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

Update as of April 10, 2020: The FDA continues to recommend that hospitals and endoscopy facilities transition to innovative duodenoscope designs to help improve cleaning and reduce contamination between patients, including designs with disposable caps or distal ends. When using these innovative duodenoscopes, remember to follow the manufacturer's instructions for the assembly of the caps and distal ends. The FDA is not aware of any patient injuries related to these innovative duodenoscope designs. However the manufacturers, Fujifilm, Pentax and Olympus have in total submitted 10 reports of device malfunctions, such as removable caps or ends falling off during endoscopic retrograde cholangiopancreatography (ERCP). Of these device malfunctions, only three occurred with models that are marketed in the United States.

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 (https://www.niddk.nih.gov/health-information/diagnostic-tests/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 (/medical-devices/reprocessing-reusable-medical-devices/how-are-reusable-medical-devices-reprocessed) 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.

Patients: Important Recommendations

- Be aware that the risk of infection from inadequate reprocessing is relatively low.
- Do not cancel or delay any planned procedure without first discussing the benefits and risks with your health care provider.

Hospitals and Endoscopy Facilities: Important Recommendations

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

carefully follow the manufacturer's instructions for the assembly of the caps and distal ends.

- Ensure staff are meticulously following reprocessing instructions.
- Institute a quality control program that includes sampling and 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 (/media/111081/download): 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.

Additional Information about Duodenoscopes in this Safety Communication

Reprocessing Duodenoscopes: Results from the Postmarket Surveillance Studies

Each duodenoscope manufacturer (Fujifilm, Olympus and Pentax) currently marketing in the U.S. was ordered by the FDA to conduct postmarket surveillance studies (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm) to determine rates of contamination after clinical use and reprocessing of its fixed endcap duodenoscopes. Fixed endcap duodenoscopes have a plastic or rubber cap permanently glued to the metal edges

around the distal end to prevent tissue injury from the metal edges on the scopes, but when permanently affixed, the endcaps also limit the accessibility to clean the crevices at the distal end.

The postmarket surveillance studies were intended to determine the real-world contamination rates for duodenoscopes in clinical use and serve as measures of the effectiveness of reprocessing. We have previously communicated (/medical-devices/safety-communications/fda-continues-remind-facilities-importance-following-duodenoscope-reprocessing-instructions-fda) interim study results demonstrating higher than expected levels of contamination. The most recent studies from Fujifilm (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=353&c_id=3725), Olympus (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=354&c_id=3726), and Pentax (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=355&c_id=3727) continue to show elevated rates of contamination, including the presence of high concern organisms, defined as organisms that are more often associated with disease transmission, such as *E. coli* and *Pseudomonas aeruginosa*.

In addition to the sampling and culturing studies noted above, each duodenoscope manufacturer was ordered to conduct postmarket surveillance studies to evaluate whether staff could understand and follow the manufacturer's reprocessing instructions for use (RIFU) in real-world healthcare settings. Failure to adhere to the RIFU may result in duodenoscope contamination. These studies are called human factors studies. The results from Fujifilm (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=353&c_id=3691) and Olympus (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=354&c_id=3692), suggest that users frequently had difficulty understanding and following manufacturers' RIFU and as a result, were not able to successfully complete reprocessing. We are continuing to work with manufacturers to conduct additional testing and revise reprocessing manuals, as appropriate.

Transition to Duodenoscopes with Innovative Designs that Can be Reprocessed More Effectively

Device design is a key factor that contributes to reprocessing challenges. **The FDA believes the best solution to reducing the risk of disease transmission by duodenoscopes is through innovative device designs that make reprocessing easier, more effective, or unnecessary.** For example, duodenoscopes that incorporate disposable components can facilitate cleaning, reduce contamination and reduce disease transmission following reprocessing. Disposable designs may reduce between-patient duodenoscope contamination by half as compared to reusable, or fixed endcaps.

To date, the FDA has cleared six duodenoscopes with disposable components that facilitate reprocessing:

- Ambu Innovation GmbH, Duodenoscope model aScope Duodeno (fully disposable duodenoscope cleared under K201098 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K201098))
- Boston Scientific Corporation, EXALT Model D Single-Use Duodenoscope (fully disposable duodenoscope cleared under K193202 (https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193202.pdf))
- Fujifilm Corporation, Duodenoscope model ED-580XT (disposable endcap duodenoscope cleared under K181745 (https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181745.pdf))
- Olympus Medical Systems, Evis Exera III Duodenovideoscope Olympus TJF-Q190V (disposable endcap duodenoscope cleared under K193182 (https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193182.pdf))
- Pentax Medical, Duodenoscope model ED34-i10T (disposable endcap duodenoscope cleared under K163614 (https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163614.pdf) and K181522 (https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181522.pdf))
- Pentax Medical, Duodenoscope model ED34-i10T2 (disposable elevator duodenoscope cleared under K192245 (https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192245.pdf))

Because of our concerns of high contamination rates associated with conventional, fixed endcap duodenoscopes, we have asked each duodenoscope manufacturer to transition away from fixed endcap duodenoscopes to those with more modern design features that facilitate or eliminate the need for reprocessing. Hospitals and endoscopy facilities should transition to innovative duodenoscope designs that include disposable components such as disposable endcaps, or to fully disposable duodenoscopes when they become available.

We recognize that an immediate transition away from conventional duodenoscopes to the newer, innovative models will take time due to cost and market availability. We encourage health care facilities purchasing new duodenoscopes to begin developing a transition plan and work to replace their conventional duodenoscopes with newer models.

ERCP procedures performed with duodenoscopes are often life-saving and the benefits continue to outweigh the risks for appropriately selected patients. The continued availability of duodenoscopes to perform these procedures remains a critical public health need.

FDA Actions

We continue to actively work with reprocessing experts, medical device manufacturers and other government agencies to advance innovative ways to decrease infection related to duodenoscopes.

Since we last shared an update in April 2019 (/medical-devices/safety-communications/fda-continues-remind-facilities-importance-following-duodenoscope-reprocessing-instructions-fda), we have taken several actions:

- Including Real-World Contamination Rates in the Labeling
- Exploring the Expansion of Available Validated Methods
- Exploring the Potential for Monitoring Reprocessing Effectiveness
- Held an FDA Advisory Committee Meeting to Discuss Duodenoscope Reprocessing

Including Real-World Contamination Rates in the Labeling

During the May 16-17, 2019 public meeting of the Centers for Disease Control Healthcare Infection Control Practices Advisory Committee (https://www.cdc.gov/hicpac/index.html), the Committee concluded that information on the effectiveness of duodenoscope reprocessing to prevent between-patient contamination should be included in the labeling of duodenoscopes. We have asked duodenoscope manufacturers to include real-world contamination rates in the labeling of all currently marketed fixed endcap duodenoscopes.

We have also ordered the manufacturers of duodenoscopes with disposable endcaps to conduct new postmarket surveillance studies to verify that the new designs reduce the contamination rate. Upon completion of these postmarket surveillance studies, we expect the labeling to be updated with contamination rate data.

Exploring the Expansion of Available Validated Methods

Reprocessing of duodenoscopes involves cleaning outside surfaces, interior channels, and the elevator recess to remove tissue and fluids, followed by treatment to kill microorganisms. After thorough cleaning, the subsequent high-level disinfection step is intended to reduce harmful microbes so that the device is reasonably assumed free of risk of disease transmission. Current results from the postmarket surveillance studies indicate that there are duodenoscopes that remain contaminated after cleaning and high-level disinfection. This demonstrates a need to implement changes to current reprocessing procedures to expand the options for validated reprocessing methods.

Sterilization, particularly terminal (e.g., gas) sterilization, provides a greater margin of safety than high level disinfection. However, currently there is limited availability and compatibility of gas sterilizers with duodenoscopes. There is a clear need for further development of sterilizer technologies for duodenoscopes.

We encourage device manufacturers to develop innovative approaches for the entire duodenoscope reprocessing procedure to provide a high margin of safety and reduce the risk of infection associated with reprocessed duodenoscopes. Such approaches may require collaboration among stakeholders, including manufacturers of duodenoscopes and reprocessing devices, to test and validate the use of innovative reprocessing approaches and to demonstrate a relative reduction in infection risk in a real-world setting.

We have also recently announced two challenges (/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices) for new, innovative sterilization methods. These challenges are intended to advance the science of sterilization with the goal of developing sterilization technologies that are compatible with a variety of medical devices; those advancements may be applied to reusable medical devices like duodenoscopes.

Potential for Monitoring Reprocessing Effectiveness

One potential method to monitor the effectiveness of duodenoscope reprocessing is the use of test strips that detect adenosine triphosphate (ATP), an indicator of the presence of live microbes. While some manufacturers of ATP test strips are promoting ATP test strips for assessing duodenoscope cleaning, as of August 29, 2019, we are not aware of any ATP test strips legally marketed for this use. The FDA premarket review is necessary to assess whether ATP test strips for this use are adequately validated and properly labeled. We have contacted manufacturers of ATP test strips advising them of our requirements for manufacturing, testing and labeling for medical devices promoted for assessing duodenoscope cleaning.

Held an FDA Advisory Committee Meeting to Discuss Duodenoscope Reprocessing

The FDA convened scientific and clinical experts at the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee Meeting held on November 6-7, 2019 (/advisory-committees/advisory-committee-calendar/november-6-7-2019-general-hospital-and-personal-use-devices-panel-medical-devices-advisory-committee) to discuss the technological design advancements and effective reprocessing of duodenoscopes that will enhance the safety of these devices.

Reporting Problems to the FDA

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. If you are aware of devices that have not been cleared or approved by the FDA being promoted for use in duodenoscope reprocessing, please see the instructions (/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct) for reporting allegations of regulatory misconduct.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.