MedSun
Medical Product Safety Network

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

November 2017

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In This Issue:

About the MedSun Program:

The MedSun Program, which was launched in 2002 by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), involves the reporting of problems with medical products from a network of approximately 300 hospitals, nursing homes and home health facilities around the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products. MedSun utilizes a secure, on-line system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

Those who are interested in having their healthcare facilities join MedSun may contact medsun@fda.hhs.gov or 800-859-9821 for additional information.

Newly Approved Devices

Recently Approved Devices (searchable listing):
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/mda/mda-list.cfm?list=1

Premarket Approval Final Decisions:
https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM561666.pdf

510(k)s Final Decisions:
https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM569547.pdf

In Brief

As of November 1, 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

Absorb GT1 Bioresorbable Vascular Scaffold (BVS) by Abbott Vascular: Letter to Health Care Providers
October 31, 2017
The FDA issued an update to the March 18, 2017 letter to health care providers to inform the health care community that interim study results through three years from the pivotal clinical trial (ABSORB III) continue to show an increased rate of major adverse cardiac events and BVS scaffold thrombosis in patients receiving the Absorb GT1 Bioresorbable Vascular Scaffold (BVS), when compared to patients treated with the approved metallic XIENCE drug-eluting stent. The FDA was made aware that the manufacturer has stopped global sales of the Absorb GT1 Bioresorbable Vascular Scaffold as of September 14, 2017.

Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) by St. Jude Medical: FDA Safety Communication
October 19, 2017

On August 28, 2017, St. Jude Medical notified physicians of the availability of Battery Performance Alert (BPA), a new battery performance management tool that detects and notifies physicians of abnormal battery performance that may lead to premature battery depletion in Implantable Cardioverter Defibrillators.

Infant Sleep Positioners: FDA Warning
October 3, 2017
FDA is reminding parents and caregivers not to put babies in sleep positioners. These products—sometimes also called “nests” or “anti-roll” products—can cause suffocation (a struggle to breathe) that can lead to death. The federal government has received reports about babies who have died from suffocation associated with their sleep positioners. In most of these cases, the babies suffocated after rolling from their sides to their stomachs.

Endovascular Graft Systems: Letter to Health Care Providers
September 28, 2017
The FDA is evaluating recent information regarding Type IIIa and IIIb endoleaks with the use of endovascular graft systems indicated for a procedure known as endovascular aneurysm repair (EVAR). EVAR treats abdominal aortic aneurysms (AAA) and aorto-iliac-aneurysms. FDA is bringing this potential complication to your attention to remind and encourage you to report Type IIIa and IIIb endoleak events to the manufacturer and the FDA. This may include reporting individual events as well as rates you may have experienced in your practice.

AAMI Foundation Annual Forum: Hot Topics in Patient Safety
November 18 and 19, 2017—San Diego, CA

This forum is intended for professionals who engage in pain management, alarm management, and infusion therapy, including nurses, pharmacists, physicians, clinical nurse specialists, respiratory therapists, and hospital senior leaders, as well as bio-medical and clinical engineers, academics, and regulators. During this event AAMI will address several patient safety challenges including:

- ◊ Learn how to save patients from “failure to rescue’ events.”
- ◊ Decrease the number of nonactionable clinical alarms.
- ◊ Address key challenges to improving infusion therapy safety.

To register - http://my.aami.org/store/events/registration.aspx?event=FDARMN17

HIGHLIGHTED REPORTS

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

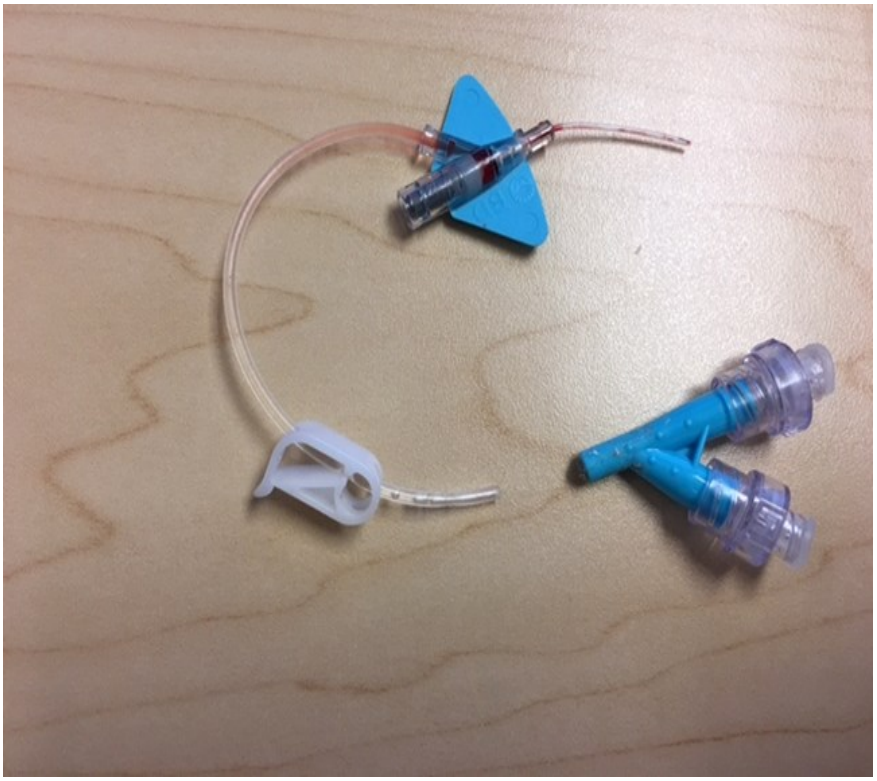
A database of all MedSun reports can be found at:

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

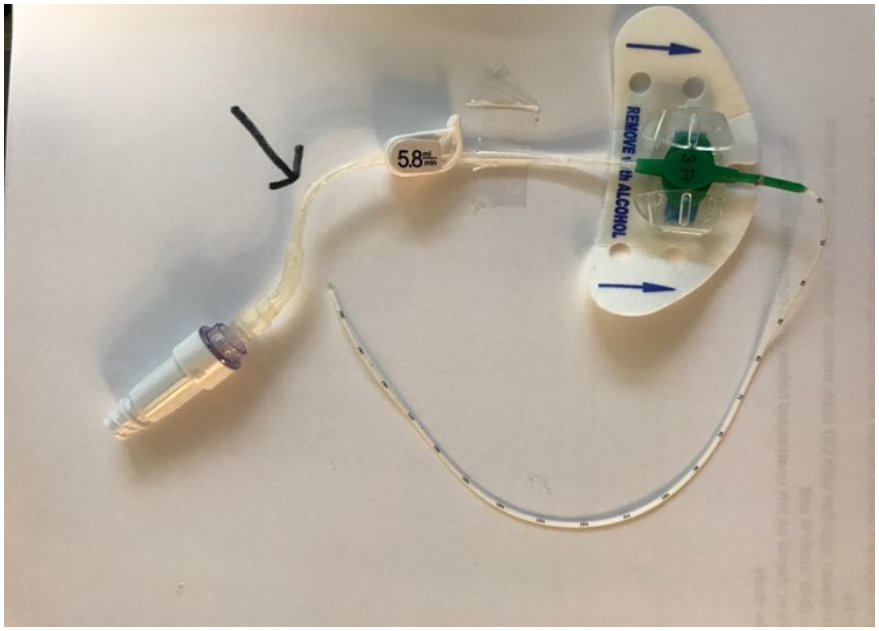
 Special Note:

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.

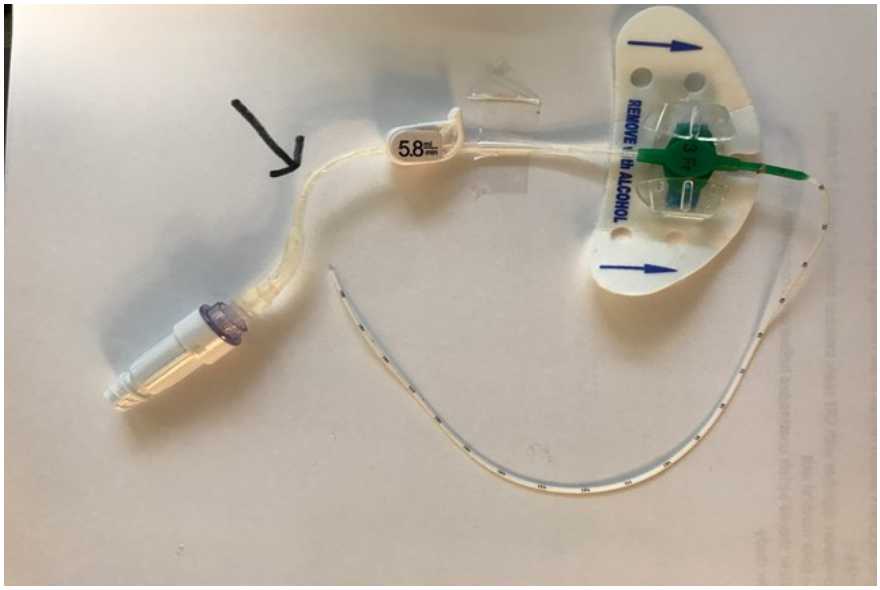
Device	Manufacturer	Problem
Bed, Ac-powered Adjustable Brand: Spirit Select 	Stryker Corporation	Moving a patient via elevator to pediatrics post op via elevator. When the nurse and transporter attempted to move the bed off of the elevator the wheel of the patient bed became stuck in the gap between the elevator car and landing. Facilities was called to assist and removed the stuck wheel using a j bar. A review of the event noted that all patient beds have wheels of the same diameter and that the wheels may become stuck in the gap between elevator car and landing when they are swiveling. The gap in the elevator is a standard gap with a minor plus or minus deviation and cannot be reduced due to seismic sensors on the elevator. Those transporting patients have been reminded to check for proper wheel alignment and signage has been placed on elevators used for patient transport. Concern was should a patient be transported emergently, or code, that there is a serious potential for negative impact to the patient should the bed become stuck.

Device	Manufacturer	Problem
Catheter, Continuous Flush Brand: Marathon Model#: 105-5056 Lot #: A378761	Covidien (Micro Therapeutics, Inc.)	The microcatheter used to deliver glue to cerebral vessels during an embolization procedure of an arteriovenous malformation (AVM) appears to have ruptured causing the glue to be inadvertently delivered to the incorrect vessels.
Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Powerpicc Solo Lot #: REBT0761 Cat #: 1395108QD	Bard Access Systems, Inc.	PICC line RN found a defective "skewed" needle in the BARD PICC line kit. The needle is deviating from midline, in relation to the plastic hub. It was not used on the patient.
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: BD Nexiva, Bd Q-syte Model#: 383532 Cat #: 383532	BECTON, DICKINSON AND COMPANY	IV tubing has a clean break near the hub of the IV. There was no negative patient impact. Please see picture below: 

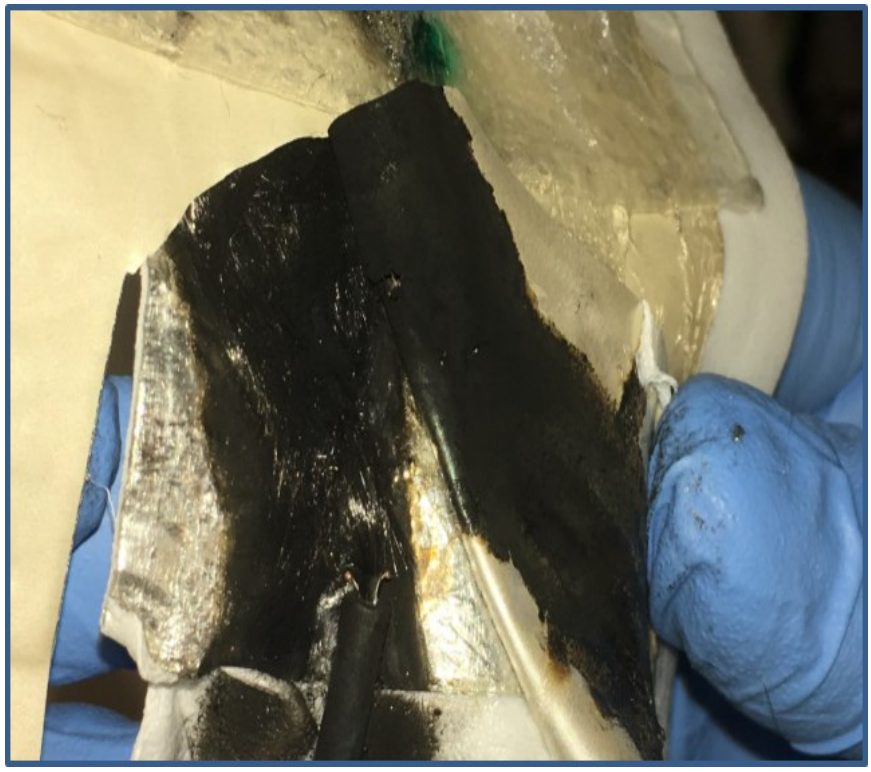
Device	Manufacturer	Problem
Device 1: Electrode, Electrosurgical, Active, Urological Brand: Classic Series™ Reusable Active Cord For Bovie™/ valleylab Connection Model#: C650-129A Cat #: C650-129A **Device 2: Electrosurgical, Cutting &Coagulation &Accessories** Brand: Force Fx Model#: Force FX-C ZE Cat #: Force FX -C ZE	Gyrus Acmi, Inc. Covidien LP	Bugbee Cord and Bovie 10138 due to bugbee cord catching fire while in surgeon's hand; extinguished with sterile water and bovie unplugged; surgeon's gown with visible hole noted; charge nurse and engineering notified.
General Surgery Tray Brand: Medline Industries, Inc. Model#: PHS74747400 Lot #: 17SB8599 Cat #: PHS747474000	Medline Industries, Inc.	Upon setting up for a case a hair was found in a Medline Basic Pack.

Device	Manufacturer	Problem
Device 1: Injector And Syringe, Angiographic Brand: Stellant Ct Injector System **Device 2: Midline Peripheral Catheter** Brand: Bard Midline Catheter	Bayer Medical Care Inc.	Patient had a midline catheter upon her arrival for her CT Scan. The midline catheter connected to the injector split when the contrast was being injected. The midline was removed and the sending facility was contacted to report the incident. Please see picture below: 

Device	Manufacturer	Problem
General Surgery Tray Brand: Medline Industries, Inc. Model#: PHS747474000 Lot #: 17SB8599 Cat #: PHS747474000	Medline Industries, Inc.	Upon opening for a case a brown unidentified contaminant was noted on a light handle in a Basic Pack Per site reporter: A Quality Control investigation has been initiated by Medline.
Heater, Breathing System W/ wo Controller (Not Humidifier Or Nebulizer Brand: Fisher & Paykel Healthcare Model#: RT266 Lot #: 210084515 Cat #: RT266 	Fisher &; Paykel Healthcare Limited	At 1100 existing ventilator was changed with a new one. Ventilator change was smooth w/o problems. 1120: Persistent desaturations with increased CO2 levels on TCM noted, it was reading 80%. RT called to bedside to evaluate TCM application & possible cause of desaturations. Baby responded to bagging with T- piece but desaturated quickly when connected to vent. 1200: Bagging at 100%, infant is retracting, CO2 on TCM in the 90's. 1230: Feeding off, doctor called to bedside. CXR ordered. Earlier suctioning, positioned prone, ETT placement checked - all these done with no response. ETT in good position per x-ray. 1245: Decision to change vent., infant was bagged with T-piece while waiting for equipment. 1310: Attached to new ventilator. O2 levels noted to stabilize & CO2 started to decrease on TCM. FiO2 slowly weaned. 1330: Feeding resumed. 1400: noticed defect in ventilator circuit. Ventilator was working properly but there was a fine CRACK noted in circuit connecting to patient. Per site reporter: The vendor brought 2 cases of circuits to replace our stock of that lot number.
Hypo/ hyperthermia Unit Brand: Cardiopulmonary Bypass Temperature Controller Model#: MCH-1000	CardioQuip, LP	Unit shutting off breaker, condensation inside of device drips onto wiring. Estimated current leakage was 1300 microamps. Unit removed from service. Vendor called in and repaired unit.

Device	Manufacturer	Problem
Device 1: Injector And Syringe, Angiographic Brand: Stellant Ct Injector System **Device 2: Midline Peripheral Catheter** Brand: Bard Midline Catheter	Bayer Medical Care Inc. Bard Access Systems, Inc.	Patient had a midline catheter upon her arrival for her CT Scan. The midline catheter connected to the injector split when the contrast was being injected. The midline was removed and the sending facility was contacted to report the incident. Please see picture below: 
Monitor, Physiological, Patient Brand: Xper Flex Cardio	Philips Healthcare	The XPER football flat lined during care and staff were unable to view patient hemodynamics. The football had to be rebooted. Staff report this equipment is not working properly. It has previously been reported to Philips by the Director of Clinical Engineering. There was no harm to the patient. There was more than one monitor on the patient and the procedure was completed without further issues.
Monitor, Physiological, Patient(Without Arrhythmia Detection Or Alarms) Brand: Expression Mr400 Mri Patient Monitoring System (Model Mr400) Model#: 866185 Cat #: 866185	Invivo Corporation	Since the opening of the MRI operating rooms, the Anesthesia providers have been complaining of poor performance from the Invivo Expression patient monitors. This year, one physician and other providers began documenting the problems in the internal adverse event reporting system. From this database, we have compiled 24 reports over the past 6 months. The typical complaints include: • Lack of ST segment analysis • Frequent SpO2 failures • Intermittent and inaccurate ECGs • Temperature probe failures • Blood pressure failures The rooms are primarily intended for neurosurgical cases, but due to the high demand for OR space are often used for non-MRI cases with patients that need high quality cardiac monitoring. In non-MRI rooms, the GE Solar series monitors provide that level of monitoring. Currently, Invivo monitors are the only monitors on the market that are MRI compatible so providers have to use them in the MRI suites.

Device	Manufacturer	Problem
Powered Laser Surgical Instrument Brand: Cook Model#: G25295 Lot #: 7895411 Cat #: HLF-S365-HSMA	Cook Incorporated	While opening for a case a piece of back debris was noted on the inside of an unopened sterile pack of laser fiber. Per site reporter: Manufacturer has opened a Quality Control investigation and requested the return of the affected product.
Pump, Infusion Brand: Medfusion Model#: 4000 Other #: Software Version V1.1.2	Smiths Medical, Inc.	The nurse began putting the medication into the syringe pump to get it programmed before the OR procedure but the unit when turned on gave a Super CAP error and required a service maintenance password to unlock it. Upon submitting the repair request to Biomed, the nurse informed us that this error had happened previously, which prompted a phone call to the manufacturer, Smiths medical. Per site reporter: Smiths Medical informed us that the syringe pumps will develop a software error (Super CAP error) when the battery is discharged below 20% and needs service to reset the unit to clear the alarm. The pump, from this point on will randomly have error return until it is sent in to manufacturer for main circuit board replacement. The manufacturer, Smiths Medical, has identified this is an issue and will perform the repair at a discounted flat rate than normal. There is no recall at this time according to the manufacturer.
Pump, Infusion Brand: Walkmed Ambulatory Tubing Lot #: 20217508 Cat #: PS360 Other #: 202747	WalkMed, LLC.	Walkmed Infusion Pump tubing leaked at connection site once infusion had begun. Multiple incidents have occured with patients in a homecare setting and the hospital.
Pump, Infusion Brand: Alaris Model#: 8100	Carefusion 303, Inc.	Bio Med reports the door latch on the pump regularly breaks at the base of the latch creating an issue with opening the door safely or being able to fully close the door. Hospital has 247 pumps and over the last year have had this issue with approximately 30 pumps.
Pump, Infusion, Enteral Feeding Brand: Kangaroo	Covidien LP	Bio Med reports continual issues with Covidien Enternal Feeding Pumps. Continue to receive error messages to plug it in when it is plugged in; will not power on, or will not keep a charge.

Device	Manufacturer	Problem
Pacemaker, Cardiac, External Transcutaneous (Non-invasive) Brand: Lifelinks (Adult) Model#: P-211-Z1 Cat #: P-211-Z1 Other #: TZ transparent Defibrillator pads (TZ Medical Defib Pads (P-211-Z1)	TZ Medical, Inc.	During defibrillation of patient, staff states there was a "pop" noise and smoke from the defibrillator pads. Patient was successfully defibrillated at 200J using the TZ Medical Defib Pads (P-211-Z1) attached to the high output defibrillator in the OR. Soot was seen at the left lateral side of the patient and defibrillator pad. Pads were immediately removed from patient and replaced with a new set. No burns were apparent on patient skin noted, device and pads taken out of service for further evaluation. Please see pictures below:  

Device	Manufacturer	Problem
Device 1: Ventilator, Continuous, Non-life-supporting Brand: Af531 Model#: 00 Lot #: 170524 Cat #: 1119007 **Device 2: Ventilator, Continuous, Non-life-supporting** Brand: Af531 Model#: 00 Lot #: 170816 Cat #: 1119007 **Device 3: Ventilator, Continuous, Non-life-supporting** Brand: Af531 Model#: 00 Lot #: 170704 Cat #: 1119007	Respironics, Inc. Respironics, Inc. Respironics, Inc.	A patient arrived to the Emergency Center in pending respiratory failure. SpO2 83% while on a NRB with very labored breathing. The physician ordered BiPAP to be started. Respiratory Therapist was preparing to use an 840 vent which requires that the elbow attachment on the mask be exchanged with Respironics product ref: 1043210. The elbow currently on the mask could not be removed at all. Another mask was retrieved and once again, that elbow could not be removed. In the process of trying to remove the elbow from the second mask, the elbow holder physically broke off of the mask. There was a long delay of care and the patient further desaturated to 75% and became cyanotic. A third mask functioned normally and the patient was able to be placed on BiPAP with improved saturation, color, and WOB. The total delay time was 30 minutes. Upon further investigation by the Clinical Engineering department, it was noted by the respiratory therapists that several masks had elbow attachments that could not be removed. 17 masks in total were collected, including the 2 masks from this event. All masks were part of 3 lot numbers. Per site reporter: The sales rep will file a complaint report and exchange the effected masks.
Set, Administration, Intravascular Brand: Zyno Medical Administration Set For Z-800 Infusion Pump Model#: AA-80075 Lot #: 107272KS Cat #: AA-80075	Zyno Medical, Inc.	A "bug" was found in drip chamber of IV tubing.

Device	Manufacturer	Problem
System, Imaging, Pulsed Echo, Ultrasonic Brand: Cx50 Diagnostic Ultrasound System Model#: 989605384711	Philips Ultrasound, Inc.	This unit is used for studies at other facilities so it is taken off the cart and put in a case for transport. When moving the unit off the cart the staff member heard something rattle inside the CX50. She placed a call with Biomed who discovered a loose screw rolling around inside. Biomed was able to get the screw to fall out one of the fan openings. Upon examination of the screw there was no evidence of Loctite on it which the Philips field service technician said all the screws should have. After removal of the screw Biomed did a preliminary check and everything appeared to work however the ECG portion failed the next day. The ultrasound technician said this happened one other time and the loose screw caused a failure of the main board. Per site reporter: The local service technician replaced the defective ECG board and removed all of the screws on the board the screw fell out of and added Loctite to each one and replaced them. He also found that a total of 2 screws were missing not just the one Biomed retrieved.
Tube, Feeding Brand: Cortrak 2Eas Electromagnetic Transmitting Stylet And Corflo Feeding Tube Model#: 20-9551TRAK2A Lot #: 79092 Cat #: 20-9551TRAK2A	CorPak Medsystems, Inc.	Upon preparing a Cortrak 2 feeding tube for insertion, the RN noticed the guide-wire protruding into the exit opening of the tube. The tube was removed from service. His safety concern is that the guide -wire could potentially harm a patient if inserted. The guide-wire tips are typically a couple of centimeters proximal to the tip of the tube. The RN directly involved in this event contacted the Corpak Medsystems/Halyard sales rep immediately, and she stated she would contact her quality service department and will make arrangements to replace our stock of tubes. Upon inspection of the remaining unopened tubes it appears there are other tubes with similar issues.
Tubes, Vials, Systems, Serum Separators, Blood Collection	Becton Dickinson	The clinic ordered one pack of gray top urine tubes. The store room mistakenly filled the order with the incorrect item and sent the clinic one pack of gray top sodium fluoride blood tubes. Not realizing the mistake, the clinic then collected patients' urine specimens into the incorrect tube type and sent them to the lab for urine culture. The tube manufacturer, Becton Dickinson, was notified of the problem and the organization filed a formal complaint that the two different tube types look so similar (the appearance contributed to the mix up). BD sent a message that the sodium fluoride tube was not acceptable for urine collection.
Ventilator, Continuous, Facility Use Brand: Co2 Analyzer Module Model#: 6881766	Maquet Critical Care AB	The Respiratory Therapist could not get the CO2 to work, prior to putting a ventilator on a patient so they sent this unit down to Biomed department for repair and got another ventilator with a functional CO2 module for use. Upon inspection of the system, Biomed determined there was a pin broken or missing on the CO2 module cable receptacle. When the R/T staff is not using the CO2 module, they normally unplug the cable so that the unit will not alarm "CO2 requires calibration". The multiple unplugging and re-plugging of this CO2 cable is what contributed to one of the pins being broken. The cable receptacle is keyed so it cannot be plugged-in incorrectly. This device has only been in service for approximately 14 months.

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 November 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:

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Food and Drug Administration
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