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.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during April 2017. 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:

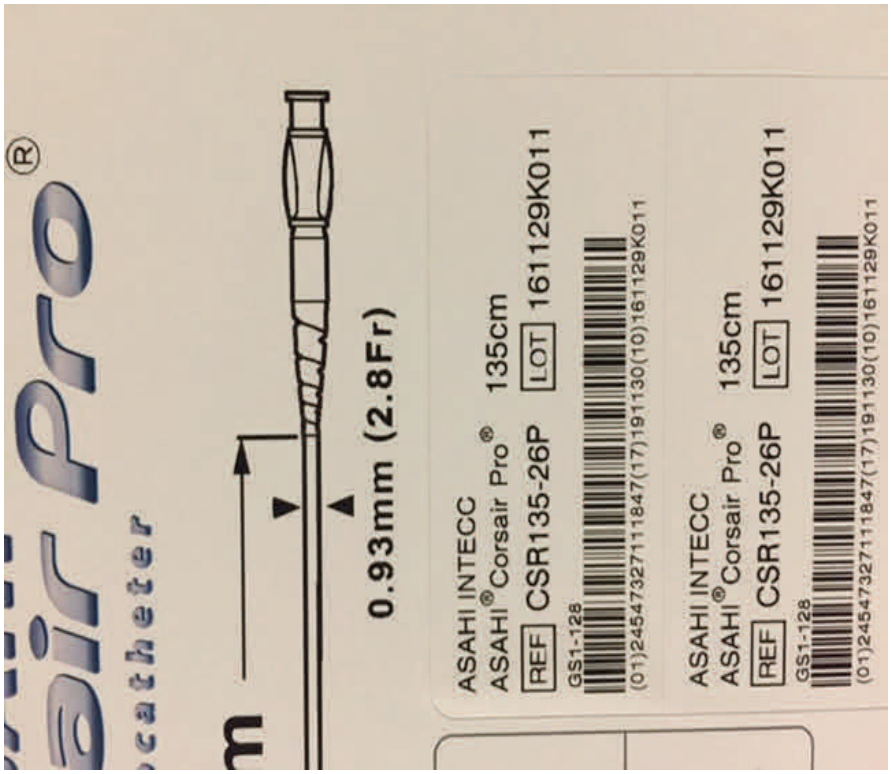
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm


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.

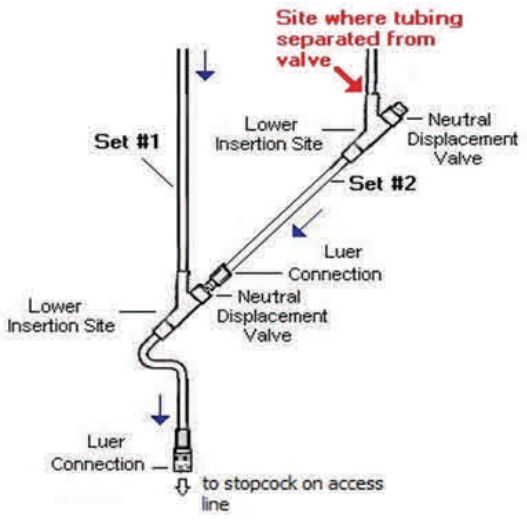
Device	Manufacturer	Problem
Pump, Infusion Brand: Cadd Solis Lockbox Model#: 21-2188-25 Cat #: 21-2188-25	Smiths Medical ASD, Inc.	When completing hourly rounds on a post-operative patient with a patient controlled analgesic pump, the nurse discovered the lock box to be opened. Further investigation revealed an empty medication bag (Dilaudid) and a puncture hole in the bag. The patient was stable. The pump was removed from the room. Security investigated the lock box and found that it was easily manipulated and opened with a credit card. Several additional lock boxes were investigated with the same end result. One lock box was opened with a paper clip. The lock box is a secure system opened with a special key used to secure opioids. Additional investigation found the pump itself could be opened with a paperclip as well. The ability to easily manipulate the lock box is of great concern especially today with drug abuse rising. The pump in question is CADD Solis PCA pump. CADD Solis Lock box # 21-2188-25.

Device	Manufacturer	Problem
Catheter, Long Term, Intravascular Brand: Arrow Pressure Injectable Quad Port Catheter Lot #: 23f17b0736	Teleflex Incorporated	The patient had a 20cm Arrow Pressure Injectable central line (lot# 23F17B0736) placed. The following day, the patient became restless and while moving about in the bed, the central line came out unintentionally. Upon assessment of the line, slits were noted in each eyelets allowing sutures to slide out of the eyelets, therefore the line wasn't secure. After the line had slid out, sutures were noted still intact in patient's skin. Pressure was applied, hemostasis was achieved within minutes, and no harm came to patient. A new quad-lumen CVC was placed as a result. The faulty device was reported to VAST including the lot# of the device. VAST also saved the faulty catheter to file a safety report with the manufacturer. This facility has had at least two other similar events with this device. In at least one previous case, the manufacturer was notified. Staff have not heard back from the manufacturer regarding the previous event reported to them.
Automated External Defibrillators (Non-wearable) Brand: XSeries 	Zoll Medical Corporation	During external pediatric patient transport to another facility, the transport critical care monitor/defibrillator non-invasive blood pressure parameter failed after two to three blood pressure determinations. The display screen gave a "NIBP Kinked Hose" error message and states to "Check all hoses and cuffs for kinks, or blockage. If failure persists contact ZOLL Customer Service." The error message is presented with an Acknowledge prompt button. This message comes up even after the hoses are triple checked for kinks or cuff tubing connections. This issue is a recurring event with varied pediatric patient populations and cuff sizes. This issue has occurred on more than one of our new transport monitor/ defibrillators. This report will connect and report two devices confirmed by Biomedical to have given this error message.
Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Powerpicc Solo2 Ft Catheter Model#: 1295108FD Lot #: REAW1727 Cat #: 1295108FD	Bard Access Systems, Inc.	Bard microintroducter 5 French from PICC kit with unexpected notch. Attempt to place into patient's skin prior to noticing the abnormal notch. Unable to place into patient. A new micro-introducer opened and successful placed in patient. Product ref # 1295108FD, Lot # REAW1727 Power PICC SOLO FT Catheter with Sherlock 3CG tip Positioning system (TPS)Stylet. Bard Rep called immediately; replacement microintroducer kits sent per company.

Device	Manufacturer	Problem
Catheter, Percutaneous Brand: Corsair Pro Model#: CSR135-26P Lot #: 161129K011 Cat #: CSR135-26P	ASAHI INTECC CO., LTD	During percutaneous coronary intervention using transluminal revascularization of chronic total occlusion vessel, the Corsair 135 catheter tip became detached in small septal collateral vessel. Unable to remove this broken catheter tip. Decision made to treat patient medically. Please see pictures below:  

Device	Manufacturer	Problem
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: Nexiva Lot #: 6350965 Cat #: 383539 Other #: 18 gauge	BD	It was reported on 3 occasions that once the needle was removed from the port making it a needleless system, the port leaked. On one occasion it leaked blood and the other two occasions when it was flushed it leaked through the white stopper. This appeared to have been isolated to one lot #. There is no patient information to apply to this report, but the lot # has been pulled from the distribution center.
Container, Specimen, Non-sterile Brand: Click NClose Model#: DYND30382	Medline Industries—Dynacor.	Incorrect red blood cells (RBC) reported in urine microscopic due to urine containers that falsely elevate the count. The Residents inquired to the lab about the high RBC count in urine results. The urine container contains silicone around the rim supposedly that was for easier placement of the lid on the urine container. Unfortunately the silicone gets into the urine, causing artifacts that resemble RBCs. These can be picked up while manually looking at microscopic urine but for automated equipment such as the Iricell 1500 by Beckman-Coulter the silicone nodules falsely elevate the RBC count on automated equipment in urine samples. When we initially called in Beckman-Coulter because we thought there were issues with the equipment they specifically told us at that time to not use Medline products because of the silicone interference.
Device 1: Disinfector, Medical Devices Brand: Getinge 88-series Model#: 88 Turbo Other #: 88 Turbo Washer Disinfector **Device 2: Disinfector, Medical Devices** Brand: 1-cart Unloading Conveyor Model#: V499925202 Cat #: V499925202 Other #: 1 -Cart Un-Loading Conveyor; 88 Turbo Washer Disinfector	Getinge IC Production Poland Sp. z.o.o. Getinge IC Production Poland Sp. z.o.o.	Faulty equipment. The company Getinge has installed off loaders for our washer decontaminator machines and they all too often stop working which causes employees to manually pull the racks out. You have to pull them really hard to move them in which case, that is how the employee injured shoulder/neck. Getinge has been contacted and they have tried several changes and adjustments to the auto unloaders but none of them have fixed the issue. The unloading stations keep damaging the doors on the 88 turbo machines and they keep locking up. We have 4 of them and all of these unloader stations have the same problem without resolution.

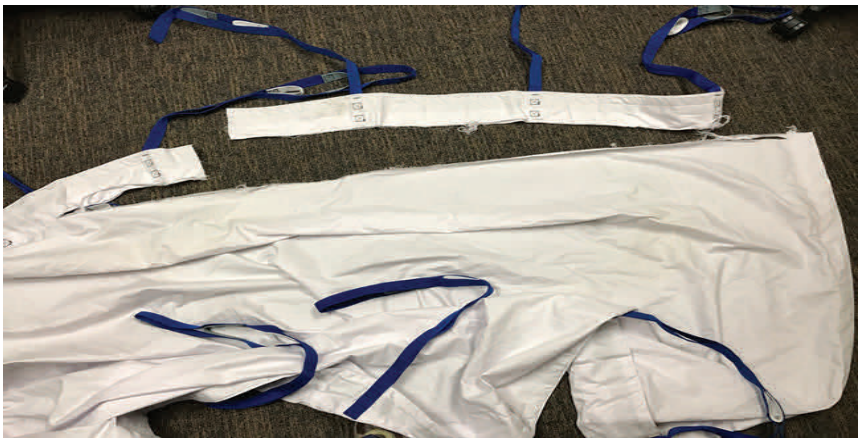
Device	Manufacturer	Problem
Disposable Handpiece, Ablation Brand: Sterile Minerva Disposable Handpiece Lot #: 17A17-03 Cat #: MIN9770	Minerva Surgical	Partially through a procedure, a disposable Minerva handpiece showed a "Fault" error message on the machine. The handpiece was removed and examined by the surgeon. The surgeon suspected a possible defect in the balloon and sent the device to Clinical Engineering. The procedure was completed with a second handpiece. No harm came to the patient.
Catheter, Hemodialysis Brand: Vas-cath Lot #: MG-ZH-710 	Bard Access Systems, Inc.	PICU RN at bedside changing VAS-Cath dressing and assessing catheter ports. PICU RN attempted to access the red port and was able to pull off air. He then noticed a crack in the tubing at the clamp site. The RN felt as though this was a manufacturing defect. NICU Clinical Leader (CL) notified and once line was removed by pediatric surgery, CL sent it to the OR to check the package with the same catheter lot numbers. Catheter replaced intraoperatively.
Gauze Sponge Brand: Curity Lot #: 16J181662 Cat #: 3033	Covidien LLC	Needed gauze for a patient's wound and opened a new box of Curity Gauze Sponges to find one was opened and empty and the other had a broken bottom seal, compromising the integrity of the gauze sponge. Please see pictures below:  

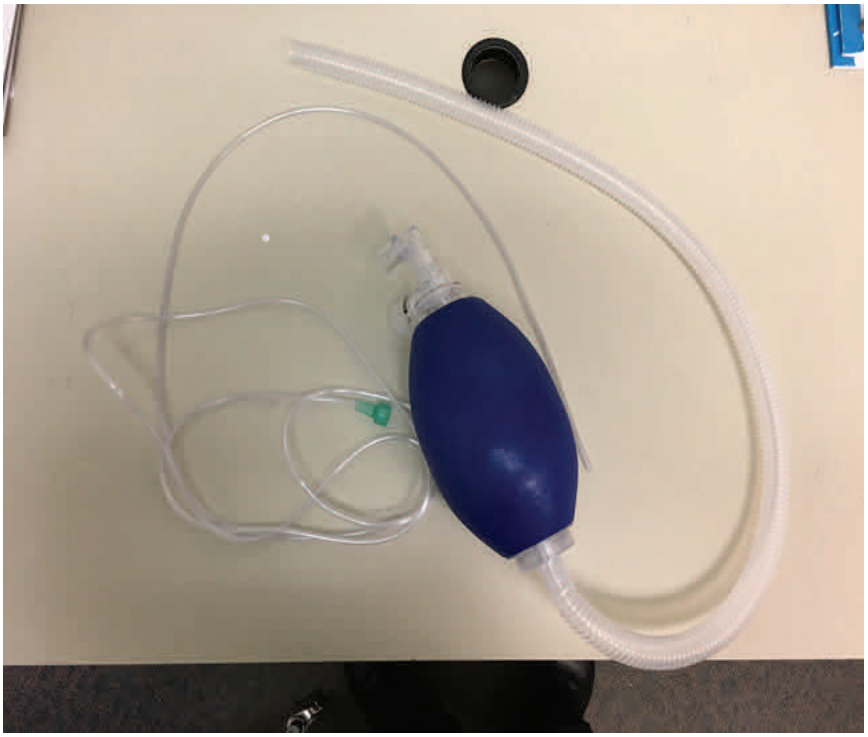
Device	Manufacturer	Problem
Endoscopic Vessel Harvesting System Brand: Vasoview Hempro Lot #: 25131169 Cat #: VH-3000	Maquet Cardiovascular, LLC.	During saphenous vein harvest procedure, the vasoview hemopro bipolar device tip broke off. The broken piece was retrieved from the surgical field and the patient was not harmed.
IV Administration Set Brand: Clearlink Continuflo Lot #: R16J15034 or R17A09075 Cat #: 2C8519s	Baxter Healthcare	What should have been a bonded connection between a tubing segment and the lower of the two Y-sites of a ClearLink primary IV set failed to hold so the 2 components came apart. This became a line open to air and it was fortunate that it was connected to the stopcock on the ACCESS line for the dialysis set so that the air was drawn into the dialysis set and detected by the machine. If the failed line had been connected to the stopcock of the RETURN line, air likely would have been drawn into the patient and created an embolism. The expensive dialysis filter set had to be disposed of because of the amount of air that got in it. Please see picture below:  
Device 1: Pump, Infusion Brand: Alaris Model#: 8100 Other #: 300-7401 **Device 2: Set, Administration, Intravascular** Brand: Alaris Model#: 11612593 Cat #: 11612593 Other #: 300-7401	CAREFUSION 303, INC. CAREFUSION 303, INC.	RN hung 2g calcium gluconate at 1611. Calcium was placed on existing TKO line on a channel that had been used on the patient for at least 2 days. The patient was scanned, the medication was scanned, the pump was scanned, the order was sent from the MAR (Medication Administration Record) to the pump with the correct rate of 100mL/hour and volume to be infused 100mL. The pump was then started. I turned the patient with another nurse and looked up approximately 5 minutes later at my IV pump and noted the calcium bag seemed to be dripping at a rate much faster than 100mL/hr. I reexamined the pump and confirmed the rate was sent to 100mL/hour and that was displayed. This was confirmed with another RN. I looked back and the calcium bag and the entire bag had been given to the patient. The pump volume to infuse said the bag should still contain 87mL of fluid when realistically 110mL of fluid had been infused. The patient suffered no ill affects, but had this been a potassium supplement or any of my other drips (amio, heparin, norepi) this would have been very detrimental to the patient. The entire pump and was taken out of the patients room and marked for biomed to look at. This is the fourth similar event at this facility with these devices. The manufacturer was contacted and is aware of some of the previous events.

Device	Manufacturer	Problem
Laryngoscope, Rigid Brand: Rusch Mac Laryngo-scope Curved Blade #3 Lot #: 140133 Cat #: 4343r Other #: 2J0516	Teleflex Medical	During patient code MAC #3 Laryngoscope blade packaging was opened and the plastic pieces on the end were broken off. No delay in intubation of patient. Please see picture below: 
Pump, Infu-sion, Enteral Brand: Kanga-roo Model#: 482400J Cat #: 482400J	Covidien LP	Tube feeding pumps in use do not flush the volume of water at the frequency with which they are set. If a pump is set for 100 cc q4h after my 12 hour shift the pump will have delivered 200 cc. If 100 q6 then only 100 cc. I think that when the pump is paused for putting patient HOB down to perform pt repositioning that the flush timer somehow is partially interrupted. At first I thought this was an issue with what time I'd cleared my pump vs the last shift. For instance, if last shift clears at 1830 and pump flushes at 00, 06, 12, 18, and I clear mine at 0500 I only encapsulate a 10.5 hour window. I think this is why we (the nursing staff) have been slow to recognize this as for sure being a problem (plus there is no way to check when the last programmed flush took place). Staff has noticed this since we started using the pumps several years ago, but oncoming and off going shifts had an informal discus-sion tonight that we are all noticing that the patients are not getting their prescribed amounts of free water. Flush volumes are always a multiple of what is programmed (300 cc q4h would usually result in a pump water delivery of 900 cc over a 12 hour period).
Regulator, Vac-uum Brand: Vacuum Regulator, Push To Set, Intermit-tent Model#: 1251 Other #: JGGM21395	Ohio Medical LLC	Coming onto shift, was told patient had NG to low intermittent suc-tion. when passing meds around 2000, was noticing the suction de-vice on the wall was not intermittently suctioning, but was continu-ously suctioning. Wall device was set to intermittent suction. MD noti-fied. The patient's NG was placed to gravity until orders for intermit-tent suction were received and new wall unit was placed and tested.

Device	Manufacturer	Problem
Retractor-elevator, Vaginal-cervical Ahluwalia Brand: Vcare Medium Lot #: 201702131 Cat #: 60-6085-201A	ConMed Corporation	A VCARE Medium device was given to the surgeon to be tested before use. The balloon would not inflate upon testing, so the device was removed from the sterile field and a new one was introduced. The same error occurred with the second device. A third device was successfully used and the procedure was completed with no harm to the patient. The second device was also removed from the sterile field and both were sent to the Clinical Engineering department. It was noted that the two failed devices were of the same lot.
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: C24101E Cat #: C24101E	CAREFUSION 303, INC.	Called emergently to bedside of patient with acute change in perfusion/hemodynamic status. Head CT performed with findings of cortical venous air consistent with air embolism. Patient is now stable but remains critically ill. Later evaluation of representative product used for patient demonstrates that filter on the tubing will empty on inlet side then allowing air to enter into tubing by "back priming" the filter with fluid distal to filter. Patient likely received a minimum of 3ml of air. It is unknown exactly how long the patient received air. IV access was a PICC in a scalp vein. Location confirmed on x-ray and estimated catheter tip location SVC/RA junction. IV pump did not alert with air in line as filter was below pump. IV pump is CareFusion Alaris pump and was not pulled out of service since filter bypasses pump.
Spinal Anesthesia Kit Brand: Pencan Model#: 333851 Lot #: 0061543682 Cat #: 333851	B. BRAUN MEDICAL, INC.	Failure of spinal anesthesia, suspect meds in spinal tray have been stored too low of temperature during winter months. Have caused medications to be ineffective for achievement of spinal anesthesia. The Patient Safety report completed by the same person:Failed Spinal, Partial spinal anesthesia obtained even though physician confirms correct placement of meds. More Marcaine/bupivacaine used on surgical field, more sedation given IV. All kits with this lot# pulled from shelves. The product was also pulled from our Distribution Center in the hospital. This facility has had more than 5 similar events with this product (anesthesia kit) within the last 2 months. The manufacturer has been notified. The facility has offered to return product for the manufacturer's investigation/analysis, but the manufacturer has refused to accept affected product for return examination/evaluation. Patients who have had ineffective spinals have had their cases converted to general anesthesia, which is a higher level of care. The staff are unable to determine which kits have affected product until the spinal is given and the patient does not experience numbing.

Device	Manufacturer	Problem
Sterilant, Medical Devices Brand: System 1e Model#: 1E	Corporation Steris Canada	Steris System 1E failed diagnostic for UV intensity of less than 12.9mA. Upon draining the UV ballast, found dirty water at discharge point. After flushing the system in service mode unit would operate for the rest of the day. Problem persisted each morning after sitting without use overnight. Mondays were worse after sitting for a weekend. Upon further investigation we found that the Pentek WS-20BB water softener filter cartridge that was installed by Steris is rated for 40-100°F (4.4-37.8°C). The water requirements for the Steris System 1E are 109-140°F (43-60°C). The minimum recommended temperature for operation exceeds the maximum operating temperature for the softener cartridge. After removing the cartridge and flushing the system the dirty water has subsided. The filter assembly in question has a recommended replacement of every three months. This assembly is not standard and is only added by Steris when hard water is present. The filter replacement did not occur during the PM because this is a user level task. We assisted in replacing the filter and had the same failure rate with a new filter. We were able to get the unit to run successfully by removing the filter media and flushing the UV ballast. The key problem we found is that the minimum recommended inlet water temperature for a System 1E is 109F and the maximum recommended operating temperature for this filter media is 100F. We believe that the higher temperature may be breaking down the filter media and causing this problem.
Sterile X-ray Detectable Peanut Sponge Brand: Sterile X-ray Detectable Peanut Sponge Model#: A1631 Lot #: 6051606058 Cat #: MDS72038	Medline	Sponges unraveled.
Surgical Table Cushion Brand: Aligel Or Overlay Pad Cat #: 95-365 Other #: KBB95-365	Alimed, Inc.	Began using a new gel pad in the operating room about 8-9 months ago. After bringing this product in, one associate has experienced several asthma attacks while caring for a patient using this product. It was discovered about two weeks ago that this was the product triggering the attacks. Per the OR Director, she was opening new gel pads and the smell of them was very strong. The nurse who had been suffering the asthma attacks, started with another attack right away. Another associate in the area who does not suffer from asthma also began to immediately start coughing. That associate was fine when she left the area, the first associate required treatment from Occupational Health. According the Director, the smell eventually lessens over time after multiple cleanings. The thought is that the odor is getting trapped under the drapes and when they go to remove them, they are taking in a concentrated amount of the odor which is what was triggering the asthma attacks. Gel Pad indicates it is made of Akton, Viscoelastic, and Polymer. It indicates that it is latex and plasticizer free.

Device	Manufacturer	Problem
System, Communication, Powered Brand: Critical Alert /Intego Model#: 5430	Critical Alert Inc. (formerly Wescom)	Our facility has Critial Alert/Intego nurse call throughout the hospital. Much of the equipment was installed over four years ago. Patient stations fail from time to time and are replaced with new ones ordered from the company. A couple of months back we had some issues with the patient bed wall backlighting. It would come on and turn off intermittently throughout the day and night. After extensive troubleshooting and research we found that Critical alert made a change to the electrical design of the patient station removing an internal ground in favor of an external ground tying a common ground to the nurse call patient station. This change was not communicated with the field and as a result it caused many patients undue stress and many lost man hours tracking down the particular cause. There was one instance where the patient had a history of epilepsy and the lighting portion of the system had to be completely disabled. No known patient harm occurred.
Tollos Disposable Linen Brand: Tollos Disposable Full Length Repositioning Sling – Bariatric Cat #: TA80LB-PSS Other #: Mfr. Date: 2016 Sep	XIANTAO YONGLI MEDICAL PRODUCTS CORP. LTD	Staff was using the ceiling lift (1000lb max) to get the patient from the chair back to bed. They were using the Tollos repositioning bariatric sling, that has a max weight of 1000lbs. The patient is around 740lbs. When lifting the patient up, the patient was approximately 1-2 inches above the chair when the lift sheet ripped. This caused the patient to fall back into the chair. No physical harm came to the patient, but he was emotionally upset about what had happened. Rip occurred along a stitched seam. Please see pictures below:  

Device	Manufacturer	Problem
Transmitters And Receivers, Electrocardiograph Brand: Lifewatch Holter Monitor	Lifewatch Services Inc.	Holter monitor done by LifeWatch and when our physician reviewed the strips, it was clearly not the correct patient. The report from LifeWatch did not have any atrial fibrillation noted when the primary reason for the holter was A-Fib. Thankfully our physician noticed the error and did not offer any treatment based on the wrong report. LifeWatch was notified and they then sent a "corrected" report that had the A-Fib noted. Based on this event, and the lack of support from LifeWatch we have ceased all activity with this vendor.
Tubes, Gastrointestinal (And Accessories) Brand: Gastrisail	Covidien LLC	During a robotic assisted laproscopic sleeve gastrectomy, the GastriSale was inserted into the patient's stomach. Physician had difficulty deploying the GastriSeal and after 2 attempts removed the device. Patient was found to have a perforated esophagus which the physician is attributing to the device.
Ventilator, Emergency, Manual (Resuscitator) Brand: Airlife Cat #: 2K8005 Other #: CF30-104	Carefusion	Self-inflating ventilation bag was connected to oxygen source and patient was ventilated after intubation. The patient experienced decreasing oxygen saturation despite ventilation. Troubleshooting the issue revealed that the oxygen tubing had disconnected from the connection to the bag, which is inside a corrugated reservoir tubing. The patient was not receiving additional oxygen as intended. The equipment issue was found quickly, and new equipment was readily available, swapped out and the patient responded quickly. No patient harm. Please see picture below: 

Device	Manufacturer	Problem
Ventricular (Assisst) By-pass Brand: Heart-ware® Control-ler Model#: 1403US Cat #: 1403US	Heartware, Inc.	We are seeing a problem with loose power ports on HeartWare LVAD controllers. Because the power port(s) is loose, we must ex-change the patients controller for a new one. Sometimes a controller needs to be exchanged for this after only 2 months of use. Subject-ing the patients to frequent exchanges. Exchanging controllers puts the patients at risk, because we are stopping their LVAD for a couple of seconds during the exchange. HeartWare did release an Urgent Medical Device Correction Field Safety Notice in April of 2016 (see FSCA APR2016). However, nothing has been done since then to rectify the problem. In fact, the frequency of occurrences is increas-ing.
Wire, Guide, Catheter Brand: Asahi Gaia Third Model#: AH-W14R011P Lot #: 160210A101	ASAHI INTECC CO., LTD.	Interventional cardiologist was attempting a percutaneous translu-minal revascularization of chronic total occlusion of the right coronary artery (RCA) via retrograde access through the left circumflex artery. A microcatheter and the Gaia 3 wire were advanced to the proximal segment of the RCA. The Gaia 3 wire knuckled and was no longer maneuverable as it became ensnared in calcium and the microcathe-ter. Upon removal it was discovered that the end of the Gaia 3 wire had unraveled leaving a wire fragment retained in the RCA. Post-procedure CT of the chest and abdomen revealed retained wire in the aorta extending from the thoracic inferiorly to the left external iliac artery. It was determined that the risks associated with surgical or procedural removal were too great and the patient would be moni-tored and managed medically.
Device 1: Wire, Guide, Catheter Brand: Amplatz Model#: G03460 Lot #: 7380659 Cat #: THSCF-35-260-3-AES **Device 2: Wire, Guide, Catheter** Brand: Amplatz Model#: G03460 Lot #: 7415287 Cat #: THSCF-35-260-3-AES **Device 3:Wire, Guide, Catheter** Brand: Amplatz Model#: G03460 Lot #: 7452013 Cat #: THSCF-35-260-3-AES	COOK INCOR-PORATED COOK INCOR-PORATED COOK INCOR-PORATED	When the doctor tries to shape this wire, the outer coating breaks. We have had several wires over the last three months where this has happened. We have to open a new wire almost all the time. We don't know if there have been other complaints noted. Staff are wondering if there are bad lot numbers. The manufacturer was contacted and said they were investigating the problem for possible causes.

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 May 2017 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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