MedSun
Medical Product Safety Network

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

# April 2022

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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/medical-devices/device-approvals-denials-and-clearances/recently-approved-devices**

**Premarket Approval Final Decisions:**
**https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals**

**510(k)s Final Decisions:**
**https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances**

# In Brief

*As of March 28, 2022*

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: Celltrion USA Recalls Certain Point of Care Celltrion DiaTrust COVID-19 Ag Rapid Tests for False Positive Test Results and Unauthorized Shelf Life

**March 15, 2022**

The Point of Care (POC) Celltrion DiaTrust COVID-19 Ag Rapid Test is intended to detect the presence of SARS-CoV-2, the virus that causes COVID-19, based on a nasopharyngeal swab sample from patients collected by healthcare providers.

Celltrion USA is recalling specific lots of the POC DiaTrust COVID-19 Ag Rapid Test due to a high number of false positive reports. A false-positive antigen test result may lead to a delay in both the correct diagnosis and treatment for the actual cause of a person's illness. False-positive results could also lead to more spread of the SARS-CoV-2 virus if presumed positive people are housed together. Additionally, the tests' labeling for the affected POC products includes a shelf life of 18 months. However, the FDA's emergency use authorization specifies these tests may only be used for 12 months.

### Class I Recall: SD Biosensor Recalls STANDARD Q COVID-19 Ag Home Tests That Are Not Authorized, Cleared, or Approved by the FDA and May Give False Results

**March 16, 2022**

The SD Biosensor STANDARD Q COVID-19 Ag Home Test uses a nasal swab sample to detect proteins, called antigens, from SARS-CoV-2, the virus that causes COVID-19. This test is not authorized, cleared, or approved by the FDA for marketing or distribution in the United States. As this test was not authorized, cleared, or approved by the FDA, there is not sufficient data demonstrating that the test's performance is accurate.

### Class I Recall: LuSys Laboratories, Inc Recalls COVID-19 Antigen Tests (Nasal/Saliva) and COVID-19 IgG/IgM Antibody Tests Because They Are Not Authorized, Cleared, or Approved by the FDA

**March 14, 2022**

The LuSys Laboratories COVID-19 Antigen Test uses a nasal swab, or a saliva sample intended to detect proteins, called antigens, on the SARS-CoV-2 virus. The LuSys Laboratories COVID-19 IgG/IgM Antibody Test uses serum, plasma, or blood samples to look for antibodies produced by a person's immune system in response to SARS-CoV-2, the virus that causes COVID-19, suggesting a recent or previous infection. Antibody tests should not be used to diagnose or exclude an active COVID-19 infection.

LuSys Laboratories is recalling these tests because they do not have an Emergency Use Authorization, 510(k), or PMA and therefore cannot be legally marketed and distributed in the United States.

# FDA Warns Against Use of Renuvion/J-Plasma Device for Certain Aesthetic Procedures– FDA Safety Communication

The Renuvion/J-Plasma system by Apyx Medical, which includes the Plasma/RF Handpiece and Plasma Generators uses radiofrequency (RF) energy and helium to generate plasma (gas-like substance with high heat). The plasma can be used to cut, coagulate, and eliminate soft tissue with heat during surgery. The Renuvion/J-Plasma device is FDA cleared for general use of cutting, coagulation, and ablation of soft tissue during open and laparoscopic surgical procedures. The use of the device has not been determined to be safe or effective in any specific procedures, including aesthetic skin procedures.

The FDA is warning consumers and health care providers against the use of the Renuvion/J-Plasma system for procedures intended to improve the appearance of the skin through dermal resurfacing (a procedure on the skin to treat wrinkles) or skin contraction (a procedure under the skin that can be performed either alone or in combination with liposuction to achieve skin effects, such as “tightening”). The FDA has received reports describing serious adverse events when the Renuvion/J-plasma device was used directly on the skin and potentially life-threatening adverse events when the Renuvion/J-plasma device was used under the skin.

## Recommendations for Health Care Providers

- Be aware that the use of Renuvion/J-Plasma is not cleared or approved by the FDA for any aesthetic skin procedure.
- Be aware that the use of Renuvion/J-Plasma for aesthetic skin procedures may result in serious and potentially life-threatening adverse events.
- Do not use the Renuvion/J-Plasma device for dermal resurfacing or skin contraction, alone or in combination with liposuction.
- Discuss the benefits and risks of all available aesthetic skin procedures with your patient. If you are performing an aesthetic procedure, inform your patient which devices you plan to use.
- Review the Apyx Renuvion/J-Plasma labeling and User Manual for proper use of this medical device.
- Report any problems or complications experienced by patients from procedures with Renuvion/J-Plasma to the FDA.

## Risks Associated with Use of Renuvion/J-Plasma for Aesthetic Skin Procedures

The FDA has received reports describing serious and potentially life-threatening adverse events after the device was used for aesthetic skin procedures. Reported events include second- and third- degree burns, infection, change in skin color, scars, nerve damage, significant bleeding, and air or gas accumulation under the skin, in body cavities, and in blood vessels. In some cases, adverse events required treatment in an intensive care unit.

To read the full Safety Communication, please visit FDA’s website.

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

In June 2021, Philips Respironics recalled certain ventilators, BiPAP, and CPAP machines because of potential health risks. The polyester-based polyurethane foam used in these devices to reduce sound and vibration can breakdown. If this occurs, black pieces of foam, or certain chemicals that are not visible, could be breathed in or swallowed by the person using the device. These issues could potentially result in serious injury, which can be life-threatening and require medical intervention to prevent permanent injury. The foam issue may get worse in hot and humid settings, and by using ozone cleaners or other cleaning methods not recommended by the manufacturer.

Please see the full Safety Communication for a complete list of affected devices but please note that since the November 2021 update, the FDA has added certain Trilogy Evo ventilators, distributed April 15, 2021 to May 24, 2021 with specific serial numbers, to the recall.

**March 2022 Updates**

On March 14, 2022, the FDA updated its Frequently Asked Questions about the Philips Respironics CPAP, BiPAP, and ventilator recall to include information about Philips Respironics' prioritization strategy for replacement devices. The FDA shared with Philips Respironics the concerns of health care providers and people who use these recalled devices, that for some patients, stopping use of the recalled device without an adequate alternative may involve significant risks to individual and public health. A first-come, first-served replacement strategy may not address these risks, or the risks from continued use of the recalled devices that such patients may face.

On March 10, 2022, the FDA issued a notification order to Philips Respironics requiring the company to notify patients and others of the company's June 14, 2021, recall of certain Philips Respironics ventilators, CPAP and BiPAP machines, and the unreasonable risk of substantial harm to the public health posed by the degradation of the polyester-based polyurethane (PE-PUR) sound abatement foam used in those products. The FDA has determined that this order is necessary to eliminate the unreasonable risk of harm posed by the recalled products, because the company's notification efforts to date have been inadequate.

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

## HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during March 2022. 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.**

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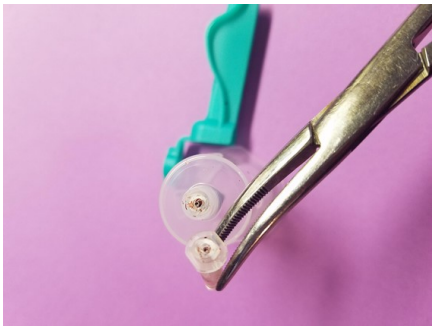
| Device | Manufacturer | Problem |
|---|---|---|
| **Apparatus, Exhaust, Surgical**<br>Brand: Rapidvac<br>Model#: SE3690<br>Cat #: SE3690 | Covidien | Within one month, there were a total of five smoke evacuation systems that were intermittently not working during surgical procedures. All connections were checked and power cycled/ restarted; however, systems continued to not always engage during the surgical procedure. Early in the month, three smoke evacuation units were reported to Medtronic with intermittent operation issues. Biomed reported to Medtronic that a fourth smoke evacuation system is having intermittent operation issues. Biomed reported a fifth unit to Medtronic with intermittent operation issues. The smoke evacuators were purchased in 2020 and were all past their one year warranty. We replaced the five smoke evacuators with new ones. Medtronic has not given any follow up of cause of intermittent operation.<br><br>This month, we have an additional three smoke evacuation systems that will need to be replaced because of the "intermittent operation" issue. These units were all purchased in 2020 with recent preventative maintenance.<br><br>Event 1: Smoke evacuation was intermittently working during a surgical procedure. Team checked all connections and power cycled/restarting system. System continued to not always engage when cautery used. Biomedical Engineering contacted<br><br>Medtronic/Covidien representative and this device will be replaced.<br><br>Event 2: Smoke evacuation intermittently not working during a case. All connections were checked and power cycled and still continued to not always engage when cautery in use. Pulled from service and Biomedical Engineering ran the unit continuously for three hours and no problem was found. This pump will be monitored for issues and is not being replaced at this time. |

| Device | Manufacturer | Problem |
|---|---|---|
| | | Event 3: Smoke evacuator intermittently not working while cautery is engaged. OR team attempted a power cycle and double-checked al connections, unit still malfunctioning. Evacuator removed from service and Biomedical Engineering inspected and tested the evacuator and the issue of intermittent on/off cycling was verified by testing. Biomedical Engineering contacted Medtronic/Covidien representative and this device will be replaced.<br><br>Event 4: Smoke evacuator was intermittently not working while cautery engaged. All connections were checked and power cycled and still continued to not always engage when cautery in use. Biomedical Engineering contacted Medtronic/Covidien representative and this device will be replaced.<br><br>No patient injury resulted in any of the above listed events. |
| **Dialyzer, High Permeability With Or Without Sealed Dialysate System**<br><br>Brand: PrisMax | Baxter Healthcare Corporation | Preventative Maintenance is due on our Baxter PrisMax CRRT machines due to lack of available supplies to complete the activity. Machine PM due dates varied by machine but were all due in winter. The kit to perform PM was obtained from Baxter however there is also a syringe required to calibrate the heparin administration device. PM cannot be completed until calibration syringe is obtained. Biomed has contacted Baxter on multiple occasions to order the syringe. When the order was not fulfilled, biomed reached out to the syringe manufacturer to see if it could be ordered from them. They are unable to provide the syringe directly to the customer. Clinical staff contacted Baxter educator, sales manager, and sales rep for our facility. None of them were able to assist with obtaining the syringe. Our Baxter technician visited to work on a warranty covered item but he was unable to supply us with a syringe either. Baxter was asked to provide the PM service since their technicians have the calibration syringe. The cost was approximately $3000 per machine for them to do the service. It would not be covered as part of the warranty and would not be compensated due to lack of supply availability. |
| **Cylinder, Compressed Gas, And Valve**<br><br>Brand: LIV (Linde Integrated Valve) | Linde Gas & Equipment Inc. | Patient on medical stepdown unit had rapid response called for hypotension and oxygen desaturations. Decision made to transfer patient to ICU. As staff were preparing to transfer the patient, they switched the patient from the wall oxygen supply to an LIV (Linde Integrated Valve) portable oxygen tank. Staff turned the top valve on, heard a release of air, and thought oxygen was flowing. Within a minute or so, the patient's oxygen saturations dropped to the 50s. The patient went into cardiorespiratory arrest, CPR was started, and code blue was activated. Once ROSC (return of spontaneous circulation) achieved, the RN checked O2 tank and found the second valve (the one that turns the oxygen on and off) which is located on the side of the tank was in the "off" (red) position.<br><br>The Linde LIV integrated valve oxygen system (portable oxygen tank with regulator) has 2 valves. The regulator valve is on top and on/off valve is on the side. Both valves need to be open for oxygen to flow. When you open the top valve, there is a hissing noise which can mislead the user into thinking that the oxygen is flowing and fully turned on. Subsequently, they may not open the side valve because they think the oxygen is already "on." We have had a number of near misses since this tank was introduced to our hospital in 2017. We believe the design of this tank presents a serious safety concern. |

| Device | Manufacturer | Problem |
|---|---|---|
| **Ventilator, Emergency, Powered, Resuscitator**<br><br>Brand: Neo-tee T-piece Resuscitator<br><br>Model#: 10-50823<br><br>Lot #: 2122150823<br><br>Cat #: 10-50823<br><br>  | Mercury Enterprises, Inc. | Infant patient became apneic after administration of ½ dose of morphine given over increased time due to known morphine sensitivity. Initial resuscitation was complicated by inability to deliver desired pressures by Neo-Tee resuscitator. Team reports that they were not able to give consistent pressures. NICU team was aware of recent concerns regarding possible decreased "head wall" medical air pressure. NICU team disconnected the Neo-Tee from the flowmeter (set at 15 LMP) and reported that they could hear a high flow of gas from the flowmeter. They then connected the Neo-Tee to a portable oxygen tank with known psi and continued to have difficulty maintaining consistent pressures. They then changed out the Neo-Tee and the flowmeter and were able to deliver the desired pressures. This "trouble shooting" of method and Neo-Tee reported over 5-8 minutes.<br><br>Respiratory effort and color improved quickly with consistent pressure delivery per new flowmeter and Neo-Tee. Infant with second apneic episode approximately 5 minutes later. Positive pressure ventilation (PPV) given without difficulty. Resuscitation required intubation, Narcan given as part of resuscitation. Infant soon found to have profound sepsis with positive blood culture.<br><br>Flowmeter was evaluated by Clinical Engineering and found to function normally. Neo-Tee was accidentally discarded post resuscitation. When staff realized their error and went to look for Neo-Tee the garbage has already been removed by environmental services (EVS). NICU staff was not able to verify medical air "flow" or psi during the resuscitation. NICU Medical Gas Zone Alarms did not alert for "low pressure" during this event. No alarms of low pressure from other ventilators in NICU during this event. |
| **Catheter, Flow Directed**<br><br>Brand: Swan-ganz Controlcath Model#: C146F7<br><br>Lot #: 64025025<br><br>Cat #: C146F7 | Edwards Lifesciences LLC | Elderly female with history of coronary artery disease (CAD), hypertension (HTN) and atrial fibrillation (A fib). Procedure: Heart cath for transcatheter aortic valve replacement (TAVR) evaluation. While having the heart cath, the balloon of the latex free Swan ruptured. Device removed and another one used. Minor delay in procedure, no known harm to the patient, discharged the same day.<br><br>Please note that this is #12 Latex Free Swans that have been reported from this facility. |
| **Oxygenator, Cardiopulmonary Bypass**<br><br>Brand: Terumo Fx15-30<br><br>Lot #: YK03 | Terumo Cardiovascular Systems Corp. | Surgeon requested a target temperature of 28°C after EP (Electrophysiology study) mapping. There was concern for the right sided NIRS (Near-infrared spectroscopy) which were 62 with a left sided NIRS of 78. Surgeon elected to cool to 18°C. Four hours on bypass, apparent fibrin formation was noted in the oxygenator bundle/arterial filter area.<br><br>The venous filter and the cardiotomy filter both appeared to have clot propagating higher in their respective areas. A TEG (Thromboelastography) was sent, which eventually resulted as hypocoagulable. The decision was made to change the entire circuit out under circulatory arrest. This was done in three minutes with the left NIRS going from 94 to 92 and the right NIRS going from 89 to 82.<br><br>Possible fibrin formation in bypass circuit oxygenator, possibly after arterial filter.<br><br>It is unclear if this is a patient related issue or an equipment issue. |

| Device | Manufacturer | Problem |
|---|---|---|
| **Wire, Guide, Catheter**<br><br>Brand: Arrow<br><br>Model#: IP-N037314<br><br>Cat #: ASK-04001-BID2 | Teleflex Medical | Patient found to be bleeding from right radial arterial line, saturating pillow hand was on. Dressing taken down to be changed when significant amount of blood squirting out from the area of the catheter closest to the line attached. Occluded with gauze and arterial line removed.<br><br>This has happened on 6 occasions in the last 2 months. 4 of the catheters were sent to Teleflex Arrow International for investigation. |
| **Needle, Hypodermic, Single Lumen**<br><br>Brand: Medline<br><br>Model#: DYNDSBCHLDR<br>Cat #: DYNDSBCHLDR | Medline Industries, Inc. | Labor & Delivery RN was screwing the luer into the vacutainer to collect the blood. When she tried to put the safety cap on, it broke off the top of the luer.<br><br>Her report was "Vacutainer (blood transfer device) broke off when I was applying the safety cap - spraying blood over my face and in my left eye." Nurse washed eyes at eyewash station then to Occupational Health as per protocol. At last review she required no further treatment beyond this First Aid.<br>   |
| **Pump, Infusion, Enteral**<br><br>Brand: Kangaroo<br><br>Model#: 384500C<br><br>Cat #: 384500C | Cardinal Health, Inc. | We received brand new replacement feeding pumps after having Original Equipment Manufacturer (OEM) refurbished pumps fail out of the box. Our facility has replaced out fleet of 150+ with OEM refurbished pumps and are noticing a very high rate of error codes.<br><br>Prior to placing these pumps into service, biomed conducted the initial inspections in the Biotech Testing Mode. During these trials we used the same bags as were used during normal PM procedures for the previous failed pumps as well as additional new bags. Out of all the new pumps we had four that gave multiple error 37 and 39 with the various sets. Following these errors, we cleaned pump sensors and retested, two out of the four passed, cleaned sensors again and were then able to get passing test values.<br><br>Since the reoccurring issue we encountered, biomed conducted a 2nd test of the 4 pumps again and instead of all passing; two pumps failed with error 37 and 39. Very high rate of out of the box issues with these and have been set aside until we receive additional guidance from OEM. |

## 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:** https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/human-factors-and-medical-devices
This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

**Medical Device Connection 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:** https://www.fda.gov/medical-devices/medical-device-safety
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**: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters
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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