

▶ February 25, 2015

[High Priority] - A23927 : Olympus—Model TJF-Q180V Duodenoscopes: Manufacturer Reminds Users of Reprocessing Instructions to Reduce Patient Infection Risk Medical Device Ongoing Action

UMDNS Terms:

- Duodenoscopes, Video [17654]
- Duodenoscopes [11359]

Product Identifier: Model TJF-Q180V Duodenoscopes [*Capital Equipment*]

Geographic Regions: Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Honduras, Mexico, Panama, Paraguay, Peru, Puerto Rico, U.S., Venezuela

Manufacturer(s): Olympus CorpShinjuku Monolith, Tokyo, 163-0914, Japan

Suggested Distribution: Clinical/Biomedical Engineering, Infection Control, OR/Surgery, Risk Management/Continuous Quality Improvement, Gastroenterology, Central Sterilization Reprocessing

Problem: In a February 19, 2015, Urgent Important Safety Information letter submitted by an ECRI Institute member hospital, Olympus states that it has received 95 reports of the above duodenoscopes being associated with patient infections following endoscopic procedures. Some of the reports are associated with patient infection with carbapenem-resistant *Enterobacteriaceae* (CRE) organisms, which is a public health concern as patient antibiotic treatment options are limited. Olympus states that the elevator mechanism of side-viewing duodenoscopes, such as the TJF-Q180V, has crevices that are difficult to access with a cleaning brush. While all endoscopes, including duodenoscopes, require thorough reprocessing after patient use for safety, the TJF-Q180V requires careful attention to cleaning and reprocessing steps to ensure effective reprocessing. While the TJF-Q180V's forceps elevator wire is sealed, the area around and under the actual moving parts, such as the elevator, needs to be meticulously manually cleaned. The TJF-Q180V reprocessing manual requires the forceps elevator to be raised and lowered multiple times in the detergent solution during manual cleaning. For customers who use an automated endoscope reprocessor for high-level disinfection or a liquid chemical sterilization system, the TJF-Q180V reprocessing manual requires the forceps elevator to be set to the intermediate position before placement into the machine to enable sufficient cleaning and disinfection of the forceps elevator and recess.

Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the February 19, 2015, Urgent Important Safety Information letter from Olympus and/or reviewed the Olympus [website](#) regarding TJF-Q180V reprocessing. Ensure that all reprocessing personnel are completely knowledgeable and thoroughly trained on the reprocessing instructions in the TJF-Q180V reprocessing manual. Ensure that all reprocessing personnel are following all precleaning, leak testing, and manual cleaning steps before performing disinfection or sterilization. Olympus states that it is very important to manually clean the TJF-Q180V before it is disinfected or sterilized, and to thoroughly dry and appropriately store the TJF-Q180V. The TJF-Q180V reprocessing manual contains detailed instructions in chapter 5, "Reprocessing the Endoscope," chapter 6, "Reprocessing the Accessories," chapter 7, "Reprocessing the Endoscopes and Accessories using an Automated Endoscope Reprocessor," and chapter 8, "Storage and Disposal."

Inspect the TJF-Q180V before patient use as per the TJF-Q180V operations manual. In particular, pay attention to the distal end of the TJF-Q180V for any stains or other evidence of inadequate cleaning as per the instructions in the operations manual, section 3.2, "Inspection of the Endoscope." Reprocess the TJF-Q180V again if you find any evidence of staining or inadequate cleaning before the next patient use.

Olympus requests that you report any infections or persistent microbial colonization associated with Olympus endoscopes to the firm's technical assistance center (TAC) by telephone at (800) 848-9024 (select option 1).

To request additional information about the proper steps to clean and reprocess the TJF-Q180V, Olympus recommends the following:

- Contact TAC by telephone at (800) 848-9024. (select option 1). The TAC department will assist in answering questions on cleaning and reprocessing and obtaining additional copies of the TJF-Q180V reprocessing manual and supplemental educational materials.
- To request a visit from dedicated field personnel (Olympus endoscopy support specialists) to your facility to assess and observe customer reprocessing methods and provide reprocessing training and education, contact the Olympus TAC by telephone at (800) 848-9024 (select option 1).
- For educational programs for endoscopy with special courses on endoscope reprocessing for both nurses and reprocessing specialists, visit the Olympus [website](#) or contact the Olympus registration help desk by telephone at (800) 231-0016 to obtain more information.
- Contact your Olympus sales representative for assistance in obtaining reprocessing information.

For Further Information:

Olympus
Website: [Click here](#)

Comments:

- For FDA's recommendations and ECRI Institute's perspectives on endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes and infection risks, see [Hazard Accession No. H0245](#).
- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert.