; however, not all from this lot are exploding as I have 2 of these indicators from the same tray and one is fine, the other exploded.

Type: Pulse generator, permanent, implantable
Manufacturer: Biotronik SE **| Brand:** Edora 8Dr-t **| UDI-DI:** 04035479147648 **| Model/Cat:** 407145
Event: The patient has a dual-chamber permanent pacemaker that was implanted approximately 7 years ago, programmed in DDD mode (paces and senses both the atrium and the ventricle) with a lower rate limit of 60 beats per minute. During MRI reprogramming, the device demonstrated 23% atrial pacing and 49% right ventricular pacing. It was set to an MRI-conditional asynchronous pacing mode (DOO) at 80 beats per minute. After the MRI scan, the device was interrogated and showed stable lead values, after which it was reprogrammed to baseline settings. Approximately 2 weeks ago, a telemetry review revealed bradycardia with a heart rate in the 30s, along with intermittent bradycardia in the 40s to 50s, and an increased frequency of bradycardia in the 30s the day after the MRI. The patient was evaluated, and it was noted that the right ventricular pacing threshold had increased after the MRI, which is a rare complication associated with permanent pacemakers. The electrophysiology team subsequently reprogrammed the device and signed off on the case. The manufacturer and their representative were notified. A representative from Biotronik interrogated the pacemaker. The most recent pacing threshold was previously 0.6 volts at 0.4 milliseconds and is now 2.6 volts at 0.4 milliseconds, resulting in the loss of capture and the absence of pacing. The right ventricular output was reprogrammed to 5.0 volts at 0.4 milliseconds. The patient has remained asymptomatic.

Type: System, balloon, intra-aortic and control
Manufacturer: Teleflex Inc. **| Brand:** Arrow Ac3 Optimus and Arrow 40cc Catheter **| Lot:** GS52353
Event: We have been experiencing a high volume of calibration issues. This event is representative of multiple events that have occurred at our location. High calibrations may be required so that there isn't an interruption in the pump. We are experiencing an inability to obtain accurate arterial waveform & blood pressure value. Staff receive an "Excessive Optics" message on the intra-aortic balloon pump console requiring calibration of +75-100. Troubleshooting is required to obtain an alternative arterial pressure source to then compare to and calibrate the balloon pump.

Type: Powder-free nitrile patient examination glove
Type: Medical Gloves with Chemotherapy Labeling Claims - test for use with chemotherapy
Manufacturer: Bosma Industries For The Blind, Inc. **| Brand:** Bosma Enterprises, Good Works, Bosma Enterprises AloeTouch ICE **| UDI-DI:** 00818634025517, 00818634025449, 00818634025456, 00818634025463, 00818634025470, 00818634025418, 00818634025425 **| Model/Cat:** 72-50900, 72-50901, 72-50902, 72-50903, 72-50904, 72-50601, 72-50602, 72-50603, 72-50802, 72-50803, 73-20301
Lot: multiple lots from all sizes
Event: We have over 81 reports from our facilities across the country in our office regarding Bosma Gloves. Numerous facilities reported issues with the Bosma gloves of numerous sizes and lots mentioning that they are easily tearing when putting on. Other facilities reported gloves were torn when they were taken out the box, before putting them on. Other reports mentioned fingers were missing off the gloves. Numerous reports mentioned gloves were also thinner and this has caused needles to slip, increasing potential for needle sticks and harm to healthcare providers. Staff are reporting "about every 3rd glove tears when removing them from the box and many are defective coming out of the box (tears,

holes, missing 'chunks' of the glove, missing fingers, fingers/thumb located in the wrong place). This lack of quality places both the patient and staff at risk for infection. The manufacturer has offered to replace products with no improvement in quality.

Type: Powder-free nitrile patient examination glove **| Type:** Surgeons gloves
Manufacturer: Medline Industries Inc **| Brand:** Bosma Precision Touch Ice, Medline Sensicare PI
UDI-DI: 10888277347915 **| Model/Cat:** 73-20501, 73-20502, 73-20503, 73-20502, MSG9080
Lot: Multiple lots
Event: We have multiple reports throughout our facilities across the country reporting issues with Medline gloves. The reports are associated with poor quality including fusing, clumping together, stuck to one another, breaks, rips, tears, and holes. Examples of staff reporting include:

- I had gloves tear when trying to open them and then when trying to put them on.
- Gloves are coming out of box with cuffs fused together, ripped, and tearing. Housekeeping personnel and nursing personnel reported gloves "disintegrating while wearing and using cleaning supplies."
- Gloves had multiple tears coming directly out of boxes. The gloves rip easily upon donning.
- This brand of gloves is not reliable for personal protective equipment.
- I have applied the new gloves all day in several rooms. Every glove I initially put on ripped. I had to go through 1-3 pairs before I got one that did not rip. They are stuffed in the boxes so tight that when you pull a glove out, they are sticking together. When you pull the gloves apart to put your hand in, they rip.
- The gloves easily rip and are very thin. Patient care is delayed due to constantly pulling new gloves because they are all sticking to each other and then rips, or the edge of the gloves fall apart and are of poor quality. As I slide my hand in, it rips. This increases risk for fluid contamination to staff.
- Gloves are unusable. There are huge tears in them as they are coming out of the box.
- Multiple pairs of gloves tore upon attempts to separate at wrist, where the opening should be. Many gloves appear to be stuck/melted/fused together at the wrist end. Also, multiple gloves tore with attempt to don. These gloves are brittle, and the glove boxes are packed so tight initially, it is extremely difficult to remove the first 10-20 pairs without damaging the box or the gloves themselves.
- The gloves provided are not OSHA (Occupational Safety and Health Administration) standard. The gloves break during donning and during direct patient care when fluids are involved in care.
- Every shift I have worked since we began using these gloves, I have had multiple in a row tear immediately while putting them on every single shift.
- I was going to provide patient care and gloved up before entering the room. Upon wearing the gloves, noticed two holes at the tip on the third and 4th digit. This was on a med-surg inpatient unit. These are non-expired. Some of these gloves have large holes present before using them.
- Most of the gloves in the box are thrown away because they are unusable. They have tears out of the box, they are missing the cuff, fingers, they have no opening to even put your hand in, they are stuck together and cannot be opened. They tear very easily which puts medical staff at risk of being exposed to bodily fluids. There is a major safety concern and delay in care trying to find a glove that is usable. This slows down workflow.
- During surgery, sterile gloves tore without impetus. A new pair was handed to the field. These also tore when attempting to put them on via sterile technique. This occurred with the Scrub RN and all three surgeons. This placed the patient at risk for SSI (surgical site infection) due to breaks in sterility.
- Gloves in the endoscopy labs tore during a colonoscopy three times this week. Every staff member is having this problem. This occurred on one occasion with a patient who has a chronic communicable virus.

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: Emergency Response Safety Kit
Manufacturer: AirLife **| Brand:** Broselow Tape Version 3
Model/Cat: AE-4800 **| Other:** Version 3
Event: The 2025 latest Broselow Tape Version 3 has two incorrect medication dosages listed in the calculation legend. The Broselow Tape is a tool used in pediatric emergencies to help dose medications and select appropriately sized equipment. Version two was released in May 2025. In the latest version three, the incorrect dosages for Vercuonium and Flumazenil are listed on the "Calculated Basis" portion. The precalculated dosages are listed correctly in the color-coded portion. This is like the issue the manufacturer reported in a bulletin about the previous version two in May 2025. We have made several attempts to reach the vendor and have not received any responses.

PRE-RSI/RSA NEUROMUSCULAR BLOCKERS		3% HYPERtonic Saline IV/IO*	2-5 mL/kg
Rocuronium IV/IO	1 mg/kg	Mannitol IV/IO	1 g/kg
Succinylcholine IV/IO	2 mg/kg	**HYPOGLYCEMIA**	
Vecuronium IV/IO	0.1 mg/mL	Dextrose IV/IO (D10, D25, & D50) 0.5 g/kg	
POST-RSI/RSA SEDATIVES AND/OR ANALGESICS		**TOXICOLOGY (800-222-1222)**	
FentaNYL IV/IO	1 mcg/kg	Naloxone IV/IO	0.1 mg/kg
Ketamine IV/IO	1 mg/kg	Flumazenil IV/IO	0.1 mg/kg
Midazolam IV/IO	0.1 mg/kg	Charcoal PO/NG	1 g/kg

Type: Set, administration, intravascular
Manufacturer: BD Switzerland Sarl **| Brand**: Alaris **| UDI-DI**: 10885403233647 **| Model/Cat**: 10011865
Event: *This is a summary of two reports.*
Patient 1: The patient needed a 20% dextrose solution for a history of low blood sugars. The dextrose solution was spiked with our normal fluid tubing and attached to a BD extension set and a transducer. This was put into the white lumen of a UVC (umbilical venous catheter). Twenty minutes later, the UVC pressure had begun to climb very high, and the pressure alarm started ringing on the Alaris pump. Three nurses started troubleshooting to try to fix the problem. We could flush the UVC just fine, but we could not move fluid through the BD extension. We had to wait about one hour for replacement fluid to arrive to keep the lumen patent, during which time the patient was not receiving dextrose. A sugar check showed a glucose of 28, a 10% dextrose bolus was ordered and given, the 20% dextrose solution was started in a new lumen with a different fluid tubing and extension set, and a follow up sugar was 74.
Patient 2: The IV pump continued to alarm for occlusion despite trouble shooting. The VAD (vascular access department) was called to assess the IV. The VAD RN found that the round 0.2-micron filter was causing an obstruction. Fluids would not go through the filter which was causing occlusion/high pressure alarms.

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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