U.S. FOOD & DRUG ADMINISTRATION

MedSun Medical Product Safety Network

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The MedSun Program, which was launched in 2002 by the 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 reporting system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

Highlighted Reports

- **The reports that follow represent a cross section of device related events sent by MedSun Reporters during the prior month. The reports are presented as submitted by MedSun Representatives and in some instances, have been summarized and/or edited for clarity.**

MedSun Report Database

Type: Pump, Infusion, Elastomeric
Manufacturer: Avanos Medical, Inc.
Brand: On-Q Pain Relief System With Select-a-flow
Model #: 13472; **Lot #:** 30179495, 30196274, 30215900; **Cat #:** CB004
Event Descriptions:
Event1: On-Q pump ran out in 30 hours instead of expected 55 hours. Pump has been returned and is currently under evaluation. Dial was set at appropriate prescribed rate of 10 ml/hr. Clamp was open and all appeared to be visibly intact as expected. Patient reported nausea and balance issues, which is thought to be likely a side effect of the faster infusion.
Event2: Patient's On-Q pump was still half full when it was time to be removed. Rate dial set at programmed rate. Infusion clamp was open.
Event3: Patient went home with an On-Q and the pump is not infusing. The pump has been connected for 24 hours and the patient says it has not decreased in size at all. Rate dial verified. Patient instructed to bring pump back for return visit.

Type: Unit, Phacofragmentation
Manufacturer: Alcon Laboratories, Inc.
Brand: Centurion Ozil Handpiece
Model #: 8065751761; **Cat #:** 8065751761
Event Description: When the pedal was pressed for the phaco to start, the occlusion bell rang and a white cloudy material emanated from the phaco tip in the eye. The pedal was pressed again and more cloudy material appeared around the corneal wound. Alcon Centurion's instructions for use (IFU) does not indicate the device should be tested prior to use. However, the Cleaning Flashcard given by the representative does state the device should be tested before use. This reporter recommends the company should add a statement in the IFU that the device should be tested before being used. Device has 400 uses as its limit, yet the company should disclose this with the product label to help support the IFU. In addition, the manufacturer's IFU instructs the user to use an "Auto

Wash Kit", but the Auto Wash kit is not available in the USA. Also, only water is allowed to be used to clean and no solvents because of residue risk. Therefore, there is significant concern of being unable to adequately clean the device.

Type: Electrode, Depth
Manufacturer: Dixi Medical
Brand: Microdeep
Model #: Microdeep Depth Electrode; **Cat #:** D08-12AM; **Other #:** part number D08-12AM
Event Description: Patient had bilateral stereotactic depth electrode placement to monitor seizures. A total of eight electrodes were placed on the left and one electrode on the right. Neurosurgery removed a right lateral loose lead during rounds and covered the area with skin closures. Patient went to the OR for removal of left-sided DIXI SEEG depth electrodes and bolts and a left-sided craniotomy for placement of a subdural grid and strip electrodes. Eight left electrodes were removed. Patient went for a CT which showed a partially retained right electrode and left electrode. Patient went back to the OR for a right-sided burr hole to remove the retained stereo-electroencephalography DIXI depth electrode. The retained left electrode is under the subdural grid that was placed and will be removed at the same time the grid is removed. It is thought that the electrodes broke after the patient had a violent seizure.

Type: Device, Hemostasis, Vascular
Manufacturer: Cardiva Medical, Inc.
Brand: Vascade MVP Venous Vascular Closure System
Lot #: G612C220907B
Event Description: Patient was taken to cardiac cath lab with an ST elevation myocardial infarction. MD obtained two venous accesses and placed two venous sheaths. The third time, MD engaged an artery and then placed a third sheath. Through this third sheath, MD did some diagnostics, treatments, placed a stent, and placed a heart pump. When all that was done, MD turned his attention back to the venous sheaths. One was used for a central line; and the other MD attempted to close it using a VASCADE Venous Closure System. The VASCADE VCS got stuck in the common femoral vein and surgical staff could not get it out. The patient was stable at that point—patient had already had three pulseless electrical activity arrests and achieved return of spontaneous circulation prior to Cath lab intervention. The MD did not feel that the foreign object in the common femoral vein would present an imminent compromise for the patient, so MD left the VASCADE device in place in the common femoral vein with a figure-of-eight stitch. The patient died soon after this procedure while on four vasopressors, having hypotension and bradycardia from a junctional escape rhythm. After discussion with family, all drips and the heart pump were turned off and patient expired.

Type: Orthopedic Manual Surgical Instrument
Manufacturer: Depuy Mitek, LLC
Brand: ExpreSew II and III
Model #: 214141; **Lot #:** 66895; **Cat #:** 214141
Event Description: This device uses a disposable needle. We got a couple of boxes that were identified (later on after we had problems) as being a "bad Lot." A plastic piece breaks off and the needle gets stuck in the ExpreSew and no longer functions until you get the needle out. A new one has to be opened and we have to carefully remove the needle from the instrument. Luckily the needle did not break off in the patient and shards didn't get lost in the joint, which could have happened. We had to then make sure we had an alternative at the hospital. We were unaware of any alternatives at the time, and it caused the surgeon great stress and anxiety both because of the patient's safety and also not having what is needed to complete surgery.

Type: Stimulator, Autonomic Nerve, Implanted For Epilepsy
Manufacturer: Livanova USA, Inc.
Brand: Vagus Nerve Stimulator Battery
Event Description: The patient reported they no longer had sensation that the vagal nerve stimulator was firing. Patient went to OR for revision of the stimulator. Findings during the surgical procedure: functional lead with a loose connection to the generator. Due to a possible malfunction of the locking screw, it was replaced, and a new model 1000 generator and torque wrench was used to tighten and lock the lead.

Type: Accessories, Photographic, For Endoscope (Exclude Light Sources)
Manufacturer: Ambu A/S
Brand: Ambu aVIEW 2Advance
Model #: 405011000; **Cat #:** 405011000
Event Description: Patient status post right redo microvascular decompression with glycerin rhizotomy was recovering when the anesthesiologist was doing rounds. During the conversation, the Ambu aView 2 Advance endoscopy monitor was placed on a trash can at patient bedside when it fell to the ground. Upon impact the monitor started to smoke and spark. The resident threw a blanket over the smoking/sparking monitor when it caught fire. The RN at the bedside retrieved the fire extinguisher and put out the flames; fire alarm was initiated. The AMBU aVIEW 2 Endoscopy monitor shorted, sparked and smoked upon impact to the floor causing the unit to be filled with electrical smoke. There were also remnants of chemical dry foam from the fire extinguisher that was used on the unit to put out the smolder from the device.

Neonatal & Pediatric Reports

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.

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: Tubes, Gastrointestinal (And Accessories)
Manufacturer: Avanos Medical, Inc.
Devices 1-3
Brand: MIC-KEY Gastrostomy Feeding Tube Kit
Lot #: 30216521; **Cat #:** 8140-12-1.0
Lot #: 20036013; **Cat #:** 0120-12-1.7
Lot #: 30215121; **Cat #:** 0120-12-1.0
Device 4
Brand: MIC-KEY Gastrostomy Feeding Tube Kit, Secur-lok Extension Set w Enfit Connector
Lot #: 30206832; **Cat #:** 0120-12-1.2
Event Description: We have had four MIC-KEY buttons rupture in the last two months. All four balloons ruptured or had a pinpoint hole.

Type: Trap, Sterile Specimen
Manufacturer: Medline Industries, Inc.
Brand: Delee Mucus Trap With Contro-vac and Plug 8F
Model #: DYND44108; **Lot #:** 18322060001; **Cat #:** DYND44108
Event Description: Newborn born with no tone, respiratory effort, low heartrate, Positive Pressure Ventilation and chest compressions begun shortly after birth. Meconium stained fluid noted, attempts to use Delee mucus trap unsuccessful over several attempts. RT feels this event could

have been related to a plug and the Delee did not work as intended for meconium above the vocal cords. This product has been noted to not stay connected to the suction tubing and is dislodged easily while in use. This is the second event that the quality of this product has been questioned.

Recalls

- Smiths Medical Issues Urgent Medical Device Correction Letter Notifying Customers of Potential Issues with CADD™ Infusion System Infusion Sets for Use with CADD Pumps **1-5-23**
- Recalls Related to the HVAD System **1-17-23**
- Datascope/Getinge Recalls Cardiosave Hybrid & Rescue Intra-Aortic Balloon Pumps for Risk That Blood May Enter Pump Via Damaged Balloon Catheter, Causing Patient Harm **1-25-23**
- Emergent Recalls Reactive Skin Decontamination Lotion Kits Due to Leak Potential **1-26-23**
- LivaNova (TandemLife) Adds to Recall for LifeSPARC System that May Experience Unintentional Extended Pump Stops Due to Controller Critical Failure **1-27-23**
- Medtronic Recalls Mahurkar Acute Dual Lumen High Flow Hemodialysis Catheters for Potential Catheter Hub Defect **1-30-23**

Warning Letters

- FDA Issues Two Warning Letters to Leading Manufacturer of Endoscopes **1-10-23**

Letters to Health Care Providers

- UPDATE: Medtronic HeartWare Ventricular Assist Device (HVAD) System **1-20-23**

FDA Seeks Public Comment: Advancing Real-World Data and Real-World Evidence with User Fee Funding

Read More

Highlighted White Papers from AAMI

The Association for the Advancement of Medical Instrumentation (AAMI) is a non-profit standards development organization, which has been accredited by the American National Standards Institute. These highlighted white papers published by AAMI are available to the public and do not require an AAMI membership to view.

- Optimizing the CMMS Failure Code Field
- Optimizing the CMMS Work Order Type Field

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