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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

- Navajo Manufacturing Co. Removes Handy Solutions Neck & Shoulders Heating Pad **3/25/26**
- Bloodline Set for Hemodialysis Systems Issue from B. Braun Medical **3/25/26**
- Erbe USA Removes Flexible Cryoprobes **3/25/26**
- Insulin Pump Issue from Insulet **3/18/26**
- Surgical Stapler Issue from Intuitive Surgical **3/18/26**
- Vantive Updates Use Instructions for Prismaflex and Oxiris Sets **3/16/26**
- Integra LifeSciences Removes Tuohy Needle **3/16/26**
- Insulet Initiates Voluntary Medical Device Correction for Certain Omnipod 5 Pods **3/13/26**
- Integra LifeSciences Removes Certain MediHoney and CVS Wound and Burn Products **3/6/26**
- Medline Industries Removes Reprocessed Electrophysiology and Ultrasound Catheters **3/5/26**
    - Product lots identified in this communication should be returned to Medline Industries
    - Product lots identified in this expanded communication should be destroyed after recall actions are completed
- Quick Link to Medical Device Recalls and Early Alerts

Safety Communication

- *Update:* FDA Encourages the Public to Follow Established Choking Rescue Protocols **3/4/26**

Announcements

FDA Updates Lists of Medical Devices Incorporating Digital Health Technology

The U.S. Food and Drug Administration (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
- Sensor-based digital health technology

The FDA lists are not comprehensive resources of medical devices that incorporate digital health technology. Instead, they include medical devices that have been identified primarily based on information provided in the summary descriptions of their marketing authorization documents. The FDA updates these lists periodically.

FDA Issues Final Guidance on Medical Devices with Indications Associated with Weight Loss

The U.S. Food and Drug Administration (FDA) issued a final guidance titled ***Medical Devices with Indications Associated with Weight Loss – Premarket Considerations***. This final guidance provides:

- Recommendations for the non-clinical testing to support premarket submissions for these devices.
- Recommendations about clinical study design for these devices.
- Discussion on how the FDA considers the benefit-risk analysis to support such indications.

Read the Guidance

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: Transducer, pressure, intrauterine
Manufacturer: Clinical Innovations **| Brand:** Koala **| UDI-DI:** 00814247020178
Model/Cat: IPC-5000E **| Lot:** 251682
Event: A pregnant patient at 39 weeks gestation labored with Pitocin and was dilated at 5cm for a while. The physician artificially ruptured her membranes and then went to place a IUPC [intrauterine pressure catheter]. The physician indicated that the IUPC was very tough to advance initially, almost like the catheter was stuck in the introducer. Adequate catheter placement required more manipulation than normal, increasing the risk of uterine and placental perforation. According to the physician, this has been an issue she consistently has been encountering with the Koala IUPCs even though there has not been a product change. She was eventually able to adequately place the catheter. The patient eventually ended up having a cesarean section. The IUPC did not cause any harm.

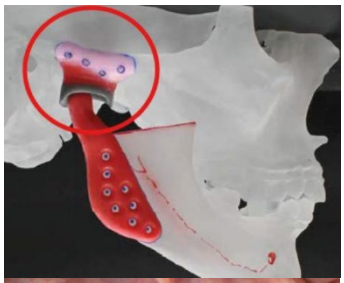
Type: Transducer, pressure, intrauterine
Manufacturer: Clinical Innovations **| Brand:** Koala **| Model:** IPC-500 **| Lot:** 251598
Event: During placement of an IUPC [intrauterine pressure catheter], the provider noted the device was difficult to advance in the uterus. The patient ended up requiring a cesarean section for fetal well-being and upon entering the uterus, it was found to be filled with blood and clots. There was concern about a potential placental laceration.

Type: System, thermal regulating
Manufacturer: Gentherm Medical **| Brand:** Blanketrol III
Event: A patient presented to the OR for breast reconstruction surgery. A Gentherm Blanketrol (fluid-circulating underbody warmer) was placed underneath the patient to help maintain temperature. The procedure lasted approximately 9.5 hours and was uncomplicated. Two days post-op, the patient reported increasing buttock pain with extensive darkening of the skin. The wound was assessed and determined to be a full thickness burn likely attributed to prolonged contact with the underbody warmer. The wound required non-surgical treatment and left permanent scarring that the patient may elect to have surgically corrected in the future. A review of the event noted that the IFU [instructions for use] for the Gentherm Blanketrol, as well as other warmers, includes a warning that skin checks should be performed every 20 minutes while in use. This is not feasible during a surgical procedure and cannot reliably be implemented. The specific device was not pulled out of service at

the time of the surgery since the team was not aware of the issue until a few days post-op. The hospital had two of these devices and both were sent back to the manufacturer for assessment. No issue was identified. The device does not have an internal memory so no logs of settings from the time of the surgery could be reviewed. No unique factors about the procedure, patient, or other devices in use were identified that may have contributed to the burn. The IFU includes a warning to check skin every 20 minutes which is not feasible in the OR setting. IFU states "At least every 20 minutes, or as directed by physician, check patient's temperature and skin integrity of areas in contact with blanket."

Type: Device, hemostasis, vascular
Manufacturer: Terumo Medical **| Brand:** Angio-Seal **| UDI-DI:** 00389701011820
Model/Cat: 610130
Event: A patient with an alpha-gal allergy had a cardiac catheterization and post-procedure the Angio-Seal vascular closure device was used. With an alpha-gal allergy, the consumption of mammalian meat will trigger an allergic reaction. The patient cannot receive collagen derived from mammals. The allergic symptoms can include itchy rash, nausea, vomiting, diarrhea, cough, difficulty breathing, drop in blood pressure. Once discharged, the patient began to investigate the angio-seal components. The patient realized the Angio-Seal collagen is derived from bovine. The patient guide to the Angio-Seal mentions a small amount of collagen is positioned on the outer wall of the artery and that the device will dissolve in 90 days. The patient went to a hospital specializing in alpha-gal allergies for removal of the angio-seal. The patient had to have a femoral cutdown and the provider noted it was worst inflammation they had seen. When the patient contacted our facility, the Angio-Seal packing was reviewed, and it does not mention collagen on the package. The only mention of collagen is in the patient's guide. The medical team does not use the patient guide because it is given to the patient at discharge.

Type: Joint, temporomandibular, implant
Manufacturer: TMJ Solutions **| Brand:** TMJ Concepts Custom Bilateral Implants
Event: The patient underwent temporomandibular joint (TMJ) arthroplasty with a custom total joint replacement (TJR) prosthesis. At the time of the procedure, all patient-specific cutting guides and prosthetic components were verified pre-operatively and noted to fit appropriately intraoperatively. Post-operatively, the patient was observed to have a right-sided posterior open bite which was not the planned bite from surgery. The occlusion was noted to approximate with gentle digital superior repositioning of the mandible. The patient was compliant with post-operative instructions. Twenty seven days after surgery, the surgeon was contacted by representatives of TMJ Concepts/Stryker and informed that the right TMJ fossa component implanted during the index procedure was not the patient-specific component fabricated for the patient, but rather a component manufactured for another patient on the same production date, meaning that the incorrect prosthetic component was installed into the patient. The remaining cutting guides, models, and prosthetic components were confirmed to correspond to the patient. The prosthesis was contained in a sterilization bag labeled with the patient's demographic information, suggesting that the error likely originated at the manufacturing facility. The same day, the patient was notified via a virtual visit with the family. The plan for this patient is to undergo revision surgery once TMJ Concepts/Stryker manufactures and ships a new glenoid prosthesis, which may take anywhere from 6-12 weeks.



Type: Dura substitute
Manufacturer: Integra Lifesciences | **Brand:** Integra Duraflex **| UDI-DI:** 10381780511359
Model/Cat: BP10608, BP10405 **| Lot:** NZA21430152, NZA24360003
Event: *This facility has submitted multiple reports for this device.*
Event 1: The patient underwent an initial dural graft implantation using a dural graft. Fifty-nine days post-implant, the patient required a revision surgery due to a cerebrospinal fluid leak and pseudo

meningocele caused by ruptured a suture patch. During this first revision, the surgeon implanted a second DuraFlex Graft. Fifteen days after the second patch implantation, the patient returned to the operating room for a second revision surgery. Intraoperatively, the previously implanted patch was found to be translucent and very thin, with a defect through which cerebrospinal fluid was actively leaking. The patch was removed in its entirety and replaced with a different product by the treating provider. The Integra representative was aware of failures and failed to notify the surgeons or the medical center.
Event 2: Patient underwent initial dural graft implantation. Thirty-four days post-implant, the patient was taken back to the operating room for diagnosis of a cerebrospinal fluid leak and pseudo-meningocele. Intraoperatively, the edges of the patch appeared to be disintegrating in certain areas and cerebrospinal fluid could be seen coming out. Those points were sutured again to the dura and multiple Valsalva maneuvers were performed, with no further cerebrospinal fluid leak identified. The suture line was augmented with surgical glue. Fifty-seven days after the initial implantation, the patient returned to the operating room for a second revision surgery. During this procedure, the previously implanted patch was no longer white but translucent and had a hole in the patch with egress of cerebrospinal fluid. The patch was removed in its entirety and replaced with a different product by the treating provider. Integra rep knew about the issue and never notified the surgeon or the medical center.

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.

Device 1 **Type:** Set, administration, intravascular
Manufacturer: Nexus Medical **| Brand:** IV Plus **| Lot:** 23322 **| Cat:** N8068
Device 2 **Type:** Set, administration, intravascular
Manufacturer: B. Braun Medical **| Brand:** Infusomat | **Model/Cat:** 490100 **| Lot:** 0062029379
Device 3 **Type:** Set, administration, intravascular
Manufacturer: BD Switzerland **| Brand:** Alaris **| Model/Cat:** 10011865
Device 4 **Type:** Transducer, blood-pressure, extravascular
Manufacturer: ICU Medical **| Brand:** ICU Medical | **Model/Cat:** 42586-05
Event: The Neonatal Nurse Practitioner was called to the bedside to assess the patient's left arm and arterial line. Mottling was noted throughout the arm, chest, and back along with decreased perfusion to the left hand. The arterial line was removed. Ultrasounds obtained of the left upper extremity and head. A large amount of air emboli was seen on the head ultrasound. The patient had worsening lactate acidosis after receiving medications and intubation. Repeat ultrasounds, CT, and an MRI indicate extensive brain injury.

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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