MedSun
Medical Product Safety Network

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

# June 2022

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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/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 May 31 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 - Avanos Medical Recalls Cortrak*2 Enteral Access System for Risk of Misplaced Enteral Tubes Could Cause Patient Harm

**May 16, 2022**

Avanos Medical is recalling the Cortrak*2 Enteral Access System because there have been reports of injuries and patient deaths after nasoenteric or nasogastric tubes have been misplaced when this device is used to help with their placement. The Avanos Medical CORTRAK* 2 Enteral Access System is designed to help trained health care personnel place medical feeding tubes into the stomach or small bowel of patients who need to receive nutrition through the tube.

This recall is being used to make updates to the device's labeling, including the instructions for use and intended uses. The updates instruct users to confirm tube placement based on their institution's protocols before using the tube to deliver nutrition.

If a nasogastric or nasoenteric tube is inserted incorrectly, patients could experience damage to the vocal cords, lungs, or trachea, all of which can lead to serious injury or death. According to Avanos Medical's recall communication, there have been 60 injuries and 23 patient deaths related to misplacement of nasogastric feeding tubes while using the CORTRAK* 2 Enteral Access System, since 2015.

### Class I Recall - SML Distribution LLC Recalls Skippack Medical Lab COVID-19 Direct Antigen Rapid Tests That Are Not Authorized, Cleared, or Approved by the FDA

**May 10, 2022**

The Skippack Medical Lab SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) uses a nasal swab sample to detect proteins, called antigens, found on the SARS-CoV-2 virus.

SML Distribution LLC is recalling these tests because these tests were distributed to U.S. customers without authorization, clearance or approval from the FDA. In addition, SML Distribution LLC did not provide the FDA with adequate validation data to show that the test’s performance is accurate. This means there is a risk of potential false negative, false positive, or misinterpretation of results.

If you use the affected product, this may cause serious adverse health consequences or death. SML Distribution has received no complaints or reports of injuries, deaths, or adverse events.

# July 28-29, 2022: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting Announcement

| Date | Time | Location |
|---|---|---|
| July 28, 2022 | 9:00 AM – 5:45 PM | Please note that due to the impact of the COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. |
| July 29, 2022 | 9:00 AM – 4:00 PM | |

**SUMMARY:** The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**AGENDA**: On July 28, 2022, the committee will discuss the topic of skin lesion analyzer technology and its application to detecting skin cancers in various patient care settings. The skin lesion analyzer devices on which the discussion is focused at this meeting are algorithm-based devices for adjunctive detection of various skin lesions, including skin cancers. We will refer to these computer algorithm-aided devices for adjunctive detection of lesions suspicious for skin cancers as Skin Lesion Analyzers (SLAs). In recent years, FDA has seen an increased interest in the development of skin lesion analyzers that employ artificial intelligence and machine learning. These devices include a range of technologies and intended user populations. FDA is interested in the committee members' perspectives on approaches for evaluating the performance of SLA devices given the heterogeneity of technologies and indications.

FDA is convening this committee to promote an open public discussion of, and seek expert opinion on, currently available scientific and clinical data pertaining to the diagnosing standard also known as ground truth, performance criteria, and patient population in future studies assisting medical providers in properly identifying skin lesions by a computer algorithm-aided device.

On July 29, 2022, the committee will discuss the possible reclassification of approved computer-aided melanoma detection class III devices: (1) MelaFind, a device that uses multispectral imaging and was approved in 2012 (P090012), and (2) Nevisense, a device that measures impedance and was approved in 2017 (P150046). Both Melafind and Nevisense devices are intended for use on cutaneous lesions suspicious for melanoma when a dermatologist chooses to obtain additional information when considering biopsy. The committee will discuss if there is sufficient information to reclassify computer-aided devices for adjunctive diagnostic information of lesions suspicious for melanoma from class III to class II, and what special controls may be appropriate to provide reasonable assurance of safety and effectiveness for these devices if they are reclassified as class II devices.

To read the full announcement, including instructions on how to submit a comment, please visit FDA's website.

# ArjoHuntleigh Polska Recalls Sara Plus Floor Lift for Risk of Smoke or Fire When Lift Is Used with Depleted Battery

The ArjoHuntleigh Polska Sara Plus is an active floor lift used for short transfers, such as raising patients from bed to a wheelchair or from a wheelchair to a toilet. It is intended for use in hospitals, nursing homes, and other health care facilities.

**Reason for Recall**

ArjoHuntleigh Polska is recalling the Sara Plus floor lift following several complaints of smoke and/or flames coming out of the lift. When the battery is low, the device's printed circuit board may overheat, leading to smoke or fire. If this situation occurs, anyone using the lift or near it could be injured, including smoke inhalation and/or burns. There have been 44 complaints about this issue. No injuries or deaths have been associated with the use of this device.

**Recommendations for health care providers/device users:**

- Stop use of the Sara Plus lift immediately if smoke appears during use.
- Push Emergency Stop Button.
- Remove the battery from battery socket to prevent any further failure.

The company also offered several precautionary steps for health care providers using the lifts:

- Do not leave patients unattended on the lift in any situation.
- Do not use the lift in humid areas or spray the lift's covers with any liquid. Accidental water ingress can contribute to the printed circuit board failure.
- Do not overload the lift.
- When using the transfer and walking sling for the transfer, the Safe Working Load is 140 kg (308 lbs).
- When using the same sling for walking practice the Safe Working Load is 190 kg (420 lbs).
- Do not use the lift with depleted or damaged batteries (over 2 years old) as it may contribute to the printed circuit board damage. Note the manufacturing date of your battery is visible on the battery's sticker.
- For cleaning, wipe down with a damp cloth using warm water to which a mild detergent has been added. To disinfect the device, clean the equipment first, then wipe it using a solution containing one of the compatible disinfectants. Refer to the Sara Plus Instructions for Use for a detailed guidance.
- Remove the battery from the battery socket on a mast if the lift is unused.
- Make sure that the lift battery is in good working condition before using the lift.
- Charge the battery as soon as battery discharge indicator (small battery symbol) on the lift display falls to three filled segments out of eight.

To read the full 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 May 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 |
|---|---|---|
| **Densitometer, Bone**<br><br>Brand: Horizon A<br>Model#: Horizon A | Hologic, Inc. | A new Hologic Horizon A bone densitometer was delivered. The vendor was onsite the following day and discovered power / c-arm related motion failures with the device. The vendor has been troubleshooting the system and traced the errors down to an unapproved change in manufacturing processes. The vendor has sourced a motor that was manufactured correctly and will be testing the system tomorrow to determine if that resolves the errors. This has the potential to impact any new equipment purchased/installed from Hologic. The failure introduces the risk of a delay in care for patients in need of bone densitometry procedures.<br><br>The device in this event was not being used on a patient. The manufacturer is aware and engaged in resolving the problem.<br><br>The manufacturer has sent staff on site to resolve the issue. Additionally, the manufacturer is investigating similar complaints of faulty motors shipped to their facilities to identify the root cause. |
| **Regulator, Pressure, Gas Cylinder**<br><br>Brand: Reg O2 135psi 3/8 Tubing Cga 540<br><br>Model#: 545012-002 Rev F | Medical Graphics Corp. | Respiratory Therapy (RT) employee received first and second degree burns when an Oxygen (O2) regulator caught fire in the Pulmonary Function Testing (PFT) lab. The O2 regulator exploded (burst) when the RT employee turned on the O2 tank valve connected to the O2 regulator. This O2 regulator was connected both to the O2 tank and the PFT medical device system. The RT employee was directly in front of both the O2 tank and O2 regulator when the flash fire started. Fire was put out by a nearby X-ray technician (employee). RT employee received burns to face, torso, arm, and hand. RT employee was taken to a local hospital and then subsequently transferred to Burn Unit. |

| Device | Manufacturer | Problem |
|---|---|---|
| | | Biomedical Engineering, along with Respiratory Therapy and PFT Manufacturer Representative, investigated the incident site day after incident. Additional Photos were taken of the incident site. The O2 regulator chassis was severely compromised and burned. The PFT Manufacturer and Biomedical Engineering noticed an issue with the O2 regulator. The low pressure side of the O2 regulator was connected to the high pressure O2 tank source. Biomedical Engineering compared a photo of the regulator setups (taken the day before the incident) to photos of the failed regulator. The O2 regulator configuration was not the same. It was determined that the O2 regulator that failed had the incorrect side of the regulator connected to the O2 source. It was determined that the incorrect inlet fitting was connected to the low pressure side of the failed O2 regulator. It was determined the O2 regulator had the correct configuration in the photo taken prior to the incident, but had a different, incorrect configuration at the time of incident. The O2 regulator assembly in use was supplied by the manufacturer for exclusive use with the manufacturer's PFT medical device system. |
| **Tube, Tracheal (W/wo Connector)**<br><br>Brand: 8.0 Taperguard Endotracheal Tube | Covidien | The patient had been intubated with the same 8.0 Covidien Taperguard ETT for approximately 11 days. On the morning of the event, the respiratory therapist found that the tube had possibly migrated. Upon repositioning of the tube and inflating the cuff, the cuff would not hold air. A large air leak was discovered, requiring an ETT tube exchange. The patient required multiple attempts to reintubate, during which emesis and airway edema was observed. A code blue was called due to the lost airway. After multiple (approximately 5) reintubation attempts an ETT tube was able to be placed. Unfortunately, the patient was not able to be resuscitated after intubation. |
| **Catheter, Angioplasty, Peripheral, Transluminal**<br><br>Brand: Evercross<br><br>Model#: AB35W06200135<br><br>Lot #: B335537 | Covidien LP | During a balloon angioplasty, the insufflator was noted to abruptly lose pressure. At this time, a syringe was attached to the inflation port and aspiration noted return of blood, consistent with rupturing of the balloon. Attempts were made to remove the 6mm balloon over a wire, however, attempts to remove the wire were met with great resistance suggesting, not only rupturing of the balloon, but inversion of the balloon material on the balloon catheter. Given the severity of the situation, a decision was made to proceed with a foreign body retrieval.<br><br>The removal caused re-thrombosis of the stented left superficial femoral artery and popliteal artery requiring additional aspiration thrombectomy followed by re-initiation of catheter directed chemical thrombolysis. |
| **Camera, Television, Surgical, With Audio**<br><br>Brand: Natus Nicview 2<br><br>Cat #: NVARM<br>  | Natus Medical, Inc. | Clinical Engineering has identified that the flex arms on 15 cameras have lost rigidity, which prevents the camera from functioning as intended (camera is held up to view the baby). No patients were harmed or involved. |

| Device | Manufacturer | Problem |
|---|---|---|
| **Pump, infusion**<br><br>Brand: CADD Solis<br><br>Model#: 321-2140 | Smiths Medical ASD Inc. | CADD-Solis VIP ambulatory infusion pump alarmed "air in line." When the CADD-Solis infusion pump was primed to get rid of the air (unhooked from patient), there was only about 2-3 inches of fluid at the end of the tubing before it went into the patient. This could have given the patient a deadly air embolus. The CADD-Solis infusion pump kept pumping even though the alarm (not a very loud alarm) was sounding. The CADD-Solis infusion pump are on vented patients that are in isolation much of the time with the door closed. |
| **Catheter, Irrigation**<br><br>Brand: Cardinal Health<br><br>Model#: SU130-0321 | Cardinal Health 200, LLC | A 10FR Jackson Pratt (JP) channel drain placed in patient during surgery. Upon removal, registered nurse (RN) met resistance. RN notified the physician who guided her through the removal of the JP drain. The tip of the device was examined and appeared intact. A few weeks later, in follow up visit, the surgeon noted a retained foreign object, i.e., a piece of broken JP drain. Patient returned to surgery and retained drain tubing was successfully removed. Patient was discharged home the same day. JP drain not saved. |
| **Protector, skin pressure**<br><br>Brand: Static Air Seat Cushion<br><br>Lot#: 22020006<br><br>Cat#: 1400106 | Molnlycke Healthcare | Waffle cushion deflated while on patient. The chair cushion is utilized for pressure reduction for skin care. If this product is deflated, it increases the risk for hospital acquired pressure injuries. Thus, it has the potential for skin integrity impairment. |

## Links to FDA/CDRH Databases and Other Information Sources

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

**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.

**Global Unique Device Identification Database (GUDID):**
https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/global-unique-device-identification-database-gudid
This is a searchable database administered by the FDA that will serve as a reference catalog for every device with a unique device identifier (UDI).

**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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