MedSun
Medical Product Safety Network

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

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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 3, 2019

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

Edwards Lifesciences, LLC, Recalls SAPIEN 3 Ultra Delivery System Due to Burst Balloons During Surgery
August 22, 2019
Edwards Lifesciences has received reports of burst balloons during implantation procedures, which have resulted in significant difficulty retrieving the valve into the catheter and withdrawing the system from the patient, which may cause vascular injury, bleeding, or surgical intervention. The use of affected product may cause serious adverse health consequences, including death. Seventeen (17) injuries and one (1) death were reported at the time when Edwards initiated the Field Corrective Action in July 2019.

Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality - UPDATE
August 7, 2019
Earlier this year, FDA notified health care providers about a late mortality signal in patients treated for peripheral artery disease (PAD) in the femoropopliteal artery with paclitaxel-coated balloons and paclitaxel-eluting stents. This update is to provide the latest information on our analysis of long-term follow-up data from premarket trials and to provide summary information from our June 2019 advisory panel meeting. In addition, FDA is including recommendations to health care providers for assessing and treating patients with PAD using paclitaxel-coated devices.

Abbott (Formerly St. Jude Medical Inc.), Recalls Ellipse Implantable Cardioverter Defibrillators Due to Exposed Aluminum Wires That May Prevent Defibrillation Therapy
August 6, 2019
Abbott is recalling the Ellipse Implantable Cardioverter Defibrillators (ICDs) because electrical failures have been identified and determined to be due to a faulty manufacturing process causing some aluminum wires to be partially exposed. ICDs which contain aluminum wires that are not fully insulated are prone to electrical shorting of the capacitor. The potential patient impact could be the inability to deliver high voltage therapy. There is currently no available method or procedure to determine which of these devices have this issue prior to failure. Abbott is aware of zero (0) related reports of this failure occurring in any affected implanted devices. Of the devices recalled in the US, 31 devices have been implanted. The complaints and MDRs available have either reported that the affected devices have been replaced or are scheduled to be replaced with another ICD generator. None of the complaints or MDRs indicate that any patient harm or adverse events have occurred, and no deaths have been reported.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during August 2019. 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 Conduction Kit Brand: Contiplex Echo Ct W/4in Tuohy Ultra 360 Set Lot #: 0061671793 Cat #: 331768	B. Braun Medical, Inc.	Anesthesia staff received a box of Echo Pain Block Needle sets which were labeled "Not for Human Use" by small pink sticker on the box. This product was sent to the Anesthesia Department as a sample product. B Braun vendor removed the sticker and took the box with her. No patient contact

Device	Manufacturer	Problem
Device 1: Aid, Cardiopulmonary Resuscitation Brand: Onestep Cat #: 8900-0224-01 **Device 2: Monitor, Defibrillator** Brand: RSeries:als, And ESeries Other #: 9310 0895	Zoll Medical Corporation Zoll Medical Corporation	The report has been submitted after an intensivist at our hospital expressed concern regarding the Zoll Monitor that gives feedback during CPR. The intensivist was running a code in which the code team followed the prompts from the monitor, and later it was found that the patient had two acute thoracic compression-type fractures. Patient coded. Zoll monitor and pads used to run code. Per RN, the Zoll monitor kept telling the team "deeper, deeper" in regards to their chest compressions; so they attempted to compress deeper. Pt returned to sinus rhythm at seven minutes later. The required two doses of epinephrine (1 mg). At 0859, patient had an abdominal CT which showed: interval development of inferior endplate fracture at T11 with widening of the intervertebral disc space at T11-T12, as well as nondisplaced posterior spinous process fracture at T12. Recommendations for further evaluation with MRI to assess for ligamentous injury. Radiologist spoke with the intensivist and told him that this is a compression-type fracture, and could be from the CPR. This patient was subsequently made a DNR, and passed away that afternoon from septic shock and pneumonia.
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: Bd Insyte Autoguard Model#: 382533 Lot #: 9085553 Cat #: 382533	Becton Dickinson and Company	A BD Insyte Autoguard shielded IV catheter was pulled for patient use. Even before the packaging was opened a black mold-like substance was noted around the needle tip. The package was left intact and the IV catheter was pulled from use. It never reached a patient.
Set, I. V. Fluid Transfer Brand: Exactamix Model#: H938737 Lot #: 60116857 Cat #: H938737 Other #: 03.20.18 22:41.36 	Baxter Corporation	After TPN was compounded on the Baxa EM 2400 Exactamix compounder in the pharmacy department, the 250 ml bag was sealed and labeled according to protocol. Upon preparing to transport the bag to the patient floor, it was noted that the middle port was leaking near the manufacturer joint where the port had been sealed during the production process. A new bag was made, and the leaking bag retained for submission to Baxter. Another bag had the same issue: 60130030 (Lot)

Device	Manufacturer	Problem
Electrosurgical, Cutting Coagulation Accessories Brand: Ligasure Model#: LF1837 Lot #: 90880142X Cat #: LF1837	Covidien LP	For colorectal case, a second Covidien 1837 blunt tip LigaSure (REF LF1837, Lot # 90880142X, exp. 2024-03-27) was opened for use, as the insulation toward the tip of the first 1837 blunt tip LigaSure device broke off/peeled off. As the surgeon began to use the device, the insulation toward the tip of the device also broke off and the device was removed from the field. (The cord was cut when the instrument was passed off the field.) A third 1837 blunt tip LigaSure was then opened and worked without incident. No patient harm.
Monitor, Physiological, Patient Model#: MP30 Other #: M8002A	Philips Healthcare	The QRS module tone for the oxygen saturation in the Inpatient Endoscopy unit is defaulted to OFF. The patient's O2 saturation dropped to 35% and we did not know until a technician noticed on the screen. A few things went wrong in this scenario. The default QRS tone setting was zero on this monitor. The desaturation alarm should have alerted them to the low oxygen saturation. Staff explained that they were getting alarms for the CO2 module and had silenced them by pressing pause alarms instead of silence, which will keep the monitor silent from all alarms for three minutes. The default QRS volume has been changed to two. This can still be manually adjusted and will not clear from the monitor until the patient is discharged (case ended). In order to ensure the case is being ended, the standby button has been removed and replaced with end case.
Ventilator, Continous, Facility Use Brand: Evita XI Other #: 319879	Draeger Medical Systems, Inc.	A trauma patient was intubated and on the Draeger Evita ventilator. While still in the ED the ventilator alarmed "peep valve error-contact Draeger services". Respiratory therapy took patient off the ventilator to ensure ventilation (bag mask with peep valve) and switched out the ventilator before taking up to shock trauma. The ventilator was evaluated for twenty-four hours and verified the problem was a leaky expiratory valve. While looking in the ventilator logbook there were multiple flow sensor, minute volume alarms, and leak alarms prior to the peep alarm. As a result, each time a flow calibration is done with a leak, the peep valve becomes further away from base line, hence a peep valve error. The exhalation valve and flow sensor were replaced. A peep valve calibration was performed and the ventilator was ran for twenty-four hours without deviation in volume or peep. It's the belief that replacement of the exhalation valve or tightening of the diaphragm would have averted this event.

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 2019 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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