MedSun
Medical Product Safety Network

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

February 2017

Volume 17, Issue 2

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):
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/mda/mda-list.cfm?list=1

Premarket Approval Final Decisions:
http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM537584.pdf

510(k)s Final Decisions:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm535481.htm

In Brief

As of January 31st, 2017

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

NucliSENS easyMAG Magnetic Silica and NucliSENS Magnetic Extraction Reagents by bioMerieux: Recall
January 27, 2017
Kits with the affected lots of the magnetic silica may not be able to fully extract nucleic acids from the sample and detect infection or provide proper diagnosis. The detection problem could lead to a risk of false negative results, invalid results, or under-quantification for clinical laboratory tests.

ED-3490TK Video Duodenoscope by Pentax: FDA Safety Communication – UPDATE
January 17, 2017
FDA is providing an important update to the February 19, 2016 Safety Communication to inform users about a design issue with this device that could increase the risk of patient infection. This safety communication contains updated recommendations to help prevent the spread of infection associated with the use of these devices.

Lifepak 1000 Defibrillators by Physio-Control: Voluntary Field Action
January 14, 2017
The company is contacting customers and advising them to immediately remove and reinstall the battery from their device(s). Customers are also being advised to implement a weekly schedule of battery removal and reinstallation for all LIFEPAK 1000 devices.

Duodenoscopes by Fujifilm Medical Systems: Safety Communication
January 13, 2017
Fuji informed the FDA of its plans to remove legacy 250/450 duodenoscope models from clinical use based on the limited number currently in use.

Implantable Infusion Pumps in the Magnetic Resonance (MR) Environment: FDA Safety Communication
January 11, 2017
The FDA has received reports of serious adverse events, including patient injury and death, associated with the use of implantable infusion pumps in the MR environment.

Implantable Cardiac Devices and Merlin@home Transmitter by St. Jude Medical: FDA Safety Communication
January 9, 2017
The FDA has reviewed information concerning potential cybersecurity vulnerabilities associated with St. Jude Medical's Merlin@home Transmitter and has confirmed that these vulnerabilities, if exploited, could allow an unauthorized user, i.e., someone other than the patient's physician, to remotely access a patient's RF-enabled implanted cardiac device by altering the Merlin@home Transmitter.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during January 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
Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Bioflo Model#: H965440250 Cat #: H965440250	Angiodynamics	The "CT" label from the back of the subcutaneous port body flaked off and was scattered inside the patient's chest port pocket when the port was removed. The remnants of the labeling were picked out of the port pocket during the removal procedure. The port pocket was flushed thoroughly before closing the incision. No patient harm. Manufacturer response for Subcutaneous central venous port, Endexo Bioflo Port (per site reporter) ========== Approximately a week post event, a call placed to product sales rep and message left on their voice mail.

Device	Manufacturer	Problem
Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Nutriline Model#: 1252.31G 	Vygon	While performing sterile PICC re-dress of L arm PICC, noted leaking of lipids from area where PICC catheter meets hub. Attempted to pull blood from PICC and air noted in line. Noticed a crack in catheter at hub connection. Removed PICC. Catheter tip intact. Infant tolerated well, no patient harm. Manufacturer response for PICC, Nutriline 2Fr PICC Line (per site reporter) ========== Waiting for information to return product.
Catheters, Suction, Tracheobronchial Brand: Kimvent Closed Suction Catheter Kit Model#: 1968127 Cat #: 1968127	ConMed Corporation	Patient was brought in for scheduled endoscopic endonasal tumor resection. Surgeon was working in patient's nose using a needle point bovie tip which is in the Head and Neck TNTA pack (4500WWHN0048). Surgeon used cautery on patient when tip of bovie melted off into the patient. Surgeon obtained the portion in the patient. A small 2mm burn was noted on patient's sella bone. Discontinued bovie machine (08CGU14) and used a new bovie machine (06AGP066) and needle point bovie tip.
Epidural Anesthesia Kit Brand: Perifix Model#: 332079 Lot #: 0061525169 Cat #: 332079	B. Braun Medical, Inc.	The nurse stated the Dr. tests all epidural catheters prior to insertion by pushing fluid through to make sure the flow is not obstructed. In this instance as well as two other recent undocumented cases, the Dr. was unable to pass fluid through the epidural catheter and an alternate epidural tray was retrieved to complete the procedure. In this case, the failed catheter and packaging was retained and delivered to Materials to report to the vendor.
Glucose Dehydrogenase, Glucose Brand: Accu-chek Inform Ii System Model#: ACCU-CHEK Inform II	Roche Diagnostics	As part of the patient's standard glucose monitoring protocol, an evening finger stick was performed using point of care testing via the ACCU-CHEK Inform II glucose meter. The initial results displayed a reading of "RRLO with a message W-510 out of reportable range, verified with venous collection. Repeat tests were done using other ACCU-CHEK Inform II glucometers that displayed the same results. Staff interpreted the error messages displayed as the actual glucose reading and reported these results to medical staff. This misinterpretation of the blood glucose level being 510 resulted in the patient receiving additional insulin coverage. A review of the case and blood glucose management was undertaken and it was determined that the display message from the device contributed to staff misinterpretation of results. It was further determined that the actual display from the ACCU-CHEK Inform II may represent a design flaw in that it displays a numerical value associated with an out of reportable range message that would require further medical management.

Device	Manufacturer	Problem
Insufflator, Laparoscopic Brand: 50l Abdominal Insufflator Model#: GS2000 Cat #: 16-03593 Other #: SR#565569	ConMed Coporation	Called to OR room. Insufflator set to general laproscopy set pressure +15, but it kept flowing and over-distended the abdomen. Surgeon disconnected tubing from trocar and nurse stopped the therapy on the unit. Therapy restarted and tubing reconnected and unit started doing the same. Nurse states she saw the actual pressure at -9 and not changing. The unit was turned off and a new (second) unit was brought into the OR on a rolling cart. The first unit was not connected to the patient but the nurse turned it back on and error codes 9 and then 10 showed up. The unit was pulled from service and company contacted. A loaner unit was received approximately 4 days later. The device was returned to the manufacturer. The manufacturer shared the following: "An evaluation and testing of the insufflator unit found the device software has a nonconformity, where the pressure calculation overflows resulting in a negative pressure when the actual pressure is in the range of 300mmHG."
Intraocular Lens Brand: Acrysof Model#: au00t0 Other #: +21.5 diopter	Alcon Research Ltd.	Lens comes preloaded to avoid any human touch and prevent scratches on the lens surface. It is supposed to fold in a way that facilitates insertion. The front haptic was bent to the right side, but should have been folded to the left side. I had to stop insertion and manually reposition the haptic properly in the bag. There was no risk or danger to the patient but the preloaded implant is supposed to make insertion easier. In this case it did not fulfill its purpose.
Light, Surgical, Fiberoptic Brand: Eigr™ Waveguide Model#: Narrow / Flat, LC Lot #: 16032301 Cat #: CEW1NF	Invuity, Inc.	During thyroidectomy surgeon noted that while using lighted retractor during the procedure, the retractor was getting hot to the touch. Staff turned down the intensity of light source. After the procedure was finished a reddened streak was noted on the patient's skin. Staff sequestered the light source and equipment and the retractor was noted to have a crack in it. The patient did not need further treatment and did not sustain significant harm. Device was not cracked at beginning of case. ========== Manufacturer response for Lighted retractor, Eigr Waveguide, Narrow/Flat (per site reporter) - They wish to analyze the device.
Ring, Annuloplasty Brand: Tri-ad Adams Annuloplasty Ring Model#: 900SFC30 Cat #: 900SFC30	Medtronic Heart Valves Division	A Tri-Ad Tricuspid Ring was implanted and patient was brought off cardiopulmonary bypass. Upon evaluation of Tricuspid Valve using trans esophageal ECHO, the tricuspid valve had significantly more regurgitation than prior to the procedure. Tricuspid ring was removed. ========== Manufacturer response for Tri-Ad Adams Tricuspid Ring, Tri-Ad Adams Tricuspid Ring (per site reporter) ========== Manufacturer provided product return kit.

Device	Manufacturer	Problem
Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms) Brand: Dash 4000 Model#: DASH4000 Cat #: 2023615-208	GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.	During the hospital visit, the patient's heart rate was primarily running around 50-70 beats per minute with two incidents of 80 to 92. Blood pressure was close to 100/50 consistently. The patient was alert and oriented to person, place and time, the patient is on 2 Liters/minute of oxygen via nasal cannula. The patient is also on contact precautions, had loose stool, and their Clostridium difficile test came back positive. The patient was moved to another room. The patient had an elevated HR and the provider was contacted and medicated per the record. The patient went to dialysis, with dash for telemetry and heart rate monitoring. 0647 Lopressor IV 2.5mg ordered. 0658 Lopressor IV 2.5mg administered. 0743 heart rate 135, blood pressure 77/51 0821 Routinely scheduled Lopressor 25mg by mouth twice per day administered. Continuous Heparin drip running at 14 units/kg/hr 1036: Dialysis initiated in inpatient dialysis. Heart rate continued to slowly trend down with lowest result at 1210. heart rate = 97 But up to 126 at 1241. Arrhythmia Alarm previously turned off/not alarming with Cardiac arrhythmia Pt. in V-tach followed by asystole - arrhythmia alarm on telemetry monitor not sounding.
Set, Administration, Intravascular Brand: Clearlink/continu-flo Model#: 2H8519 Lot #: R16H16050 Cat #: 2H8519	Baxter International Inc.	IV tubing that was part of the taxotere infusion leaked when roller clamp was released on start of infusion. Immediately stopped infusion, disconnected, and contained leak. Noted an abrasion thinning of tubing in the line that caused a small hole in tubing when clamp was released. The patient was unharmed and the leak was cleaned up.
Set, Administration, Intravascular Brand: Cadd Yellow Striped Administration Set Lot #: 46x896 and 46x817 Cat #: 21-7339-24	Smiths Medical ASD, Inc	The tubing previously labeled as CADD yellow striped administration set with label yellow in color is now packaged CADD administration set and is no longer yellow. Also, the written description of the product states a 0.2u air eliminating filter. However, the photo on the package depicts 2.0u filter.

Device	Manufacturer	Problem
Stand, Infusion Brand: Mckesson Model#: LP-2814-1102	Regulatory Insight, Inc.	The patient underwent esophageal dilation. At the end of the procedure the OR table was being repositioned. The IV pole fell onto the patents face and hit the patents left eye, which caused a laceration as well as dislocation of the intraocular lens.
Station, Pipetting And Diluting, For Clinical Use Brand: Dsx Automated Elisa System Model#: DSX	Dynex Technologies, Inc.	A Trep-Sure qualitative enzyme immunoassay was performed on the patient. This test is used for diagnostic detection of Treponema Pallidum (the bacteria causing Syphilis) antibodies in human serum. The lab analysis resulted as negative. Because the patient was exhibiting clinical symptoms, including elevated liver enzymes, a liver biopsy was performed a few weeks later. A tissue sample from liver biopsy showed the presence of Treponema Palladium and a second tissue sample sent to the Center for Disease Control confirmed the finding. The patient's medical team was notified of the findings and treated the patient with Penicillin for secondary Syphilis. Another serum Trep-Sure sample from this patient was tested after the liver biopsy and returned as positive. An additional sample from the same patient was located and also tested positive on Trep-Sure. This was further validated with a positive finding on a sample sent to the state lab for confirmatory testing. As of a few weeks ago we stopped performing TrepSure testing by our lab. Syphilis screening testing is being sent out to a reference lab until we complete our root cause analysis. Mfr. Service Representative from Dynex technologies serviced the analyzer. Report as follows: Verification performed onsite, passed. Replaced Pipette anyhow. Replaced z spring, performed work space and drawer calibration. Adjusted drawer coordinates. Plate movement cycle passed. Pipette check passed.
Surgical Pack, ENT Brand: Head And Neck Tnta Pack Cat #: 4500WWHN0048 Other #: Needle point bovie tip In Head and Neck TNTA pack	Linvatec Corporation D/B/A	Patient was brought in for scheduled endoscopic endonasal tumor resection. Surgeon was working in patient's nose using a needle point bovie tip which is in the Head and Neck TNTA pack (4500WWHN0048). Surgeon used cautery on patient when tip of bovie melted off into the patient. Surgeon obtained the portion in the patient. A small 2mm burn was noted on patient's sella bone. Discontinued bovie machine (08CGU14) and used a new bovie machine (06AGP066) and needle point bovie tip.

Device	Manufacturer	Problem
System, Dialysate Delivery, Single Brand: Dialog+ Evolution Hemodialysis Machine Model#: Dialog+	B. Braun Medical, Inc.	Hemodialysis staff noticed fluid pooled on the floor of the separate single-patient isolation dialysis room near the Dialog+ Evolution hemodialysis machine. This was not considered to be a "major" leak. Biomedical Engineering was informed, and the equipment was taken out of service and replaced with an identical hemodialysis machine. The new replacement dialysis machine was not used that evening or weekend. A few days later, the second dialysis machine began a pre-programmed disinfection routine during which hot sterile water (temperature of up to 83 degrees C) and a citric acid solution is flushed throughout the tubing of the equipment to cleanse and prepare it for patient use. This cleansing cycle takes approximately 30 minutes to complete. At approximately 7 am, when staff members began to arrive, a large volume of water nearly covered the floor of the isolation dialysis room, seeped under the back wall, almost filled a back hallway, and leaked into the Pharmacy one floor below. Floor molding and tiles of the isolation dialysis room, hallway, and ceiling tiles of the pharmacy were damaged, according to the Maintenance and Operations Supervisor. Biomedical Engineering Staff investigated the event and determined that the problem originated in the rinsing chambers for concentrate subassembly. More specifically, at the interface where the inner retainer tubes are press-fitted into the outer silicone tubing of the rinsing chambers assembly. It is believed that a combination of the high heat of the water, pressurized fluid flow, and internal vibrations causes the outer silicone tubing to slip off of the inner Retainer tubes, allowing a potentially large volume of water to leak if unattended. Biomedical Engineering staff have installed zip ties onto the outer silicone tubing within each Dialog+ Evolution machine. This was done to tighten the fit between the outer silicone tubing and inner retainer tubes. It is unknown whether or for how long this will be effective. One facility has seventeen (17) B. Braun Dialog+ Evolution Dialysis machines currently in use. A search of the work order system revealed that between 8/25/2015 and 12/13/2016, there were 10 "leaking" work orders entered in for the Dialog+ equipment that is currently in use. Seven work orders were submitted with task descriptions apparently describing the present issue. Approximately 35% (6) of the 17 Dialog+ units have had work orders submitted for this type of leak in that time frame at this one facility. Some of the other tubes in the area are sealed with black hose retainer rings clamped tight onto barb connectors. The Dialog+ Evolution does not appear to have a sensor feedback system that will automatically shut off the water flow when a leak occurs.
System, Perfusion, Kidney Brand: Sps-1 Lot #: PBR-0060-392	Organ Recovery Systems, Inc.	Received kidney from OPO (Organ Procurement Organization), implanted in patient. Approximately 43 days after implant, received general notice from UNOS (United Network for Organ Sharing) regarding the contamination of organ preservation fluid. The following day, received notice from OPO that they had used the affected lots. Two days after OPO notice, received notice from OPO that one of our patient's had received kidney from the affected lot of contaminated organ preservation fluid. Our hospital epidemiologists reviewed patient chart. Determined that patient complications were not due to contaminated fluid.

Device	Manufacturer	Problem
System, Perfusion, Kidney Brand: Sps-1 Lot #: PBR-0074-330	Organ Recovery Systems, Inc.	Our OPO (Organ Procurement Organization) received communication from UNOS (United Network for Organ Sharing) that there was contaminated organ preservation fluid used in transplant cases. Our OPO escalated information regarding patients at our facility. Impacted patients were as follows: We received a notification over the weekend that there was contaminated organ preservation solution discovered per the message from the United Network of Organ Sharing (UNOS). We received the e-mail below from our OPO (organ procurement organization) informing us that they checked the solution batch numbers and discovered that we used this solution on several of our patients. A total of six patients at this facility received organ transplants that were affected by the contaminated organ preservation fluid. The first patient was readmitted approximately two weeks after transplant for treatment of hydronephrosis and chronic UTIs. The second patient received additional medication to cover the potential infection related to the contaminated organ preservation fluid. The third patient's medications during hospitalization and at discharge were adjusted to cover the organisms reported in the contaminated organ preservation fluid. The fourth patient has no signs of infection and had no changes to their plan of care. The fifth patient is being seen by ID (Infectious Disease) consult team and pt on empiric therapy for the organisms in the preservation solution and possible HCAP (Health Care Associated Pneumonia).
Transmitters And Receivers, Physiological Signal, Radiofrequency Brand: Pressurewire™ Aeris™ Agile Tip Model#: Aeris™ Agile Tip Lot #: 5488346 Cat #: C12058	St. Jude Medical, Inc.	Patient was undergoing an elective percutaneous coronary intervention. The mid-LAD had intermediate stenosis in the mid-portion of the vessel. For measurement of flow, an FFR wire was advanced through the guide sheath to the mid-LAD; however, due to the patient's coronary anatomy, difficulty accessing desired location in the mid-LAD occurred. The FFR wire was repeatedly withdrawn by the physician to be physically manipulated and redirected to reach the designated location of the mid-LAD. After repeated attempts, the FFR wire was withdrawn, leaving the distal portion of the wire retained in the mid-LAD. Based on consultation with the physician and the rep, we estimate that approximately 3 cm of the wire remained in the patient's vessel. The St. Jude representative was given the remaining portion of the FFR device so that the manufacturer could evaluate the product. The sales rep informed us that he would be sending a report to the manufacturer's risk management team. The rep removed the remaining FFR wires from the same lot number and provided us with replacements of another lot number. Manufacturer response per site reporter: The St. Jude representative was given the remaining portion of the FFR device so that the manufacturer could evaluate the product. The sales rep informed us that he would be sending a report to the manufacturer's risk management team. The rep removed the remaining FFR wires from the same lot number and provided us with replacements of another lot number.

Device	Manufacturer	Problem
Tube, Tracheal (W/wo Connector) Brand: Halyard Model#: 13222 Cat #: 13222-01	HALYARD HEALTH, INC.	Incident Report from Respiratory Therapist(RT): RT called to bedside for patient in CSU on vent, vent alarming low pressure, low minute ventilation, RN holding ETT in place while ventilator alarmed. RT manipulated tube by pushing down approx. 2cm then deflated and re-flating cuff of ETT. Cheeks were billowing with air around ETT and obvious cuff leakage was noted by both RN and RT. Anesthesiologist attending was notified of event and requested sedation be held and patient extubated. Patient was extubated to BIPAP for respiratory support without incident. Upon inspection of ETT post extubation, there was no obvious leak in cuff, would hold air. RNs involved state this incident happened randomly without turning the patient or manipulating ETT. Incident Report from RN: Vent was alarming, large cuff leak noted, sounded like it was getting worse, RT notified, they came to bedside, as CSU RNs held ETT in place, RT repositioned tube, and attempted to deflate/re-inflate cuff with no results. Staff could still hear pt breathing around tube. Anesthesiologist notified. Sedation was then held to allow pt to awaken, and attempt extubation. Patient was extubated approx. 35 minutes later to BIPAP for additional support. This facility has had at least three recent similar issues with this device. Staff have noticed a small cut/crack/slit in the device where the clear tubing connects to the blue portion of the device. The problem is visually present on devices that are new/unused and pulled off the storage shelf. The facility has noted that the problem area feels smooth to the touch. The manufacturer has been notified and the devices have been returned to the manufacturer. At least one patient required re-intubation as a result of this problem.
Tubes, Gastrointestinal (And Accessories) Brand: Mini One® Balloon Button Model#: M1-5-1412-I Lot #: 161216-054 Cat #: M1-5-1412-I	APPLIED MEDICAL TECHNOLOGY, INC.	Patient for second OR related to a GT complication originally inserted approximately three days previously. Pt to OR for Lap Nissen/GT (14FR 1.2cm AMT Button) Three days later in the morning, feedings were increased. That same day in the afternoon, stay sutures removed by surgical fellow. RN found GT (Gastric Tube) elevated away from skin. Unclear to RN if balloon was filled with water. Pt made NPO. Surgery called notified. Dye study ordered to assess for proper placement. Reading by radiologist stated that GT in place with no leak. Confirmed. That same day in the evening, feeing was restarted. The following morning, GT leaking. Formula colored fluid accumulated under dressing. NNP notified, pt made NPO. Surgery team called and removed GT and placed 10 Fr foley. Pt administered ISO dye by MD and X-rays obtained. Patient scheduled for OR. Patient was taken to OR that day: dislodged gastrostomy tube with peritonitis, diagnostic laparoscopy, laparotomy, stamm gastrostomy.

Device	Manufacturer	Problem
Ventilator, Continuous, Facility Use Brand: Base Unit Servo-u Model#: 6694800	Maquet Critical Care AB	The patient was in Pressure Support Ventilation and the therapist went into the alarm limits menu during her assessment. She thought she was adjusting the apnea interval up to our standard 20s when she realized it was, in fact, the apnea audio delay, which defaults to 0s. She went to set it back to 0, the screen paused, went black, came back on in standby for about 5s and then started ventilating in PSV stating "the mode has been changed to PSV". Unsure of what just occurred, it was duplicated off the patient while another therapist manually ventilated and the ventilator was changed out. The ventilator is in Biomed currently. There was absolutely no harm to the patient as the therapist was standing there and quickly manually ventilated. The event was able to duplicate the issue on the other two available Servo-U in my office yesterday. Maquet was immediately contacted to make them aware and report the event. The Maquet field engineer came in the next morning to download the logs from all three ventilators for analysis. The sales representative also came to campus and informed Respiratory therapy leadership that the company was aware of this glitch in software and was working on a correction as it has occurred at other facilities. This information was not disseminated to front-line sales and support staff. The sales rep also mentioned that the company was preparing for a voluntary recall. He was unsure when the software would be ready for upload to our machines. Subsequent to this trial it was noted that if a second attempt to correct the audio delay resulted in the blank screen (~5 sec) then a blue screen with MAQUET printed across the screen followed by stand by to the full display screen. The vent was working through all.
Ventilator, Continuous, Facility Use Brand: Base Unit Servo-u Model#: 6694800	Maquet Critical Care AB	The Maquet Servo U ventilator had rebooted in the past on a patient. There was no harm to the patient, but the cause was unknown. Recent testing uncovered that the Servo U will reboot due to a software fault under the following scenario. 1. In any of these three modes: CPAP/PS, VS, NAVA. 2. Go to alarm window. Select "apnea audio delay" 3. Change the setting and hit the check mark. Do not hit "accept" in the alarm window. 4. Go back to try to select "apnea audio delay" again. 5. At this point, the screen blanks out and reboots. 6. It starts up again in the correct mode. 7. It appears that the Servo U continues to ventilate during this process using a test lung.

Device	Manufacturer	Problem
Staple, Implantable Brand: Premium Plus Ceea Model#: 111989 Cat #: 111989	Covidien LP.	During initial surgery approximately 6 months ago, the CEEA stapler was used. As part of the procedure, it is necessary to remove the plastic trocar tip before inserting the anvil. With a closed laparoscopic procedure the trocar tip may not be taken out of the body until the connection between the anvil and the stapler is complete. If the anastomosis is difficult, the trocar tip may not be removed until the connection is determined to be laying appropriately, with correct placement, right angle, with the correct tension. Because of limited visibility of the surgical field, distraction and focused concentration on securing the anastomosis, the trocar tip was forgotten and left in the surgical field. Approximately two months ago, the patient underwent a CT Abdomen/ Pelvis with contrast which revealed "Intraperitoneal metallic tubular density in the lower pelvis which appears to contact a loop of small bowel measuring approximately 3.5 x 0.8 cm and may represent a radiopaque retained foreign body". The patient returned to surgery approximately three weeks after the CT for the ileostomy take down and the retained stapler trocar tip was retrieved. While this is not generally a problem for open procedures, when done by laparoscopy, it is easy to leave the trocar tip behind. Ideally, the device could be redesigned to reduce the chances of this happening.

Links to FDA/CDRH Databases and Other Information Sources

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

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

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

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 February 2017 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