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 June 5, 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

Medtronic recalls StealthStation auto-registration feature due to inaccuracies during deep brain stimulation (DBS) procedures

June 1, 2020

Medtronic has recalled the auto-registration feature of the StealthStation DBS Software due to inaccuracies caused by minor patient movements during the auto-registration process when used with NexFrame during a DBS procedure, which may not be detected by the surgeon or the device system. This may provide inaccurate registration data which could lead surgeons to inaccurately navigate lead placement during image guided DBS procedures. This could result in serious or life-threatening patient harm. As of June 2020, a total of 33 medical device reports were identified: 22 related to device malfunction and 11 related to injuries.

Medtronic Recalls HeartWare HVAD Pump Outflow Graft and Outflow Graft Strain Relief Due to Risk of Breaks and Tears During Set Up

May 28, 2020

Medtronic is recalling their HeartWare HVAD Pump Outflow Graft and Outflow Graft Strain Relief because the outflow graft of the HVAD Pump may tear and the strain relief screw may break during assembly prior to implant but might not be observed until during or after the pre-implant pump assembly and attachment to the HVAD pump. The use of the affected products may cause serious patient harm including dizziness, loss of consciousness, bleeding, fluid buildup around the heart, additional medical procedures and death. Medtronic has received 92 complaints related to the pre-implant pump assembly process, which includes both the strain relief screw breaking and outflow graft tears.

Applied Medical Recalls Python Embolectomy, BARD Embolectomy, and OTW Latis Cleaning Catheters Due to Risk of Separation During Use

May 12, 2020

Applied Medical is recalling their Python Embolectomy Catheters, Bard Embolectomy Catheters, and OTW Latis Cleaning Catheters because there is a risk of the catheter tip detaching during use. If the tip detaches, pieces of the catheter could break off into the patient's body. If this occurs, there is also the potential for serious health consequences including additional surgical procedures to remove the tip, damage to the blood vessel, or death. There have been 46 complaints regarding this device issue since 2015. The FDA has received three medical device reports (MDRs) and no reports of death or injury.

Transport Media Safety Risk - Use Compatible Transport Media with SARS-CoV-2 Tests that Use Bleach - Letter to Clinical Laboratory Staff and Health Care Providers

The U.S. Food and Drug Administration (FDA) reminds laboratory staff to use transport media (the liquid that maintains a specimen sample while it is transported to a laboratory) that are compatible with the SARS-CoV-2 testing platforms and the processes used in their laboratory to process samples collected from people who are being tested for SARS-CoV-2. There is a risk of exposure to harmful cyanide gas, a by-product of a reaction between guanidine thiocyanate or similar chemicals and bleach (sodium hypochlorite), when certain transport media are used with an incompatible testing platform or laboratory process. Guanidine thiocyanate may be referred to as guanidinium rhodanide, guanidinium thiocyanate, or guanidinium.

There are numerous transport media that contain guanidine thiocyanate or similar chemicals. PrimeStore molecular transport media (MTM) (LH-1-02 and LH-1-03), Zymo DNA/RNA Shield, Spectrum Solutions Saliva Collection Device, and any other transport medium containing guanidine thiocyanate or similar chemicals, should not be used in a testing platform such as the Hologic Panther and Panther Fusion Systems that use bleach or in laboratories that use bleach as part of their normal laboratory processes. When the bleach interacts with the guanidine thiocyanate or similar chemicals in the transport media, it produces cyanide gas.

While there have been reports of these potentially hazardous interactions, there have been no injuries reported to the FDA associated with exposure to cyanide gas as a result of using incompatible media with testing platforms.

Background

PrimeStore MTM (LH-1-02* and LH-1-03*), Zymo DNA/RNA Shield, and Spectrum Solutions Saliva Collection Device contain a transport medium which maintains patient specimens while they are transported to a laboratory for RNA and DNA testing. These media contain guanidine thiocyanate or similar chemicals, which produces a potentially hazardous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite) and should not be used in a testing platform, or in laboratory processes, that use bleach. Many laboratories may use bleach in their cleaning or decontamination processes in response to laboratory spills.

Other transport media may contain guanidine thiocyanate or other similar chemicals, and ingredients in transport media may not be listed on individual tubes. If laboratory staff do not know the ingredients in the transport media, they should handle it as though it has guanidine thiocyanate or similar chemicals to avoid a potential reaction. If laboratory staff receive samples in unfamiliar transport media, or transport media without appropriate labeling, they should make sure the media does not contain guanidine thiocyanate or similar chemicals before processing the samples in a testing platform that uses bleach, or before using the samples in a laboratory that regularly uses bleach for laboratory cleaning and decontamination processes.

Transport Media Safety Risk - Use Compatible Transport Media with SARS-CoV-2 Tests that Use Bleach - Letter to Clinical Laboratory Staff and Health Care Providers

Recommendations

The FDA recommends that clinical laboratory staff and health care providers:

- Do not use PrimeStore MTM, Zymo DNA/RNA Shield, Spectrum Solutions Saliva Collection Device, or any other transport media containing guanidine thiocyanate or similar chemicals with the Hologic Panther or Panther Fusion Systems due to a disinfecting step involving bleach that is specific to the testing platform.
- Review the manufacturer's instructions for the testing platform used in your laboratory about which transport media should be used.
- Do not use cleaning agents containing bleach on testing platforms that use guanidine thiocyanate or similar chemicals, either in transport media or sample processing reagents.
- Do not separate transport media tubes from the manufacturer's labeling.
- If you can identify the contents of the tube through associated packaging or information from the distributor, you may place a label on a specimen collection tube that does not have a label identifying the type of transport media inside. If you do not have a label, you may contact the manufacturer to obtain one.
- If you cannot identify the type of transport media in the specimen collection tubes or if you do not know if the transport media contains guanidine thiocyanate or similar chemicals as an ingredient, handle tubes as if they contain guanidine thiocyanate or similar chemicals.

FDA Actions

The FDA is collaborating with manufacturers of transport media and SARS-CoV-2 testing platforms to improve product labeling.

The FDA is working with federal and state health agencies to inform laboratory staff about the risk of exposure to harmful cyanide gas when certain transport media are used with an incompatible testing platform or laboratory process.

The FDA will continue to keep clinical laboratory staff, health care providers, manufacturers, and the public informed of new or additional information.

The complete Letter to Health Care Providers can be found on FDA's website.

Use the Correct Cycle and Compatible N95 Respirators When Decontaminating Respirators with STERRAD Sterilization Systems - Letter to Health Care Providers

The U.S. Food and Drug Administration (FDA) reminds reprocessing staff in health care facilities to use the correct decontamination cycle associated with certain models of the Advanced Sterilization Products (ASP) STERRAD Sterilization Systems and to only decontaminate compatible N95 or N95-equivalent respirators for reuse during the COVID-19 pandemic.

ASP STERRAD Sterilization Systems use vaporized hydrogen peroxide to decontaminate medical devices. Only the combination of certain models of the ASP STERRAD Sterilization System and their associated STERRAD Decontamination Cycle listed in the FDA's Emergency Use Authorization (EUA), are authorized for the decontamination of compatible N95 respirators.

Background

ASP STERRAD Sterilization Systems use hydrogen peroxide vapor to decontaminate medical devices at low temperatures through a process that uses a combination of heating and sub-ambient pressures. Several models of ASP STERRAD Sterilization Systems are available, offering decontamination cycles that vary among system models.

During the COVID-19 pandemic, health care facilities are rapidly adopting conservation practices such as decontaminating compatible N95 or N95-equivalent respirators for single-user reuse. Health care facilities alerted the FDA of the potential for reprocessing staff that decontaminate respirators to use an incorrect decontamination cycle and incompatible respirator when using ASP STERRAD Sterilization Systems.

Using the correct decontamination cycle is necessary to avoid potentially compromising the performance, fit, and breathability of decontaminated compatible N95 respirators. Using the correct cycle also helps preserve the electrostatic properties (such as leakage resistance) of the polypropylene filter in these respirators. These electrostatic properties play a vital role in the respirators' filtration efficiency.

Recommendations

The FDA recommends that reprocessing staff in health care facilities:

- Recognize that new N95 and N95-equivalent respirators, when available, are always the first choice for health care personnel.

Use the Correct Cycle and Compatible N95 Respirators When Decontaminating Respirators with STERRAD Sterilization Systems - Letter to Health Care Providers

Recommendations

The FDA recommends that reprocessing staff in health care facilities:

- Recognize that new N95 and N95-equivalent respirators, when available, are always the first choice for health care personnel.
- Confirm the N95 or N95-equivalent respirators you are decontaminating do not contain cellulose (i.e., paper-based materials). Respirators that contain cellulose are incompatible with vaporized hydrogen peroxide decontamination.
- Use only the **Express** cycle for the STERRAD 100NX System. Do not use other cycles available on the STERRAD 100NX System to decontaminate compatible N95 respirators.
- If your system currently does not have the **Express** cycle, consider the software upgrade available from the manufacturer to add this cycle to the STERRAD 100NX System at your facility.
- Use only the 100S cycle to decontaminate compatible N95 respirators with the STERRAD 100S System.
- Use only the **Standard** cycle to decontaminate compatible N95 respirators with the STERRAD NX System.
- Review the Fact Sheet and Instructions associated with the Emergency Use Authorization:
- Fact Sheet for Health care Personnel
- Instructions for Health care Facilities
- Instructions for Health care Personnel

FDA Actions

On April 11, 2020, the FDA issued an EUA for decontaminating compatible N95 or N95-equivalent respirators using ASP STERRAD Sterilization Systems, enabling health care facilities to conserve their supply of respirators during the COVID-19 pandemic. The EUA also specifies that these decontaminated respirators are only for single-user reuse, which means the same user uses the same respirator following decontamination.

The FDA updated the Fact Sheet for Healthcare Personnel, Instructions for Healthcare Facilities, and Instructions for Healthcare Personnel for the ASP STERRAD Sterilization Systems to clarify the importance of using the correct decontamination cycle.

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 May 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:

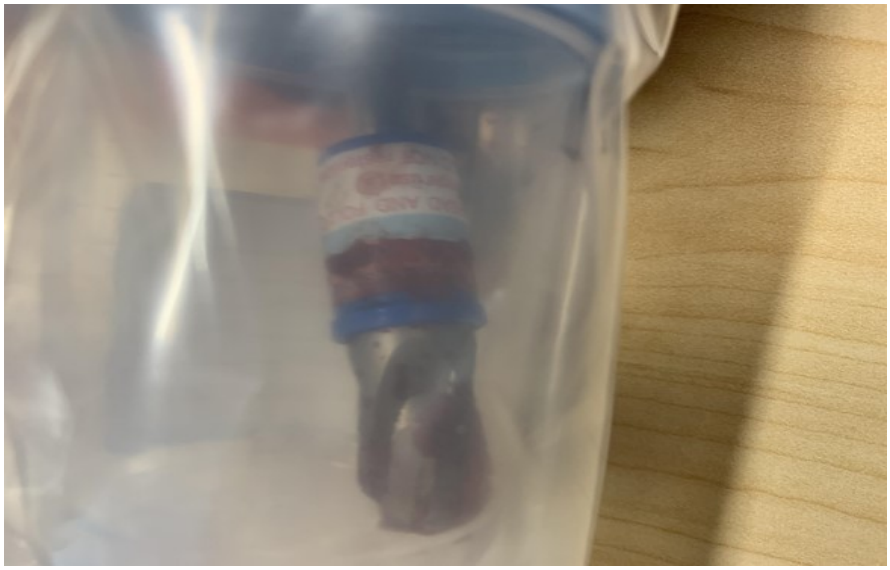
The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years 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
Aortic Valve, Prosthesis, Percutaneously Delivered Brand: Edwards Commander Delivery System Model#: 9600LDS26 Cat #: 9600LDS26A	Edwards Lifesciences LLC	During a TAVR procedure, the insertion of the valve deployment device was successful, however upon deployment of the valve, the balloon only inflated partially. It also got caught up on the circular wire mesh of the device preventing its retraction and a subsequent valve deployment. While attempting to remove the device, the patient went into a lethal cardiac arrhythmia initiating a Code blue, compressions were started and medications were given. The code lasted, approximately, 10-15 minutes before the normal rhythm returned. Afterwards, a successful transfemoral approach for valve placement was done, but the deployment device could not be removed from the subclavian artery. The balloon and valve tip remained in the patient since the CT surgeon decided to conclude the surgery due to the prolonged period of time, 4 hours, that the patient been under anesthesia. The patient was transported to ICU afterwards.

Device	Manufacturer	Problem
Automated Insulin Dosing ,Threshold Suspend Brand: T:slim X2 Insulin Pump With Basal-iq Model#: 1005698 	Tandem Diabetes Care, Inc.	The patient was being followed by the Hospital Endocrine clinic for diabetes type I. Her family was using insulin injections as prescribed. 3 months later, the endocrine team started discussions with the family about future use of an insulin pump. Before using the insulin pump, the family required several teaching sessions with the diabetes nurse educator per usual process. The insulin pump was ordered from the company for this international patient in January in preparation for future use. The pump is often ordered much ahead of time because of the lengthy insurance/embassy approval process. The pump was delivered to the family home. The father of the patient called the tech support number for the Tandem insulin pump the following day and requested guidance via phone support for setting up and applying insulin pump to the pre-school aged patient at home. There were no prescriber orders for insulin pump settings. The endocrine team had no knowledge of the father's plan to start the insulin pump against medical instructions without proper teaching and competency. Somehow, the tech support person gave the father instructions to set up the pump and "install" pump on child's body. The father used inappropriate insulin vial to set up the pump which was the insulin being used previously for subcutaneous injections. There had been no prescription written yet for the appropriate insulin to be used in the future for the pump. That night, the child sustained low blood sugars due to the continuous infusion of basal rate insulin which was incorrectly set-up. The low blood sugars were treated by the parents at home. The next day, the father called the endocrine team to notify them of the low blood sugars. When it was discovered that the father had started the insulin pump incorrectly with the inappropriate guidance of the Tandem tech support staff, the parents were instructed to immediately take the insulin pump off the child and return to the previous insulin injections of which they were competent.
Blade, Saw, General &Plastic Surgery, Surgical Brand: Arthrex Dissector, Sj 3. 0mm X7cm Model#: AR-7300DS Lot #: 10491341 Cat #: AR-7300DS	Arthrex, Inc.	The inner cannula tip of the arthroscopic shaver broke off in the patients soft tissue. A second shaver was then opened and used, it also broke off at the tip in the patients wrist joint. The surgeon then used a mosquito clamp to retrieve both metal tips. Xray was utilized to verify the metal pieces were retrieved. No harm to patient.

Device	Manufacturer	Problem
Catheter, Coude Brand: Bardex Lubricath Foley Catheter Tiemann Model Coude Model#: 0102L12 Lot #: NGEN-X514 Cat #: 0102L12	C.R. Bard, Inc.	When the surgeon was placing the foley into the patient's urethra and deploying the balloon the foley ruptured. The foley was removed from the urethra. The scheduled procedure for an artificial sphincter was abandoned. The patient was taken to the recovery room.
Catheter, Retention Type, Balloon Brand: Bardex Lubri-sil I. C. All-silicone Foley Catheter Model#: 1758SI16 Lot #: NGDU3876 Cat #: 1758SI16 Other #: 303416A	C.R. Bard, Inc.	When placing catheter there are no issues with placement or function, however when it is time to remove the catheter there is resistance when trying to deflate the balloon. When and if any fluid does return it is not the sterile water it is supposed to be, it is urine. In order for the catheter to be removed it has to be cut and removed that way. Equipment is foley catheter, size 16fr silicone lot #NGDU3876 on this particular event.
Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Powerpicc Solo2 Catheter Model#: 1194108D Lot #: REDX1468 Cat #: 1194108D	Bard Access Systems, Inc.	Patient noticed PICC line leaking at home, reported to ED. Site care done, leaking persisted. PICC removed. Hole in catheter noted at 4cm.

Device	Manufacturer	Problem
Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System Brand: ICU Medical Spiros Chemo Connector Red Cap Model#: CH2000S-C Cat #: CH2000S-C 	ICU Medical	During chemo administration, patient's father called and notified RN to come into room ASAP. RN found that the chemo line became undone and blood had spilled out of pt's line and followed the line and noticed that the Spiros Connector had come undone accidentally. RN alerted the resource RN to take another look. RN and Resource RN brought in new tubing line. Per Dad, patient did not manipulate the line as they were just sitting in bed playing with toys. MD and Pharmacy were notified.
Defibrillator, Automatic Implantable Cardioverter, W/ Cardiac Resynchronization Brand: Claria Mri™ Quad Crt-d Surescan™ Model#: DTMA1Q1	Medtronic, Inc.	Patient had intermediate Implantable Cardioverter Defibrillator (ICD) interruptions due to a Juul e-cigarette being placed adjacent to ICD in a shirt pocket. No harm.
General Surgery Tray Brand: Adult Body Bags With Id Tags Model#: NON70548WM	Medline Industries, Inc.	Post mortem body bags are thin and weak and sometimes the sling harness is missing. When the body bags reach cold temperatures, they become brittle and rip in the process of moving patients out of the morgue and onto the funeral home stretchers. With the body bags ripping, employees may be exposed to infection (ie. COVID-19).
Rapid Flu Test Brand: Binaxnow Influenza ABCard 2 Model#: 575-000 Lot #: 113348 Cat #: 575-000	Alere Scarborough, Inc.	NO Solution in elution vial to run influenza test. Elution vial was empty and cap was intact prior to opening

Device	Manufacturer	Problem
Drills, Burrs, Trephines Accessories (Compound, Powered) Brand: Codman Model#: 26-1221 Lot #: J11Y52 Cat #: 261221	CODMAN & SHURTLEFF, INC	During a craniotomy procedure, a perforator used to drill through the skull did not function as intended. Normally the usual CODMAN disposable perforator bit will stop as you breach the skull as to not affect the brain or dura. This one did not stop and resulted in torn dura and a small nick (cut or notch) to the brain. Surgeon reported that this was not the first bit to do this in the last week. No serious injury to the patient was noted during or after the incident. Requested product, CODMAN Disposable Perforator Drill, was returned to Integra Lifesciences. Please see pictures below:  

Device	Manufacturer	Problem
Set, Administration, Intravascular Brand: Maxzero Model#: MZ9273 Lot #: 18095666 Cat #: MZ9273	CAREFUSION 303, INC.	Unable to flush IVF through filter line (red clamp lumen). Multiple issues with this tubing not flushing, manufacturer is actively investigating the issues.
Set, Administration, Intravascular Brand: Powerloc Max Port Access Needle Model#: 0142075 Lot #: AS-DUF028 Cat #: 0142075	Bard Access Systems, Inc.	Patient port tubing distal to needle but above the cab had a small hole. When I went to draw patients labs, upon flushing normal saline, I discovered that saline was squirting out of the hole.
Surgical Mask, Single Use Brand: Earloop Face Masks 3Ply Single Use Surgical Mask Cat #: MS3P501001 Other #: Executive Standard: GB/T 32610	Minimum and Maximum Inc	Surgical face masks being used by hospital personnel during COVID-19 crisis-the ear loops are breaking. These are not N95 face masks. There are a few defective masks being reported at this time. No lot number was provided. I am not certain that the lot number was noted at the time of the report. This has been an on-going concern for several months. A previous report was submitted earlier this year and the defective masks were sent to the manufacturer. The samples of masks that I was given have been saved and are available for return.
Table, Operating-room, Electrical Model#: 3602 UltraSlide	SKYTRON, LLC	After case was completed, bed was turned back to original position to get ready for extubation, with head at anesthesia, bed locked. Suddenly bed began to rise on its own. Attempted to lower bed with control but when the lower bed button pushed bed stopped rising, once button let go, bed continued to rise again. All this time patient on the OR bed. Bed unplugged and manual switches utilized but bed continued to rise. Dr. had to manually hold down the bed lower button on the manual buttons on the base of the bed so that we could safely transfer patient onto patient bed. Patient safely transferred to patient bed. OR table unlocked via emergency button and moved out of the way. Biomed notified. We have had numerous incidents in the last year involving the buttons getting stuck on the pendant hand control.

Device	Manufacturer	Problem
Tube, Tracheal (W/wo Connector) Brand: Size 8. 0Cuffed Endotracheal Tube Model#: 18780 Lot #: 19G1030JZX Cat #: 18780	Covidien LP	Multiple ET tube cuff's were blowing or not inflating properly. Patient intubated during Code Blue on step down unit with #8.0 Covidien tube. Per the RT, by the time they got to critical care, they already had a blown cuff. They obtained the 8.0 from the intubation box and tested the cuff which not hold. They grabbed the second 8.0 ETT and tested the cuff and it would not hold. They then went to the 7.5 tested the cuff, it held the air. That was what they used to intubated the patient.
Tube, Tracheal (W/wo Connector) Brand: Halyard Model#: 35216	Avanos Medical, Inc.	RN informed Respiratory Tech that Pt had an audible cuff leak on Pt ET Tube. Respiratory Tech inspected Pt ET Tube and confirmed that a cuff leak was present. Respiratory Tech fixed Pt cuff leak. Respiratory Tech left room. RN returned to Respiratory Tech within 5-10 mins stating that the cuff was leaking again. Respiratory Tech used manometer to measure cuff pressure and the manometer read below the green zone. Respiratory Tech then re-inflated cuff with manometer and disconnected the manometer. Respiratory Tech then retested cuff pressure with manometer and the ET Tube cuff pressure had fallen significantly and was no longer holding a proper cuff pressure. Respiratory Tech informed MD who called anesthesia and assisted in ET Tube exchange on the Pt.
Ventilator, Continuous, Facility Use Brand: Hamilton -mr1 Model#: 161010	Hamilton Medical AG	1. The ventilator apparently got too close to the MRI magnet and caused it to shut down while on a patient. a. Contributing Factors i. No visual or audible warnings or alarms from the Tesla Spy feature of the ventilator as designed ii. Upon further investigation, the ventilator showed "FAN FAILURE" b. Actions Taken i. Troubleshot the ventilator 1. Tesla Spy system seem inoperable – no indicator lights at all 2. "FAN FAILURE" error noted upon turning on the ventilator The trolley brakes were engaged at the time of the event. The ventilator was not attached to the wall anchor. TeslaSpy indicator lights were not lit.
Respirator, Surgical Brand: Kimberly -clark® Fluidshield™ Pfr95™ Respirator And Surgical Mask Model#: 46767 Cat #: 46767 Other #: NIOSH TC-84A-0005 small	KIMBERLY-CLARK GLOBAL SALES, LLC	I was given a Duckbill mask that a staff member had tried to use the previous day. The straps to the mask disintegrated in her hand while trying to don the mask. On the next day, a different nurse tried to use 2 different duckbill masks and both masks straps disintegrated in her hand while donning the mask.

Device	Manufacturer	Problem
Set, Administration, Intravascular Brand: Plum Model#: 1233605 Lot #: 4180982 Cat #: 1233605 	Hospira, Inc.	While checking on the patients scheduled IV line status the nurse noted that the IV line was leaking at the 0.2 micron filter and dripping onto the floor. The RN check on the IV line distal to the filter and note no air in line. IV set removed and exchanged. This is a reoccurring issue with this particular Primary Filtered IV set. The clinician reference the set's LOT number and provide that information to Biomedical Engineering for reporting to MedWatch and to the manufacturer. There has been several attempts to work with the manufacturer to resolve this issue. The manufacture has informed us that they are working with the filter manufacturer to help determine a root cause. All reported issues with this leaking has occurred with TPN medication and primarily with our Neonate population. We now keep a running log of these events and have recorded on this log over 45 distinct events.

Links to FDA/CDRH Databases and Other Information Sources

FDA U.S. FOOD & DRUG ADMINISTRATION
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Device Listing: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.

Establishment Registration: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This is a searchable database of U.S. and foreign establishments engaged in the manufacturer, preparation, propagation, compounding, assembly, or processing of medical devices for U.S. distribution. Note: This database is updated once a month.

Human Factors Website: http://www.fda.gov/medicaldevices/deviceregulationandguidance/humanfactors/default.htm. This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Luer Misconnections Website:
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 June 2020 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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