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/medical-devices/device-approvals-denials-and-clearances/recently-approved-devices

Premarket Approval Final Decisions:
https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals

510(k)s Final Decisions:
https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances

In Brief

As of April 27, 2022

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

FDA Safety Communication: Genetic Non-Invasive Prenatal Screening Tests May Have False Results

April 19, 2022

The FDA is warning patients and health care providers about the risks of false results with genetic non-invasive prenatal screening (NIPS) tests, sometimes called noninvasive prenatal testing or tests (NIPT). Results from NIPS tests can provide information about the possibility of a fetus having certain genetic abnormalities that could result in a child being born with a serious health condition.

While health care providers widely use NIPS tests, none have yet been authorized, cleared, or approved by the FDA. The accuracy and performance of NIPS tests have not been evaluated by the FDA and these tests can give false results, such as reporting a genetic abnormality when the fetus does not actually have one. NIPS tests are screening tests, which means the NIPS test may only tell you the risk of the fetus having certain genetic abnormalities. They are not diagnostic tests, which are generally used to more definitively confirm or rule out a suspected genetic abnormality.

The FDA is aware of reports that patients and health care providers have made critical health care decisions based on results from these screening tests alone and without additional confirmatory testing. Specifically, pregnant people have ended pregnancies based only on the results of NIPS tests. Without confirming the results with a diagnostic test, there is no way to know whether the fetus actually had the genetic abnormality reported by the screening test. The FDA is aware of cases where a screening test reported a genetic abnormality and a confirmatory diagnostic test later found that the fetus was healthy.

Class I Recall: Medtronic Recalls Harmony Delivery Catheter, Part of Transcatheter Pulmonary Valve (TPV) System, for Risk of Capsule Break During Use

April 26, 2022

Medtronic is recalling the Harmony Delivery Catheter because the bond holding the capsule at the end of the delivery catheter may break during a procedure to place the TPV. A capsule bond break could cause procedure delays while the device is replaced with a new one or it may require the patient to undergo additional surgeries. Additionally, a capsule bond break while in use during a procedure could cause serious harm to the patient. Those risks include preventing blood flow and/or completely blocking (embolization or occlusion), tearing and/or splitting (perforation or dissection), or other types of damage to the patient's blood vessels.

There have been 6 reported complaints from clinical cases, one injury, and no deaths associated with the use of these devices.

Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

The FDA is updating the April 2020 Safety Communication to provide new information supporting the transition to fully disposable duodenoscopes and those with disposable components as well as new information on completed postmarket surveillance studies (also known as 522 studies).

Given the cleaning and contamination concerns with fixed endcap duodenoscopes and the increasing availability of duodenoscope models that facilitate or eliminate the need for reprocessing, hospitals and endoscopy facilities should complete transition to innovative duodenoscope designs that include disposable components such as disposable endcaps, or to fully disposable duodenoscopes. The use of a removable component to facilitate cleaning leads to significantly less contamination; interim results from one duodenoscope model with a removable component show a contamination rate of just 0.5%, as compared to older duodenoscope models which had contamination rates as high as 6%. Use of the newer models of duodenoscopes can reduce the risk of infection for patients, compared to the older fixed endcap duodenoscope models. Duodenoscope manufacturers no longer market fixed endcap duodenoscopes in the US, and healthcare facilities should replace fixed endcap duodenoscopes with newer models.

Recommendations for Health Care Providers, including Hospitals and Endoscopy Facilities

- Use duodenoscopes that have disposable components or are fully disposable, if available at your facility. Disposable components may lower, but not eliminate, risks of infection.
- If your facility uses fixed endcap duodenoscopes, transition to newer models of duodenoscopes that have disposable components or are fully disposable. We recommend you contact duodenoscope manufacturer(s) for information about the newer duodenoscope designs. Some duodenoscope manufacturers are offering replacement programs to upgrade fixed endcap duodenoscopes to a model with a disposable component at no-cost.
- Follow the manufacturer's instructions for the assembly of the disposable components.
- Develop schedules for routine inspection and periodic maintenance in accordance with the duodenoscope manufacturer's instructions.
- Ensure staff are meticulously following reprocessing instructions.
    - Institute a quality control program that includes sampling, microbiological culturing, and other monitoring methods.
    - 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 the 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.
- Review the Recommendations for Patients and Caregivers with patients who have contact with the affected devices.

To read the full Safety Communication, with data from the 522 studies and a list of currently marketed duodenoscopes with disposable components, please visit FDA's website.

Infections Associated with Reprocessed Urological Endoscopes – Letter to Healthcare Providers

The FDA wants to raise awareness among health care providers, including those working in reprocessing units in health care facilities, about the risk of infections associated with reprocessed urological endoscopes, including cystoscopes, ureteroscopes, and cystourethroscopes, used for viewing and accessing the urinary tract. The FDA has received numerous Medical Device Reports (MDRs) that describe patient infections post procedure or other possible contamination issues associated with reprocessing these devices.

The FDA is currently investigating the potential causes and contributing factors associated with the reported infections and contamination issues. While some reports indicate possible inadequate reprocessing or maintenance issues (for example, device failed leak testing) as a potential cause, the FDA is also evaluating other potential issues including reprocessing instructions in the labeling and device design. Although the FDA is early in our evaluation, based on the available data we believe the risk of infection is low. The FDA is emphasizing the importance of following the manufacturer's labeling and reprocessing instructions for these devices, including accessory components, for cleaning and subsequent processing to minimize the risk of infection.

Recommendations

The FDA recommends that health care providers:

- Carefully follow the reprocessing instructions described in the manufacturer's instructions for use.
    - Reprocessing steps should include one of the following two options:
        - Precleaning, leak testing, cleaning, disinfecting, rinsing and drying; or
        - Precleaning, leak testing, cleaning, and sterilization.
    - Be aware that reusable accessory components may have separate reprocessing instructions.
    - Be sure to follow the applicable instructions for disassembly of the endoscope and other components when reprocessing.
- Do not use damaged devices or those that have failed a leak test, as they could be a potential source of contamination.
- Develop schedules for routine inspection and periodic maintenance in accordance with the manufacturer's instructions.
- Discuss the benefits and risks associated with procedures involving reprocessed urological endoscopes with your patients.

To read the full Letter to Health Care Providers, please visit FDA's website.

Change in Reprocessing Methods with Certain Karl Storz Urological Endoscopes – Letter to Health Care Providers

As the FDA continues to evaluate the risk of patient infections and contamination issues associated with reprocessed urological endoscopes, the FDA is aware that the current reprocessing instructions for certain urological endoscopes manufactured by Karl Storz are inadequate and therefore, have been updated by Karl Storz. The affected urological endoscopes include cystoscopes, ureteroscopes, cystourethroscopes and ureterorenoscopes.

In April 2021, the FDA communicated about reported patient infections and possible contamination issues with reprocessed urological endoscopes. At the FDA's request, Karl Storz conducted reprocessing validation testing on a sample of flexible urological endoscopes and identified reprocessing failures following high-level disinfection. Inadequate reprocessing of urological endoscopes may increase the risk of patient infection.

On April 1, 2022, Karl Storz initiated a voluntary recall and issued an urgent field safety notice to instruct users to discontinue all high-level disinfection methods for all affected urological endoscopes and discontinue liquid chemical sterilization for most of the affected urological endoscopes. The affected urological endoscopes should be sterilized after each use by an appropriate sterilization method recommended in the instructions for use. The FDA wants to ensure that health care providers and users are aware of the change in reprocessing methods for certain urological endoscopes by Karl Storz. The FDA will continue to monitor reports of patient infections or contamination issues with urological endoscopes, and work with manufacturers on adequate reprocessing methods and instructions.

Recommendations

- Review the recall notice from Karl Storz.
- **Do not use high-level disinfection methods or liquid chemical sterilization** to reprocess affected urological endoscopes.
- **Sterilize affected urological endoscopes after each use** by using sterilization methods recommended in the instructions for use specific to each device.
- Do not use affected urological endoscopes if you do not have access to an appropriate sterilization method recommended in the instructions for use. Karl Storz will provide instructions for returning the affected endoscopes.
- Be aware that Karl Storz will provide updated instructions for use for affected devices.
- Do not use damaged devices or those that have failed a leak test, as they could be a potential source of contamination.
- Develop schedules for routine inspection and regular maintenance as specified in the manufacturer's instructions.
- Discuss the benefits and risks associated with procedures involving reprocessed urological endoscopes with your patients.

To read the full Letter to Health Care Providers, please visit FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during April 2022. 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
Automated External Defibrillators (Non-wearable) Brand: Onestep Complete, Single, RSeries, Electrodes Model#: 8900-0224-01 Lot #: 4321M Cat #: 8900-0224-01	Zoll Medical Corporation	Nurse on unit doing defibrillator testing with the One Step pad connected. Nurse reported that unable to do the full test with the release of joules. Nurse reported this same scenario has happened multiple times. In this instance with the transport monitor, the nurse changed the pads and applied new pad and this fixed the issue. The pad in question does not expire until 2023. The defective pads were saved and sent to Biomedical Engineering to test the monitor and the pads. Biomedical Engineering found the pads to be faulty--error message, "Check Pads"--indicating that the pads are bad. Biomedical Engineering reported that this happens frequently in the Emergency Department; however, specific event details are not available. Nursing concerned this could be an issue when needing to use the pads in a code situation and deploy joules. Testing is recommended to be automatic by Zoll or manually once a week. Most transport monitors are tested once a week.
Unit, Liquid-oxygen, Portable Brand: Portable Therapeutic Liquid Oxygen System Model#: 50C-0021-1 Cat #: 50C-0021-1	Essex Industries, Inc.	The liquid oxygen system failed, ran completely out of oxygen 90 minutes into a patient fixed wing transport with 90 plus minutes of the transport remaining. The patient was on ECMO, so both the ECMO device and ventilator were using oxygen. The crew had to divert the flight to the closest ECMO capable center and manage the patient on a portable oxygen cylinder on the aircraft until met at the airport. The Essex Industries, Inc 10 liter liquid oxygen convertor system had a pressure release valve/vent failure sometime during the course of the transport and lost all oxygen.

Device	Manufacturer	Problem
Ventricular (Assist) By-pass Brand: Heart-ware Hvad Model#: 1103 Cat #: 1103	HeartWare, Inc.	This LVAD (left ventricular assist device) is the subject of a recall initially issued in December 2020. The patient was undergoing a proactive controller change per manufacturer recommendation because the age of the controller was approaching two years. Upon changing the controller, the pump did not restart. The patient was admitted for the exchange, and was admitted to the ICU when the pump would not restart. The plan is to take the patient to the OR and exchange this pump for another device.
Catheter, Intravascular, Therapeutic, Short-term Brand: Insyte Autoguard	Becton, Dickinson and Company	Our institution transitioned to the BD Insyte Autoguard IV catheters and are having the following issues/concerns: 1. Catheter bends when trying to break the skin (using technique given by rep) 2. Catheter hub spins when trying to advance catheter so you lose the only piece to advance catheter 3. Catheter hubs are excessively long making it difficult to place foam appropriately to protect skin, most times catheter is lost or dislodged 4. Multiple blown veins due to catheter placement struggles 5. More sticks than normal due catheter issues- Greatly impacting patient care and satisfaction 6. More IV infiltrates/ extravasations during CT scan injections. Some units have already had the BD rep back to the unit for troubleshooting technique and unfortunately this has been ineffective at this time.
Pump, Infusion Brand: Iradimed 1056 IV Set, Sterile Disp, W/Drip Chamber Model#: 1056 Cat #: IVP1056	Iradimed, Corp.	MRI ordered for evaluation of patient's neurological status concerning anoxic brain injury in the setting of cardiac arrest. MRI standard tubing that was being used with Norepinephrine developed a leak/hole/crack in the tubing between the pump and patient after getting into the MRI room. Patient was very dependent on her medications keeping her blood pressure up. After lining up the table to the scanner, nurse noted small liquid drips starting to appear on the floor. After following/feeling tubing, determined the outside of the tubing was wet, but nurse could not locate the hole. Medication was immediately transferred to a different tubing. Tubing was later tested/flushed looking for a hole and one was found. No tubing leaks or blood pressure problems prior to entering MRI room. Tubing was from groin on top of patient in full view on transfer into MRI room and was never caught or pinched anyplace. Patient's blood pressure dropped due to tubing change, she was slow to recover. Showed no arrhythmia on monitor but lost her pulse. Code blue called, pulse recovered after 2 min of CPR, 1mg epinephrine, and blood pressure meds catching up. MRI was aborted. Blood pressure somewhat labile in the process of transferring patient back to bed, and Levophed increased to 30mcg/min to keep mean arterial pressure (MAP) >65.

Links to FDA/CDRH Databases and Other Information Sources

U.S. FOOD & DRUG ADMINISTRATION
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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: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/human-factors-and-medical-devices
This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Medical Device Connection Website:
https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/medical-device-connectors
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: https://www.fda.gov/medical-devices/medical-device-safety
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: https://medsun.fda.gov/
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: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters
This database contains the most recent manufacturer warning letters.

To access additional newsletter articles, including a selection of recent MedSun Reports and product-related and patient safety-related information, go to www.fda.gov/medsun

Contact the MedSun Program Staff:

Telephone: 800-859-9821
Fax: 800-859-1292
E-mail: medsun@fda.hhs.gov

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993