



May XX, 2015

**URGENT DEVICE SAFETY INFORMATION:
UPDATED LABELING AND NEW REPROCESSING INSTRUCTIONS FOR THE
OLYMPUS TJF-Q180V DUODENOSCOPE**

ATTENTION: Endoscopy Department, Risk Management and Reprocessing Units

Re: OLYMPUS TJF-Q180V Duodenoscope Updated Instructions,
Reprocessing Manual and MAJ-1888 Brush

Dear Health Care Professional:

Olympus XXX ("XXX") is writing to inform you that XXX is replacing the previously distributed TJF-Q180V Reprocessing Manual with a **new Reprocessing Manual** and is providing a **new cleaning brush** for use in cleaning the elevator recess area.

These 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. **Please take the actions indicated below to implement the reprocessing changes.**

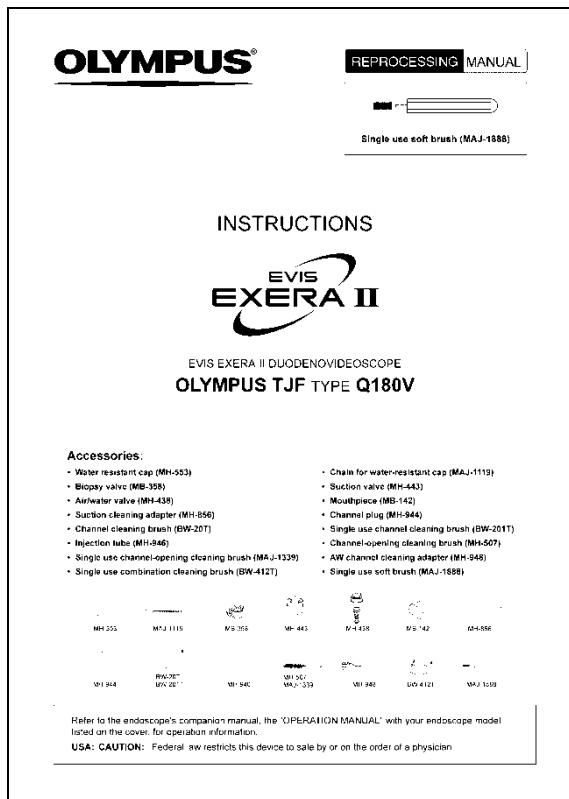
Background:

As a medical device manufacturer, Olympus continuously strives to improve our products for safe and effective use. We are working with competent authorities, relevant medical societies and our customers regarding concerns of patient infections including the consideration of alternative cleaning and reprocessing methods and the development of an additional safeguard. In such activity, we have improved these cleaning and reprocessing instructions. The new cleaning brushes (MAJ-1888) and an updated Reprocessing Manual are enclosed with this letter.

New TJF-Q180V Reprocessing Manual and MAJ-1888 Cleaning Brush:

XXX is now replacing previously distributed TJF-Q180V Reprocessing Manuals with a new Reprocessing Manual. The new TJF-Q180V Reprocessing Manual contains additional, required cleaning and reprocessing flushing steps and requires use of the new cleaning brush. This brush is a smaller-bristle brush for use in cleaning the forceps elevator in addition to using the current brush. That is, the forceps elevator recess will now be cleaned with two different-sized brushes.

The new Reprocessing Manual is distinguished from the prior Reprocessing Manual versions as illustrated in the image below. The new cleaning brush, MAJ-1888, is described on the cover of the new TJF-Q180V Reprocessing Manual. The new Reprocessing Manual has version number RC2603 01 on the back cover, lower left corner.



Action Steps:

Our records indicate your facility has purchased a TJF-Q180V duodenoscope. **XXX** requests you take the following immediate action:

1. Olympus has discontinued previously distributed copies of the TJF-Q180V Reprocessing Manual. **Inspect** your inventory of Reprocessing Manuals and **discard** any existing inventory of TJF-Q180V Reprocessing Manuals.
2. Implement use of the enclosed TJF-Q180V Reprocessing Manual, which contains new brushing and flushing steps for the TJF-Q180V's elevator mechanism and the forceps elevator recesses. **Meticulous** cleaning of the TJF-Q180V elevator mechanism and the forceps elevator recesses is required. The new cleaning brush should be used for cleaning the device.
3. Ensure all reprocessing personnel are completely knowledgeable and **thoroughly** trained on the new reprocessing instructions in the new Reprocessing Manual.
4. Additional copies of the new TJF-Q180V Reprocessing Manual can be obtained by contacting **XXX**.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact **XXX** directly at **XXX** or by e-mail at **xxx@xxx.xxx** for any additional information on this matter.

Sincerely,

XXX