MedSun
Medical Product Safety Network

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

February 2020

Volume 20, 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):

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 February 1, 2020

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

King Systems Issues Recall of King Vision Video Laryngoscope Video Adapter Size ½

January 24, 2020

King Systems voluntarily recalled the products after receiving reports of some products exhibiting a reversed image. Although the image may appear normal, the user's actions will be reversed on the display for left and right directions. The affected products have been found to exhibit a reversed image, which could potentially result in difficulty navigating during intubation and/or delay in intubation. As of January 20th, 2020, King Systems has not received any reports of adverse events (no patient injuries) resulting from this issue.

Surgical Gowns and Packs by Cardinal Health: FDA Statement - Potential Quality Issues Affecting Some of its Level 3 Surgical Gowns and Accompanying PreSource Procedural Packs

January 16, 2020

Cardinal Health alerted its customers to potential quality issues affecting some of its Level 3 surgical gowns and accompanying PreSource procedural packs. Customers should immediately discontinue use of all affected surgical gowns and PreSource procedural packs that include the surgical gowns because the manufacturer cannot provide assurance the products are sterile. Customers with questions about whether their own inventory is affected should contact Cardinal Health directly.

Stryker Launches Voluntary Field Action for Specific Units of The LIFEPAK® 15 Monitor/Defibrillator

January 10, 2020

The company is notifying a population of LIFEPAK 15 customers of an issue that may cause their devices to fail to deliver a defibrillation shock after the "Shock" button on the keypad is pressed. This is a result of oxidation that may have formed over time within the "Shock" button. Stryker is contacting customers with impacted devices to schedule the correction of their device(s), which will include replacement of the affected keypad. Stryker anticipates that all devices subject to this field action will be serviced by June 2021. Most complaints associated with this issue were detected prior to patient use. Routine testing of the device can detect this fault condition. If a customer experiences this issue, they should contact Stryker as soon as possible at 1-800-787-9537 and select option 2.

FDA Safety Communication: Cybersecurity Vulnerabilities in Certain GE Healthcare Clinical Information Central Stations and Telemetry Servers

Background: FDA is raising awareness among health care providers and facility staff that cybersecurity vulnerabilities in certain GE Healthcare Clinical Information Central Stations and Telemetry Servers may introduce risks to patients while being monitored. A security firm has identified several vulnerabilities in certain GE Healthcare Clinical Information Central Stations and Telemetry Servers, that may allow an attacker to remotely take control of the medical device and to silence alarms, generate false alarms and interfere with alarms of patient monitors connected to these devices. These vulnerabilities might allow an attack to happen undetected and without user interaction. Because an attack may be interpreted by the affected device as normal network communications, it may remain invisible to existing security measures. To date, the FDA is not aware of any adverse events related to these vulnerabilities.

Recommendations for Health Care Providers:

- Work with health care facility staff to determine if a medical device used by a patient may be affected and how to reduce associated risk.

Recommendations for Health Care Facility Staff (including, Information Technology and Cybersecurity Staff):

- GE Healthcare will be issuing a software patch to address the vulnerabilities and will notify affected customers to deploy them when the patches are ready. Information about the patches will be posted on the GE Healthcare product security portal.

- The risk posed by the vulnerabilities can be reduced by segregating the network connecting the patient monitors with the GE Healthcare Clinical Information Central Stations and Telemetry Servers from the rest of the hospital network, as described in the GE Healthcare documentation for these devices.

- Use firewalls, segregated networks, virtual private networks, network monitors, or other technologies that minimize the risk of remote or local network attacks.

For more information and to read the complete safety communication, click here.

FDA Safety Communication: The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety

Background: Duodenoscopes play a vital role in the assessment and treatment of diseases and conditions of the pancreas and bile ducts, and are used in more than 500,000 endoscopic retrograde cholangiopancreatography (ERCP) procedures each year in the U.S. These devices have complex designs that include reusable hard-to-clean components. Failure to correctly reprocess a duodenoscope could result in tissue or fluid from one patient remaining in a duodenoscope when it is used on a subsequent patient. In rare cases, this can lead to patient-to-patient disease transmission. The FDA takes the risk of patient infection very seriously and continues to take steps to help improve the effectiveness of duodenoscope reprocessing and are sharing the following recommendation and updates:

FDA Actions and Recommendations for Health Care Facilities:

- FDA is now recommending that hospitals and endoscopy facilities transition away from fixed endcap duodenoscopes to those with newer design features that facilitate or eliminate the need for reprocessing. Please note, we recognize that a full transition away from conventional duodenoscopes to the newer, innovative models will take time.

- FDA continues to work with manufacturers to increase the supply of disposable cap duodenoscopes and the development of other new and innovative device designs that will further minimize or eliminate the risk of patient infection.

- FDA continues to address challenges with current reprocessing methods and support expanding the types of validated methods available to reprocess duodenoscopes.

Additionally, FDA has important recommendations for hospitals and endoscopy facilities:

- Consider using duodenoscopes that have disposable components, if available at your facility; this design may lower but not eliminate risks of infection.

- Ensure staff are meticulously following reprocessing instructions.

- Institute a quality control program that includes sampling and microbiological culturing, and other monitoring methods.

FDA Safety Communication: The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety

- Consider reprocessing with supplemental measures such as sterilization or use of a liquid chemical sterilant processing system consistent with the device's labeling.

- Monitor your reprocessing procedures. Examples of monitoring are sampling and culturing using Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection developed by the FDA-Centers for Disease Control and Prevention-American Society of Microbiology Working Group on Duodenoscope Culturing.

- Develop schedules for routine inspection and periodic maintenance in accordance with the duodenoscope manufacturer's instructions.

For more information and to read the complete safety communication click here.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during January 2020. 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.

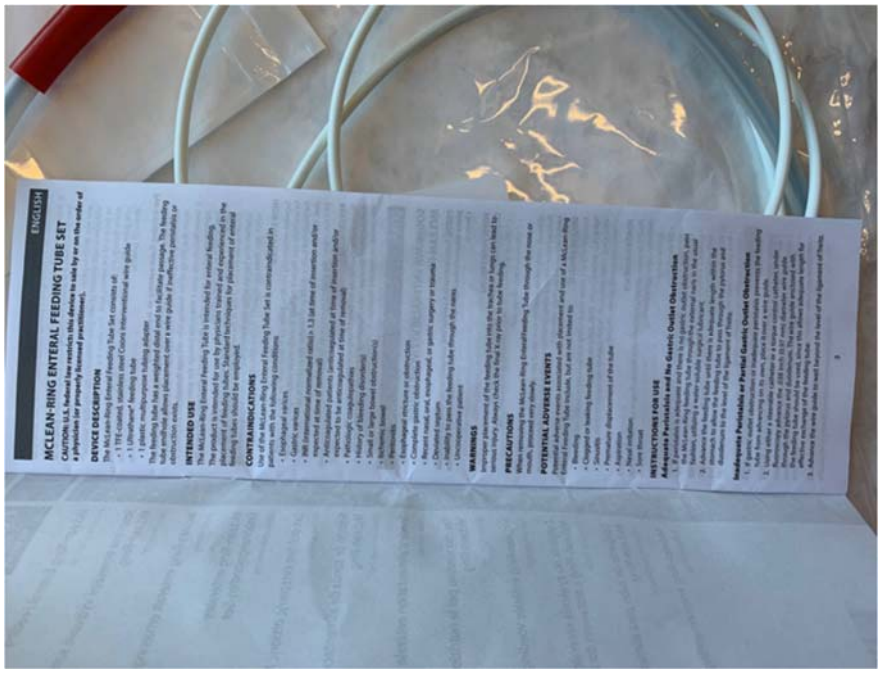
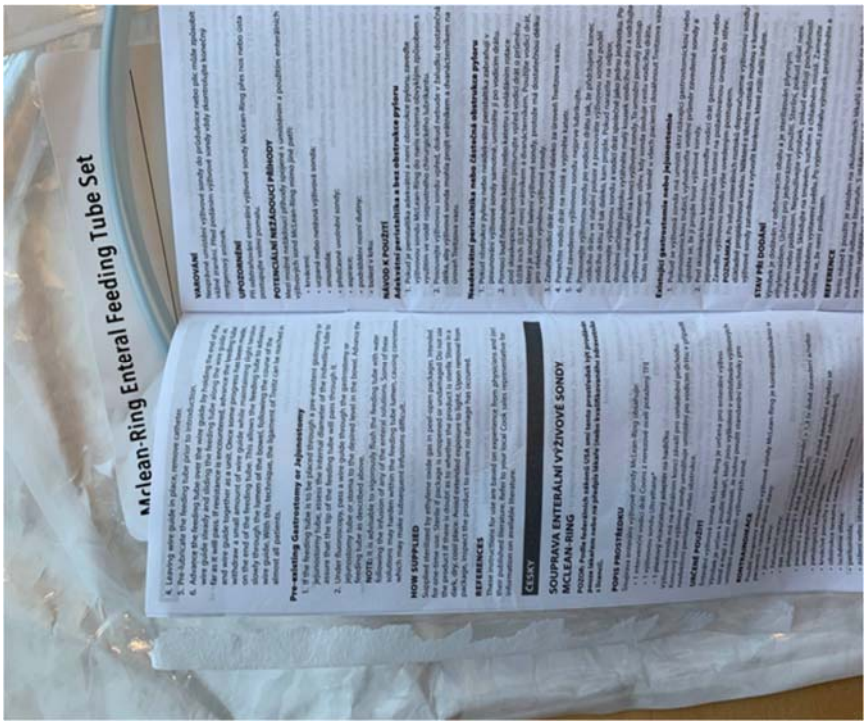
Device	Manufacturer	Problem
Device, Occlusion, Tubal, Contraceptive Brand: Filshie Clips Model#: Twenty pair sterile Filshie Clips Lot #: 37920 Cat #: AVM-851	Femcare Limited	During tubal ligation, the Filshie clip applicator was inserted and Filshie clip was attempted to be deployed, but it would not lock on the tube. Three other Filshie clips were tried and none of them would lock on the tube. Surgeon attempted to close and engage the clips outside the body, and they would not engage.

Device	Manufacturer	Problem
Electrocardiograph, Ambulatory(Without Analysis) Brand: digitrak Xt Model#: 860322 Cat #: 860322	Phillips Medical Systems	Upon setting up holter testing, an error message (602) was displayed and staff were unable to program device to apply on patient for testing.
Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms) Brand: Carescape Model#: B850	GE Medical Systems, Inc.	A time change was made via Webmin on a B850 GE monitor. The time was changed to 11:39pm (to reflect falling back an hour). However, the date is a separate field that would have needed to have been changed to Nov 2nd 2019 and it was not. This meant the change that was made actually set the clock ahead 23hrs to 11:39pm Nov 3rd. This caused all monitors on the network to update to the same date and time 23hrs ahead. Unfortunately, throughout the night the issue was not noticed and it was at 10am Sunday morning on the 3rd (10hrs after the change took place) that GE and Epic team started looking into the issue because data was not flowing into patient electronic records. At 12:09pm (2 hours after the team started working on the issue) the time corrected itself. (It is still unknown as to why at this time it automatically corrected itself without an actual person correcting the time). Monday morning on the 4th, clinicians report unknown data showing up in the patients electronic charts. The data that was not showing up the previous day it turned out was still stored in the Epic system and was now populating for Monday the 4th even though it was data from Sunday the 3rd. This was a very serious issue of data being given the wrong time stamp in the patient's electronic record as well as full disclosure data on the GE servers being marked with the wrong date (and then overwritten). The first problem is that any networked device in the GE domain that gets a time change has that change made across all GE monitoring devices. Someone thinking they are just making a simple correction to one monitor may not realize they are making a change to all devices. The second is that there is no alert or notification to let someone know that the time has been changed to something far off from the standard time. The last issue is that this data could still be stored in the patient's record even though it was so far into the future.
Screw, Fixation, Bone Brand: Axsos Model#: 703586 Cat #: 703586	Stryker Trauma SA	While performing a tibial plateau fracture Open Reduction Internal Fixation, two drill bits broke inside the patient's tibia. Broken drill bits left inside the patient's bone as it would require significant effort and likely cause more harm to remove then.

Device	Manufacturer	Problem
Device 1: Tissue Cassette Brand: Thermofisher Epredia Lot #: I17C9Q1 Cat #: B851730YW Other #: B8517 **Device 2: Tissue Cassette** Brand: Thermofisher Epredia Lot #: I17C9Q5 Cat #: B851734PK Other #: B8517 **Device 3: Tissue Cassette** Brand: Thermofisher Epredia Cat #: B851729TN **Device 4: Tissue Cassette** Brand: Thermofisher Epredia Cat #: B851729WH **Device 5: Tissue Cassette** Brand: Thermofisher Epredia Cat #: B851729LG	THERMO FISHER SCIENTIFIC INC. THERMO FISHER SCIENTIFIC INC. THERMO FISHER SCIENTIFIC INC. THERMO FISHER SCIENTIFIC INC. THERMO FISHER SCIENTIFIC INC.	We have what appears to be a new biopsy cassette in yellow. The lids do not fit properly on these cassettes and we are experiencing loose closure and the possibility of tissue free floating during processing. It appears the newer cassettes are lighter in color than our original ones. Also neither the older lids nor the ones that are supposed to be the companion to the lighter colored cassettes is fitting. I am highly concerned about case integrity and patient safety with this happening. This is a serious issue when considering the integrity of the tissue, case, and providing accurate patient results. (above information was from Lab Director) These samples are irretrievable. So if we compromise identity, we lose the ability to diagnose. Often there is no additional tissue to go back to.

Device	Manufacturer	Problem
Set, Administration, Intravascular Brand: Safestep Port Access Needle Model#: LH-0031 Lot #: ASDV051 Cat #: LH-0031	Bard Access Systems, Inc.	Port-a-cath line (PAC), which was hep-locked, was entered in order to draw scheduled AM labs. The line flushed well without resistance and appeared intact at the insertion site. When blood was attempted to be drawn from the line, the syringe filled with air and the line began to leak blood below the clave. The RN clamped the line above the perceived line break and de-accessed the PAC. The CVC was re-accessed and blood cultures were drawn prior to drawing labs. Huber needle assembly brought to Biomedical for reporting and assessment. Biomedical confirmed line was leaking at the junction where the tubing entered the female luer hub. BME noted adhesive/sealant may have leaking from bonding point resulting in tubing leak. Line saved for mfg. evaluation.
Device, Hemostasis, Vascular Brand: Perclose Proglide Model#: 12673-03 Lot #: 9100141 Cat #: 12673-03	ABBOTT VASCULAR INC.	It was reported that during an elective coronary angiogram (uneventful with minimal luminal irregularities noted), suture repair was attempted of the right femoral artery using a Proglide device when the device had an unspecified issue and broke / got stuck and it could not be removed. The customer was taken to the operating room emergency for an open groin exploration with femoral artery repair, removal of the partially deployed Proglide device (the catheter tip was severed from device and was retained within the common femoral/external iliac artery), and the artery was repaired with primary closure. Suction dressing was placed. Customer was observed overnight, and discharged the next day with a wound vacuum device.
Anesthesia Conduction Catheter Brand: Design Options Model#: 552030 Lot #: 0061690042 Cat #: 552030	B. BRAUN MEDICAL INC.	Anesthesiologist was placing the epidural for the patient at bedside when the epidural catheter broke, leaving 5.5-6 cm of the catheter in the patient's epidural space. Anesthesiologist covered the insertion site with a gauze. He consulted with other anesthesiologists and neurosurgery. A spinal block was performed. Patient was advised that Neurosurgery would be consulting with her during her hospital stay. Patient remained stable. Lower lumbar x-ray was taken. Epidural catheter was not visualized. After evaluation by neurosurgery, no interventions recommended at this time. The patient will be followed up later this month to discuss necessity of a CT scan for actual visualization. Neurosurgery only recommends this should she wish to proceed with having it removed.
Accessories, Cleaning Brushes, For Endoscope Brand: Pull Thru Cleaning Device Model#: 100405 Lot #: 438970 Cat #: 100405 Other #: 1 x Pull Thru 2.8-5.0 mm	Medivators	The Endoscopy Department changed to a new scope lumen cleaning brush (Pull-Thru lumen channel brush). The decision to change to this new system was to achieve optimal cleaning. Prior to using the new brushes, the representative educated the Endoscopy team on how to use the brushes. It was decided that the new brushes were not to be used until the old brushes were used up. On [date redacted], the Endoscopy team were instructed they could begin to use the new brushes. During the cleaning process, the Endoscopy technicians found that the new brush applied to a balloon lumen did not perform as intended. This new brush could not be p ulled through the balloon lumen channel and the effective brush component did not reach the end of this channel. This information was communicated to the department manager. Use of this device was stopped at this time and stored scopes were reprocessed using the former brush method. The manufacturer of the brush listed that the new brush could be used with the Endoscopic and Endobrachial Ultrasound units owned by this facility. Nine patients received scope procedures within this two week timeframe with a balloon lumen. Four patients (two Endoscopic Ultrasounds, two Endobrachial Ultrasounds) had scopes cleaned with the new brush. Follow up: Infection Prevention and Endoscopy reviewed the medical records of the patients who had scopes inadequately cleaned with the new brush. Many various factors were applied to assess infection risk for these cases. The conclusion was that it is assumed all scope processing steps were followed. The new brush applied to a balloon lumen did not perform as intended. The manufacturer of the brush listed that the new brush could be used with the EUS and EBUS models owned by this facility. No blood borne pathogens were identified in the total patient population (9). No biopsies were collected. No complications (balloon rupture, perforation, bleeding) occurred. Risk has been assessed to be low.

Device	Manufacturer	Problem
Tubes, Gastro-intestinal (And Accessories) Brand: Mclean-ring Enteral Feeding Tube Set Model#: G02647 Cat #: MRT-9.5-130	Cook Incorpo-rated	Concern with MR (Magnetic Resonance) labeling on Cook Medical feeding tube. Weighted-tip naso jejunal enteral feeding tube as nothing on label, instructions for use, or otherwise to indicate MR safety profile of device. The weighted tip is metal, patients may re-quire MR scanning while tubes are in place. Images obtained while patients have these devices contain artifacts which are not evident until the patient has already been scanned. Please see pictures below:  

Device	Manufacturer	Problem
Tubes, Gastro-intestinal (And Accessories) Brand: Mclean-ring Enteral Feeding Tube Set Model#: G02647 Cat #: MRT-9.5-130	Cook Incorpo-rated	Concern with MR (Magnetic Resonance) labeling on Cook Medical feeding tube. Weighted-tip naso jejunal enteral feeding tube as nothing on label, instructions for use, or otherwise to indicate MR safety profile of device. The weighted tip is metal, patients may re-quire MR scanning while tubes are in place. Images obtained while patients have these devices contain artifacts which are not evident until the patient has already been scanned. Please see pictures 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 Ill 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 2020 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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