May 6, 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 America Inc. ("OAI") is writing to inform you that OAI 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.**

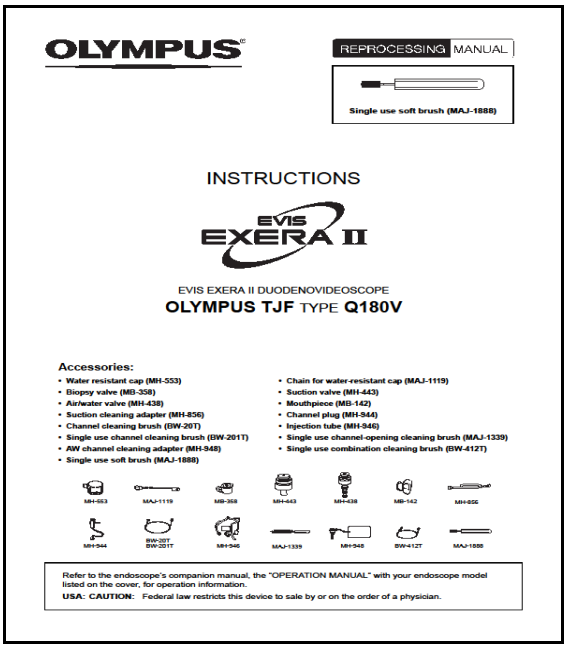
Background:
By letter dated March 26, 2015, OAI provided Supplemental Flushing Instructions and informed you to implement new flushing steps for pre-cleaning and manual disinfection of the TJF-180V duodenoscope. That letter also informed you that OAI would be shipping to your facility the new MAJ-1888 brushes and an updated Reprocessing Manual no later than May 8, 2015. They are enclosed with this letter.

In addition, to ensure that we have adequate supply to fairly provide the new MAJ-1888 brushes to meet the needs of all of our customers, we will not be taking normal sales orders for these products for the initial 6-month period beginning May 8, 2015. Instead, we will be automatically providing without charge the MAJ-1888 brushes in limited quantities that are required by your facility to cover your monthly reprocessing needs. After that time, the brushes will be available for purchase in sufficient quantities to meet your needs through our normal sales order process.

New TJF-180V Reprocessing Manual and MAJ-1888 Cleaning Brush:
OAI 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 RC2409 01 on the back cover, lower left corner.

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



OLYMPUS

REPROCESSING MANUAL

Single use soft brush (MAJ-1888)

INSTRUCTIONS

EVIS EXERA II

EVIS EXERA II DUODENOVIDEOSCOPE

OLYMPUS TJF TYPE Q180V

Accessories:

- Water resistant cap (MH-553)
- Biopsy valve (MB-358)
- Air/water valve (MH-438)
- Suction cleaning adapter (MH-856)
- Channel cleaning brush (BW-20T)
- Single use channel cleaning brush (BW-201T)
- AW channel cleaning adapter (MH-948)
- Single use soft brush (MAJ-1888)
- Chain for water-resistant cap (MAJ-1119)
- Suction valve (MH-443)
- Mouthpiece (MB-142)
- Channel plug (MH-944)
- Injection tube (MH-946)
- Single use channel-opening cleaning brush (MAJ-1339)
- Single use combination cleaning brush (BW-412T)

Refer to the endoscope's companion manual, the "OPERATION MANUAL" with your endoscope model listed on the cover, for operation information.

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Action Steps:

Our records indicate your facility has purchased a TJF-Q180V duodenoscope. OAI 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. In the new Reprocessing Manual, the inside cover page lists the revision history and all changes in the new Reprocessing Manual. 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 our Technical Assistance Center at 1-800-848-9024, 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. Fax the completed form to (484) 896-5128.

The U.S. Food and Drug Administration is aware of this action.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly 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/Clinical Affairs & Quality Assurance