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

- Boston Scientific Removes Certain AXIOS Stents and Electrocautery-Enhanced Delivery Systems **2/25/26**
- Fresenius Kabi Issues Correction for Ivenix Large Volume Pump Software **2/25/26**
- Heart Pump Purge Cassette Issue from Abiomed **2/25/26**
- Olympus Removes High Flow Insufflation Units **2/23/26**
- Trividia Health Issues Correction for TRUE METRIX Blood Glucose Monitoring Systems **2/17/26**
- Medline Updates Use Instructions for Homecare Beds **2/13/26**
- Airlife Removes Certain Broselow Pediatric Emergency Rainbow Tapes and Broselow ALS Organizers **2/11/26**
- J&J MedTech/CERENOVUS Inc. Remove CEREPAK Detachable Coil System **2/5/26**
- Abbott Diabetes Care Removes Certain FreeStyle Libre 3 and FreeStyle Libre 3 Plus Sensors **2/5/26**
- Heart Pump Issue from Abiomed **2/3/26**
- Quick Link to Medical Device Recalls

Safety Communication

- Update: Risk of False Positive Lead Tests Results with Certain Capillary Blood Collection Tubes Used with Magellan Diagnostics LeadCare Testing Systems **2/3/26**

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: Prosthesis, elbow, constrained, cemented
Manufacturer: Encore Medical **| Brand:** DJO Surgical **| UDI-DI:** 00190446254553
Model: 540-01-001 **| Lot:** 838W1085 **| Cat:** 28178408
Event: During surgery, the surgeon discovered the loaner ulna tray contained an implant from a prior procedure at another hospital. The vendor representative was present, but no backup device was available. After assessing the risks and benefits, the surgical team decided to proceed. The

procedure was completed without incident, and no injury or additional treatment was required. The device is designed to remove an existing implant. In this case, a prior implant had been retained inside the tool and was not visible without disassembling the device, which is not required as part of routine checks. The implant should have been removed either during the original surgery at the outside facility or during the vendor's inspection and cleaning process. The device was delivered by the vendor, properly sterilized, and correctly set up in the operating room. This incident was not due to a failure of the surgical steam or sterilization staff.

Type: Stimulator, hypoglossal nerve, implanted, apnea
Manufacturer: Inspire Medical Systems | **Brand:** Inspire
Event: During an MRI scan, a patient with an Inspire device experienced unintended stimulation, leading to uncontrolled tongue movement and difficulty breathing despite all proper MRI safety procedures being followed. This incident caused the scan to be terminated early. The device failed. Although the investigation concluded there were no procedural errors, the lack of formal guidance from Inspire on managing such situations presents a significant gap. The report suggests broad communication and training to prevent similar incidents across all facilities. A safety training session was set up with an Inspire representative. It was determined that our procedures were correctly followed.

Type: Light, surgical, ceiling mounted
Manufacturer: Skytron **| Brand:** Aurora Surgical Light Series **| Model:** AUA5
Event: A surgical team member was adjusting the position of a boom light during the case. The in-light camera detached from the boom light and fell onto table, hitting the patient's upper arm. Biomed came to the department at time of incident to assess the light and camera. Staff found that the release button on the camera head had inadvertently been pressed, which caused the camera to fall. Biomed re-educated the OR team on different buttons on the light/camera and notified the vendor. This is the second incident of the in-light camera head unexpectedly detaching during a surgical case with these boom lights. The location and appearance of the disposable cover button and the in-light camera detect button are very similar to one another.

Type: Device, hemostasis, vascular
Manufacturer: Teleflex Inc. **| Brand:** D-STAT **| UDI-DI:** 10841156109080
Model: IPN922573 **| Lot:** 47G2400657 **| Cat:** 4000
Event: Multiple flowable hemostat packages have an additional label underneath the packaging label. The label underneath states same device, lot number, and UDI-DI; however, the expiration date listed is 7-31-2025 versus the new label placed over top is 11-30-2025.

Type: Powered laser surgical instrument
Manufacturer: Gyrus ACMI, Inc. **| Brand:** Soltive **| UDI-DI:** 00821925043985
Model: TFL-FBX200BS **| Lot:** KR485823
Event: The laser fiber caught on fire when the laser fiber was secured into the laser. Several minutes after the fiber was secured into the laser, the laser fiber caught on fire at the port site where the white plastic plugs into the laser receptacle. The laser fiber was smothered with saline and a blue towel. The fire did not reach the patient or the drapes. Laser one was pulled out of circulation placed at the OR control desk. Laser two was used for the rest of the case.

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: Clamp, umbilical
Manufacturer: Medline Industries **| Brand:** Medline **| Model/Cat:** DYNJ04220 **| Lot:** 41225040001
Event: An infant was born by Cesarean section, and an umbilical cord clamp was placed at delivery.

Approximately six hours later, a physician entered the room to assess the infant, who was being held skin to skin by the mother. When handing over the infant, the physician noted blood on the mother, sheets, and infant's clothing. The physician undressed the infant, discovered the cord clamp was not attached to the infant, and the umbilical stump was bleeding. The nurse had been in the room 20 minutes prior and no bleeding was noted. The infant required neonatal intensive care admission, Vitamin K, and blood transfusion.

Type: Ventilator, non-continuous (respirator)
Manufacturer: Fisher & Paykel Healthcare **| Brand:** Fisher Paykel **| UDI-DI:** 09420012412430
Model/Cat: BC161-10
Event: Two patients had incorrect CPAP (continuous positive airway pressure) settings. One patient had orders for a CPAP setting of 5 but it was found set at 8. The second patient had orders for a CPAP setting of 6 but it was at found set at 7. The respiratory orders were confirmed, and appropriate CPAP pressure changes were made. Staff discovered that the stick indicator which adjusts the pressure was loose on both patients' bubble CPAP circuits. Each of the circuits were immediately replaced with new ones. The CPAP probes on the new circuits were tighter and remained at the graduated pressure lines as expected. No patients were injured. We discussed the issue of loose CPAP probes with the product representative because when loose, the pressure will increase. We are now checking all new circuits for tightness before use.

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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