MedSun
Medical Product Safety Network

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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 August 31, 2020

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

Smiths Medical Recalls Medfusion 3500 and 4000 Syringe Pumps Due to Risk of Medication Delivery Error

August 24, 2020

Smiths Medical is recalling specific software versions of the Medfusion 3500 and 4000 Syringe Pumps because of a software error that may lead to over-delivery or under-delivery of fluids or medication. Over- or under-delivery can occur if the following specific sequence of events occur: a bolus or loading dose is interrupted, the pump is primed, and the infusion is restarted. Use of the affected syringe pumps may cause serious adverse health consequences including death.

CME America Updates Recall of BodyGuard Infusion Pump System Due to Risk of Over-, and Under-infusion

August 5, 2020

CME America is updating their previously announced recall from April 27th because the BodyGuard Infusion System Administration Sets may have a slower than expected delivery of medication (under-infusion), faster than expected delivery of medication (over-infusion) or a delay in therapy. The reason for the infusion errors is not known. Depending on the medication used in the affected infusion pump it may cause serious adverse health consequences including death. There have been 165 complaints regarding this device issue. There have been no injuries or deaths.

Verathon, Inc. Recalls GlideScope Core One TouchSmart Cable ("OneTouch cable"), Due to partial or complete loss of image during use

July 17, 2020

Recall due to the potential for temporary or complete loss of image when used with Core 10 and Core 15 video monitors. If there is an interruption in the video signal during use, this may cause the patient to experience serious adverse health consequences, including hypoxia and death. Verathon Inc. has received 74 complaints in total about these devices, and the FDA has received 9 Medical Device Reports (MDR). There were no injuries or deaths reported as a result of any of the complaints.

Stop Using Gowns, including Surgical Gowns, from Laws of Motion PPE - Letter to Health Care Providers
August 28, 2020

FDA is alerting health care facility risk managers, procurement staff, and health care providers that gowns sold as medical gowns, including surgical gowns, sold by Laws of Motion PPE (LawsofMotionPPE.com) have potential quality issues that affect the level of fluid barrier protection. The FDA is recommending that gowns manufactured or sold by Laws of Motion PPE should not be used as personal protective equipment at this time while the FDA continues our investigation.

Recommendations:
The FDA recommends health care facility risk managers, procurement staff, and health care providers:

- Stop using gowns, including surgical gowns, purchased from Laws of Motion PPE until further notice.
- Identify the supplier or manufacturer of the gowns in your inventory.
- Report any issues with the quality or performance of gowns, including surgical gowns, to the FDA.

FDA Actions:
The FDA is alerting health care facility risk managers, procurement staff, and health care providers about serious concerns with the quality of gowns, including surgical gowns, from Laws of Motion PPE. The FDA is assessing the extent of the concerns and is working with Laws of Motion PPE to understand and address the issue. The FDA will continue to keep health care providers and the public informed as significant new information becomes available.

The complete letter to health care providers can be found on FDA's website.

Protective Barrier Enclosures Without Negative Pressure Used During the COVID-19 Pandemic May Increase Risk to Patients and Health Care Providers - Letter to Health Care Providers
August 21, 2020

FDA is alerting health care providers (HCP) and health care facilities that the use of passive protective barrier enclosures (those without negative pressure) when treating patients who are known or suspected to have Coronavirus Disease 2019 (COVID-19) may pose an increased health risk to patients and HCPs.

On May 1, 2020, the FDA issued an Emergency Use Authorization (EUA) for passive protective barrier enclosures used as a physical barrier to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection, when used in addition to Personal Protective Equipment (PPE), to reduce the risk of transmitting COVID-19 from a patient to HCPs treating them.

However, the FDA now is aware of preliminary evidence in simulated intubation procedure models of potential adverse events that could occur or complications with protective barrier enclosures without negative pressure recently reported in the literature. Although, the FDA has not received any medical device adverse event reports related to the use of passive protective barrier enclosures during the COVID-19 pandemic, the FDA believes HCPs should be aware of potential risks or complications associated with their use so they can take appropriate precautions. Based on this information, the FDA is also revoking the current umbrella EUA for passive protective barrier enclosures issued in May.

Recommendations for Health Care Providers:

- Should not use passive protective barrier enclosures without negative pressure as they may not be effective in decreasing HCP exposure to airborne particles, and in some circumstances, may instead increase HCP exposure to airborne particles. Their use may also contribute to complications such as increased intubation times, lower first-pass intubation success rates, increased patient hypoxia time, and damage or tearing to PPE from the enclosures. These complications may be due in part to the barrier enclosure design characteristics and restricted mobility of the HCP's arms in a restricted space to maneuver the accessories needed to establish a definitive airway.
- If electing to use a protective barrier enclosure for additional protection during aerosolizing procedures by HCPs, FDA recommends the use of devices that incorporate negative pressure. FDA has authorized the use of several negative pressure barrier enclosures, which can be found on FDA's Emergency Use Authorization website. Based on detailed review of data showing decreased HCP exposure to airborne particles, usability, and other safety and performance measures of negative pressure devices, the FDA continues to believe that the known and potential benefits for emergency use of these devices, when used as authorized, continue to outweigh the known and potential risks and do not present public health or safety concerns at this time.

- Although it is unknown whether negative pressure devices have the potential for similar complications as passive devices, at this time, the Agency does not have reasons, or evidences of any adverse events to believe that is the case. FDA is constantly monitoring for signals, and available literature related to authorized devices for emergency use.

- Protective barrier enclosures (with or without negative pressure) should never be a replacement for using PPE.

- Any protective barrier enclosure should be removed if it impedes the HCP's ability to perform a medical procedure on a patient.

The complete letter to health care providers can be found on FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during August 2020. 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
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: Powerglide Pro Midline Catheter Model#: F118100 Lot #: REEN2159 Cat #: F118100 Other #: 18G, 10cm	Bard Access Systems, Inc.	Registered nurse (RN) trained in ultrasound guided IV placement was preparing to place an ultrasound guided Powerglide midline. RN reported that prior to placement, the RN checked the guidewire and noted it would not deploy. The RN attempted to loosen the guidewire by moving the "purple slide" up/down but the wire would not deploy. This device was removed, and a new catheter was obtained.

Device	Manufacturer	Problem
Catheter, Conduction, Anesthetic Brand: Arrow Flextip Plus(R) Epidural Catheterization Kit Model#: IP-N045606 Lot #: 23F20D0276 Cat #: AK-05501	Teleflex Incorporated	Per anesthesiologist, attempt at L4/5, os at multiple angles before LOR (Loss Of Resistance), unable to thread catheter smoothly. Considered thin epidural space at that level not suitable for epidural catheter. Attempt at L3/4, os at multiple angles before LOR, again unable to thread catheter smoothly. Attempt at L5/S1, LOR at 7 cm, epidural catheter advanced smoothly into epidural space. Resistance when retrieving needle, stopped pulling immediately on needle, and decided to pull needle and epidural catheter together. When needle removed, saw exposed inner wire from catheter. Pulled all of wire out. Compared pulled catheter to new catheter and noted approximately 5 cm of catheter presumed to remain in epidural space. Patient denied paraesthesias or neurological symptoms during all the attempts and after removal of catheter. Another catheter was placed without complication. Patient underwent cesarean section without complication. Neurosurgeon consulted. CT scan order of the lumbar spine to determine the position of the retained catheter fragment. CT scan confirmed presence of retained catheter at the L4-5 level, appeared to be epidural, left side extending into the proximal portion of the left L4-5 foramen. Laminotomy performed - retained catheter fragment was successfully retrieved. Patient did well post operatively and was discharged.
Respirator, Surgical Brand: N95 Particulate Respirator Model#: N95 Cat #: 8110S	3M Company	While providing patient care in the Emergency Room, the piece of elastic of the 3M N95 mask broke causing the mask to fall off. Notably, on the same day, two other nurses reported the same problem, fortunately they were not providing patient care at that time. Three days later, two RNs reported the same problem; one while providing patient care. The nurses describe the elastic ear pieces as "stretching out" and "breaking." Nurses on the patient units have made similar complaints and have complained the 3M N95 face portion loses its seal. In an effort to conserve limited inventory, hospital policy requires one mask to be worn for a total of three 12-hour shifts. Masks are to be discarded if they become soiled or defective in any manner. If the practice of wearing the same mask for 3 shifts is not recommended by the manufacturer it must be clearly stated on the box.

Device	Manufacturer	Problem
Device 1: Applicator, Absorbent Tipped, Sterile Brand: Cultura Model#: 00884450495834 Lot #: H1843322 Cat #: C100F/A **Device 2: Applicator, Absorbent Tipped, Sterile** Brand: Cultura Lot #: H1852581 Cat #: VCTS100	Merit Medical Systems Merit Medical Systems	COVID-19 Testing swabs broke off inside multiple patient's noses sometimes requiring ENT to remove them. These 6 events occurred system wide and not specific to a single hospital.
Instrument, Biopsy Brand: Biopince Ultra Full Core Biopsy Instrument Model#: 360-1080-02 Lot #: 11312929 Cat #: 360-1080-02	Argon Medical Devices, Inc.	During a lung biopsy, the cocking lever of ARGON MEDICAL DEVICES BioPince™ Ultra Full Core Biopsy Instrument 18ga x 10cm broke requiring the use of a new gun. The breaking of the cocking lever is a recurrent failure mode. During this last event, the patient underwent a lung biopsy and the failure of the BioPince device delayed the retrieval of the tissue specimen. The patient did not experience any harm during this incident. Nevertheless, any delays during a lung biopsy may lead to serious injury to the patient since the needle has to be introduced on their lungs multiple times. The BioPince biopsy gun was saved by the UF for further inspection/evaluation as needed.

Device	Manufacturer	Problem
Introducer, Catheter Brand: Introcan Safety Model#: 4251890-02 Cat #: 4251890-02	B. Braun Medical, Inc.	The patient was brought to the operating room and laid supine on the operating table. After adequate general anesthesia was obtained, the right shoulder was prepped and draped in the usual sterile fashion. A small incision was made and a large amount of purulent material was then evacuated. There does appear to be extension down to the shoulder joint just on manual palpation with the suction device. Fluid was sent for culture. At this point, the patient went into cardiac arrest with ventricular fibrillation. ACLS protocol was initiated with eventual return of spontaneous pulses as well as respirations; however, I did not place a drain. I merely quickly closed the small incision due to the ongoing need for chest compressions and resuscitation. The patient was taken to the ICU in critical condition. During the resuscitation of the patient on the aforementioned incident, the B.Braun Medical Inc. Introcan FEP Straight Safety® IV Catheter 14 Ga. x 1.25 in. broke inside the patient's AV fistula where the hub meets the catheter shaft. The broken end was not retrieved at the time due to the patient's critical condition. It is presumed that it migrated to the pulmonary vasculature.
Needle, Hypodermic, Single Lumen Brand: Bd Safety-lok Model#: 305900 Lot #: 9316337 Cat #: 305900	Becton Dickinson and Company	While preparing the OR for a surgical procedure, the scrub tech found a BD SafetyGlide 22g x 1 1/2 hypodermic needle in its packaging with no protective cover on the sharp end which was also protruding out the plastic packaging. The scrub tech was able to prevent the device from reaching the surgical table and also from stabbing herself during the process.
Neurological Stereotaxic Instrument Brand: Stealthstation I7 Other #: system number N29859394 System type S8 premium	Medtronic Navigation, Inc.	Laser fiber length was incorrect causing fiber to extended beyond the target and into the brainstem. Patient with a history of metastatic adenocarcinoma as well as multiple sclerosis presented to the OR for a biopsy and possible laser ablation. Surgery was being performed with the Stealth Navigation System and there were 3 Medtronic Reps present for the case. Biopsy portion of the case went as planned and surgeon moved onto the next portion of the case. Measurements for 3 different laser fiber lengths were taken with trajectory confirmation of each. The 3 separate laser fibers were measured to appropriate length and labeled appropriately. Lengths were confirmed and double checked. The 1st fiber was inserted without difficulty. When the 2nd laser fiber was being placed it was discovered that the length generated was too long. This laser fiber was immediately removed. Patient became hypertensive and there was concern for possible brainstem injury. Decision to abort the procedure and not perform the laser ablation was made. Patient was brought to CT and it was identi-

Device	Manufacturer	Problem
Orthopedic Manual Surgical Instrument Brand: Dallmiles System Single-sided Tensioner Model#: 6704-9-320 Cat #: 6704-9-320	Howmedica Osteonics, Corp.	Patient had a left Total Hip Arthroplasty and was discharged home without any complications. The patient returned to the Emergency Department with a fractured left femur around her previous THA. She was taken to the OR for revision of her left femoral component with ORIF of proximal femur. During the surgery, a cable would not thread through Single-sided Tensioner so the staff removed it from service and used the second one in the tray. That tensioner would allow for a cable to pass and surgery was completed. Two days later, the Central Sterile Supply manager was evaluating the "broken" tensioner only to find it was not broken at all but was full of debris from previous patients. He then disassembled the "used" tensioner to find it was full of debris as well. We sent off for loaner replacements from the company and those received, under video inspection, were found to be caked with debris too. These devices are difficult to clean and visually confirm clean because they do not come apart close to the difficult areas to clean.The patient has now developed a hip infection requiring explanation of hardware, placement of a spacer x 6w and then a redo hip arthroplasty in 3 months.
Pump, Infusion, PCA Brand: Cadd Model#: 2110 Cat #: 21-2112-0401-249	Smiths Medical MD, Inc.	4 separate times over the last 3 years we have had Smith Medical Computerized Ambulatory Drug Delivery (CADD) Solis infusion pumps fail. All four times, with the most recent being in February of 2020, high alert medications were hung by a Registered Nurse (RN), verified by another RN, and the Smith Medical CADD infusion pump alerted low volume for the medication, but when the RN checked the hanging medication, the IV bag was full. Between the four separate cases, three were post-op cases and was a patient in out OB suite in active labor. In only one instance, in early 2019, the pump again stated that it had finished the infusion, but the bag was found to be full. The IV line was found to be occluded, but the pump did not alarm in any way. In the most recent case of this happening, the bag was once again found full, even though it stated it administered the amount entered the CADD pump.
Set, Administration, Intravascular Brand: Clearlink/continu-flo Solution Set 2c8537 S Model#: 2C8537 S Lot #: R18B14130 Cat #: 2C8537 S	Baxter Healthcare Corporation	5 sets of Baxter Clearlink Continu-Flow Solution Set 2C8537 s, 109" tubing, that had a peach/brown hue to the IV tubing.

Device	Manufacturer	Problem
System, Balloon, Intra-aortic And Control Brand: Arrow Lot #: 18F18L0011	Teleflex Incorporated	Called to bedside by RN for report of debris within the helium supply line. Black dots seen inside helium tubing (definitely on inside of tubing; could not remove from external catheter with alcohol swab) concerning for blood from balloon puncture. IABP device was not alarming and pt's hemodynamics not affected at the time of event. Dr notified immediately. IABP dropped to 1:4 and later to off with plan to exchange balloon emergently. Attempted left IABP removal with sheath over long guidewire with the intention of replacing sheath and IABP on this side but resistance met with removal of IABP/sheath unit with distal third of balloon still in the femoral vessel. This was ultimately removed by Dr. and new sheath could not be advanced in this site, so manual pressure was held by staff while a new IABP was placed in the right femoral artery.
Ventilator, Continuous, Minimal Ventilatory Support, Facility Use Brand: Philips Respironics Model#: V60 Cat #: 144164-M	Respironics California, Inc.	Deep Tissue Pressure Injury (DTPI) to bridge of nose from wearing a Bilevel Positive Airway Pressure (BiPAP) mask.
Ventilator, Continuous, Minimal Ventilatory Support, Facility Use Brand: Philips Respironics Cat #: REF1121065	Respironics California, Inc.	Pressure injury to the bridge of nose under Bilevel Positive Airway Pressure (BiPAP) mask.
Ventilator, Non-continuous (Respirator) Brand: Af541 Model#: 00 Cat #: 1121065	Respironics, Inc.	BiPAP (Bilevel Positive Airway Pressure) mask contributed to a Hospital-Acquired Pressure Ulcer (HAPU) on bridge of patient's nose.

Device	Manufacturer	Problem
Ventilator, Non-continuous (Respirator) Brand: Respi-ronics Model#: 144166-S Cat #: 144166-S	Respironics, Inc.	Deep Tissue Pressue Injury (DTPI) to bridge of nose related to wearing a Bilevel Positive Airway Pressure (BiPAP) mask.
Ventilator, Non-continuous (Respirator) Brand: Af541 Cat #: 1121065	Respironics, Inc.	Pressure injury noted on right eye from medical device.

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:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm
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: http://www.fda.gov/medsun/
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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