Olympus Validates New Reprocessing Instructions for Model TJF-Q180V Duodenoscopes: FDA Safety Communication

Date Issued: March 26, 2015
Update: January 15, 2016

The Agency is redistributing the March 26, 2015 Safety Communication with updated status information about the Agency's 510(k) clearance decision and Olympus Corporation of the America's Customer Notification.

On March 4, 2015, the FDA provided **Updated Information for Health care Providers Regarding Duodenoscopes (/7993/20170722213115/https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/UCM436588.pdf)**. At that time, Olympus had a pending 510(k) application for its TJF-Q180V duodenoscope. The company continued to market this device while its application was under review. On January 15, 2016, the FDA cleared the TJF-Q180V duodenoscope 510(k) with design modifications to the elevator channel sealing mechanism to create a tighter seal and reduce the potential for leakage of patient fluids and tissue into the closed elevator channel.

Also on January 15, 2016, Olympus notified its customers by issuing a **Customer Notification Letter (http://wayback.archive-it.org/7993/20170722213115/http://medical.olympusamerica.com/sites/us/files/pdf/160118-Olympus-TJF-Q180V-Customer-Letter.pdf) (http://wayback.archive-it.org/7993/20170722213115/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**that:

- Includes information about the TJF-Q180V duodenoscope's design and labeling changes per the cleared 510(k);
- Outlines Olympus' strategy to repair all customers' TJF-Q180V elevator mechanism in accordance with the new design; and
- Informs customers that Olympus will set up a return schedule with them for duodenoscope repair.

The validated manual reprocessing procedures outlined in the March 26, 2015 Safety Communication '**Validated Manual Reprocessing Procedure'** section below **remain the same**. Health care facilities should continue to use these validated instructions when reprocessing Olympus TJF-Q180V duodenoscopes.

Audience: Users of the Olympus TJF-Q180V and reprocessing facilities including:

- Gastroenterologists
- Gastrointestinal surgeons
- Endoscopy nurses
- Staff working in endoscopy reprocessing units in health care facilities
- Infection control practitioners
- Facility risk managers

Medical Specialties: Gastroenterology, Infection Control

Device: Olympus Duodenoscope model TJF-Q180V

Olympus has issued new, validated manual reprocessing instructions for the TJF-Q180V duodenoscope to replace those provided in the original labeling. The FDA has reviewed these new reprocessing instructions and the validation data as part of its ongoing review of the 510(k), and recommends that any facilities that are using Olympus' TJF-Q180V duodenoscope train staff on the new instructions and implement them as soon as possible. **Update:** the FDA cleared the 510(k) application on January 15, 2016.

Summary of Problem and Scope:

As noted in FDA's **February 2015 Safety Communication (/7993/20170722213115/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm)**, the complex design of ERCP endoscopes (also called duodenoscopes) may impede effective reprocessing. Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable devices. Recent medical publications and adverse event reports associate multidrug-resistant bacterial infections in patients who have undergone ERCP with reprocessed duodenoscopes, even when manufacturer reprocessing instructions are followed correctly. FDA has been working with duodenoscope manufacturers as they modify and validate their reprocessing instructions to further enhance the safety margin of their devices and show with a high degree of assurance that their reprocessing instructions, when followed correctly, effectively clean and disinfect the duodenoscopes.

In September 2014, Olympus initiated testing to validate new reprocessing instructions. The cleaning validation reports were provided to FDA in October 2014. While FDA found Olympus' cleaning validation data acceptable, initial high level disinfection reports did not demonstrate an adequate safety margin, and so Olympus conducted additional testing. At the end of February 2015, Olympus submitted new high level disinfection validation data to FDA. The agency has reviewed this data and believes that, when followed, the new, validated reprocessing instructions for the Olympus TJF-Q180V duodenoscope are robust, and demonstrate consistent and reliable cleaning and high-level disinfection. At FDA's request, Olympus has issued the new, validated instructions for reprocessing the TJF-Q180V duodenoscope.

To validate reprocessing instructions for duodenoscopes, manufacturers should soil their device with bacteria to simulate use in a procedure and then demonstrate that the device can be adequately disinfected through a sufficient reduction in microbes when the reprocessing instructions are correctly followed. To support high level

disinfection of duodenoscopes, the disinfectant should result in a six-log reduction in the number of microbes at each of several locations on the scope – that is a one million-fold reduction; or a reduction of 99.9999%.

The FDA is closely monitoring the possible association between reprocessed duodenoscopes and the transmission of infectious agents, including multidrug-resistant bacterial infections caused by Carbapenem-Resistant Enterobacteriaceae (CRE) such as Klebsiella species and Escherichia coli. If not properly reprocessed, residual body fluids and organic debris may remain in microscopic crevices of the device following an attempted cleaning and high level disinfection. If these residual fluids contain microbial contamination, subsequent patients may be exposed to serious infections. The FDA's investigation into the possible association between inadequately reprocessed duodenoscopes and patient infections, including the agency's recommendations for health care facilities, is more fully discussed in its **February 2015 Safety Communication (/7993/20170722213115/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm)**.

Olympus sent **letters dated March 26, 2015 (http://wayback.archive-it.org/7993/20170722213115/http://medical.olympusamerica.com/sites/default/files/pdf/150326_TJF-Q180V_Customer_letter.pdf) (http://wayback.archive-it.org/7993/20170722213115/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** to health care facilities and other users of the TJF-Q180V outlining the new, validated reprocessing instructions, and will soon be distributing revised user manuals.

Validated Manual Reprocessing Procedure:

Please note the key changes to the reprocessing procedure for Olympus' TJF-Q180V duodenoscope:

Precleaning:

- During immersion, raise and lower the elevator three times

Manual Cleaning:

- Additional brushing of the forceps elevator recess area
  - The revised cleaning procedure requires brushing of the forceps elevator recess with two different-sized brushes. In addition to the brush that is currently used to clean the elevator recess area, the MAJ-1888 brush (or MAJ-1888 equivalent) will be provided for further cleaning of this area. Olympus anticipates shipping the MAJ-1888 brushes to facilities no later than May 8, 2015.
- Additional flushing of forceps elevator recess area
- Additional raising/lowering the forceps elevator

Manual High Level Disinfection:

- Additional manual flushing steps and increased flushing volume of each endoscope channel, as well as the elevator recess area
- Additional raising/lowering the forceps elevator

In addition, FDA has the following recommendations for facilities and staff that use and reprocess the Olympus TJF-Q180V:

- Implement the new manual cleaning and high level disinfection procedures for the Olympus TJF-Q180V duodenoscope in accordance with the manufacturer's reprocessing instructions

- Implement the new TJF-Q180V high level disinfection procedure immediately. The high level disinfection procedure does not require additional equipment for implementation.
- Implement the new TJF-Q180V manual cleaning procedure as soon as possible. It involves the use of a new, smaller bristle cleaning brush (model MAJ-1888) which Olympus anticipates shipping to facilities no later than May 8, 2015. Continue using the existing cleaning procedure for manual cleaning of the TJF-Q180V until the new brush is available.

- Train appropriate staff on Olympus' new reprocessing instructions and implement them as soon as possible.
- Contact Olympus directly with specific questions and concerns or to schedule a site visit with their Endoscopy Support Specialists:
  - Technical Assistance Center (TAC), 1-800-848-9024, option 1 Monday - Friday between 7AM EST - 8 PM EST.

FDA's recommendations are based on currently available information. If new, important information becomes available, FDA will update its recommendations.

As noted in **FDA's Updated Information for Healthcare Providers Regarding Duodenoscopes (/7993/20170722213115/https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/UCM436588.pdf)** issued March 4, 2015, Olympus has a pending 510(k) application for its TJF-Q180V duodenoscope and the company continues to market its device while its application is under review. The removal of its device from the market could lead to an insufficient number of available duodenoscopes to meet the clinical demand in the United State of approximately 500,000 procedures per year. **Update:** the FDA cleared the 510(k) application on January 15, 2016.

FDA Activities:

The FDA is actively engaged with other government agencies, including Centers for Disease Control and Prevention (CDC), and the manufacturers of duodenoscopes used in the United States to identify the causes and risk factors for transmission of infectious agents and develop solutions to further increase the safety margin of reprocessed devices and minimize patient exposure to infectious agents.

The agency will convene a public **Advisory Committee Meeting (/7993/20170722213115/https://www.fda.gov/AdvisoryCommittees/Calendar/ucm437500.htm)** on May 14th and 15th, 2015 to seek expert scientific and clinical opinion related to reprocessing of duodenoscopes and other endoscopes, as well as use of automated endoscope reprocessors for duodenoscope reprocessing, based on available scientific information. The committee will make recommendations on: (1) The effectiveness of cleaning, high level disinfection, and sterilization methods; (2) the amount and type of premarket validation data and information needed to support labeling claims and technical instructions; (3) the appropriate use of other risk mitigations, such as surveillance cultures; (4) best practices and guidelines for reprocessing duodenoscopes and endoscopes at user facilities to minimize the transmission of infections; and (5) recommended approaches for ensuring patient safety during ERCP procedures, including a discussion of appropriate patient selection. Recommendations on these issues will assist FDA in minimizing patient exposure to infectious agents that may result from reprocessed duodenoscopes and endoscopes.

The FDA is also working closely with the manufacturers of reusable medical devices such as duodenoscopes to ensure that their reprocessing instructions are adequate to clean and disinfect the devices. The FDA continues to actively monitor this situation and will provide updates as appropriate.

Reporting Problems to the FDA:

Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) regulations (/7993/20170722213115/https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)**.

Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (/7993/20170722213115/https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** 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. Health care providers should submit voluntary reports of the transmission of an infection due to an inadequately cleaned duodenoscope to the agency via the **Medical Device Reporting (MDR) (/7993/20170722213115/https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm)** process.

If a health care provider suspects bacterial contamination—either because of an increase in infections after ERCP, or because of the results of bacterial surveillance culturing of duodenoscopes—we encourage the health care provider to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/7993/20170722213115/https://www.fda.gov/Safety/MedWatch/HowToReport/ucm2007306.htm)**.

Additional Resources:

- **FDA clears Olympus TJF-Q180V duodenoscope with design modifications intended to reduce infection risk. FDA News Release. January 15, 2016. (/7993/20170722213115/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm481956.htm)**
- **Olympus Customer Notification. January 15, 2016. (http://wayback.archive-it.org/7993/20170722213115/http://medical.olympusamerica.com/sites/us/files/pdf/160118-Olympus-TJF-Q180V-Customer-Letter.pdf)**
- **Olympus Customer Notifications. March 26, 2015 (http://wayback.archive-it.org/7993/20170722213115/http://medical.olympusamerica.com/sites/default/files/pdf/150326_TJF-Q180V_Customer_letter.pdf)**
- **Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication (http://wayback.archive-it.org/7993/20170722213115/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm)**
- **Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (http://wayback.archive-it.org/7993/20170722213115/http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf)**

More in Safety Communications (/7993/20170722213115/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm)

2017 Safety Communications (/7993/20170722213115/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)

2016 Safety Communications
(/7993/20170722213115/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553855.htm)