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 and Early Alerts

- Instrumentation Laboratories Removes HemosIL AcuStar HIT-IgG(PF4-H) **10/30/26**
- Nova Biomedical Updates Use Instructions for StatStrip Glucose Hospital Meter Systems **10/30/26**
- *Early Alert:* Medline Removes or Corrects All Medline Brand Beds and Accessories **10/29/26**
- *Early Alert:* B. Braun Removes Streamline Bloodline Set for Dialog+ **10/27/26**
- *Early Alert:* Cardinal Health Updates Use Instructions for Presource Packs Containing BD Alaris Pump Infusion Sets (updated use instructions for convenience kits containing infusion sets affected by the BD and CareFusion BD Alaris Pump Infusion Set Recall) **10/20/26**
- *Early Alert:* Cardinal Health Issues Correction for Presource Packs Containing BD Alaris Pump Infusion Sets (correction to convenience kits containing infusion sets affected by the BD and CareFusion BD Alaris Pump Infusion Set Recall) **10/20/26**
- Philips Ultrasound Issues Updated Use Instructions for Lumify Diagnostic Ultrasound System **10/19/26**
- *Early Alert:* Transcatheter Mitral Valve Delivery System Issue from Edwards Lifesciences **10/15/26**
- AVID Medical Removes Convenience Kits Affected by BD ChloraPrep Applicator Recall (removal of BD ChloraPrep applicators affected by the BD ChloraPrep Applicator Recall) **10/14/26**
- Medline Removes Convenience Kits Affected by BD ChloraPrep Applicator Recall (removal of BD ChloraPrep applicators affected by the BD ChloraPrep Applicator Recall) **10/13/26**
- ICU Medical Updates Use Instructions for IV Tubing Sets **10/5/26**
- BD and CareFusion Remove BD Alaris Pump Infusion Sets **10/5/26**
- Draeger Removes VentStar Resus Neo Hoses **10/2/26**

Link to Device Recalls & Early Alerts

Letters to Health Care Providers

- *Updated:* **Import Alert for Certain Olympus Medical Devices Manufactured in Japan** **10/20/26**
  The FDA is alerting health care providers about an import alert for certain medical devices manufactured in Japan by Olympus Medical Systems Corporation (Olympus) and its subsidiaries. Despite extensive and ongoing efforts to address compliance issues, the FDA

continues to have concerns related to outstanding Quality System regulation violations by Olympus. Therefore, the FDA has issued an import alert to prevent future shipments of certain devices from entering the United States.

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: Chair, adjustable, mechanical
Manufacturer: Stryker Corp. **| Brand:** Prime TC
UDI-DI: 07613327282665 **| Model/Cat:** 1460-000-000
Event: During a recent wheelchair inventory and assessment process, multiple Stryker wheelchairs were identified with missing buttons on the armrests. The missing locking mechanisms allow the armrests to move freely and fail to remain securely locked in place during patient use. The wheelchairs are currently in circulation and being used for patient transport within the facility. The defective armrests create instability when patients are sitting in the wheelchair or using the armrest for support during repositioning or transfers. The missing locking buttons present a patient safety concern and increase the risk of patient injury, including loss of balance during transfers, armrest collapse or unexpected movement, increased fall risk, and potential injury to patients and staff during transport or repositioning. The wheelchairs affected may not meet safe operational standards for patient use until repaired or removed from service. We are removing affected wheelchairs from patient use immediately until evaluated and repaired, inspecting all Stryker wheelchairs throughout the facility for similar defects, developing a process for routine wheelchair safety inspections to identify defective equipment proactively, and replacing missing locking components or remove unsafe wheelchairs from circulation. This issue may affect other facilities because the same model Stryker wheelchairs are utilized throughout multiple medical centers and outpatient clinics. If the locking armrest buttons are subject to wear, breakage, or detachment over time, other facilities may also have wheelchairs with similar defects currently in circulation. This creates a potential system-wide patient safety concern related to wheelchair stability, patient transfers, and fall risk.



Type: Intrauterine tamponade balloon
Manufacturer: Cook Incorporated **| Brand:** Bakri **| UDI-DI:** 00827002590946
Model: G59094 **| Cat:** J-SOS-100500-V
Event: The patient was taken to the operating room for a postpartum hemorrhage where a uterine balloon was placed under general anesthesia and ultrasound guidance. Staff instilled 500 cc of fluid and confirmed inflation digitally and by ultrasound. The patient was taken to the post anesthesia recovery unit for recovery. The obstetric team was called to the unit by staff, sharing that they were trying to flush the balloon. Approximately one hour after the conclusion of surgery, there was approximately 550 cc of watery blood appearing in the Bakri bag raising concern for continued bleeding and possible disseminated intravascular clotting. An ultrasound was performed and noted the balloon was deflated without any evidence of fluid on bed. The balloon was removed and was intact. Testing did not reveal a defect of the balloon itself;

however, the team concluded based on clinical presentation that the fluid in the bag was the fluid from the balloon. There may be an internal defect allowing the fluid to come out into catheter connected to bag.

Type: Set, tubing, blood, with and without anti-regurgitation valve
Manufacturer: Fresenius Medical Care **| Brand:** Combiset **| Model/Cat:** 03-2722-9
Lot: 25PRO1123, 23BR01023, 24JRO1113, 15LR01180, 15LR01220,15JR01305, 15KR01255, 15DR01185
Event: During pre-treatment safety checks in the hemodialysis unit, staff identified cracks on the arterial side of the Fresenius Combi Set blood tubing just below the medication port on multiple sets. At least one set exhibited 200-300 mL of saline leakage during priming. These defects were detected before patient connection. No direct patient harm occurred, and all affected sets were removed from service. The defect appears related to the lot numbers and not related to user error. Concerns were raised that some micro-leaks could go undetected, possibly leading to blood loss and hemodynamic instability, risk of air embolism, bloodstream infection, and interrupted or incomplete dialysis treatment. No alternative causes for the decreased fluid levels were identified.

Type: DNA-reagents, Neisseria
Manufacturer: Roche Molecular Systems **| Brand:** cobas PCR Media Dual Swab Sample Kit
UDI-DI: 00875197005738 **| Model/Cat:** 07958021190 **| Lot:** N24780, P01919
Event: Staff were checking expiration dates on the swab kits and found a vial inside the kit had a crystalized "crust" where the cap meets the tube. The cap is tight and not actually leaking. Staff checked inventory and identified multiple lot numbers affected by leaking and crystallization. Approximately thirty tubes are affected. All affected products were pulled from use. We contacted the manufacturer. The Roche representative reported this is a known issue and is being investigated, but that the investigation could take up to a year. He asked that we inspect tubes carefully before using them.

Type: Tube, tracheal (w/wo connector)
Manufacturer: Avanos Medical **| Brand:** Avanos Endotracheal Tube
Model/Cat: 35214 **| Lot:** CM3009002
Event: Upon reviewing a newly intubated patient’s chest x-ray, the physician was unable to see any radio-opaque stripe indicating the position of the endotracheal tube. The radiopaque stripe on the orogastric tube was apparent on both x-rays that were obtained but neither film revealed the position of the endotracheal tube. The radiologist confirmed that the endotracheal radiopaque stripe was not visible.

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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