

May xx, 2015

**FIELD SAFETY CORRECTIVE ACTION:
UPDATED LABELING AND NEW REPROCESSING INSTRUCTIONS FOR THE
OLYMPUS TJF-Q180V DUODENOSCOPE**

Re: OLYMPUS TJF-Q180V Duodenoscope Updated Instructions,
Reprocessing Manual and Brushes MAJ-1888/MyBrush

Dear Health Care Professional:

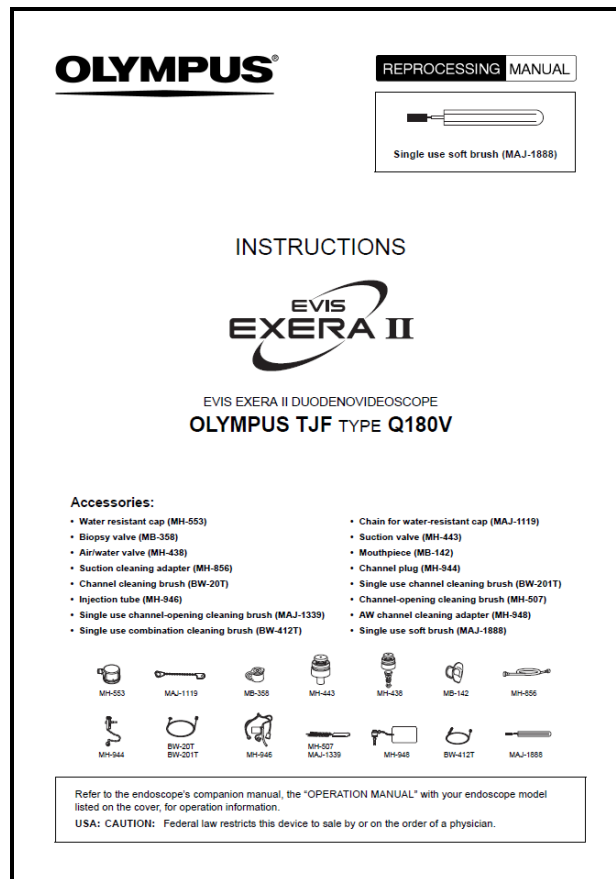
The purpose of this letter is to inform you that Olympus is replacing the previously distributed TJF-Q180V Reprocessing Manual with a **new Reprocessing Manual** and is providing **new cleaning brushes** for use in cleaning the elevator recess area.

These new reprocessing procedures are required to 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.**

New TJF-180V Reprocessing Manual and Cleaning Brushes MAJ-1888/MyBrush (Art.-Nr.E0427985) :

Olympus is replacing previously distributed TJF-Q180V Reprocessing Manuals with a new Reprocessing Manual. The new TJF-Q180V Reprocessing Manual contains **additional, mandatory cleaning and reprocessing flushing steps and requires use of the cleaning brush MAJ-1888 or MyBrush**. These brushes are smaller-bristle brushes for use in cleaning the forceps elevator. 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 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.



Remark to subs: Please insert your local version, here

Action Steps:

Our records indicate your facility has purchased a TJF-Q180V duodenoscope. Olympus 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 brushes are required to 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 "Olympus subsidiary, Tel number xxxxxx", option1, or by indicating on the enclosed questionnaire. Additional Reprocessing Manuals will be mailed to your facility
5. Please indicate on the enclosed questionnaire that you have received this notification.

The concerning Competent Authorities are aware of this action.



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

Sincerely,

Olympus subsidiary/distributor address

Name

Tel

REPLY FORM

Olympus Subsidiary/Distributor
[Dept/Attn]
[Street No.]
[ZIP City]
Date Ref No. EXT-xxx
Field Safety Information: REPROCESSING INSTRUCTIONS FOR THE OLYMPUS TJF-Q180V DUODENOSCOPE

Dear Sirs and Madams,

We herewith confirm the receipt of your Field Safety Corrective Action and the new instructions for use. We will share this information with the relevant departments.

Name _____

Hospital _____

Department _____

Street _____

Postal Code/ City _____

Date Signature