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.

## Guidance Documents

### Final Guidance Issued to Clarify Two terms in FDA Documents

FDA issued a final guidance to provide clarity on how we intend to reference the terms "device" and "counterfeit device" and how we intend to interpret existing references to section 201(h) of the FD&C Act, in guidance, regulatory documents, communications, and other public documents.

**Read the Announcement** | **Download the Final Guidance Document** | **Read the Federal Register Notice**

## FDA Meetings, Conferences and Workshops

### 2022 FDA Digital Transformation Symposium

**December 5-7, 2022**

- Learn about FDA's IT vision and strategic direction.
- Hear from FDA leaders on how the agency is leveraging advances in data, cloud, user experience, cybersecurity, IT governance, and operational/organizational excellence to deliver on its mission to protect public health.
- Participate and engage in information sharing on how the FDA can continue to collaborate with stakeholder constituents.

### FDA Grand Rounds: Wastewater Surveillance for SARS-CoV-2 Variants: a pandemic response project leveraging FDA's GenomeTrakr network

**December 8, 2022 12:00PM – 1:00PM ET**

- Learn how FDA scientists leveraged an existing laboratory network normally tasked for foodborne pathogen surveillance to start sequencing SARS-CoV-2 from regional wastewater treatment plants across the US.

**Find more upcoming FDA Meetings, Conferences and Workshops here!**

## Highlighted Reports


- These reports 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.

| Device | Manufacturer | Problem |
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| **Type:** Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days<br><br>**Brand:** Broviac 4.2 F Single-lumen CV Catheter<br><br>**Model #:** 0600520<br>**Lot #:** HUDV0700<br>**Cat #:** 0600520<br><br>  | Bard Access Systems, Inc. | Patient returned from surgery post central line placement. Upon arrival in unit, noted smeared blood on the line. Nurse cleaned off the line and then drew from it. When she flushed the line to clear it of blood, it was noted that there was a hole leaking blood (with the pressure of flushing) near the hub of the Broviac line. The surgeon believes the hole was caused by the clamp. Line is packaged to be sent to manufacturer for inspection. The IV team was notified to start another peripheral IV and to evaluate if they could repair the line. Once the line was repaired, the original defective line was sent to OR nurse who was investigating it for doctor post repair. The repaired line could not be used for 4-6 hours, then for 24 hours could only be used for continuous infusions.<br><br>The repair and use limitation delayed plans for quick extubation and necessitated deep sedation and neuromuscular blockade to maintain this active patient safely with a breathing tube. The delay in full use of the line also impacted our ability to draw blood from the line for 24 hours post repair. |
| **Type:** Pump, Infusion<br><br>**Brand:** Plum 360<br><br>**Model #:** 300100405<br>**Cat #:** 30010 | ICU Medical, Inc. | Patient suffered a ST-elevation myocardial infarction (STEMI) and was brought to Cath Lab after being found down at home. Cardiac Cath showed a 100% thrombotic occlusion in the Left Circumflex artery which was ballooned and stented with a drug-eluting stent (DES). The artery was opened down to 0% blockage. Patient suffered acute respiratory failure requiring intubation and ventilator support. Vasopressors were required to maintain his |

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| | | blood pressure. About 6-7 hours post intervention, he had an unexpected drop in his blood pressure. About the same time, the RN went to exchange the Levophed IV bag out for a new one as it was nearing empty. The IV pump infusing the Levophed started to alarm "cassette failure". Another IV pump was obtained, and they attempted to switch the medication to this pump and it too malfunctioned, stating battery will not charge. The patient proceeded to go into cardiac arrest. Pulseless electrical activity (PEA) rhythm was noted, CPR and ACLS measures were implemented without return of function. After 20 minutes of ACLS, the patient died. |
| **Type:** Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days<br><br>**Brand:** L-cath S/l PICC S/l 26ga (1. 9f) X30cm<br><br>**Model #:** 384539<br>**Lot #:** 11438264, 11401159, 11410069, 114382464, 11401159, 11410069, 11424716<br><br>**Cat #:** 384539<br>  | Argon Medical Devices, Inc. | We have experienced a trend involving several L-caths leaking or breaking at the hub. There are several lot numbers included, however we have specifically removed 1148264 due to more events related to this specific lot number (3 events in a 12-day time period). All have taken place in one unit. These lines are having to be repaired or completely replaced.<br>Event 1: Lot number 11438264: A 1.9 French L-cath placed, with lot number 11438264 with cracked hub. Midline had to be replaced.<br>Event 2: Lot number 11438264: PICC line placed, cracked hub noted (<24 hours after placement).<br>Event 3: Lot number 11438264: 1.9 French cath midline cracked at hub, new midline had to be placed. Line had just been placed.<br>Event 4: Midline catheter was cracked on plastic piece of line. Lot number 11401159.<br>Event 5: PICC line placed at 1315 in the left upper arm. Called to the bedside at 2200 to assess a wet dressing. Found a crack in the hub. Was able to repair the line and redress. L-cath lot #11438264.<br>Event #6: Lot number: 11410069. The PICC dressing for the patient was wet and appeared to be leaking. As RN started to remove the old dressing, an obvious crack in the clear hub of the PICC was noted, with IV fluids leaking out from the crack. RN then repaired the PICC using a sterile PICC repair kit and applied a sterile dressing.<br>Event #7: Lot number: 11424716.<br>Line RN placing new PICC line. During insertion, PICC line broke off in patient's arm. Stat CXR and ultrasound obtained. Attending and general surgery to bedside. |

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| | | Event #8: Lot number: 11410069.<br>Line RN called to bedside due to line leaking when RN was flushing. Line was repaired and removed next day with a new midline placed. |
| **Type:** System, X-ray, Tomography, Computed<br><br>**Brand:** Canon Aquilion One<br><br>**Model #:** TSC-301C | Canon Medical System, USA, Inc. | The CT scanner went down while performing a stroke series scan. The scanner froze during a pivotal moment in the series. The scanner then had to be rebooted which delayed the images being sent and read for the patient. Patient was moved to other room to quickly complete scans. There have been recent issues with the scanner malfunctioning during angio studies and volume studies. Additional events with freezing scanner include:<br>Event 1: head and c-spine w/o;<br>Event 2: pelvis w/o. Error message was "RTM error";<br>Event 3: recon of hip. Error message was "MPR not working";<br>Event 4: angio portion of dissection;<br>Event 5: head (scanner froze when pulling patient up on worklist;<br>Event 6: stroke (after perfusion, before carotid);<br>Event 7: trauma C/A/P with contrast;<br>Event 8: during QC, error in recon sequence. All of these failures require a reboot which leads to a delay in care and additional steps for the technical team.<br><br>Canon has escalated this to both their National Parts Team and National Service Team. |

## Links to FDA CDRH Databases and Other Information Sources

We've streamlined your resources into clickable links below. And, coming soon, you'll find them inside the MedSun Resources tab.

**Establishment Registration & Device Listing**

**GUDID**

**MedSun: Medical Product Safety Network**


**Contact MedSun**

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