MedSun
Medical Product Safety Network

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

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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 September 28, 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

Armstrong Medical Limited Recalls AMSORB PLUS PREFILLED G-CAN 1.0L Due to Reduced Gas Flow to Patients During Anesthesia

September 23, 2021

Armstrong Medical Limited is recalling this product due to reports that some AMSORB PLUS PREFILLED G-CAN 1.0L canisters have difficulties with gas flow that may cause a reduced flow of air to the patient. The difficulties in flow may cause a failure in the pre-use or “CHECK-OUT” test on the anesthesia machine. It may also occur when a patient is already under anesthesia if an affected canister is attached to the anesthesia machine while a patient is already under anesthesia. If the flow issue is not addressed, this may prevent the ventilator from providing enough breathing assistance to the patient (hypoventilation), leading to a build-up of carbon dioxide in the patient’s body and causing negative health effects. There have been no deaths or injuries reported for this recall.

Medtronic Recalls Pipeline Flex Embolization Devices for Risk of Delivery System Fractures During Placement, Retrieval, or Movement of Device

September 22, 2021

In the US, Medtronic is recalling the Pipeline Flex Embolization Device due to a risk of the delivery system’s wire and tubes fracturing and breaking off when the system is being used to place, retrieve, or move the stent inside a patient. Fractured pieces could be left inside the patient’s brain bloodstream. It is also possible that attempts to retrieve the fractured pieces may make the patient’s condition worse. The fragments can also cause other serious adverse health consequences such as continued blockage of blood vessels, stroke, and death. There have been 59 reported device malfunctions, 10 serious injuries, and two deaths related to this recall.

Cordis Recalls SUPER TORQUE MB Angiographic Catheter with Radiopaque Marker Bands Due to Potential for Marker Bands to Move or Dislodge

September 22, 2021

Cordis Corporation is recalling the Cordis SUPER TORQUE MB Angiographic Catheter with Radiopaque Marker Bands due to the potential for the marker bands to move or dislodge during procedures. This can happen during procedures where the catheter is trapped between another device and the vessel wall, and could result in a procedural delay, additional medical procedures, heart attack, or stroke. There have been 167 complaints, 8 injuries, and no deaths reported for this issue.

Potential Risk of Aluminum Leaching with Use of Certain Fluid Warmer Devices – Letter to Health Care Providers

FDA is reminding health care providers about the use of certain fluid warmers and the potential for aluminum leaching and exposing the patient to high levels of aluminum. Based on information reviewed by the FDA, aluminum leaching may occur when the fluid warmer is designed with an aluminum heating element where the heated aluminum is in direct contact with the fluids or blood products being administered to a patient. FDA has identified the devices listed in the table below as having this type of design. Three original equipment manufacturers (Eight Medical International BV, Smisson Cartledge Biomedical and Smith Medical) provided revised instructions for use for these devices (see associated recall notice links). A fourth original equipment manufacturer (Vyaire Medical) voluntarily removed its product from the market.

Manufacturer Name	Device Information	Recall Notice
Eight Medical International BV	Recirculator 8.0 Disposable Lavage kit (Product Code: 8100) Lot #s: 20021361, 20202106, 20018480, 19854186, 20019438, 19854185, 20019438, 19854184,18687686	Recall Notice Initiated 6/4/21
Smisson-Cartledge Biomedical	ThermaCor 1200 Disposable Sets Disposable Set Models: PTC-1200, DNC-1200, PNC-1200	Recall Notice Initiated 2/18/21
Smiths Medical	Level 1 Fluid Warmer Models: H-1000, H-500	Recall Notice Initiated 8/6/21
	Level 1 Fluid Warming System Models: H-1028, H-1200	
	Level 1 Normothermic I.V. Fluid Administration Set Models: D-100, D-300, D-50, D-60HL, DI-100, DI-300, DI-50, DI-60HL	
	NORMOFLO Irrigation Warming Set Models: IR-40, IR-500, IR-600, IR-700, IRI-600, IRI-600B, IR-700	
Vyaire Medical	enFlow Fluid Warmer System Disposable Cartridges Models: 980200EU enFlow - Disposable Cartridge, 980202EU enFlow - Disposable Cartridge with IV Extension Set	Recall Notice Initiated 3/13/19

Highlighted Recommendations:

- Conduct a clinical benefit-risk analysis before using an affected fluid warmer.
  - When possible, avoid using these fluid warmers in high-risk patient populations, e.g., patients with poor renal function, neonates, pregnant women, and elderly.
  - If available, use alternative therapies to maintain patient temperature, e.g., an alternative fluid warmer or a warming blanket.

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

Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication

FDA is alerting users of Philips Respironics ventilators, BiPAP, and CPAP machines and their health care providers that Philips Respironics has recalled certain devices (see tables below) due to potential health risks. The polyester-based polyurethane (PE-PUR) sound abatement foam, which is used to reduce sound and vibration in these affected devices, may break down and potentially enter the device's air pathway. If this occurs, black debris from the foam or certain chemicals released into the device's air pathway may be inhaled or swallowed by the patient.

CPAP and BiPAP Devices

Device Type	Model(s)
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne, ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

Ventilators

Device Type	Model(s)
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

Highlighted Recommendations for People Who Use Affected BiPAP or CPAP Machines:

Talk to your health care provider to decide on a suitable treatment for your condition, which may include:

- Stopping use of your device
- Using another similar device that is not part of the recall
- **Continuing to use your affected device**, if your health care provider determines that the benefits outweigh the risks identified in the recall notification.
- Using alternative treatments for sleep apnea, such as positional therapy or oral appliances, which fit like a sports mouth guard or an orthodontic retainer.
- Initiating long term therapies for sleep apnea, such as losing weight, avoiding alcohol, stopping smoking, or, for moderate to severe sleep apnea, considering surgical options.

To read the full safety communication, all of FDA's recommendations, and the recall notification please visit FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during September 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
Temporary Non-roller Type Left Heart Support Blood Pump Brand: Impella 5.5 with Smartassist Set Model#: LOG1508821329 Lot#: 315419	Abiomed Inc.	After changing purge cassette on Impella VAD, a leak was noted on connector of purge line and purge cassette. After consulting with Abiomed, the manufacturer, cassette was changed again with no resolution in problem. Second recommendation from the manufacturer was to cut cassette off and splice line with 19-gauge needle. After performing this intervention, purge pressure and flow reestablished. Pump working correctly.
Oximeter Brand: Nellcor Model#: 10005941 Cat#: 10005941	Covidien LP	The time drifts on the Pulse Oximeters. It was brought to our attention that the times were off by a few minutes. We set all the times to get a fresh start and about 2 months later we found that these the times had drifted forward 3-4 minutes.
Ventilator, Continuous, Facility Use Brand: Trilogy Ev300, USA Model#: DS2200X11B Cat#: DS2200X11B	Respironics, Inc.	In August 2021, Philips field service representative came on-site and repaired a EV300 ventilator that had failed with the red screen and message "ventilator inoperative" displayed, just like the other 3 similar incidents that we had in March of 2021. This time however the issue was the main circuit board (PCA board), not a software issue like the previous ones. This makes 4 total EV300's in the last 6 months that have had "ventilator inoperable" alarms that had to be resolved by Philips.

Device	Manufacturer	Problem
Ventricular (Assist) By-pass Brand: Thoratec® Heartmate 3™ Sealed Outflow Graft With Bend Relief Model#: 105581US Cat #: 105581US	Thoratec Corporation	Abbott HeartMate 3 left ventricular assist device (LAVD) was implanted in 2021. The outflow graft formed an obstruction causing the patient to be upgraded on the United Network for Organ Sharing (UNOS) transplant list due to increasing AI, valve thrombus. Patient was transplanted as a result of the complication. Surgical pathology confirmed the original findings.
Ventricular (Assist) By-pass Brand: Thoratec® Heartmate 3™ Sealed Outflow Graft With Bend Relief Model#: 105581US Lot#: 6637364 Cat#: 105581US	Thoratec Corporation	Abbott HeartMate 3 left ventricular assist device (LAVD) was implanted in 2019. The outflow graft formed an obstruction causing the patient to be upgraded on the United Network for Organ Sharing (UNOS) transplant list due to increasing aortic insufficiency and cardiogenic shock. Patient was transplanted as a result of the complication. Surgical pathology found the HeartMate 3 LAVD showing complete coating of the inflow cannular with neo-intimal type fibrous tissue, extending over the lip into the inner bore. Fibrin clot in the bend relief, around the synthetic tube graft.
Accessories, Cleaning, For Endoscope Brand: DSD Edge Endoscope Reprocessing System Model#: DSD Edge 120V	Medivators, Inc.	Black smoke appeared from back of Medivator DSD Edge located in Endoscopy Lab decontamination room. Staff called out for help. Co-worker then attempted to cut power to machine from wall circuit. Machine continued to smoke and grow larger, but co-worker was too short to reach back to unplug machine from wall. Another staff member reported to room jumped on counter reached behind machine and pulled electrical cord out of machine/unplugged from machine (still connected to wall). Smoke/ flames/sparks slowed stopped and team cleared out area and ventilated space. Ground Fault Interrupter (GFI) located in machine was directly under hose (plastic) containing liquid chemical. Hose failed, fluid expelled onto internal outlet and caused electrical fire.

Device	Manufacturer	Problem
Dialyzer, High Permeability With Or Without Sealed Dialysate System Brand: Prismaflex Model#: 5.XX Cat #: 113081	GAMBRO AB - Baxter	Scale malfunction alarm kept repeating and could not be resolved by the nurse which could have resulted in a potential large volume blood loss due to inability to return the patient's blood, and also the patient fluid loss could be above the prescribed amount. So we had to exchange to another CRRT machine which led to a delay in therapy or care. This machine failure takes machines out of service when we desperately need them for lifesaving care. We only have 11 Prismaflex CRRT machines and this scale alarm has occurred on multiple occasions on several of our CRRT machines within our fleet. Our main patient population that has needed this therapy is our COVID ICU patients. This model of Prismaflex CRRT machine is also required to deliver MARS (liver dialysis) therapy, and for these patients that is life-saving. These scale malfunction alarms and the resulting removal of CRRT machines from service puts a stress on our system (patients, biomed, nurses, physicians) when our focus should be on life-saving care. In working with the manufacturer, Baxter, on ongoing quality issues we reviewed 18 months of equipment service reports, and their diagnosis was that the issue was a "scale firmware malfunction". We received information that this model of CRRT machine has a known scale software problem but we have not heard of a fix from the manufacturer. We need to also purchase more CRRT machines for our volume of need but lack confidence that this manufacturer will be cooperative and transparent to help us get the best service for these machines. We have notified the manufacturer, Baxter, for multiple events relating to the malfunctioning scale alarm.

Links to FDA/CDRH Databases and Other Information Sources

U.S. FOOD & DRUG ADMINISTRATION
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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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