MedSun
Medical Product Safety Network

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

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In This Issue:

About the MedSun Program:

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

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

Newly Approved Devices

Recently Approved Devices (searchable listing):

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm596872.htm

Premarket Approval Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm595393.htm

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm589381.htm

In Brief

As of September 5, 2018

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

Temporary Total Artificial Heart Companion 2 Driver System by SynCardia Systems: Letter to Health Care Providers

August 17, 2018

FDA has reviewed the final results from the post-approval study conducted by SynCardia Systems for their Temporary Total Artificial Heart (TAH-t) Companion 2 Driver System (C2 Driver System). These final results indicate a higher mortality rate and higher stroke rate for patients initially supported with the C2 Driver System compared to patients initially supported with the previous generation driver, the Circulatory Support System (CSS) Console.

CARDIOSAVE Hybrid Intra-aortic Balloon Pump by Maquet Datascope Corp.: Class I Recall

June 26, 2018

Maquet Datascope Corp. is recalling the IABP due to a design issue that allows fluid (such as saline) to seep into the device. The fluid can cause corrosion of internal components such as the electronic circuit boards, and lead to device malfunction (e.g., sudden stops) which can cause a delay or interruption in therapy.

Various Aortic Endovascular Graft Systems: Letter to Health Care Providers - UPDATE on Type III Endoleaks

June 19, 2018

In a Letter to Health Care Providers from September 2017, FDA communicated its concern related to an increase in the occurrence of Type III endoleaks with the use of endovascular graft systems indicated for a procedure known as endovascular aneurysm repair (EVAR). Endologix has not manufactured the AFX with Strata graft material since July 2014, and in December 2016 requested that all AFX with Strata devices be removed from hospital inventory.

FREE FDA Webinar:

Hospitals, Manufacturers and FDA Partnering on Duodenoscope Reprocessing Safety – 1 CE Credit

October 3, 2018

1 PM - 2 PM Eastern Time
12 PM - 1 PM Central Time
11 AM - 12 PM Mountain Time
10 AM - 11 AM Pacific Time

Target Audience:

- Staff working in endoscopy reprocessing units in health care facilities;
- Infection control practitioners;
- Facility risk managers;
- Endoscopy nurses;
- Gastroenterologists;
- Gastrointestinal surgeons.

Is your healthcare facility interested in assessing the duodenoscope reprocessing practices in your hospital? Would you like to partner with FDA and scope manufacturers to address the public health concern of infections associated with contaminated scopes? Would you like to participate in an ongoing study that is designed to evaluate the real-world effectiveness of duodenoscope manufacturers' reprocessing instructions? If so, you'll want to participate in the upcoming FDA webinar. This webinar may be of interest to infection control practitioners and other healthcare professionals from facilities where Endoscopic Retrograde Cholangio-Pancreatography (ERCP) procedures are performed.

FDA Presenters:

Lauren J. Min, PhD, obtained her graduate degrees from Johns Hopkins University and University of Pittsburgh. In 2011, Dr. Min joined the FDA's Center for Devices and Radiological Health as an epidemiologist in the Office of Surveillance and Biometrics. Dr. Min currently is the lead reviewer for post-market surveillance studies of duodenoscope reprocessing.

Shani Haugen, PhD, is a microbiologist at the FDA's Center for Devices and Radiological Health in the Office of Device Evaluation. She evaluates the safety and effectiveness of reprocessing instructions for gastrointestinal endoscopes. Dr. Haugen worked with the Centers for Disease Control and Prevention (CDC), the American Society for Microbiology (ASM), duodenoscope manufacturers, and other experts to develop a validated protocol for surveillance sampling and culturing of duodenoscopes.

CE Credit: The US Food and Drug Administration, as a provider approved by the California Board of Registered Nursing, Provider Number CEP 16323, grants 1 contact hour of Continuing Education credit for this program. The certificate for CE credit will be sent once we receive the responses to a brief evaluation form.

Recording: The program will be recorded for those who are not available for the live session. The link to the recording will be provided to all who indicate interest in the program (for their use and for others in their hospitals/healthcare systems as well).

To Indicate Interest: Please e-mail medsun@fda.hhs.gov, attention '10/3 Webinar', and include your name, email address and phone number. Please indicate interest even if you are not sure of your availability for the live webinar.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during August 2018 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
Anesthesia Breathing Circuit Brand: Vital Signs Adult Breathing Circuit Model#: A5U510X4 Lot #: 0004033682 Cat #: A5U510X4	CareFusion	During the daily anesthesia automated performance testing, the anesthesia machine failed breathing circuit leak test. Trouble-shooting by the Bio-Medical Engineering Technician (BMET) noted that when 3 liter breathing bag was connected during leak test the system would fail pre-operative leak test. The BMET replaced the breathing bag with a silicon test plug and the leak self test passed. When 3 liter bag was placed on separate 22mm bag arm connector the BMET validated that the bag connector would not hold pressure and would leak. Several breathing bags were tested with similar results, some with more significant leaks than others. The breathing bags are a component part of a single patient use anesthesia breathing circuit.

Device	Manufacturer	Problem
Bed, Ac-powered Adjustable Hospital Brand: Intouch Zoom Model#: Intouch Zoom	Stryker Corporation	Our Radiology department has had numerous calls when they have a patient on a Stryker Zoom bed that stalls in the CT Radiology hallway. It appears when these beds roll over a conductive covering of the floor, the bed will stall. This will disable the zoom drive option and shutdown the bed. The bed can be restarted and can be driven again. However this is a potential safety issue for staff and could potentially delay care for our patients.
Cannula, Surgical, General Plastic Surgery Brand: Monoject Model#: 8881540111 Lot #: 808717 Cat #: 8881540111	CARDINAL HEALTH 200, INC.	A Monoject Needleless Med Prep Cannula was being prepared for use. The nurse removed the gray-colored cap from the blunt cannula and observed that there were brown and black "spots" (unknown substance) on the cannula. The cannula was removed from the patient care area and sent to the Purchasing department for follow-up with our vendor. Follow up: Thus far, no other cannulas with spotting have been found. However, inspection of all packaging of cannulas is limited as the clear plastic blunt end is covered with a gray cap. The clear blunt tip (where spotting was located) is not viewable until the gray cap is removed. A report of the event along with a photograph of the cannula were sent to the vendor and their initial response was "not sure what may have caused the issue." They requested that we return the cannula with spots to them so they can investigate the cause of this issue. The cannula will be sent to the vendor per their request.
Circuit, Breathing (WConnector, Adaptor, YPiece) Brand: Anes Circuit, Adult, 108 In, Expandable, Vital Signs Model#: AXXXX171 Lot #: 0001196683 Cat #: AXXXXX19 Other #: Vital Signs Anesthesia circuit	Vyaire Medical, Inc.	Anesthesiologist applied the new ventilation circuit and found as the case began the circuit failed and was leaking. The incident was not an isolated event the leaks happened several times over a few months with new from the package circuited. We have emails from the manufacturing rep that shows there is was a manufacturing problem and damaged breathing circuits left the Vyaire factory. PRODUCT NUMBER: AXXXXX19 & AXXXX171 PRODUCT DESCRIPTION: ANES CIRCUIT, ADULT, 108 IN LOT NUMBER: 0001196683 0004004715 0001201963 QUANTITY: 3 VYAIRE COMPLAINT # has been issued.

Device	Manufacturer	Problem
Clip, Implantable Brand: Weck Model#: IP-N010797 Lot #: 73D1800376 Cat #: AE05ML	Teleflex Medical	Staff reported that during the procedure, the surgeon wanted to use the Weck Automatic Hem-o-lock Applier. After successfully firing twice, the device stopped working, and it would not fire at all. The device was removed from the field and saved for Clinical Engineering. A new device was used and the procedure was completed as planned without harm to the patient. Upon reviewing the device, it was noted that a clip was lodged in the distal end of the instrument, and would not release, nor would the handles depress. A photo is attached to this report and the device will be returned for failure analysis.
Electrosurgical, Cutting And Coagulation And Accessories Brand: Aesculap, Monopolar Cord Model#: US354 Cat #: US354	Aesculap Implant Systems, LLC	During surgical case, the monopolar cord severed causing spark and flame to run the course of the cord toward the Bovie Machine. The RN immediately extinguished the spark.
Esophageal Thermal Regulation And Gastric Suctioning Device Brand: Ensoetm Model#: ECD01-A	Advanced Cooling Therapy, Inc. d/b/a "Attune Medical"	Patient is admitted status post cardiac arrest. MD ordered hypothermia protocol to be applied. Obtained cooling wraps/blanket with a goal temp of 36. Cooling blanket states it is cooling patient with a water temperature of 27. Cooling blanket feels as though it is room temperature, and the patient's temp continued to rise.
I. V. Start Kit Brand: Lsl Sterile Iv Start Kit Lot #: 8F3162 Cat #: 3272	LSL INDUSTRIES, INC.	1) One kit missing tourniquet 2) One kit missing all contents
Infusion Pump Module (CareFusion) Brand: Alaris Pump Model#: 8100	BD	RN went into the patient's room because the pump was alarming. The alarm read "air-in-line" and RN saw that fentanyl was infusing on the pump. The pump was programmed to deliver 2 mcg/hr, but the entire bag of fentanyl had been delivered. The medication was started at 0930 am, and empty bag was found approximately around 1030 am. The RN removed the tubing from the patient and removed the module and brain from the patient's room. Patient newly intubated and agitated with CPOT 5. Fentanyl started at 20mcg/hr (2ml/hr) as ordered at 0930. Nurse answered "air in line" alarm and found the fentanyl bag empty at 1030. The nurse disconnected the IV from the patient and removed the pump from the room and had it put in the manager's office. Vital signs pre event: HR 95 BB 121/66 Sat 100% RR 16 per vent. 0945: HR 69 BP 85/42. 10:24am: HR 56 BP 75/38. 1029am: HR 58 BP 91/49. 1044am: HR 61 BP 110/57. ABGs, the pre-extub. abg @1329pm showed ph 7.45, pCO2 44, PO2 132, HCO3 30. Next abg not done until 0220 which showed ph 7.17, PCO2 98, P02 89, HCO3 35.

Device	Manufacturer	Problem
Instrument, Ultrasonic Surgical Brand: Harmonic Ace Model#: HAR36 Cat #: HAR36 Other #: 22441	ETHICON ENDO-SURGERY, LLC	During a liver resection, the attending was using a laparoscopic ACE harmonic 36cm shears handpiece and the white piece in the tip melted and broke inside the patient. The handpiece was immediately removed from the field and the broken piece was retrieved from the patient. This happened with a second harmonic handpiece. The RN called the head of another service that uses harmonic devices and they said they had also encountered this problem and advised allowing more time between uses of the harmonic and not using it for as long each time. The third handpiece lasted slightly longer and then broke as well.
Device 1: Growing Rod System- Magnetic Actuation Brand: Magec® Spinal Bracing And Distraction System Model#: MS1-4590S Lot #: A141219-13 Cat #: PA0516 **Device 2: Growing Rod System- Magnetic Actuation** Brand: Magec® Spinal Bracing And Distraction System Model#: MS1-4590S Lot #: A150105-06 Cat #: PA0516 	NUVASIVE SPECIALIZED ORTHOPEDICS, INC. NUVASIVE SPECIALIZED ORTHOPEDICS, INC.	The patient was seen in orthopedic clinic for growth spinal rod lengthening with a magnet. The MD made 3-4 attempts to lengthen rods without success. Arrangements were made to remove and replace the malfunctioning rods. Surgery to remove and replace the rods was scheduled for a few months later. The vendor returned the rods to the manufacturer for testing. No report available at this time.

Device	Manufacturer	Problem
Laser, Urology	ForTec Medical	During surgery the Fortec green light laser malfunctioned. The laser was foggy and did not provide good visualization. The physician could not proceed. The original intended procedure was a photovaporization of the prostate and minimally invasive surgery through the urethra. Physician then completed procedure as a transurethral resection of the prostate (TURP), which is a different modality. The patient ended up having to stay overnight. These are rented devices from Fortec who the hospital contracts with. They are brought in by representatives solely for surgery. They do routine diagnostic checks on the equipment before it is used. The rep that was here for the case did not have any backups for this specific lens. We have had issues over the past several months with Fortec. We have had problems with reps being late for cases as well as reps unfamiliar with our Fortec equipment here, specifically equipment that they say is old. However, it is Fortec equipment and it is unacceptable that they are saying they do not know how to operate it. Their unfamiliarity with the equipment has caused delays in case starts.
Left-ventricular Assist Device (Lvad) Brand: Heartmate 3 Model#: Heartmate 3	Abbott Laboratories	The patient presented to our ED with persistent low flow alarms. The low flow alarms would not resolve with increasing fluid intake. The patient went to OR where it was visually confirmed that the outflow graft was twisting, occluding the flow of the LVAD. The surgeon was able to leave the pump in and only replace the outflow graft.
Mask, Surgical Brand: Fluidshield N95 Particulate Filter Respirator And Duckbill Surgical Mask Lot #: AM9258B81 Cat #: 46767	HALYARD HEALTH, INC.	We are having an issue with the duckbill mask 46767 from Kimberly-Clark. The lot number in question AM9258B81. The Elastic doesn't retract, just stretches and sometimes breaks. It looks like some of these masks could have dry rot. This was identified prior to use.
Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms) Brand: Cns Model#: CNS 6201	Nihon Kohden America, Inc.	It was discovered during implementation of our nurse secondary alarm notification that any staff could disable the secondary notification output at any of our Nihon Kohden (NK) Centrals. Staff would simply go to the gear icon and disable the "Arrhythmia Recall" button. By clicking or dis-enabling the Arrhythmia Recall functionality, any alarm notifications that would send via the NK CGS server would be disabled. Since this feeds our Vocera Engage secondary alarm notification system, this action would disable our Vocera secondary notification that could pose a risk to our patients. Per site reporter: The manufacturer is aware of this scenario and will be working on a solution to help implement.

Device	Manufacturer	Problem
N2o Needle Valve Brand: Assy-msn, Needle Valve Kit N2o, Finished Good-make Model#: 1006-8345-000 Lot #: 09APR2018/BB Cat #: 1006-8345-000	Datex-Ohmeda, Inc (GE)	During the routine Preventative Maintenance of an Astevia MRI Gas Machine it was noticed the device was failing the Proportioning System Verification Test. The Biomedical Engineering Tech performing the Preventative Maintenance identified that the Nitrous Oxide Needle Valve required replacement. A new Datex-Ohmeda (GE) Needle Valve was ordered. When the package was opened the tech noticed that the needle was not stable and could easily be moved within its casing, indicating that the valve was defective. The technician then ordered a second Needle Valve. The second needle valve, which had the same Lot number as the first, when opened would not turn to advance the needle. A third valve of the same lot number was sent. The third valve would also not rotate to advance the needle. Three defective needle valves, all of the same Lot number, were shipped to our Biomedical Engineering Department and failed directly out of the box.
Needle, Hypodermic, Single Lumen Brand: Autoshield Duo Model#: Autoshield Duo Lot #: 7349817	Becton, Dickinson and Company	Nurse was giving insulin this am and when she was injecting it, it stopped halfway through and she couldn't push the rest of the insulin, she then pulled it out and the whole safety cap popped off and the needle was exposed. An exact similar event occurred 4 days earlier with another nurse, using the same lot number of needles. We investigated to make sure that the nurses are using the needle in the correct way, and were able to confirm it.
Outflow Graft Brand: Heartmate 3 Model#: Heartmate 3 Lot #: 173667 Cat #: 105581	Abbott Laboratories	The patient presented to our ED with persistent low flow alarms. The low flow alarms would not resolve with increasing fluid intake. The patient went to OR where it was visually confirmed that the outflow graft was twisting, occluding the flow of the LVAD. The surgeon was able to leave the pump in and only replace the outflow graft.
Separator, Automated, Blood Cell, Diagnostic Brand: Trima Accel	Terumo BCT, Inc.	The patient has had serial platelet donations over a long period, approximately 20 collections this year alone. The patient was found to have reduced CD4 counts. The hematologist following the patient is suspicious that the reduction in counts may be related to the apheresis devices used during platelet collection to yield leukoreduced platelet units.

Device	Manufacturer	Problem
Set, I. V. Fluid Transfer Brand: Exactamix Cat #: H938740	Baxter Healthcare Corporation	The two liter TPN bag had been done in the in patient pharmacy. The TPN bag never left their department, as they noticed the bag started to leak from the port. The pharmacist sent me two pictures of the bag leaking. Apparently, this has been an on going problem when I spoke with the pharmacy senior manager, but this is the first SMDA report submitted. The ExactaMix bag is currently in the in patient pharmacy. Once the manufacturer gets the SMDA report, I will ask them to send me a mailing container and label to return the bag to them. Please see picture below: 
Stationary Angiographic X-ray System, Digital Brand: Axiom Artis Model#: Zee	SIEMENS MEDICAL SOLUTIONS USA, INC	Patient placed on table in IR (Interventional Radiology) room 1: Siemens Artis Biplane Room. After starting the procedure the table locked and it couldn't be moved. Lost ability to use tableside controls.
Tissue Retractor System Brand: Urolift Lot #: P38024, 38124, P37656	Neotract, Inc.	In cysto OR, the Neotract urolift system malfunctioned while the surgeon attempted to use it. A total of five urolift systems malfunctioned. Staff bagged the five systems in a red bag and placed it in the original manufacturer box to be returned to the vendor. The rep was also notified. Surgery was completed with a different urolift without patient harm.

Device	Manufacturer	Problem
Tubes, Gastro-intestinal Brand: Medela Lot #: J4270 Cat #: ENFPU2065LD Other #: (Q1) 000204511Q1538 	Footprint Medical, Inc.	The orogastric tube broke while it was being retaped by the RN. Tegaderm tape is used to hold the OG tube in place. This OG tube had been placed soon after the birth of baby and it broke approximately twenty-two days later.
Ventilator, Continuous, Facility Use Brand: Servo-n Model#: 6688600 	MAQUET MEDICAL SYSTEMS, USA	Second occurrence, first was over a month prior. Ventilator screen went blank and then into standby screen while on patient
Wire, Guide, Catheter Brand: Zipwire Hydophilic Guidewire Lot #: 10995369 Cat #: m006630216B0	Lake Region Medical	A Patient undergoing central venous line placement, very difficult procedure due to prior central venous line history, with short bowel syndrome. During the procedure, the left internal jugular vein was accessed percutaneously. Due to central venous stenosis, a ZIPwire hydrophilic guidewire (150cm straight tip 0.025in, Lot 10995369) was used. While maneuvering the wire, the coating of the wire was sheared off remaining within the patient. The black outer coating peeled off and was now a foreign body within the patient. This was visualized on fluoroscopy and ultrasound to be within the left internal jugular vein itself. This was removed entirely through an already present incision which was enlarged slightly to accommodate retrieval of the foreign body. The fragment was removed entirely under direct visualization. Fluoroscopy confirmed complete removal. There was no blood loss or injury to the patient attributable to this event other than enlarging slightly an already present incision.

Device	Manufacturer	Problem
Endoscopic Tissue Approximation Device Brand: Endo Stitch Model#: 173016 Lot #: J8D0893EX Cat #: 173016	Covidien LLC	During Gastric Sleeve Procedure, surgeon loaded the device and the device would not open. Staff tried all attempts that were taught to them by the rep, and the device was still stuck. Device malfunction, no harm to patient.
Clip, Implantable Brand: Ligamax Model#: EL5ML Cat #: EL5ML	ETHICON ENDO-SURGERY, LLC	Pt s/p laparoscopic cholecystectomy. Surgery was uneventful. The patient had 2 clips placed on the cystic artery and ligation thereof and did well postoperatively. On the evening of POD #0, patient began having increasing abd pain and hemodynamic instability. Patient brought to OR for emergent laparoscopic diagnostic and conversion to exploratory laparotomy. Surgeon intention of assessing whether patient had pneumoperitoneum. Large amounts of blood throughout the liver and hepatic fossa with clots. The cystic artery was actively bleeding and the previous placed clips were not visible. It was surmised that the clips were somehow dislodged from placement to the postoperative period. Clips could not be located and abdomen was copiously irrigated. The cystic artery was ligated with sutured. The patient did require fluid bolus and 2 units of PRBC transfusions. Post operative diagnosis: Hemorrhagic shock and bleeding cystic artery.
Staple, Implantable Brand: Echelon Flex Model#: PVE35A Lot #: R9312X Cat #: PVE35A	ETHICON ENDO-SURGERY, INC	During a living donor nephrectomy, the surgeon was not able to open the stapler after one use. One artery had already been stapled causing a delay in removing the kidney with partial ischemia time initiated. A new stapler obtained, without issues.
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 11171447 Lot #: 18065368 Cat #: 11171447	CAREFUSION 303, INC.	Nurse removed primary tubing set from package. Tubing was found to be the same on both ends. Normally it has a spike and drip chamber on one end that goes into a medication, a segment in the middle that goes through the infusion pump,and a male end with clamps that connects to the patient. This tubing had two male ends with a pump segment in the middle so there is no way to spike the medication, tubing is not usable.

Device	Manufacturer	Problem
Lavage, Jet Brand: Pulsavac Model#: 00-5150-475-00 Lot #: 63899751 Cat #: 00-5150-475-00 Other #: H129005150475002	Zimmer Surgical, Inc.	The OR staff were preparing for the case (patient was not in the room) when they noticed smoke and heard a sizzle coming from the battery pack of the device. Staff alerted Fire Safety and Biomed, and reported that the battery pack was smoking and starting to melt. The cord to the device was cut and the battery pack was opened to safely dislodge the batteries that were causing it to smoke and melt. No staff or patients were harmed in the event. The device was removed from service. Please see picture below: 

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 September 2018 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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