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 December 22, 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

Possible False RPR Reactivity with BioPlex 2200 Syphilis Total & RPR Test Kit Following a COVID-19 Vaccine - Letter to Clinical Laboratory Staff and Health Care Providers
December 17, 2021

The FDA is alerting clinical laboratory staff and health care providers that false reactivity, or "false-positive", Rapid Plasma Reagin (RPR; non-treponemal) test results, when using the Bio-Rad Laboratories BioPlex 2200 Syphilis Total & RPR kit, can occur in some people who received a COVID-19 vaccine. Based on information provided by the manufacturer, Bio-Rad Laboratories, RPR false reactivity was observed in some individuals for at least five months following a COVID-19 vaccination.

COVID-19 vaccines do not cause syphilis. Health care providers should continue to strongly encourage patients to get vaccinated against COVID-19 and be aware of their patients' vaccination status when interpreting reactive RPR test results.

Class I Recall: Arrow International Inc Recalls Arrow-Trerotola Over-The-Wire PTD Kit Percutaneous Thrombolytic Device: 7Fr, Due to Risk of Separation
December 3, 2021

Arrow International Inc, a subsidiary of Teleflex, is recalling the Arrow-Trerotola Over-The-Wire 7FR PTD Kits due to the risk of the orange inner lumen of the catheter's tip component separating from the basket.

If the orange inner lumen separates from the basket, it may fracture and detach and block the blood vessel(s). If the orange inner lumen detaches from the basket, health consequences depend upon where the fractured tip component embolizes. If the embolization is local to the treatment target site, retrieval may be attempted, requiring an additional intervention and consequent delay of therapy. In some cases, the embolization could be central or possibly even to the heart or pulmonary arteries. This may lead to serious adverse events such as vessel damage, need for additional medical procedures, or possibly death. There have been seven complaints and no injuries or deaths reported for this device.

Class I Recall: Covidien Puritan Bennett 980 (PB980) Series Ventilator System
December 9, 2021

Manufacturing assembly error where a capacitor within the ventilator was assembled incorrectly, which may cause the device to become inoperable during use. Serial Numbers: 35B1700507, 35B1700533, 35B1700539, 35B1700465, 35B1700580, 35B1700530, 35B17005363, 5B1700542, 35B1700509, 35B1701614, 35B1700527, 35B1700537, 35B1700541, 35B1700508, and 35B1701569.

3D Printing Medical Devices at the Point of Care: Discussion Paper

The discussion paper provides background information on 3D printing and proposes potential point of care (PoC) manufacturing scenarios for public comment. The discussion paper does not constitute guidance; instead, its purpose is to gather feedback from the public to inform future policy development.

The discussion paper:

- Considers relevant background, including terminology, on the FDA regulation of devices and 3D printing, and how capabilities at a 3D printing facility factor into device safety and effectiveness.
- Identifies challenges presented by 3D printed medical devices at PoC and presents a potential approach for regulatory oversight under various scenarios to inform future policy development.
- Poses 16 key questions to facilitate public comment.

The FDA is seeking input on each of the above topics and more specifically, on the following three proposed scenarios:

1. Health care facility (HCF) using a 3D printing medical device production system (MDPS), where the MDPS manufacturer assumes responsibilities for FDA regulatory requirements and manufacturing of devices printed by the HCF using the MDPS.
2. Traditional Manufacturer on or near the HCF site
3. HCF assuming all Traditional Manufacturer responsibilities

Submitting Comments on the Discussion Paper

The FDA seeks further input from the medical device industry, manufacturers, health care providers, health care facilities, and other stakeholders to address these topics and questions to further explore appropriate regulatory approaches for PoC 3D printing of medical devices. The FDA encourages stakeholders to provide comments under docket number FDA-2021-N-1272. The last day to submit comments is February 8, 2022.

To read the full discussion paper and/or submit a comment, please visit FDA's website.

Potential Biocompatibility Concerns with NuVasive Specialized Orthopedics' Precice Devices – Letter to Healthcare Providers

The FDA continues to monitor potential biocompatibility concerns associated with NuVasive Specialized Orthopedics' Precice devices made from stainless steel and titanium. In this letter, the FDA is providing updated information and recommendations on the **titanium-based Precice devices**.

On November 30, 2021, NuVasive issued a field safety notice to inform health care providers of updated labeling and the ship hold in the United States was lifted for titanium-based Precice devices. NuVasive also announced a voluntary recall to notify users of the updated labeling for titanium-based Precice devices listed here.

Titanium-Based Precice Devices:

- Precice Freedom
- Precice Intra-medullary Limb Lengthening Device
- Precice Short
- Precice Unyte

The FDA believes it is in the best interest of patients to make titanium-based Precice devices available in the United States. At this time, the overall benefits of the devices outweigh the known risks for on-label use with the updated labeling, compared to alternative treatments.

The Instructions for Use for titanium-based Precice devices have been updated to include:

- Clarification that the device is intended for use only in patients 18 years and older,
- That patients should weigh 50 lbs. or more while undergoing treatment, and
- That no more than two devices should be implanted at a time.

Recommendations

For the Titanium-Based Precice devices listed above,

- Be aware of the above updates to the U.S. labeling.
- For care of patients who currently have one of these devices and weigh <50 pounds and/or have more than two devices implanted, the health care team should assess treatment progression and consider removal of nails promptly at the end of treatment. This can minimize the potential risks while also minimizing the risks associated with repetitive surgical interventions and suboptimal conversion to alternative therapies mid-treatment.
- Follow the actions provided by NuVasive in their recall notice.
- Report any adverse events or suspected events through MedWatch: the FDA Safety Information and Adverse Event Reporting program.

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

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during December 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
Motor, Surgical Instrument, Ac-powered Brand: Kincise Automated Surgical Impactor Model#: 1000-00-101 Cat #: 1000-00-101	Depuy Synthes Products, LLC.	Ongoing issues with cleaning this device. (The device is difficult to clean according to the IFU as it is hand-wash only and cannot be submersed.) We reported our cleaning concern to DePuy. The concern was raised that when reprocessing the device, blood would come out of the seams that were not sealed. Sterile Processing Department staff would use air to blow out what they could but were concerned about the efficacy of the cleaning in light of this. The DePuy rep attended our Sterile Processing Department meeting and promised action. Now more and more physicians are starting to use this device, and when it needs to be turned over quickly, it's becoming a huge burden and concern for the staff because it's not a quick device to clean. DuPuy attended another Sterile Processing Department meeting, and we relayed ongoing issues with cleaning this. CleanTrace (ATP testing) is not part of the IFU. It's something we did because we knew they were hard to clean and were curious. Since then, we've implemented ATP testing after cleaning so we know it's clean before sterilizing.
Pump, Infusion Brand: Sigma Spectrum Infusion Pump Model#: 35700BAX2 Cat #: 35700BAX2	Baxter Healthcare, Corp.	16 pumps delivering the incorrect amount of fluid to patients throughout 2021. The following are scenarios: 1. NO INFUSION: 0.9% NaCL IV fluid bag was not emptying, however the pump was running. Registered Nurse (RN) noticed that the pump stated it was running at 999ml/hr but it was not pulling any fluid from the bag. The fluid bag had been restarted and none of it had infused into the patient. 2. UNDERINFUSION: Medication hung at 100ml/h x 15 min.

Device	Manufacturer	Problem
		Ramped up to 300ml/h until complete which should have been at the one hour mark. At approximately 1.5 hours later, staff noted 390 ml had infused with more still in bag. The bag was a 250 ml bag as noted per pharmacy as well. 3. UNDERINFUSION: Most of the dose still remained in the bag. Pump did not run entire dose. 4. UNDERINFUSION: IV drip pulling from both primary and secondary line simultaneously. Tubing at appropriate heights, pump at hip height, all lines open. Medication did not infuse over the 30 minutes and extra time had to be added for full infusion. 5. UNDERINFUSION: Patient was to receive 2, 20mEq bags of Potassium Chloride over 4 hours. However, when the pump finished infusing the first bag at the 2 hour mark, at least half of the product was still in the IV bag. The RN restarted the infusion but it was apparent that the pump was not pumping properly. 6. NO INFUSION: IV pump would not pull from secondary medication. Nurse immediately recognized. Pump was replaced. No harm met patient. 7. OVERINFUSION: RN went into check beeping pump and found that patient had received double the dose of 500mL (1000mL) of Lactated Ringers (LR). RN checked pump to ensure it was programmed correctly and the pump was programmed correctly but pump administered all of LR. Administered IV vancomycin dose, RN verified pump was correctly set prior to administration. 8. UNDERINFUSION: RN entered room because of infusion completion. RN noticed that pump stated infusion was complete but there was still 200mls left in the IV bag. 9. UNDERINFUSION: Patient secondary IV medication was hung and programmed into Baxter infusion pump according to medication administration guidelines. Pump alarmed that infusion was complete after expected amount of time and it was found to have over half the medication was still left in the bag. 10. UNDERINFUSION: IV infusion pump was programmed to dispense 260ml over 60 minutes. After 60 minutes of infusion, the "infusion complete" message came on screen and the pump signaled to indicate the completion of the infusion. Despite this message, there was still fluid in the secondary medication(caspofungin). The estimated volume was 100ml. 11. UNDERINFUSION: Dose of Vancomycin was found with half of dose still left in the bag. 12. UNDERINFUSION: IV pump did not deliver full volume. 20ml extra was left after the infusion alarmed as complete. 13. UNDERINFUSION: Pump was found in patient's room with 50% of caspofungin medication given. Pump read infusion complete. 14. OVERINFUSION: Patient was receiving a bolus. Fluid placed on a pressure bag. Once the bag was fully infused, it continued to deliver air down the line and into loop of point-of-care infusion. System did not alert that there was air in the line.

Device	Manufacturer	Problem
		15. Volume delivery issues. 16. Volume delivery issues.
Automated External Defibrillators (Non-wearable) Brand: Aed Pro Model#: 900102024999 91010	Zoll Medical, Corp.	The AED Pro design includes a window to allow visualization of patient's cardiac rhythm. The windows are cracking and shattering without displacement of pieces. The devices were purchased few years back and cracks were noticed after two years from the purchased date. Zoll did replace all the screens because they did not have a reason for the cracking of the screens. Once replaced, we followed Zoll's recommendations for cleaning and displaying of device. Recently, we have had incidents of the window shattering. The shattered window prevents the team from interpreting the cardiac rhythm doing a cardiac arrest or cardiac event. The AED pro provides a manual option that changes the AED from semiautomatic to manual. With the manual mode, the team was able to interpret the cardiac rhythm, manually charge the device and deliver a shock. This process decreases interruptions in cardiopulmonary resuscitation.
System, Appendage Closure, Left Atrial Brand: Watchman Lot #: 27793289	Boston Scientific, Corp.	During an implant procedure for the Boston Scientific WATCHMAN left atrial appendage closure device, after insertion of the double curved sheath, patient had rhythm change and large air embolism was noted in the left ventricle. Cardiopulmonary resuscitation was initiated and attempt to resuscitate was unsuccessful.
Ventricular (Assist) Bypass Brand: Thoratec Heartmate 3 Lvas Implant Kit Model#: Heartmate 3 Cat #: 1065324US	Thoratec Corp.	The patient was admitted for heart failure symptoms including shortness of breath. He reported his VAD flow was lower (3.0-3.5) than his normal flow in the 4-5 range. The patient was not experiencing any alarm. A ventricular assist device (VAD) download was done that showed a steady decline in flow and pulsatility index (PI) suspicious for VAD inflow/outflow restriction. Imaging (CT of the outflow/inflow and transthoracic echocardiogram) was performed and was unrevealing and did not show any obstruction. Despite the negative imaging findings the patient was taken to the OR for urgent VAD exchange due to high suspicion of inflow obstruction which was confirmed on examination of the VAD device during the explantation.
Dialyzer, High Permeability With Or Without Sealed Dialysate System	Outset Medical, Inc.	Patient was undergoing hemodialysis when the Tablo had a water module failure. The Tablo instructed the user to rinse the patient back, which was done. The module was changed out, and the failure occurred again. The user called Tablo. Tablo attempted to remotely troubleshoot. While this was occurring, the user smelled smoke. The device was disconnected and shut off. Another Tablo was obtained, and the patient's hemodialysis was completed without further incident. No untoward patient effects.

Device	Manufacturer	Problem
Brand: Tablo-Hemodialysis System Model#: PN-0006000		
Tubes, Gastrointestinal (and Accessories) Brand: Flexi Seal Protect Fecal Management System (Fms) Model#: 421630 Cat #: 421630	ConvaTec	Patient with fecal management system (FMS) in place. Ten days after FMS placed, large amount of bright red blood noted in fecal management system. Inpatient due to Upper GI (gastrointestinal) bleed related to alcohol abuse, initially thought bleeding from Upper GI. Day 11, colonoscopy finding circular ulceration likely from fecal management system bulb found to be source of bleeding, cauterized and biopsied area. Procedure to stop bleeding initially successful, but overnight unresponsive with bright red blood and clots from rectum. Coded and ROSC (return of spontaneous circulation) achieved, but in unstable condition. Massive transfusion initiated and second surgery with epi injection and clips x3 tried and unsuccessful. Then taken for rectal artery embolization. Ultimately patient made comfort measures and expired on Day 12.
System, Surgical, Computer Controlled Instrument Brand: Endowrist Vessel Sealer Extend Model#: 480422 Lot #: M91210901-0363	Intuitive Surgical, Inc.	The patient was middle-aged with a history of obesity, hypertension and rectal cancer diagnosed earlier this year. He underwent robotic-assisted abdominoperineal resection. Approximately 1 hour after surgery while in the post-anesthesia care unit he was noted to be unresponsive and pulseless. At that time CPR was initiated. Noted to be in pulseless electrical activity (PEA) arrest. Return of spontaneous circulation (ROSC) was obtained after two rounds of CPR. The team was concerned for an acute myocardial infarction. The patient was taken to catheterization lab for intervention, and heparin and aspirin were administered for a presumptive coronary thrombus or pulmonary embolism. No evidence of acute blockage of coronary arteries was noted, and repeat hemoglobin measurement showed severe anemia and volume resuscitation with blood products and fluids was continued. An emergency exploratory laparotomy was performed, and 3 to 4 units of blood were noted in the abdomen which was then extensively packed to control the bleeding. However, despite control of the intraabdominal bleeding and transfusion of blood products, return of spontaneous circulation was not achieved. The injuries were deemed nonsurvivable. The patient expired. Subsequent autopsy reveal a patient inferior mesenteric artery where sealant had been used intraoperatively.
Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Broviac Cv Catheters (White Adapter) Model#: 0601620	Bard Access Systems, Inc.	Bard Access Systems, Inc. 6.6F Broviac single lumen catheter was placed and repaired two months later. Chest X-ray (CXR) showed repair intact. Family brought patient into the emergency department (ED) to evaluate positioning after line was caught on car seat as patient got out and it later became difficult to flush. CXR in ED showed that the tip remained in good position but repair site showed transverse latency without stent. Repair stent appears to have migrated to ~1.5cm from where line enters the skin, requiring line to be surgically replaced. The stent comes from the manufacturer permanently attached to the repair section of the repair kit, and the sleeve slides over the repair site and is glued in place. While the family originally came in with the history of the line being caught in a car seat, for the

Device	Manufacturer	Problem
Cat #: 0601 		stent to migrate to the position it was in, it would have first had to become dislodged from the manufacturer's attachment point without the repair site separating and then travel 14cm toward the patient within 3.5 hours. It's also held together by glue outside the line. Between the layers of the external catheter and internal lumen of the repair sleeve. There is little, if any glue that is in contact with the stent and therefore a pulling force would put shearing force on the glue of the repair between the layers, and not on the stent itself.
Introducer, Syringe Needle **Device 1** Brand: Onpro Kit Model#: 9002136 Lot #: A41042-0006145 **Device 2** Brand: Onpro Kit Model#: 9002136 Lot #: A41029	Amgen, Inc.	We are reporting 8 events that happened in the 5 month period, where the Neulasta On-Pro (Pegfilgrastim) Device either failed to deploy, fell off, and/or leaked. Each device failure was reported to and each device was sent back to the company. Each device was assessed by the company. Devices were replaced by the manufacturer. These events resulted in delayed treatment and inconvenience for the patients.
Type: Warmer, Thermal, Infusion Fluid **Device 1** Brand: Belmont Rapid Infuser Model#: RI-2 Cat #: 903-00039 **Device 2** Brand: 3-spike Disposable Set Model#: 903-00006P Lot #: 2021-09-06 Cat #: 903-00006P	Belmont Instrument Corp.	During a surgical event involving a patient death it was noted that the bedside rapid infuser had a "burning smell" and heat rising from the warming cassette on the infuser. Infuser sequestered and sent to Biomedical Engineering for reporting and analysis. Biomedical Engineering received the infuser with noted blood outside of the cassette with indications of cassette overheating, distortion, and what looked like blistering of the outer cassette ring.

Links to FDA/CDRH Databases and Other Information Sources

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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