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.

If you are interested in having your healthcare facility join MedSun, contact medsun@fda.hhs.gov for additional information or see https.www.fda.gov/medsun for details.

Highlighted Reports

The reports that follow represent a cross section of device related events sent by MedSun Reporters during the prior month. Reports are presented as submitted and may have been summarized and/or edited for clarity.

The lollipop icon distinguishes 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 from birth through 21 years of age at the time of the diagnosis or treatment.

MedSun Report Database

Manufacturer: Gyrus Acmi, Inc
Brand: Slimline Scope Adaptor
Device Type: Electrode, Electrosurgical, Active, Urological
Event Description: MD was attempting to perform HTA (hydrothermal) ablation. The adaptor to the Slimline Scope was leaking fluid. A total of six more trays were opened to change out the adaptor and every adaptor was misaligned. Unable to realign rings/couplings; they were frozen in place. Family made aware that procedure was unable to be completed due to equipment failure. Patient was extubated and taken to PACU (post anesthesia care unit) without any issues.

Manufacturer: Intuitive Surgical, Inc
Brand: Sureform
Device Type: System, surgical, computer controlled instrument
Model #: 480460
Lot #: L11220801 (x1), L10220814 (x2)
Cat #: 480460
Event Description: Three SureForm staplers did not fire in the case causing an approximate 15-minute delay in surgical procedure: we kept getting the message "instrument engagement failed, remove and install. Changing the drape did not help, changing the robot arm did not work, finally a 4th stapler worked after we called the support 1-800 number who told us this was a chronic problem. On a separate case another Sure Form 60 stapler was not engaging in the base plate and the robot could not recognize it. Other than the 15-minute delay in the first case, there were no patient harms.

Manufacturer: Becton, Dickinson and Company
Brand: BD Safetyglide
Device Type: Needle, Hypodermic, Single Lumen
Model #: 305916
Lot #: 2024137; 2076930; 2003405
Cat #: 305916
Event Description: Multiple reports received regarding BD Safety Glide Needle (25g x 1): Clogged Needles. When drawing vaccines and attaching this needle, the back pressure pushes into the syringe making it look like more than the amount is drawn. A provider was using the needle for Moderna bivalent vaccine and mentioned the following: I have to draw 0.5ml. After drawing the proper amount from the vial, I waited almost 20 sec to see if the plunger moved, it doesn't. However, when connect the syringe to the needle, it pushes the plunger to 0.55 position. When trying to push the plunger back to the 0.5mL, you can feel a resistance; and then the plunger would move away past the 0.5mL to greater than the amount. This is an issue as it looks like more than the amount was drawn. I tested different ways to try and correct the issue, with no resolution (e.g., slightly uncapping the needle cap, etc.). Sometimes you can 'push' to pop the needle open with air from an empty syringe, but this would be a safety issue, risk of infection; if using same syringe containing the vaccine dose, there could be possible waste of vaccine if pushed too far. Another report mentioned: Needles clogged and unable to use. When nurses attempted to administer the COVID Booster (Pfizer Bivalent) and Influenza (Afluria) vaccines intramuscularly into deltoid muscle of different patients, the resistance was met. After changing the needles, the nurses were able to administer the medication.

Manufacturer: Zoll Medical Corporation
Brand: Onestep Complete, Single, RSeries
Type: Automated External Defibrillators (Non-wearable)
Model #: 8900-0224-01
Lot #: 1122F
Cat #: 8900-0224-01
Event Description: Multiple reports received regarding Zoll defibrillator pads that caused patient skin burns after shock. Patients admitted with skin intact. After applying and using the Zoll defib pads, it was observed patient skin burns and tears as a result. Provider removed Zoll pad from right lateral chest; noted what appeared as a blister that popped and is now weeping along the border of where the Zoll pad was.

Manufacturer: Gyrus Acmi, Inc.
Brand: Uropass Ureteral Access Sheath
Type: Accessories, Catheter, G-u
Model #: 61224BX
Lot #: 09E2100062
Cat #: 61224BX
Event Description: Facilities have identified an issue with the disposable Olympia Uropass Access Sheath tips- it is breaking apart within the package and during the procedure. Multiple lot# and product # are affected. Multiple tips across various procedures broke off of the device during the procedures. The surgeons were able to recover them without any harm to the patient. Our clinicians have also noted that the tip of the device can be easily broken off within the package. Multiple lot numbers/product numbers affected:
09E2100062 / # 61224BX, 09J1800111 / # 61134BX, 09B1900153/ # 61238BX, 09A1900139 / #61338BX, 09D2000303 / # 61324BX, 09L2100130 / # 61138BX

Device 1:

Manufacturer: Medtronic, Inc
Brand: Visia Af Mri Vr Surescan
Device Type: Implantable Cardioverter Defibrillator (Non-crt)
Model #: DVFB1D4
Lot #: PKX215883H

Device 2:
Manufacturer: Medtronic, Inc
Brand: Sprint Quattro Secure S
Device Type: Implantable Cardioverter Defibrillator (Non-crt)
Model #: 6935M55
Event Description: Received notification that patient had an implantable cardioverter defibrillator (ICD) placed which appeared to not work as it should when patient went into cardiac arrest. The patient was resuscitated by bystanders, and an automated external defibrillator (AED). The ICD was sent to the company, and the company returned a report back to the cardiologist indicating the ICD malfunctioned. Patient's right ventricular lead was extracted. When the patient's right ventricular RV lead was extracted, a DF-1 dual-coil ICD lead was implanted.
Per patient's discharge summary:
Patient presented as a transfer after having 12 unsuccessful ICD shocks. The first episode lasted about 4 minutes with 2 bursts of anti-tachycardia pacing (ATP) and 6 shocks (36J, 36J, 3.6J, and 3 shocks with 0J energy). The second episode lasted about 2 minutes and had 6 shocks with 0J of energy delivered. Ultimately patient collapsed in a parking lot and received bystander cardiopulmonary resuscitation (CPR) and shocks from an AED, and ultimately achieving return of spontaneous circulation (ROSC). Patient was never intubated and remained stable after that point. Given these shocks, patient was transferred for further management. On arrival, patient appeared stable and did not have any recurrent arrhythmia. On interrogation, it was revealed that patient's RV lead impedance had decreased significantly, giving concern to an insulation breach of the RV lead. Patient ultimately underwent RV lead explanation, dual chamber ICD implantation and higher voltage can with patient’s provider. Patient’s initial event was thought to be due to coronary vasospasm leading to ischemia and ventricular fibrillation arrest. Patient’s antianginals were up titrated and patient was discharged.

Manufacturer: AbbVie
Brand: Natrelle 133s Tissue Expanders
Device Type: Expander, Skin, Inflatable
Serial #: 24517662
Model #: 133S-MX-15-T
Cat #: 133S-MX-15-T
Event Description: Patient had a left mastectomy and placement of a pre-pectoral tissue expander (Allergan Natrelle Tissue Expander 700 cc,) with allograft soft tissue reinforcement. On the day of surgery, the tissue expander volume of fill was 250cc with four subsequent fills as follows: 1 month later with 100cc; two months after original procedure 150cc; and then two additional 100cc= 700cc total. After tissue expansion, the patient had subsequent left chest wall radiation therapy. Patient had been doing well until (about 2 weeks prior to surgery) when the patient noticed that the left breast tissue expander was quite a bit softer than it had been. The patient noticed that the volume seemed to have decreased. When the patient was seen in the surgeon's office (approximately one week prior to her surgery), it was obvious that the tissue expander had failed.

The patient went to surgery for replacement of ruptured left breast tissue expander. During the procedure, the deflated tissue expander was removed. There was some serous fluid within the tissue expander and it was noted to have failed at a posterior seam of the 2 piece shell, at about

the 1 o'clock position when viewed anteriorly. A replacement tissue expander (Allergan 133S-MX-15-T, 700cc) was implanted without incident. The patient tolerated the procedure well and was discharged home the same day.

Recalls

Class I Dewei Medical Equipment Co. Recalls DNA/RNA Preservation Kits That Are Not Authorized, Cleared, or Approved by the FDA **12-8-22**

Class I Remel, Inc Recalls Thermo Scientific Gram Negative IVD AST Sensititre Plate for risk of potential false susceptible results **12-9-22**

Class I Teleflex and Arrow International, LLC Recall Arrow MAC Two-Lumen Central Venous Access and Pressure Injectable Arrowg+ard Blue Plus Three-Lumen Central Venous Catheter (CVC) Kits **12-16-22**

Class I Arrow International, LLC, subsidiary of Teleflex, Inc Recalls Arrow AutoCAT 2, AC3 Intra-Aortic Balloon Pumps for Unexpectedly Short Battery Run Times **12-20-22**

Safety Notices

Update on Endologix AFX Endovascular AAA Graft Systems and Risk of Type III Endoleak: FDA Safety Communication **12-6-22**

Read More

Letters to Health Care Providers

Getinge Maquet/Datascope Intra-Aortic Balloon Pump (IABP) Shortage - Letter to Health Care Providers **12-2-22**

Read More

UPDATE: Impella RP System Post-Approval Study Results and Updated Labeling - Letter to Health Care Providers **12-5-22**

Read More

Links to FDA CDRH Databases and Other Information Sources

Registration & Device Listing

GUDID

MedSun: Medical Product Safety Network

Contact MedSun	
Food and Drug Administration	Telephone: 800-859-9821
10903 New Hampshire Avenue	Fax: 800-859-1292
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