Infections Associated with Reprocessed Duodenoscopes

Background

Duodenoscopes are flexible, lighted tubes that are threaded through the mouth, throat, and stomach into the top of the small intestine (duodenum). They are used during endoscopic retrograde cholangiopancreatography (ERCP), a potentially life-saving procedure to diagnose and treat problems in the pancreas and bile ducts. In the United States, duodenoscopes are used in more than 500,000 ERCP procedures each year.

Duodenoscopes are complex instruments that contain many small working parts. If not thoroughly cleaned and disinfected, tissue or fluid from one patient can remain in a duodenoscope when it is used on a subsequent patient. In rare cases, this can lead to patient-to-patient transmission of infection.

In fall 2013, the Centers for Disease Control and Prevention (CDC) alerted the FDA to a potential association between multi-drug resistant bacteria and duodenoscopes. Upon further investigation, it became clear that these cases of infection were occurring despite confirmation that the users were following proper manufacturer cleaning and disinfection or sterilization instructions.

FDA's Ongoing Activities

Duodenoscopes are critical to diagnosing and treating severe, often life-threatening diseases. While the overwhelming proportion of procedures with these devices are carried out safely and effectively, the FDA takes the risk of infection very seriously and is working intensively to address it.

Ensuring the safety of reprocessed medical devices for use in multiple patients is a shared responsibility among the FDA and other federal agencies, public health systems, state and local health departments, medical device manufacturers, health care facilities, professional societies and others. The FDA is actively engaged with many of these stakeholder groups to better understand the causes and risk factors for transmission of infectious agents and develop solutions to minimize patient exposure.

In October 2015, the FDA ordered (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm) each U.S. duodenoscope manufacturer (Olympus, Fujifilm and Pentax) to conduct postmarket surveillance studies (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm) ("522 study") to better understand how these devices are reprocessed in real-world settings and their impact on duodenoscope transmitted infections. Postmarket surveillance studies are important tools for collecting useful data about a device that can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect public health.

On February 26, 2018, the FDA, Centers for Disease Control and Prevention (CDC), and American Society for Microbiology (ASM), together with other endoscope culturing experts, released voluntary standardized protocols (/media/111081/download) for duodenoscope surveillance sampling and culturing. These protocols are an update to the Interim Duodenoscope Surveillance Protocol released by CDC in March 2015, and address the concerns regarding validation of duodenoscope culturing protocols raised in ASM's April 2015 Policy Statement on Culturing of Duodenoscopes. For health care facilities that choose to implement duodenoscope surveillance sampling and culturing, these protocols can be used to help monitor the quality of a facility's endoscope reprocessing procedures. Adequate monitoring may reduce the risk of infection.

On March 9, 2018, the FDA issued Warning Letters (/news-events/press-announcements/fda-warns-duodenoscope-manufacturers-about-failure-comply-required-postmarket-surveillance-studies) to all three manufacturers (Fujifilm Medical Systems USA, Inc, Olympus Medical Systems Corporation, and Pentax of America), who make duodenoscopes sold in the U.S. for failure to provide sufficient data to address the postmarket surveillance studies requirements under Section 522 of the Federal Food, Drug, and Cosmetic Act (the Act). All three manufacturers responded to the warning letters and submitted plans that outlines how study milestones will be achieved including enrolling new sites and collecting samples.

On December 10, 2018, the FDA issued a Safety Communication (/medical-devices/safety-communications/fda-provides-interim-results-duodenoscope-reprocessing-studies-conducted-real-world-settings-fda)to provide interim results from the ongoing mandated postmarket surveillance studies of duodenoscopes reprocessing. Interim results from the ongoing postmarket surveillance studies indicate higher than expected contamination rates after duodenoscope reprocessing. Facilities and staff that reprocess duodenoscopes are reminded of the importance of manual cleaning prior to disinfection or sterilization and proper servicing of duodenoscopes.

On April 12, 2019, the FDA issued a Safety Communication (/medical-devices/safety-communications/fda-continues-remind-facilities-importance-following-duodenoscope-reprocessing-instructions-fda) to provide an update on the postmarket surveillance study results for duodenoscopes used in Endoscopic Retrograde Cholangiopancreatography procedures (ERCP) since the December 2018 Safety Communication. The FDA is also

reminding health care facilities about the importance of strictly adhering to the manufacturer's reprocessing and maintenance instructions, following best practices, and reporting adverse event information to the FDA.

On August 29, 2019, the FDA issued a Safety Communication (/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication) to provide an update on the mandated postmarket surveillance study results for duodenoscopes used in ERCP since the April 2019 Safety Communication. This Safety Communication also provides additional recommendations and updates including the FDA:

- Recommending that hospitals and endoscopy facilities begin transitioning to duodenoscopes with innovative designs that facilitate or eliminate the need for reprocessing.
- Issuing new mandated postmarket surveillance study orders to manufacturers of duodenoscopes with disposable endcaps to gather more information and verify that the new designs reduce the contamination rate. Upon completion of the postmarket surveillance studies, the FDA expects the labeling on duodenoscopes with disposable endcaps to be updated with contamination rate data.
- Warning health care facilities that adenosine triphosphate (ATP) test strips should not be used to assess duodenoscope cleaning. To date, the FDA has not evaluated them for effectiveness for assessing duodenoscope reprocessing. Manufacturers of ATP test strips are advised to submit data to support the legal marketing of these strips for this use.
- Planning to convene the General Hospital and Personal Use Device Panel of the Medical Device Advisory Committee (/advisory-committees/medical-devices-advisory-committee/general-hospital-and-personal-use-devices-panel) in late 2019 to further discuss duodenoscope reprocessing.

The FDA continues to actively:

- Encourage innovative device designs to make it possible to transition away from fixed endcap duodenoscopes to those with more modern design features that facilitate or eliminate the need for reprocessing.
- Learn about the challenges with current reprocessing methods and supports expanding the types of validated methods available to reprocess duodenoscopes.
- Evaluate information from multiple sources, including medical device adverse event reports (/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems) submitted to the FDA, the medical literature, the health care community, professional medical societies, international public health agencies, federal partners and state and local governments.
- Communicate recommendations to health care providers and end users to mitigate the risk associated with infection transmission.
- Work with industry as they modify and validate their reprocessing instructions to enhance the safety margin of the methods used to clean, disinfect and sterilize the duodenoscope, specifically all three companies that manufacture duodenoscopes marketed in the US and manufacturers of Automated Endoscope Reprocessors (AERs) (/medical-devices/reprocessing-reusable-medical-devices/information-about-automated-endoscope-reprocessors-aers-and-fdas-evaluation) marketed in the US that reprocess duodenoscopes as stated in their labeling.
- Investigate firms that manufacturer duodenoscopes (Olympus, Fuji, Pentax). The FDA issued 483s (/about-fda/center-devices-and-radiological-health/cdrh-foia-how-get-records-cdrh) and Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters) describing violations to the Federal Food, Drug and Cosmetic Act to all three manufacturers and 510(k) status letters (/medical-devices/industry-medical-devices/letters-industry) to two duodenoscope manufacturers (Fuji and Pentax).
- Evaluate the effectiveness of current duodenoscope reprocessing instructions in health care settings.
- Collaborate with health care facilities, professional societies and federal partners to evaluate additional strategies for mitigating infections associated with duodenoscopes.

The FDA will continue to provide additional information to the public as new information becomes available.

May 2015 Advisory Committee Meeting

On May 14-15, 2015, the FDA convened the Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee Meeting (https://wayback.archive-it.org/7993/20170112002249/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommiUrologyDevicesPanel/ucm445590.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to seek expert scientific and clinical opinion related to reprocessing of duodenoscopes based on available scientific information. Meeting materials, including presentations and a meeting summary (http://bit.ly/2vofKAM) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) are available on the FDA's panel website (http://bit.ly/2uFXUNQ) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

The panel was comprised of health care, consumer and industry representatives. Over the course of the two-day meeting, panel members heard presentations from key stakeholders including health care providers from the US and other countries, various subject matter experts, industry, and the general public.

Following two days of presentations, testimony and other input, panel participants were asked to answer questions focused on duodenoscope and AER safety and effectiveness, notably strategies to promote adherence to reprocessing instructions, the CDC's Interim Duodenoscope Surveillance Protocol (http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html), and risk communication. From the Advisory Committee meeting discussions, potential strategies emerged in the following areas:

1. Manual Cleaning and Human Factors

Both panel members and meeting participants emphasized that manual cleaning prior to disinfection or sterilization is critical to effective reprocessing. To ensure that manual cleaning is performed consistently and accurately, the panel recommended:

- strengthening competency training for reprocessing staff in health care facility reprocessing units; and
- incorporating Human Factors testing when developing reprocessing instructions

It is important to consider the device, end user and use environment when developing reprocessing instructions. Thus Human Factors testing plays an important role in ensuring that end users will be able to understand and correctly follow the reprocessing instructions in the labeling. The FDA's Reprocessing Final Guidance (/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling) introduces Human Factors and provides recommendations regarding Human Factors in developing reprocessing instructions.

2. Device Design

Meeting participants stressed the importance that duodenoscopes be designed to enable meticulous cleaning and disinfection or sterilization and urged industry to design duodenoscopes that enable thorough cleaning and effective reprocessing through device disassembly or disposable parts.

Based on the FDA's experience reviewing reprocessed devices and research conducted by the Agency and others, the FDA has identified design features that facilitate cleaning, disinfection and sterilization and reduce the likelihood of retaining debris, which are outlined on the Factors Affecting Quality of Reprocessing webpage (/medical-devices/reprocessing-reusable-medical-devices/factors-affecting-quality-reprocessing).

3. Microbiological Culturing of Duodenoscopes

Health care facilities may perform microbiologic culturing, which involves sampling duodenoscope channels and the distal end of the scope and culturing those samples to identify any bacterial contamination that may be present on the scope after reprocessing.

The panel discussed CDC's Interim Duodenoscope Surveillance Protocol that was released in March 2015 and recommended that additional data and validation testing is needed to demonstrate the methodology is robust and demonstrates consistent and reliable culturing results before health care facilities can incorporate as a best practice.

4. Supplemental Measures to Enhance Duodenoscope Reprocessing

At the Advisory Committee meeting, representatives from several health care facilities and the panel discussed additional strategies that they have implemented to reduce the risk of infection transmission, such as: microbiological culturing, sterilization, use of a liquid chemical sterilant processing system and repeat high-level disinfection. In each case, staff applied these supplemental methods in addition to meticulous cleaning as part of strict adherence to the manufacturer's reprocessing instructions.

The FDA's August 2015 Safety Communication (http://wayback.archive-it.org/7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) provides a list of supplemental duodenoscope reprocessing measures that emerged from the Advisory Committee meeting. Hospitals and health care facilities that utilize duodenoscopes can, in addition to meticulously following manufacturer reprocessing instructions, take one or more of these additional steps to further reduce the risk of infection and increase the safety of these medical devices.

While the risk of infection transmission cannot be completely eliminated, the benefits of these devices continue to outweigh the risks in appropriately selected patients.

FDA Correspondence to Duodenoscope Manufacturers

- Warning Letter - Hoya (Pentax) Corporation 3/9/18 (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hoya-corporation-pentax-life-division-546991-03092018)
- Warning Letter - Olympus Corporation of the Americas 3/9/18 (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/olympus-corporation-americas-470191-08122015)
- Warning Letter - Fujifilm Medical Systems U.S.A., Inc. 8/12/15 (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/fujifilm-medical-systems-usa-inc-08122015)
- Warning Letter - Hoya (Pentax) Corporation 8/12/15 (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hoya-corporation-08122015)

- Warning Letter - Olympus Corporation of the Americas 8/12/15 (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/olympus-corporation-americas-470191-08122015)
- Fujifilm Medical Systems U.S.A., Inc., Wayne, NJ, 483 Issued 4-20-2015 (/media/93202/download) (PDF - 535KB)
- Aizu Olympus Co. Ltd - Aizuwakamatsu-City, Fukushima, Japan - 483 Issued 04-17-2015 (/media/93240/download) (PDF - 1.1MB)
- Fujifilm - Ashigarakami Gun, Japan - 483 Issued 05-01-2015 (/media/93248/download) (PDF - 843KB)
- Fujifilm - Hitachiomiya City, Japan - 483 Issued 04-20-2015 (/media/93257/download) (PDF - 362KB
- FujiFilm Optics Co - Sano City, Tochigi, Japan - 483 Issued 04-22-2015 (/media/93266/download) (PDF - 544KB)
- Hoya (Pentax) Life Care Division - Kurihara-shi, Miyagi, Japan - 483 Issued 04-24-2015 (/media/93277/download) (PDF - 1.1MB)
- Hoya (Pentax) Corp - Akishima-shi, Japan - 483 Issued 04-21-2015 (/media/93288/download) (PDF - 2.4MB)
- Olympus Medical Systems Corp - Hachioji-Shi, Japan - 483 Issued 04-24-2015 (/media/93294/download) (PDF - 558KB)
- Fujifilm Corp 510k Status Letter - August 12, 2015 (/media/93215/download) (PDF - 604KB)
- Hoya (Pentax) Corp 510k Status Letter - August 12, 2015 (/media/93227/download) (PDF - 449KB)
- Olympus 510(k) status letter - March 18, 2014 (/media/90874/download) (PDF - 391KB)

FDA Communications on Duodenoscopes

- The FDA Continues to Remind Facilities of the Importance of Following Duodenoscope Reprocessing Instructions: FDA Safety Communication (4/12/2019) (/medical-devices/safety-communications/fda-continues-remind-facilities-importance-following-duodenoscope-reprocessing-instructions-fda)
- The FDA Provides Interim Results of Duodenoscope Reprocessing Studies Conducted in Real-World Settings: FDA Safety Communication (12/10/2018) (/medical-devices/safety-communications/fda-provides-interim-results-duodenoscope-reprocessing-studies-conducted-real-world-settings-fda)
- FDA warns duodenoscope manufacturers about failure to comply with required postmarket surveillance studies to assess contamination risk: FDA News Release (3/9/2018) (/news-events/press-announcements/fda-warns-duodenoscope-manufacturers-about-failure-comply-required-postmarket-surveillance-studies)
- Duodenoscope Surveillance Sampling & Culturing – Reducing the Risks of Infection (2/26/2018) (/media/111081/download) (PDF - 2.9MB)
- Updated Status of Pentax Medical Duodenoscope Model ED-3490TK: FDA Safety Communication (2/7/2018) (/medical-devices/safety-communications/updated-status-pentax-medical-duodenoscope-model-ed-3490tk-fda-safety-communication)
- FDA clears the Pentax ED34-i10T model duodenoscope with a disposable cap, a new feature that will improve access for cleaning and reprocessing: FDA News Release (9/20/2017) (/news-events/press-announcements/fda-clears-first-duodenoscope-disposable-distal-cap)
- Updated Status of FUJIFILM Medical Systems, U.S.A., Inc Model ED-530XT Duodenoscopes: FDA Safety Communication (07/21/2017) (/medical-devices/safety-communications/updated-status-fujifilm-medical-systems-usa-inc-model-ed-530xt-duodenoscopes-fda-safety)
- FUJIFILM Medical Systems, U.S.A., Inc. removes certain older duodenoscope models from clinical use: FDA Safety Communication (1/13/17) (/medical-devices/safety-communications/fujifilm-medical-systems-usa-inc-removes-certain-older-duodenoscope-models-clinical-use-fda-safety)
- FDA clears Olympus TJF-Q180V duodenoscope with design modifications intended to reduce infection risk. FDA News Release. (1/15/2016) (/news-events/press-announcements/fda-clears-olympus-tjf-q180v-duodenoscope-design-modifications-intended-reduce-infection-risk)
- Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication (http://wayback.archive-it.org/7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Updated Information for Healthcare Providers Regarding Duodenoscopes (/media/90881/download) (PDF - 219KB)
- Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication (http://wayback.archive-it.org/7993/20170722213105/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Updated Duodenoscope Reprocessing Instructions

- UPDATE: Importance of Following Validated Reprocessing Instructions for PENTAX ED-3490TK Video Duodenoscopes: FDA Safety Communication (1/17/2017) (/medical-devices/safety-communications/update-importance-following-validated-reprocessing-instructions-pentax-ed-3490tk-video-duodenoscopes)

- Olympus Customer Notification Letter to Olympus TJF-160F/VF duodenoscope customers. March 14, 2016 (http://medical.olympusamerica.com/sites/us/files/pdf/Urgent-Safety-Notification-TJF-Q160F-VF-Duodenoscope.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Fuji Customer Notification Letter to ED-530XT duodenoscope customers. December 23, 2015 (http://www.fujifilmusa.com/products/medical/endoscopy/pdf/urgent_field_correction_ed_530XT.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Fuji Customer Notification Letter to 250 and 450 duodenoscope customers. December 23, 2015 (http://www.fujifilmusa.com/products/medical/endoscopy/pdf/urgent_field_correction_ed_250_450.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Olympus Validates New Reprocessing Instructions for Model TJF-Q180V Duodenoscopes: FDA Safety Communication (http://wayback.archive-it.org/7993/20170722213115/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm439999.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Letter dated March 26, 2015 to health care facilities and other users of the TJF-Q180V Duodenoscope (http://medical.olympusamerica.com/sites/default/files/pdf/150326_TJF-Q180V_Customer_letter.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)