MedSun
Medical Product Safety Network

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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In This Issue:

About the MedSun Program:

The MedSun Program, which was launched in 2002 by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), involves the reporting of problems with medical products from a network of approximately 300 hospitals, nursing homes and home health facilities around the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products. MedSun utilizes a secure, on-line system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

Those who are interested in having their healthcare facilities join MedSun may contact medsun@fda.hhs.gov or 800-859-9821 for additional information.

Newly Approved Devices

Recently Approved Devices (searchable listing):

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm596872.htm

Premarket Approval Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm595393.htm

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm589381.htm

In Brief

As of October 27 2021

For the FDA Enforcement Report containing the most recent Class I, II and III recalls, go to http://www.accessdata.fda.gov/scripts/ires/index.cfm

If you see any problems of the type described in these announcements or other device safety issues, please report them through the MedSun reporting system at https://medsun.fda.gov as soon as possible. If you need password information or want to report by phone, please call us at 1-800-859-9821 or e-mail at medsun@fda.hhs.gov.

Recalls and Safety Alerts

Cook Medical Issues Voluntary Recall of Transseptal Needle and Transseptal Needle with Catheter

October 19, 2021

Cook Medical issued a global, voluntary recall of the Transseptal Needle and the Transseptal Needle with Catheter. This recall includes all unexpired lots for both of these products. The needles were recalled due to complaints of rust on the products. Use of affected products could result in increased procedural time and inflammatory reactions, including systemic reactions which may lead to permanent impairment or death.

A complete list of products affected by this recall can be found below:

Product Brand Name	Intended Use	Reference Part Number (RPN)	Order Number (GPN)	Lot Number/ UDI	Range of Manufacture Dates for Affected
Transseptal Needle	Intended for transseptal left heart access in both diagnostic and interventional proce-	TSNC-18-71.0	G02364	All	October 2, 2016 – July 22, 2021
		TSNC-19-56.0	G02365		
Transseptal Needle with Catheter	Intended to facilitate transseptal entry into the left atrium	TSN-17-75.0-ENDRYS	G19261	All	

Class I Recall: MEDTECH SAS Recalls ROSA One 3.1 Brain Application for a Software Anomaly

October 25, 2021

MEDTECH SAS has become aware of a software anomaly affecting the ROSA One 3.1 Brain application, which led to the inaccurate placement of an electrode during surgery. The device is intended to be used by trained surgeons during brain and spine surgeries to determine the spatial position and orientation of instrument holders and/or tool guides, which are being used to guide standard surgical instruments.

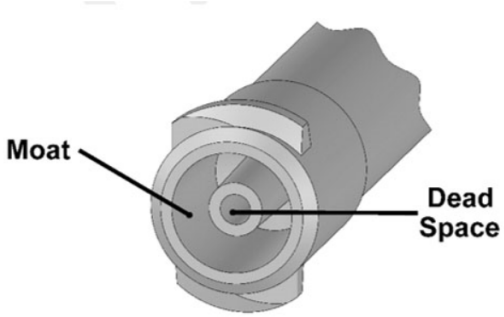
The firm has received 3 global complaints related to the issue. An incorrect trajectory could result in serious injury or death if undetected during surgery.

The firm has issued Urgent Medical Device Correction letters to affected consignees with details on what actions may lead to the identified issue.

Potential for Medication Overdose with ENFit Low Dose Tip Syringe: FDA Safety Communication

The FDA is informing patients and health care providers about the potential for overdose, under certain clinical use conditions, when using ENFit low dose tip (LDT) syringes.

The FDA is aware of the potential for overdose if the user does not clear the moat area around the tip of the ENFit LDT syringe before administering a medication. The moat area is unique to the design of the ENFit LDT syringes. The FDA is providing recommendations for patients and health care providers to promote the safe use of ENFit LDT syringes, including steps users can take to optimize dose accuracy.



Recommendations for Health Care Providers, Patients, and Caregivers

To optimize dose accuracy using ENFit LDT syringes, users should:

- Ensure the syringe is free of air bubbles and the moat of the syringe is free from fluids by tapping or flicking the tip of the syringe before administering the medication.
- Use a filling adapter, such as an ENFit compatible cap or medication straw, to prevent fluid and medications from entering the moat area of the syringe tip.
- Be aware that using a medicine cup to fill may cause fluid or medications to enter the moat of the syringe and lead to possible overdose.
- Use a new syringe to flush the medication or fluid after administering any medication to prevent overdose due to the dead space (remaining fluid in the tip of the syringe after administration) in the syringe.

The FDA continues to recommend the use of enteral devices and syringes that reduce the risk of misconnections, such as ENFit LDT syringes.

To read the full letter, please visit FDA's website.

Do Not Use Needle-Free Devices for Injection of Dermal Fillers – FDA Safety Communication

The FDA is warning the public and health care professionals not to use needle-free devices such as hyaluron pens for the injection of hyaluronic acid (HA) or other lip and facial fillers, collectively and commonly referred to as dermal fillers or fillers.

The FDA is aware of serious injuries and in some cases, permanent harm to the skin, lips, or eyes with the use of needle-free devices for injection of lip and facial fillers.

Recommendations for Health Care Providers

- Be aware that needle-free devices for injection of dermal fillers are not approved by the FDA.
- Do not perform any aesthetic filler procedures with needle-free injection devices.
- Do not use injectable filler products that are not FDA-approved dermal fillers.
- Do not transfer FDA-approved dermal fillers into needle-free injection devices.
- Be aware that FDA-approved dermal fillers are supplied by prescription for injection by a licensed health care provider using a syringe with a needle or cannula.

If you encounter a patient who has experienced adverse effects from a procedure that involves the use of needle-free devices to inject fillers, please consider filing a report through the FDA's voluntary reporting webpage, MedWatch, the FDA Safety Information and Adverse Event Reporting program.

Risks Associated with Needle-Free Devices Used to Inject Lip and Facial Fillers

Needle-free injection devices for aesthetic purposes do not provide enough control over where the injected product is placed. Lip and facial filler products sold directly to consumers online may be contaminated with chemicals or infectious organisms.

Additional risks may include:

- Bleeding or bruising
- Infection
- Transmission of disease between people who use the same device
- Blockage of a blood vessel, leading to tissue death, blindness, or stroke
- Scarring
- Damage to eyes from the pressure
- Formation of lumps in the skin
- Discoloration of the skin
- Allergic reaction

Complications may require immediate medical attention by a licensed health care provider. Some complications may not be reversible. To read the full safety communication please visit FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during October 2021. The reports are displayed within clinical specialty areas based on analysis of the information submitted. The reports are presented as submitted by MedSun Representatives and in some instances have been summarized and/or edited for clarity.

A database of all MedSun reports can be found at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm

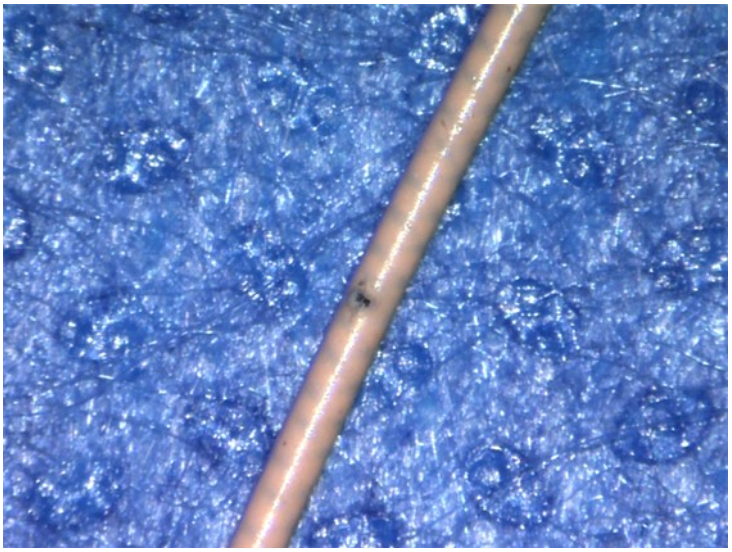
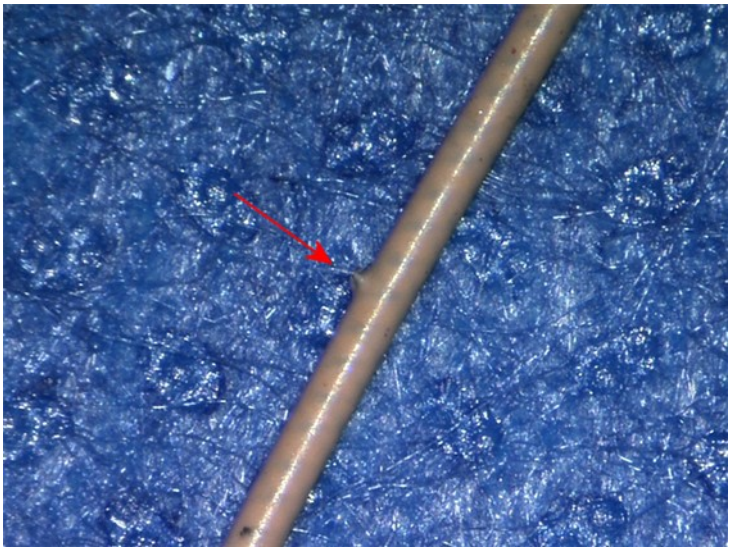

Special Note:

The lollipop icon distinguishes highlighted reports that 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. 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	Manufacturer	Problem
Pump, Infusion, Elastomeric Brand: Homepump C-series Elastomeric Pump Model#: 5FU C series Lot #: 30117471	Avanos Medical, Inc.	Patient was sent home with 46 hour 5FU Avanos Home Pump C -Series. When patient returned to have pump removed, noted white substance on tubing filter related to chemo leaking.
Tubes, Gastrointestinal (and Accessories) Brand: Kangaroo Nasogastric Feeding Tube, 5GWeighted Tip, Rigid Port, Stylet Model#: 8884721088 Lot #: 2028702864 Cat #: 8884721088	Covidien LP	The 10Fr gastric feeding tube placed. After a nurse tried to pull guide wire, the green cap on the end of the wire came off on the first pull. The wire itself would not dislodge from the tube even after putting fluid in the side port to activate lube, and using kelly clamp to pull wire. Feeding tube had to be pulled out and replaced with another. So customer had to have another feeding tube placed and get another x-ray exposure. Unfortunately, this feeding tube was discarded by the nurse and is not available for return. A different nurse placed the next feeding tube, wire was checked prior to placing and was free. After placement again when wire was attempted to be removed, the green cap came off on the first pull (wire was barely pulled on) the wire cut nurse's glove and finger. Again, the wire was stuck, much manipulation, pulling with kelly clamp, much water to side port to loosen wire. Finally released. The nurse indicated that they have never had a wire cap come off before, and never had this difficulty with the wire coming out. This feeding tube was saved and is available for inspection upon request.

Device	Manufacturer	Problem
Analyzer, Gas, Carbon-dioxide, Gaseous-phase Brand: Capnostream 35 Model#: PM35MN	Medtronic	While monitoring a patient for EtCO2 the respiratory therapist (RCP) noted a low battery message on the EtCO2 monitor. The therapist noted that the monitor was connected to AC power but there was not an AC connected indication on the monitor. The RCP located and attempted to exchange the monitor but noted the same issue and the second monitor. The RCP continued the search and found an operational monitor and exchanged with the defective monitor in order to continue monitoring patient's EtCO2. An additional check of the Capnometers found an additional monitor that would not indicate unit plugged into AC and charge. Units sent to Biomedical for repair and reporting. Biomedical found that a previous MedWatch was filed on the same manufacture/model with the same issue.
Device, Hemostasis, Vascular Brand: Perclose Proglide Model#: 12673-03 Lot #: 1081041 Cat #: 12673-03	Abbott Vascular, Inc.	Per post-procedure note. Left ventriculography was performed. The catheter was aspirated and flushed and pullback pressures were recorded. A J-wire was then placed up into the abdominal aorta and the sheath was gently pulled back across the right iliac artery where there was a gradient of approximately 20-25 mmHg. A PERCLOSE PROGLIDE 6F suture-medicated closure system was then placed. The sutures appeared to capture, but the foot did not fully flatten out and could not be pulled out from the femoral artery without substantial pain. Multiple attempts made to readjust the feet of the PERCLOSE PROGLIDE 6F suture-medicated closure device, but all of them were unsuccessful in removing it. A STAT vascular consult was obtained. Manual pressures held and patient prepped for transport to operating room for open repair of the right common femoral artery. Per post-op note. The common femoral artery was dissected free as well as the profunda femoris and superficial femoral arteries. At this time it was apparent that there was a dissection due to the purple discoloration and the hue of the artery in the iliac artery. The inguinal ligament was mobilized to provide more exposure and to avoid making an abdominal incision to get proximal control. This dissection within the artery continued proximally up to the takeoff of the external iliac artery from the common iliac artery. The external iliac artery was then dissected free and this was encircled with a vessel loop. There was also an injury to the femoral vein. The repair was done using interrupted sutures of 6-0 Prolene. Once the patient was therapeutically anticoagulated clamps were placed both proximally and distally. An arteriotomy was made using an 11 blade and Potts scissors were utilized to carry the arteriotomy both proximally and distally form the device. There was a large amount of plaque and the footplate of the ProGlide device was caught in the plaque causing the dissection. The device was removed and sent to pathology. Upon inspection, the device and the footplate was still attached to the device and not within the patient. Given the extent of the injury and the amount of plaque, an iliofemoral endarterectomy was completed. Patient had 7-day stay and discharged home with wound vacuum and HomeHealth.

Device	Manufacturer	Problem
Bed, Ac-powered Adjustable Hospital Brand: Intouch Model#: 2141 Cat #: 2141-PX2-000	Stryker Corporation	We have received numerous service calls on our Stryker Intouch Zoom beds. The number one call is the bed will stall or shut down. After trying different battery vendors and going back to the Manufacturer's recommended battery, no battery performed on a consistent basis in correcting the issue. We actually shorten our preventative maintenance frequency from the manufacturer's two year schedule to a once per year schedule. When switching to the one year we would see some improvement initially but then return to numerous calls on beds stalling. Our technicians noticed all the batteries that were being used would have to have the wire connector bent almost to a 90 degree position to fit in the battery component. The technician ordered a different battery that allowed a flat connection point that eliminated this bent position. One bed was trialed with this new battery configuration and no stalling was reported. With the beds coming up for their annual preventative maintenance, we replaced all the batteries with this new battery configuration. We have reduce dramatically the number of service calls related to beds stalling.
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: BD Insyte Autoguard Model#: 382544 Lot #: 1090021 Cat #: 382544	Becton, Dickinson, and Company	Nurse discovered IV catheter had mold inside the package and she did not open the package. The nurse immediately reported it to Quality & Safety. All lot numbers were sequestered.
Pump, Infusion, Enteral Brand: Kangaroo Model#: 382400 Cat #: 382400 	Cardinal Health, Inc.	A: My patient has been vomiting excessively throughout my shift, which is baseline for him, while he is waiting for his G-tube/Nissen. I've (RN) had him two previous nights, but I noticed he is having more emesis tonight. B: His feed is running at 20mL/hr on a Kangaroo pump. They increased his feeds from 19mL/hr to 20 mL/hr in the past 24 hours. I thought he was having more emesis because of the increase in volume. C: I have measured out my milk for the entire shift and calculated how much I needed to prep and warm every 4 hours. I noticed that my kangaroo pump bag was getting emptier faster than usual, but I thought I just did my math wrong. However, at 0630, I noticed that my Kangaroo bag was empty again and I realized that I only have 60 mL of milk left in the fridge (formula that is made by Dietary) and I knew it wasn't right. I traced my lines all night to make sure the connections were tight and secure. I think the kangaroo pump was overfeeding my patient and causing him to have increased emesis. D: I red-tagged the Kangaroo pump and ran his feeds on a syringe pump. Technician's Comments: Found unit on during rounds with red tag indicating "loud beeping says "possibly over feeds". Checked unit's condition and performed unit verification. All tests passed. Returned to service.

Device	Manufacturer	Problem
		Please note: IFU, Section II, Safety and Warnings #14 – "premature infants may require higher accuracy rates than specified for this enteral feeding pump" This event caused minimal temporary harm.
Agent, Injectable, Embolic Brand: Apollo Model#: 105-5095-000 Lot #: B189389	Micro Therapeutics, Inc.	Patient underwent a cerebral angiogram and ethylene-vinyl alcohol copolymer (EVOH) embolization. While injecting the embolic agent during the procedure, the agent was observed to be coming out of the catheter at a point proximal to the tip, which led to a stroke. Patient is currently reported to be stable but guarded. Post procedure, the catheter was examined under a microscope and a small hole was found about 6cm from the tip.  
System, Imaging, Pulsed Doppler, Ultrasonic Brand: Epiq 5	Philips Ultrasound, Inc.	Philips EPIQ ultrasound crashed in the middle of a case and would not power back up immediately. Device had to be reset before it would come up again for use, almost certainly related to a software issue. Device runs software version 2.0.3, and per Philips: the only more "stable" software versions to fix the issue require an upgrade to a newer software version, which the manufacturer has not released for free. Upgraded software versions that fix the issue must be purchased by the hospital.

Links to FDA/CDRH Databases and Other Information Sources

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Device Listing: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.

Establishment Registration: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This is a searchable database of U.S. and foreign establishments engaged in the manufacturer, preparation, propagation, compounding, assembly, or processing of medical devices for U.S. distribution. Note: This database is updated once a month.

Human Factors Website: http://www.fda.gov/medicaldevices/deviceregulationandguidance/humanfactors/default.htm. This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Luer Misconnections Website:
https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/medical-device-connectors
This site provides information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other facilitated by the use of Luer connectors.

MAUDE (Manufacturer and User Facility Device Experience): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Medical Device Safety Website: http://www.fda.gov/medicaldevices/safety/default.htm
One-stop for safety information with links to published safety tips and articles, archived patient safety news programs, safety alerts, recalls, and a link to report a device-related problem.

MedSun Website: https://medsun.fda.gov/
This site provides patient safety information via current and past issues of the MedSun newsletter, educational materials, and search capability for MedSun adverse event reports.

Premarket Notifications [510(k)]: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
This database of releasable 510(k) s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information are available via the web interface for more recent records. The database is updated monthly.

Premarket Approvals (PMA): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
This database of premarket approvals of Class III devices may be searched by a variety of fields and is updated on a monthly basis.

Product Classification: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
This database can be used to determine the classification of a device and the regulations it is subject to.

Warning Letters: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
This database contains the most recent manufacturer warning letters.

To access additional newsletter articles, including a selection of recent MedSun Reports and product-related and patient safety-related information, go to www.fda.gov/medsun

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