



January 15, 2016

**URGENT MEDICAL DEVICE REMOVAL and CORRECTIVE ACTION:
ELEVATOR MECHANISM REPLACEMENT, UPDATED OPERATION MANUAL, AND NEW REPROCESSING
INSTRUCTIONS FOR THE OLYMPUS TJF-Q180V DUODENOSCOPE**

ATTENTION: Endoscopy Department, Infection Control and Reprocessing Units

**Re: OLYMPUS TJF-Q180V Duodenoscope
All Serial Numbers manufactured prior to January 2016**

Dear Health Care Professional:

Olympus America Inc. ("OAI") is writing to inform you that OAI is conducting a voluntary removal/corrective action of all TJF-Q180V duodenoscopes in order to replace the forceps elevator mechanism. The TJF-Q180V is a flexible gastrointestinal endoscope used in procedures such as endoscopic retrograde cholangiopancreatography (ERCP).

OAI will be replacing the forceps elevator mechanism on your existing TJF-Q180V duodenoscope(s) with a new forceps elevator design consistent with the design specifications in the recently cleared TJF-Q180V 510(k). You must return your current TJF-Q180V duodenoscopes to OAI so that OAI can perform this replacement service. You can continue to use the TJF-Q180V duodenoscope until the forceps elevator mechanism is replaced.

Separate from this forceps elevator mechanism replacement, Olympus is initiating annual inspections of the TJF-Q180V's forceps elevator mechanism. This annual inspection will include inspection of the TJF-Q180V's forceps elevator area and recommendations for any parts replacement.

New TJF-Q180V duodenoscopes manufactured with the new forceps elevator design will have a serial number which has a "1" as the third digit and are not included in this corrective action.

OAI has updated the existing TJF-Q180V Operation Manual and Reprocessing Manual with a **new Operation Manual and a new Reprocessing Manual**. The new Manuals are available on our customer web portal. Download a copy of the new Operation and new Reprocessing Manuals by visiting our OlympusConnect customer website at <https://www.OlympusConnect.com>. New users will need to register. Once registered select the Product Support button on the left navigation bar, select the [Instruction Manuals] button or the [Reprocessing Manuals] button respectively, locate the TJF-Q180V Manuals and select the [Download] button. Paper copies of the new Operation Manual and the new Reprocessing Manual will be available to be mailed to your facility starting February 8th 2016.

Beginning in February 2016, OAI will start replacement of the TJF-Q180V forceps elevator mechanism with the new forceps elevator design. However, the new reprocessing procedures should be implemented as soon as possible. It is important that reprocessing personnel be thoroughly trained and knowledgeable on the new reprocessing instructions.

OLYMPUS AMERICA INC.

3500 CORPORATE PARKWAY, P.O. BOX 610, CENTER VALLEY, PA 18034-0610
TELEPHONE (484) 896-5000

New TJF-Q180V Operation Manual:

OAI is replacing previously distributed TJF-Q180V Operation Manuals with a new Operation Manual. The new TJF-Q180V Operation Manual contains new information on the required inspection of the TJF-Q180V before and after patient procedures that must be performed by the user facility, and the annual inspection of the forceps elevator mechanism, to be performed by Olympus service personnel. This new information is found in a new chapter "Chapter 6 Inspection Schedule related to Forceps Elevator" on pgs 71-72. The new Operation Manual has version number RC2408 02 on the back cover, lower left corner.

New TJF-Q180V Reprocessing Manual:

OAI is replacing previously distributed TJF-Q180V Reprocessing Manuals with a new Reprocessing Manual. The new Reprocessing Manual has version number RC2409 04 on the back cover, lower left corner.

The new TJF-Q180V Reprocessing Manual requires users to conduct TJF-Q180V precleaning and manual cleaning as instructed in the TJF-Q180V Reprocessing Manual even when you use an Automated Endoscope Reprocessor ("AER") that has instructions that may indicate a user could forego certain steps in precleaning and manual cleaning of the endoscopes. See page 38 for this new Warning.

The new TJF-Q180V Reprocessing Manual has updated parameters for ethylene oxide gas sterilization cycles. See pages 32-33 for these updated parameters.

Olympus has been working with the FDA to revalidate the TJF-Q180V reprocessing in the Olympus OER-Pro AER. Only use of Acecide-C High-Level Disinfectant in the OER-Pro is permitted for reprocessing the TJF-Q180V. The new Reprocessing Manual has been updated to reflect this information; see page 107.

Action Steps:

Our records indicate your facility has purchased one or more TJF-Q180V duodenoscope(s). **OAI requests you take the following immediate action:**

1. Inspect your inventory of duodenoscopes and identify any TJF-Q180V models.
2. **Olympus will contact your facility to make arrangements for return of your TJF-Q180V duodenoscope(s) for the forceps elevator mechanism replacement.** You will be provided instructions on returning the TJF-Q180V for this replacement. We anticipate the turnaround time for repairing the TJF-Q180V to be four business days.
3. Olympus has discontinued previously distributed copies of the TJF-Q180V Operation and Reprocessing Manuals. Inspect your inventory of Operation and Reprocessing Manuals and **discard** any existing inventory of TJF-Q180V Operation and Reprocessing Manuals.
4. Download the new TJF-Q180V Operation and Reprocessing Manuals. Implement use of the TJF-Q180V Reprocessing Manual, which contains new parameters for ETO sterilization and new requirements for performing precleaning and cleaning regardless of the use of an AER. In the new Reprocessing Manual, the inside cover page lists the revision history and all changes in the new Reprocessing Manual.
5. Ensure all reprocessing personnel are completely knowledgeable and thoroughly trained on the new reprocessing instructions in the new Reprocessing Manual. Meticulous cleaning of the TJF-Q180V forceps elevator recesses and attention to following all reprocessing instructions is required.

6. Starting February 8, 2016, paper copies of the new TJF-Q180V Operation and Reprocessing Manuals can be obtained by contacting our Technical Assistance Center at 1-800-848-9024, option1, or by indicating on the enclosed questionnaire. The new TJF-Q180V Operation and Reprocessing Manuals will be mailed to your facility.
7. If you may have further distributed the TJF-Q180V, please identify your customers, notify them at once of this product recall, and appropriately document your notification process. Your notification to your customers may be enhanced by including a copy of this recall notification letter.
8. Please indicate on the enclosed questionnaire that you have received this notification. Fax the completed form to (484) 896-7128.

The U.S. Food and Drug Administration is aware of this action. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly Monday through Friday from 8AM EST to 6PM EST at (484) 896-5688 or by e-mail at laura.storms@olympus.com for any additional information on this matter.

Sincerely,



Laura Storms

V.P., Regulatory Affairs & Quality Assurance