Infections Associated with Reprocessed Urological Endoscopes - Letter to Health Care Providers

April 1, 2021

The U.S. Food and Drug Administration (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) which 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.

Background

Cystoscopes, cystourethroscopes, and ureteroscopes are used by health care providers to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of the urinary tract (e.g., urethra, bladder, ureters, and kidneys) depending on the intended use and design of the device.

Since 2017, the FDA has received over 450 Medical Device Reports (MDRs) which describe patient infections post procedure or other possible contamination issues associated with reprocessing these devices. In those reports which provided the name of the device manufacturer, either Olympus Corporation or Karl Storz were cited. However, the FDA has not concluded that such risks are limited to a particular manufacturers' devices nor that any specific manufacturer or brand of these devices is associated with higher risks than others. Of these reports, there were three death reports which occurred outside of the United States, submitted by Olympus Corporation. The three reports describe patients who developed Pseudomonas aeruginosa infections post procedure. Two of the death reports were associated with the use of a forceps/irrigation plug (MAJ-891), which is an accessory component used to control water flow and enable access to the working channel of the endoscope. It was reported by Olympus that the isolates from clinical samples matched strains of Pseudomonas aeruginosa isolated from the forceps/irrigation plug (MAJ-891). The third patient death involved a cystoscope, and the report noted that the cystoscope did not pass a leak test. Failure to pass a leak test indicates the cystoscope was damaged and could be a potential source of infection. It is unknown whether or to what degree the reported infections contributed to the patient deaths, and patient co-morbidities may have been a factor. MDRs are not, by themselves, definitive evidence of a faulty or defective medical device, and cannot be used to establish or compare rates of event occurrence.

FDA Actions

The potential causes and contributing factors associated with the reported infections or contamination issues are under review, including reprocessing methods, reprocessing instructions in the labeling, and device design.

The FDA will continue to keep health care providers and the public informed if new or additional information becomes available.

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with cystoscope, ureteroscope, and cystourethroscope devices. If you suspect or experience a problem with your device, we encourage you to use the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) to report the problem. In the report, include the device name, model number, and FDA 510(k) clearance number, if known.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (DICE) (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice).