MedSun
Medical Product Safety Network

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

August 2020

Volume 20, Issue 8

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 August 1, 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

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.

CME America Announces a Follow-Up on the Voluntary Recall of BodyGuard® Infusion System Administration Sets

July 8, 2020

As part of CME America's commitment to quality, following the previously announced recall (April 27, 2020) of the BodyGuard® Infusion Pump Systems, the company conducted additional flow-rate accuracy testing. This testing revealed that some infusion sets do not meet the ±5% delivery accuracy for the system or the ±13% accuracy identified in the earlier recall notification. Therefore, the use of the pump system potentially could cause over-infusion or under-infusion of therapy and patient harm. Based on those test results CME America is providing additional information and customer actions regarding its previous recall to include all infusion sets used with the BodyGuard® infusion pump distributed beginning May 2016.

Endologix Issues Correction Notice for Ovation iX Abdominal Stent Graft System

July 8, 2020

Endologix announced that a correction notice has been issued for the Ovation iX system, that identifies the root cause of polymer leaks. This voluntary action has been classified by the FDA as a Class 1 recall. No physical product removal of the product is planned or needed.Correction Z-2263-2020 was issued in May 2020 to current users of the Ovation iX system and informs users of a material weakness adjacent to the polymer fill channel that may become compromised during pressurization with liquid polymer.

FDA Safety Communication: Risk of Loss of Coordination during Water-Related Activities in Parkinson's Patients with Deep Brain Stimulators
July 30, 2020

FDA would like to remind patients and health care providers about the risk associated with using deep brain stimulation (DBS) devices for Parkinson's Disease. Patients may be at risk of injury during water-related activities (such as swimming) because of the loss of coordination while using the device. Patients should also be cautious while bathing.

Recommendations for Health Care Providers:

Review the Important Recommendations for Patients and Caregivers with patients who have these devices.

Discuss the risk of a loss of coordination involving several sequential movements in a coordinated fashion during swimming.

Monitor for patient reports of loss of coordination during activities requiring coordination and report adverse events to FDA MedWatch program, using the information in the "Reporting Problems with Your Device."

Recommendations for Patients and Caregivers:

Be aware that, although reported infrequently, when the device is turned on some patients with Parkinson's Disease who use implanted DBS have noted difficulties in performing complex coordinated movements associated with swimming and may be at risk of drowning.

Consult with your doctor before participating in water-related activities.

You should not swim alone. When possible, consider having another adult with you in the water.

Notify your health care provider if your symptoms get worse or you experience loss of coordination during water activities. Discuss your device's settings with your health care provider and do not make any changes to your system without consulting your physician.

The complete safety communication 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 June 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
Syringe, Piston Brand: Bd Luer-lok Model#: 305060 Lot #: 0057522 Cat #: 305060	Becton Dickinson and Company	3mL syringe taken out of a sealed package and found a hole in the syringe. The hole is at the end of the 3mL marking on the syringe.

Device	Manufacturer	Problem
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 2420-0500 Lot #: 20043249 Cat #: 2420-0500	Carefusion 303, Inc.	Went to prime the "BD Alaris pump infusion set" and the tubing was missing a roller clamp. So, I grabbed another one and that tubing was missing a luer lock at the end. Lot is (10) 20043249 for both packages of tubing.
Accessories, Cleaning, For Endoscope Brand: Rapicide Pa High-level Disinfectant Model#: ML02-0117	Medivators, Inc.	Viewed box that arrived with a cap less bottle of Rapicide that had spilled into box. Cap visible at bottom of box. Box with visible damage, wetness. Surprised to see that the bottles of Rapicide have a simple cap (no safety features) and the bottles have no seal under the cap or other anchor/seal to minimize chance for leakage or loss of cap en route. Staff noted that when they open the boxes of Rapicide they never remove the bottles from the box without tightening them first as they are often loose. This has happened at another facility as well.
Catheter, Coude Brand: Bardex® Lubricath® Foley Catheter Tray Model#: 899916 Cat #: 899916	C. R. Bard, Inc.	Patient with latex allergy had catheter from Foley kit used and developed allergic reaction. Packaging does not make it very evident that product contains latex. Foley has an asterisk which is defined in very small print on the side as containing latex. On the packaging of the device, there are two small asterisks next to the catheter, but the legend for what that means it is in small print on the side of the package. Patient contacted physician's office post-op day 3 with complaints of irritation from catheter and thinking the patient may have yeast infection. Patient seen by MD in the office where swelling and erythema on bilateral labia minor and majora was noted. Catheter was removed and patient completed voiding trial successfully. Patient was prescribed triamcinolone cream to the vulva TID. Packaging was not saved at MD's office. Hospital was notified 2 days after patient's visit to the MD office.

Device	Manufacturer	Problem
Catheter, Coude Brand: Bardex® Lubri-cath® Foley Catheter Tray Model#: 899916 Cat #: 899916	C. R. Bard, Inc.	The concern with this event was that the packaging doesn't make it very obvious that the product contains latex. Even though RN was aware of patient's allergy, they were not aware that product contained latex since it is not clearly marked. We can send one of these to the manufacturer if needed, but we wanted to raise this concern more in regard to the product labeling (which led to this adverse event) rather than product being contaminated or containing a compound that was not listed. Please see picture below: 
Device, Hemostasis, Vascular Brand: Perclose Proglide 6f (2. 0mm) Model#: 12673-03 Lot #: 0052141 Cat #: 12673-03	ABBOTT VASCULAR, INC.	During deployment of the Proglide closure device, it was noted that the device was defective. Doctor had difficulty time removing from body. Significant bleeding noted, Doctor controlled the bleeding. Patient was sent to recovery in stable condition. The paddles on the closure device failed to properly close after the suturing was complete. The physician had to use force to remove the device. Significant bleeding was noted and he had to up size to a bigger sheath to achieve hemostasis. Internal balloon tamponade was preformed to close the puncture site. This took time and required a femostop to hold pressure external after the procedure was complete. Because of bleeding groin complication, the patient required increase monitoring in the ICU.

Device	Manufacturer	Problem
Dialyzer, High Permeability With Or Without Sealed Dialysate System Brand: Prismaflex Set Model#: HF1000 Lot #: 20C3005 Cat #: 107140	Gambro Industries	Blood was leaking from a crack in tubing just below the filter junction. The tubing was attached to the CRRT device at time of the incident. Prior to incident priming of the tubing went smoothly.
Dialyzer, High Permeability With Or Without Sealed Dialysate System Brand: Prismaflex Model#: 7.20 Cat #: 955542	Gambro AB	The Baxter (formally Gambro) PRISMAFLEX CRRT System (Product Code/REF#: 955542, Serial #: PA20126) was set up and initiated per manufacturer instructions. Upon initiation the deaeration chamber and hemofilter filled with air. Blood could not be returned to the patient due to the risk of air embolism. 150mL of blood were loss due to the failure of the device. In May of this year a similar Baxter PRISMAFLEX CRRT System, that had been red tagged for the same issue, was sequestered by the Clinical/Biomed Team for repairs. The defective product was placed in a dedicated location for pick up. A "Do Not Use" red tag was placed on the device.
Gown, Surgical Brand: Convertors Model#: 39079 Lot #: 19KCC042 Cat #: 39079	Cardinal Health 200, LLC	Surgical Smartgown was donned in preparation for surgery. After arms were in the gown and before picking up gloves, a large hole was found along a seem on the left sleeve near the wrist. The gown was removed and saved for evaluation.
IV Administration Tubing Brand: Alaris Model#: 10800175 Lot #: 19036752 Other #: 350838	Carefusion 303, Inc.	Tubing set crack and leak.

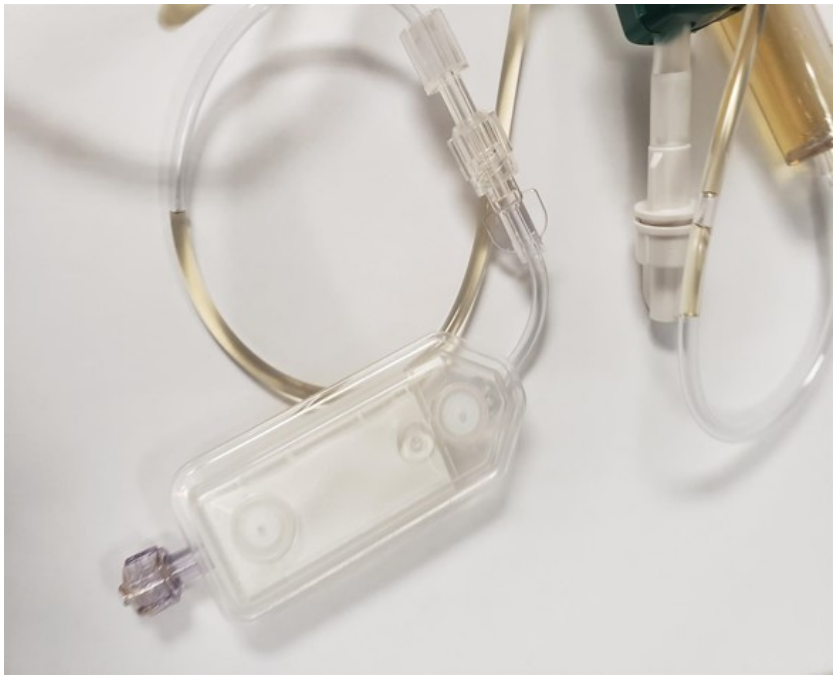
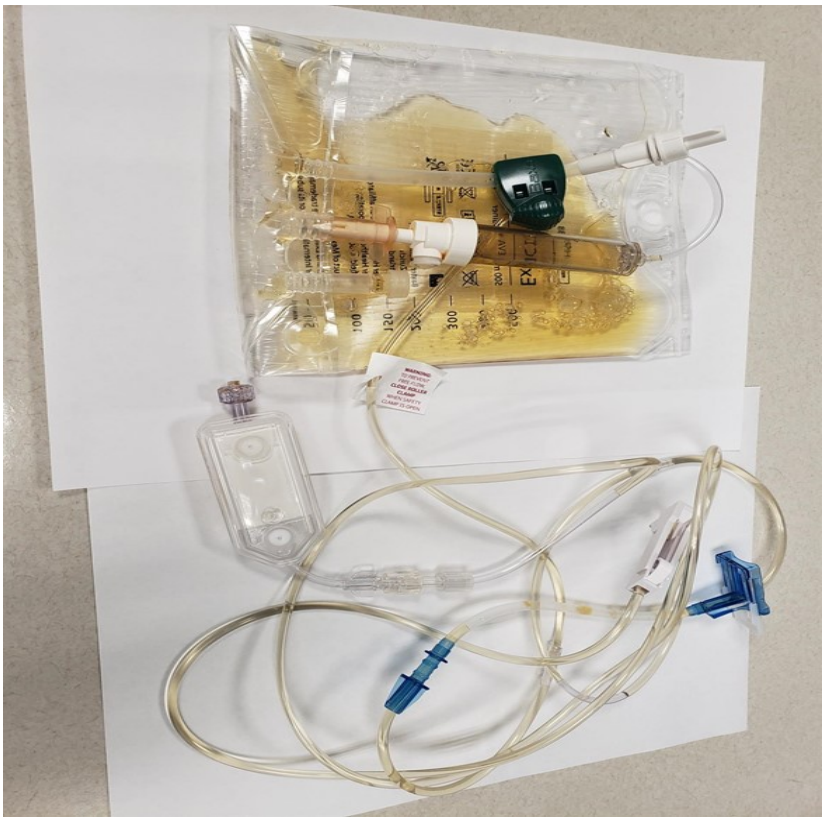
Device	Manufacturer	Problem
Laparoscope, General Plastic Surgery Brand: Genistrong Model#: 550-000-003 Lot #: J0833-A Cat #: 550-000-003 Other #: LU550-000003G Rev AA	Genicon, Inc.	A Genicon GeniStrong Medium Specimen Retrieval Bag (550-000-003) broke during a laparoscopic cholecystectomy procedure. This failure mechanism is a recurring issue during surgical procedures at this facility. When GeniStrong specimen retrieval bag break it poses a risk to the patient since the original intended procedure has to be extended to replace the defective device by a new one. A similar event previously occurred.
Needle, Hypodermic, Single Lumen Brand: BD Vacutainer Eclipse Blood Collection Needle Model#: 368608 Lot #: 0010861 Cat #: 368608	Becton Dickinson and Company	Needle safety malfunction, safety device and needle cover came off of needle, exposing it and risking unnecessary poke
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 2426-0500 Lot #: 20053526 Cat #: 2426-0500	Carefusion 303, Inc.	Brand new IV tubing in package used to spike brand new IV bag and tubing fell apart right below chamber. Another set of tubing came apart near one of the injection ports. The tubing was replaced prior to patient contact. No harm came to the patient.

Device	Manufacturer	Problem
Pump, Infusion Brand: Sigma Spectrum Pump Model#: 35700BAX Cat #: 35700BAX	Baxter Healthcare Corporation	After implementing manufacturer's IFU cleaning procedure, battery failure alert rates increased drastically. The failures were primarily the 'red screen' battery reset notice, and the replace battery alert. Our data shows that the primary suspect of recent failures is a residue/film on the battery pads, which appears to be cleaning agent residue. As a result, we had to promptly alter the cleaning procedure so that the only cleaning agent used on the battery contacts and pins was alcohol, which has helped. Our failure rates are still much higher that they have historically been however. Since late April, when we began the new cleaning procedure, we are averaging 168 battery failures per week, compared to a pre-remediation average of 52. All preventative maintenance has been followed normally per procedure. Cleaning procedure concerns- 1) IFU states not to touch the battery terminals but also states to clean and dry the battery terminals and pins. These statements seem to contradict each other. 2) Concern that the case will After implementing manufacturer's IFU cleaning procedure, battery failure alert rates increased drastically. The failures were primarily the 'red screen' battery reset notice, and the replace battery alert. Our data shows that the primary suspect of recent failures is a residue/film on the battery pads, which appears to be cleaning agent residue. As a result, we had to promptly alter the cleaning procedure so that the only cleaning agent used on the battery contacts and pins was alcohol, which has helped. Our failure rates are still much higher that they have historically been however. Since late April, when we began the new cleaning procedure, we are averaging 168 battery failures per week, compared to a pre-remediation average of 52. All preventative maintenance has been followed normally per procedure. Cleaning procedure concerns- 1) IFU states not to touch the battery terminals but also states to clean and dry the battery terminals and pins. These statements seem to contradict each other. 2) Concern that the case will degrade and screw heads will strip out over continuous removal and insertion of the power cord retainer, as it just screws into the plastic, and is difficult to screw in. 3) Concern for lost screws as they are small and difficult to replace during the cleaning process. 4) Concern for ability of all staff who would normally clean the pump after use that each and every step can be reasonably followed. Nurses, Patient care assistants, Central Service staff, Environmental Services staff, etc. Access to two different types of screw drivers (one for power cord clamp and one for battery module) 5) Ability to ensure screws are not overtightened resulting in damage 6) Concern for the overall length of time needed to clean when the IFU is completely followed. It's unrealistic to expect all types of staff will be able to consistently follow each step properly.

Device	Manufacturer	Problem
Pump, Infusion Brand: Sigma Spectrum Pump Model#: 35700BAX Cat #: 35700BAX	Baxter Healthcare Corporation	Hundreds of pumps have been sent back to the manufacturer for evaluation. Including only a few examples of events in which harm or potential harm occurred to a patient. Event1- IV pump infusing high dose of Epinephrine plugged in and in use since arrival from OR with no prior alarms abruptly alarmed "BATTERY ALERT" and then "BATTERY FAILURE." While getting a new pump and switching med/tubing over patient's BP dropped significantly with MAP's in the 50's. Event2 - in TMS, The pump had Norepi running at 0.5 mcg/kg/min. The pump randomly failed. The patient was extremely sick on 3 pressors. We were essentially chemically coding her at the time. I had to pull the tubing out of the pump and run it open in order to keep patient's BP stable until a new pump was programmed. Luckily, her BP never dropped but there was serious potential for severe hypotension causing death. Event3- while patient was transferring to chair, became hypotensive. RN attempted to adjust dose of norepinephrine. Pump "shut down improperly" and auto restarted, all settings were lost. This occurred three times in a row, necessitating use of a different IV pump. Event4- IV pump plugged in, states charge complete. Rings for "battery alert" and shuts down immediately after unplugging. Nonessential drug infusing through IV, no harm to patient. Event5- IV pump plugged in, states charge complete. Rings for "battery alert" and shuts down immediately after unplugging. Nonessential drug infusing through IV, no harm to patient. Event6- The pumps were infusing propofol and sodium phosphate when they failed Event7- IV pump battery failure. Heparin running.
Pump, Infusion Brand: Sigma Spectrum Pump Model#: 35700BAX Cat #: 35700BAX	Baxter Healthcare Corporation	Continuing from previous report, after implementing manufacturer’s IFU cleaning procedure, battery failure alert rates increased drastically. The failures were primarily the ‘red screen’ battery reset notice, and the replace battery alert. Hundreds of pumps have been sent back to the manufacturer for evaluation. Including only a few examples of events in which harm or potential harm occurred to a patient. Event8- patient had Heparin running through pump, then alarmed to plug pump in. Verified that pump was plugged into powerstrip, then screen turned red and said battery failure. Event9- Patient had lasix infusing, Pump failure, auto shut down. Had to remove medication infusion and change out pump. Event10 - Bumex infusing when pump shut off. Medication for diuresis. Stopped med and changed out pump. Event11 -Propofol running through pump with battery alert on a paralyzed, proned intubated patient. Intervened prior to sedation wearing off. Two pumps failed. Event12- Baxter IV Pump had battery failure. Pump was running continuous paralytic medication. Pump was immediately switched over to back up IV Pump. No harm reached the patient.

Device	Manufacturer	Problem
Pump, Infusion Brand: Sigma Spectrum Pump Model#: 35700BAX Cat #: 35700BAX	Baxter Healthcare Corporation	Pump was removed from room and placed aside, tagged as battery failure. Event13-Running zosyn when pump failed. Event14- RN intended to use pump to give IV albumin, immediate battery malfunction, pump warned "battery alert" Event15- Battery failure alarm although plugged in to outlet. This pump was infusing Norepi. Event16- IV pump infusing RBCs had battery failure alert, unable to continue infusion with pump. Event17- IV pump infusing RBCs had battery failure alert, unable to continue infusion with pump. Event18- Baxter pump battery failure while infusing medication Event19 - setting up room for patient actively coding on floor. Battery alert on pump. Event20- IV pump battery failure with red blood cells currently infusing for patient. Pump exchanged, affected IV pump removed from room. Event21 Iv pump failed with pressor in line. Pressor moved to new pump, MAP maintained > 65. Will continue to monitor Event22- IV Infusion pump infusing propofol suddenly stopped infusing presenting a "malfunction" warning. Propofol was quickly reprogrammed into a pump that was not in use.
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 2426-0500 Lot #: 20053526 Cat #: 2426-0500	Carefusion 303, Inc.	Brand new IV tubing in package used to spike brand new IV bag and tubing fell apart right below chamber. Another set of tubing came apart near one of the injection ports. The tubing was replaced prior to patient contact. No harm came to the patient.
Ventricular (Assisst) Bypass Brand: Thoratec® Heartmate 3™ System Controller Model#: 106531US Cat #: 106531US	Thoratec Corporation	Patient's spouse sent in remote monitoring data and noted that the Left Ventricular Assist Device's (LVAD's) power has been elevated the past few days. Patient instructed to have bloodwork drawn at nearest laboratory & to report to nearest LVAD center for device interrogation. Manufacturer representative notified of event. Device logfiles sent to the manufacturer by the LVAD coordinator. Noted that, on one day patient experienced a 4 second pump reset/stop while connected to Mobile Power Unit. Unclear whether patient heard audible alarm at this time, patient reported no symptoms. LVAD's power remained elevated after that day. LVAD system controller changed at the nearest LVAD center without event, remained in observation overnight.

Device	Manufacturer	Problem
Stopcock, I. V. Set Brand: ICU Medical Model#: B1729 Lot #: 4734904 Cat #: B1729 	ICU Medical, Inc.	There has been three separate events in the NICU involving the use of the ICU Medical B1729 Luer Lock Extension Set with 0.2 Micron Filter. The first event (EVN20034144) noted the malfunctioning of a B1729 IV Ext Set connected to an umbilical venous catheter (UVC). When the micron filter was placed at the same level as the newborn patient, the UVC bled back into the IV line and tubing. The micron filter worked as expected when held in the "house up" position. The IV flow rate during this event was 17.5 mL/hr. The issue with the B1729 Ext Set started when the filter had to be added to the no-port IV tubing. The 0.2 filter is shorter than the filters used in the past which are 14 cm in total length. The second event (EVN20029089) involved blood backing up in the UVC line using the B1729 micron filter connected to a BD Alaris IV infusion set. The BD IV pump was used to infuse fluids at a rate of 7.3 during a total parenteral nutrition (TPN) procedure. RN noted the presence of blood in the line and called the physician. Health care providers noted that fluid started to flow normally on the IV set when the filter was held in a vertical position (up higher in the air). Blood started backing up in the line immediately after the filter was lowered back down despite using a 7.3 pump rate. A large amount of backed up air was noted on the filter as well. The filter is being used a substitute product to a shortage of the regular product due to COVID-19. The third event (EVN20028764) involved the use of a dual lumen UVC, large volume bag and a syringe pump infusing fluids into a patient. The issue started with the infusion of gentamicin. All pumps began alarming occlusion and neither the outgoing nurse nor the neonatal nurse practitioner were able to flush line/lumen. It is unclear if the infusion into the lumen was from the large volume bag or syringe pump. Physician was called to assess line. Physician was able to get line to flush sluggishly. Physician ordered fluids to be infused by syringe pump only, and to loosen sutures on UVC for being too tight. Fluids were able to infused into UVC without incident afterwards. Please see pictures below:

Device	Manufacturer	Problem
Stopcock, I. V. Set Brand: ICU Medical Model#: B1729 Lot #: 4734904 Cat #: B1729	ICU Medical, Inc.	 

Device	Manufacturer	Problem
System, Balloon, Intraaortic And Control Brand: Arrow Model#: IP-N000302 Cat #: IAP-0400	Teleflex Incorporated	While in use on a patient, a balloon pump alarmed "High Baseline." Clinical staff attempted to troubleshoot the issue but did not notice any obvious kinks in the tubing. The balloon pump was exchanged, and staff did not experience any further issues or alarms with the new pump. This incident appears to be related to a recent FDA recall (Z-2408-2020).
Device 1: Tubes, Gastrointestinal (And Accessories) Brand: Neoconnect Enteral Extension Set Model#: PEXT-60NC Lot #: 20191126 Cat #: PEXT-60NC **Device 2: Tubes, Gastrointestinal (And Accessories)** Brand: Neoconnect Enteral Extension Set Model#: PEXT-60NC Lot #: 20191218 Cat #: PEXT-60NC Other #: 851035	NEOMED, INC. NEOMED, INC.	The caregivers found the ENfit feeding extension leaking at the patient connection. All have been checked to make sure they were secured appropriately with no "tilting" or misconnection noted. Also that they were not "too tight" or "loose". Some have been noted to be cracked at patient side securement. Once we had 2 extensions that were compromised, we immediately notified our nursing staff to watch for others. Because our staff was aware, they have been able to catch the leaks early on so infants receive their full calories as ordered. They have worked with materials to pull those lot numbers as defective batches have been found. Only four patients are included in this report although there were more affected. Breakdown of Lot #'s: 20191126 - 8 total 20191218 - 3 total 20191230 - 3 total 20200110 - 1 total Unknown - 7 Total (Packaging not saved but connection/ tubing was)

Device	Manufacturer	Problem
Ventilator, Continuous, Facility Use Brand: Hamilton-t1 Intelligent Transport Ventilator Model#: T1 Other #: Last PM 1/2020	Hamilton Medical, Inc.	Emergency Medical Service (EMS) team attempted to do a critical care transport where a patient had to be placed on bilateral positive airway pressure (BiPAP). Patient tolerated the BiPAP well at the hospital, and on the EMS Hamilton Vent in the hospital, and in the back of the ambulance initially. The ventilator was working perfectly despite the patient breathing rapidly at roughly 25-30 times a minute. Patient was loaded into the ambulance and transferred to truck oxygen (O2). Shortly after transferring to truck oxygen, the vent started to alarm that "Oxygen Supply Failed." EMS double checked both tanks were open and the tank switch was activated; confirmed they were. Patient's peripheral capillary oxygen saturation (SP02) began to rapidly decline. EMS switched the Vent O2 line to the second tank and activated the switch; the vent continued to indicate that the "Oxygen Supply Failed." EMS activated both Emergency By-pass Oxygen Valves. The vent continued to indicate that the "Oxygen Supply Failed," as well as switching between "Low Oxygen," and "High Oxygen," alerts multiple times and the patient's SP02 was rapidly declining. EMS performed set up on original port and attached a Bag Valve Mask (BVM) at 15 lpm to it. The BVM reservoir bag was fully inflated and the ball indicator showed that the oxygen was flowing perfectly. Patient was BVMed successfully and SP02 decline halted, and then showed slight improvement. Patient diverted to closest facility as the patient was declining. The patient was initially supposed to go to a different facility, however EMS figured they would not have enough oxygen in the spare portable tank to get to other facility while bagging the patient. Throughout transport EMS could not get the saturations above 86%. Before the oxygen source was switched, the patient's saturations were above 90% on BiPAP. After the call, EMS ran tests on the ventilator with the truck and the ventilator O2; pre-op check passed on both ports. The truck and the ventilator were taken out of service and brought to the garage. At the garage, EMS team and supervisor attempted to use a vent circuit and vent balloon to recreate the issue using the same lines of trouble shooting as listed above (both ports, tank switch on and off, emergency oxygen valves opened and closed). No scenario was able to recreate the issue. The ventilator and truck were taken out of service.

Links to FDA/CDRH Databases and Other Information Sources

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.

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

Contact the MedSun Program Staff:

Telephone: 800 859 9821
Fax: 800 859 1292
E mail: medsun@fda.hhs.gov

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993