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 July 26, 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

Class I Recall of Vero Biotech's GENOSYL DS, Nitric Oxide Delivery System, Due to Software Error

July 21, 2021

Vero Biotech is recalling its GENOSYL DS; Nitric Oxide Delivery System due to a software issue that leads to errors in the delivery of nitric oxide. Typically, this issue caused delivery of lower-than-expected dosage of nitric oxide during the transition between primary and backup console. If this happens, this could cause serious adverse events such as drops in oxygen level, heart problems, and clinical instability in the newborn. There have been 11 complaints, three injuries and no deaths reported for this issue.

Risk of False Results with the Curative SARS-CoV-2 Test for COVID-19: FDA Safety Communication

July 15, 2021

The Curative, Inc., Curative SARS-Cov-2 Assay (originally authorized as the Korvalabs, Inc. Curative-Korva SARS-Cov-2 Assay) Emergency Use Authorization was revoked at the company's request effective July 15, 2021, because the company is now using different EUA-authorized tests for the testing offered at its laboratories. The test that is the subject of this safety communication is no longer being offered and is no longer authorized for emergency use by the FDA.

Potential Concerns with NuVasive MAGEC System Implants - FDA Safety Communication

July 15, 2021

The U.S. Food and Drug Administration (FDA) is informing patients, their caregivers, and health care providers of potential mechanical failures and concerns about tissue incompatibility (biocompatibility) associated with components of the following NuVasive Specialized Orthopedics' MAGEC devices:

- MAGEC Spinal Bracing and Distraction System
- MAGEC 2 Spinal Bracing and Distraction System
- MAGEC System
- MAGEC System Model X device
- MAGEC System Model X rod
- MAGEC System Rods

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 from FDA:

- Do not stop or change ventilator use until talking to a health care provider.
- Follow the manufacturer's instructions and recommended cleaning and replacement guidelines for your CPAP machine and accessories. Ozone cleaners may worsen the breakdown of the foam.
- The safety and effectiveness of using an inline bacterial filter, as mentioned in the Philips recall notification, has not yet been evaluated by FDA. Note that the use of a filter will not prevent exposure to off-gassed chemicals and may cause increased air flow resistance.
- Service affected devices and evaluate for any evidence of foam degradation. If there is evidence of foam degradation, such as black debris in the device, stop use of the device, if possible, and report any problems with a device to MedWatch.

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

Sodium Citrate Blood Specimen Collection Tube Conservation Strategies – Letter to Health Care and Laboratory Personnel

FDA is aware that the U.S. is experiencing significant interruptions in the supply of sodium citrate blood specimen collection (light blue top) tubes because of an increase in demand during the COVID-19 public health emergency and recent vendor supply challenges.

The FDA recommends that health care providers, laboratory directors, phlebotomists, and other personnel consider the following conservation strategies:

- Do not include sodium citrate (light blue top) tubes in routine collections of a variety of specimens at the time of other blood sampling or IV insertion.
- Do not use sodium citrate (light blue top) tubes unless medically necessary.
- Do not use sodium citrate (light blue top) tubes as discard tubes; consider clear top or red stopper (no additive) tubes as an alternative.
- Limit allocation of 1.8mL sodium citrate (light blue top) tubes for difficult blood collections.

The FDA also recommends health care and laboratory facilities develop and implement the above strategies to minimize the use of these tubes and maintain the quality and safety of care for patients for whom testing is medically necessary.

FDA has taken the following actions:

- On June 10, 2021, the FDA added these tubes (product codes GIM and JKA) to the section 506J of the Federal Food, Drug, and Cosmetic Act device shortage list during the COVID-19 public health emergency.
- On July 22, 2021, the FDA issued an Emergency Use Authorization (EUA) to Becton Dickinson for certain sodium citrate blood specimen (light blue top) collection tubes used to collect, transport and store blood samples for coagulation testing to aid in the identification and treatment of coagulopathy in patients with known or suspected COVID-19.
- The FDA continues to monitor the current situation to help ensure that coagulation testing remains available for patients for whom such testing is medically necessary. The FDA will inform the public if significant new information becomes available.

To read the full letter and all of FDA's recommendations for health care providers please visit FDA's website.

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HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during July 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
Insufflator, Laparoscopic Brand: Pneumoclear Cat #: 0620-050-000 	W.O.M. World of Medicine GmbH	The machine was set to 8mmhg of pressure, as typical with pediatric patients and started at a flow of 1L/min. Once the pressure of 8mmhg was achieved it was set to a max of 5L/min of flow. This doesn't mean it will flow at 5L the whole time, the machine is constantly measuring the pressure and adjusts the flow accordingly, 5L is the max it would allow. Once the scope was put in and started, the physician yelled out to remove the camera and the port immediately. He noticed the pressure was so high that the abdomen was "rock hard" and the pressure caused the patient to void urine. The machine was reading 25mmhg but we are not sure how accurate that reading was but the machine was still set to a 8mmhg limit and have no clue how it would get that high. Once the insufflation was removed we immediately called the Stryker Rep to consult the malfunctioning machine. We've had problems with this port and lens before but never to this degree. We are wondering if the port and scopes are not ideal when used together, usually a scope is a bit smaller than the port to allow insufflation to flow around it and be able to read the internal pressure, this scope and port are a near perfect fit, possibly too much that the machine might have a hard time accurately reading the pressure and might over compensate.

Device	Manufacturer	Problem
Laparoscope, General & Plastic Surgery Brand: Hydro-surg Plus Model#: 0026870 Lot #'s: JUFQ0994, JUFP1218, JUF20994, JUFQ0946, JUFN0541, JUFN2457, JU-DY3305 Cat #: 0026870	BD	All devices have been single use only. The products are being sent to the manufacturer. JUFQ0994 - Fluids leaked into battery compartment. JUFP1218 - Fluids leaked into the battery compartment. JUFQ0994 - Green liquid found in chamber where batteries are held upon completion of case. JUFQ0994 - Fluid in battery pack. JUFP1218 - Yellow colored fluid inside battery compartment. JUFQ0994 - Saline leaked into the battery compartment. JUF20994 - Irrigator leaked water on floor and on my hands after the case when trying to remove the batteries. Water and battery acid were in battery container. JUFQ0994 - Water leaked into pump assembly (battery compartment). JUFP1220 - Saline is in the battery compartment. JUFP1218 - Green liquid found in chamber where batteries are held upon completion of procedure. JUFP1218 - Chunky, green liquid found in chamber where batteries are held upon completion of case. JUFQ0946 - First it began irrigation motor began to run but no irrigation was coming out of the equipment. Then it began to run continuously, after words began to put an odor in the room. JUFP1218 - Normal saline inside battery compartment when opened up to remove batteries at the end of the case. JUFN0541 - Green liquid found in chamber where batteries are held upon completion of the procedure. JUFN0541 - Once procedure was finished, looked inside of suction irrigator and there was fluid inside. JUFP1218 - Button on top fell off. JUFQ0994 - After the procedure, green liquid was found in the chamber where batteries are held. JUFN0541 - Green liquid was found in chamber after use where batteries are held. JUFN2457 - After the procedure, green liquid was found in the chamber where the batteries are.

Device	Manufacturer	Problem
		JUEZ1471 - After procedure, it was noted that fluid had invaded the battery compartment, and had also caused an electrical short inside the compartment and the battery/pump pack was hot to the touch. JUEV1316 - Suction irrigator was not working properly, making loud noises. Hot to touch near the on/off switch. When removed brown liquid came out from the base. JUDY3305 - At the end of the case when taking apart the battery compartment, water was in the battery chamber. Is there a leak potential for patient contamination?
Pump, Infusion Brand: CADD Legacy 100 Ml Cassette	Smiths Medical MD, Inc.	The CADD pumps are unexplainably shutting down when infusing home medications and giving the error message “No disposable, pump won’t run”. The pumps have been interrogated, when known, and have all been determined to be performing appropriately. Per the technicians setting up the pumps, it appears the design of the cassette allows the tubing to migrate, which caused a disruption, and the pump no longer senses that the cassette is attached and then ultimately a shutdown of the pump with the error message.
Saline, Vascular Access Flush Brand: Monoject 3 mL Ns Syringe Model#: 8881570123 Cat #: 8881570123 Brand: Monoject 10 mL Ns Syringe Model#: 8881570121 Cat #: 8881570121	Cardinal Health, Inc.	Syringe Plunger slides back allowing syringe to de-prime and fill with air if positive pressure is not maintained. 3 ml and 10 ml Covidien prefilled NS syringes are at issue. After removing the cap and breaking the seal to remove the small air bubble if constant pressure is not held on the plunger, the plunger slides backward when the syringe is held vertical, allowing the syringe to de-prime and fill with air. Nurses have to keep constant pressure on the plunger while attaching to connector/tubing to prevent air from entering the connection and potential bolus to the patient. Cardinal Health contacted, in which they acknowledged this occurrence. Plan is to submit 1-2 unused syringes for their evaluation. No harm has occurred that we are aware of, but the potential is great.
Analyzer, Gas, Carbon-dioxide, Gaseous-phase Brand: Capnostream 35 Model#: PM35MN	Medtronic	During end tidal CO2 monitoring, the capnography device alerted "Low Battery" on display. The Respiratory therapist (RCP) attempted to plug the unit into AC power to charge. After several hours the battery did not charge. The RCP tested the charger on another unit and the charging icon on the device presented itself. Defective unit removed from patient and unit secure for Biomedical repair. Biomedical noted several other units with the same battery not charging issue. Our medical center currently has 7 units out for warranty repair with this same failure. Battery in use is a 7.2VDC 19.24Wh LiIon Battery.

Device	Manufacturer	Problem
Catheters, Suction, Tracheobronchial Brand: Kimvent® Model#: 196 Lot #'s: 30099905, 30053163, 30057091, 30109707 Cat #: 196 	Kimberly Clark Corporation	A fragment from an inline suction catheter was found in the left bronchus of an neonatal patient several days after initial intubation. Surgical intervention was needed to remove the foreign object confirmed to be a fragment from a Kimberly Clark KIMVENT Closed Suction System for Neonatal/Pediatric, 6 Fr "Y" Endotracheal Tube Adapter. 1800 CXR chest x-ray showed possible foreign object, linear 1.7cm length, 3mm diameter. Imaging history reviewed by MD and bedside nurse. Object was appreciated on previous CXR, but was difficult to see and was not identified on radiology report. Previous x-rays did not show anything that could be identified as a foreign object. Infant's bed was checked for external object and new imaging was obtained to confirm object was indeed inside of the patient's lung field. When confirmed that object was not external, a pediatric medical center was consulted and the decision was made to transport infant for further evaluation and intervention due to the availability of a transport ventilator that is available at the pediatric center. Follow up by the pediatric center and retrieval of the foreign body confirmed that it was a 6fr SUCTION TRACHCARE NEONATE 6FR 196.
Device, Hemostasis, Vascular Brand: Perclose Proglide 6f Model#: 12673-03 Lot #: 0081141 Cat #: 12673-03	Abbott Vascular Inc.	While attempting to deploy the Perclose ProGlide vascular closure device according to manufacturer's instructions and specifications, the device misfired and upon removal of the plunger, the Prolene sutures were not extending from the device, as in normal operation. The device's footplate remained deployed/extended despite attempts at advancing the device several centimeters into the artery and maneuvering it to try to close the footplate for extraction. Since the footplate would not straighten, the device could not be removed percutaneously. After conferring with the device representative by telephone, the only way to extract the device from the patient was by open surgical cutdown. The patient had to be converted from MAC/IV (monitored anesthesia care/intravenous) sedation to general endotracheal anesthesia, undergo an unplanned open operation emergently, and even with meticulous proximal control, removal of the device from the artery entailed significant blood loss requiring transfusion and extensive repair of the artery, prolonging the procedure and operative time by 3 to 3.5 hours.
Enema Kit Brand: Gent-l-kare	Medegen Medical Products, LLC	OB (obstetrics) patient developed ileus post C-section and required an enema. The instructions had become separated from the kit and the relatively new nurse, did not realize that the end of the tubing was a blue colored cap. Rather, she believed this was something to measure the amount that should be inserted. The cap became lodged in the patient's rectum and could not be removed manually. GI was consulted and removed the cap via flexible sigmoidoscopy. The patient complained of pain prior to removal, but had no significant sequalae. Recommendation: Distinguish the cap by color, text directly on it, or other means, as a way to highlight that this is an item to be removed.

Device	Manufacturer	Problem
Tubes, Gastro-intestinal And Accessories Brand: Avanos Cat #: 8100-16LV	Avanos Medical, Inc.	Defective gastric tube balloon. Tube was placed in patient and found to be defective & leaking once in position. Needed to re-start procedure as access had been lost by this point.
Apparatus, Suction, Ward Use, Portable, Ac-powered Brand: Duo Fluid Cart With Power Iv Model#: 00-5140-103-00	Zimmer Orthopaedic Surgical Products, Inc.	Zimmer IntelliCart extremely loud and vibrating the floor. Surgeon asked that the suction to be turned off and utilized the carousel suction device. Staff could not hear the name of specimen and could not hear report from surgical pathology report on frozen specimen. No harm to patient. Reported incident to Perioperative Nurse Manager.
Bed, Patient Rotation, Powered Brand: Rotoprone	Arjohuntleigh Magog, Inc./ Arjohuntleigh AB	With the patient in the bed, the bed became non functional in the supine position. At first, it was giving a "rotating" alert when the patient was not rotating. A call to the help line guided us through the process to reboot however the bed became stuck in supine position again. Call was again placed to the rep who stated they could get a replacement bed. Patient was then shifted to an ICU bed to wait for new bed. New bed arrived and is also malfunctioning with the patient in prone positioning at 62 degrees. ICU manager states beds often malfunction.

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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