March X, 2016

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

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

Dear Health Care Professional:

Olympus is writing to inform you that we are conducting a corrective action of all TJF-Q180V duodenoscopes manufactured prior to January 2016. We will be conducting this corrective action in two phases.

In a first step, we are distributing new versions of the operation and reprocessing manuals with this letter. Shortly afterwards, we will begin successive exchange of the elevator wire mechanism of your TJF-Q180V duodenoscope, installing a newly designed mechanism with updated production tolerances.

As the hygienic efficacy of the existing design has been validated, you can continue to use your existing TJF-Q180V duodenoscope until contacted by Olympus for exchange. This letter provides a full overview of the planned actions and information about who to contact should you require assistance.

Step 1: Update of operation manual and reprocessing manual – immediate user action necessary

New TJF-Q180V Operation Manual:
Olympus is replacing previously distributed TJF-Q180V Operation Manuals with a new Operation Manual. The updated 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". The new Operation Manual has version number RC2609_02 on the back cover, lower left corner.

New TJF-Q180V Reprocessing Manual:
Olympus is replacing previously distributed TJF-Q180V Reprocessing Manuals with a new Reprocessing Manual. The new Reprocessing Manual has version number RC2603_02 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 skip certain steps in precleaning and manual cleaning of the endoscopes. (So-called “brushless cleaning” systems).

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

1. Inspect your inventory of duodenoscopes and identify any TJF-Q180V models.
2. **Olympus XX will contact your facility to make arrangements for return of your TJF-Q180V duodenoscope(s) for the 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 10 business days. You do not need to proactively contact Olympus and can continue to use your existing TJF-Q180V endoscope.
3. Olympus XX 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. The new TJF-Q180V Operation and Reprocessing Manuals are enclosed with this letter. Implement use of the TJF-Q180V Reprocessing Manual, which contains new requirements for performing precleaning and cleaning regardless of the use of an AER.
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 indispensable.
6. 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.
7. Please indicate on the enclosed questionnaire that you have received this notification. Fax the completed form to XXX-XXX-XXXX.

Step 2: Update of elevator mechanism design tolerances and annual inspection process – no immediate user action necessary

Olympus will be replacing the forceps elevator mechanism on your existing TJF-Q180V duodenoscope(s) with a new forceps elevator featuring updated design tolerances. Olympus will successively contact users in the period between June 2016 and June 2017 to arrange the return of your endoscope to Olympus, so that we can perform this replacement service. The replacement will be performed free-of-charge and we will provide you with a free-of-charge loaner scope to bridge the repair. You can continue to use your current TJF-Q180V duodenoscope until the forceps elevator mechanism is replaced, as the hygienic efficacy of the previous design has been validated.

Separate from this forceps elevator mechanism replacement, Olympus is initiating annual inspections of the TJF-Q180V forceps elevator mechanism. This annual inspection will be conducted by Olympus service and will include inspection of the TJF-Q180V's forceps elevator area and recommendations for any parts replacement. The first inspection will be due 12 months after purchase of a TJF-Q180V duodenoscope or 12 months after replacement of the elevator mechanism of existing TJF-Q180V duodenoscopes.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. A dedicated website is available at www.olympus.eu/TJFupdates providing you with the latest information on the TJF-Q180V duodenoscope as well as related downloads and information material. Should you require further assistance, please do not hesitate to contact us at XXXXXXXXXXX.

Yours sincerely,