



March 14, 2016

**URGENT SAFETY NOTIFICATION
IMPORTANT UPDATED LABELING INFORMATION:
NEW REPROCESSING INSTRUCTIONS FOR THE OLYMPUS TJF-160F/VF DUODENOSCOPE**

ATTENTION: Endoscopy Department, Risk Management and Reprocessing Units

Dear Health Care Professional:

Olympus America Inc. (OAI) is writing to inform you that we are issuing validated, new reprocessing instructions for the Olympus TJF-160F/VF duodenoscopes ("TJF-160F/VF"), consisting of revised manual cleaning and high level disinfection procedures.

These new reprocessing procedures should be implemented as soon as possible. The new cleaning procedure requires the use of a new cleaning brush (MAJ-1534), which is enclosed with this letter.

Olympus is providing one box of MAJ-1534 brushes (3 brushes/box) per TJF-160F and TJF-160VF duodenoscopes owned, without charge. After that time, the brushes will be available for purchase in sufficient quantities to meet your facility's needs through our normal sales order process. Please note the MAJ-1534 brush is a reusable brush, which can be sterilized by autoclave following use. Instructions for sterilizing the MAJ-1534 brush can be found in the enclosed, new Reprocessing Manual.

In addition to the new cleaning brush referenced above, the new TJF-160F/VF reprocessing procedures require additional flushing and forceps elevator raising/lowering steps during precleaning and manual cleaning, manual disinfection, endoscope rinsing and alcohol flushing. The new Reprocessing Manual is enclosed with this letter.

Please note the key differences in the new reprocessing procedure:

Precleaning:

- Flush the elevator wire channel with water

Manual Cleaning:

- Additional brushing of the forceps elevator recess area and the elevator wire
 - The revised cleaning procedure requires brushing of the forceps elevator recess. In addition to the brushes that are currently used to clean the elevator recess area, the MAJ-1534 brush is a new brush required for further cleaning of this area. Enclosed with this letter is one box (three brushes/box) of MAJ-1534 brushes for each TJF-160F/VF duodenoscope purchased from Olympus as indicated by our purchasing records.
 - The following three types of brush models are all required for the revised brushing steps of the TJF-160F/VF.

OLYMPUS AMERICA INC.

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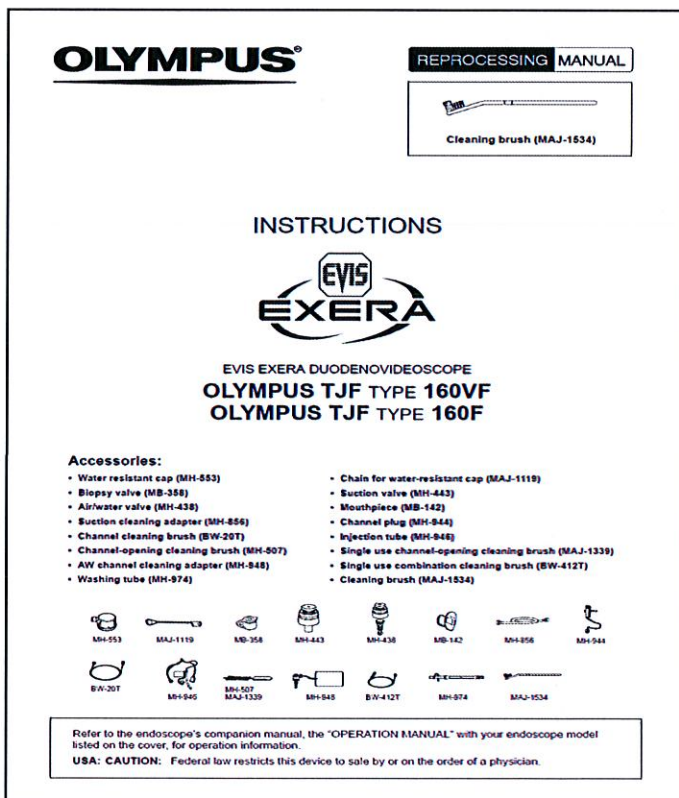
	Types of brush models	Brushing Point
1	Channel-opening cleaning brush (MH-507 or MAJ-1339 or BW-412T)	<ul style="list-style-type: none"> • Distal end of the endoscope (including Forceps elevator, Forceps elevator recess etc.) • Suction cylinder • Instrument channel port
2	Channel cleaning brush (BW-20T or BW-412T)	<ul style="list-style-type: none"> • Forceps elevator • Forceps elevator recess • Instrument channel • Suction channel
3	Cleaning brush (MAJ-1534)	<ul style="list-style-type: none"> • Forceps elevator • Forceps elevator recess • Elevator wire

- Additional flushing of forceps elevator recess area and the elevator wire
- Additional raising/lowering the forceps elevator

Manual High Level Disinfection:

- Additional manual flushing steps and increased flushing volume of each endoscope channel, as well as the elevator recess area
- Additional raising/lowering of the forceps elevator

The new Reprocessing Manual is distinguished from the prior Reprocessing Manual versions as illustrated in the image below. The new cleaning brush, MAJ-1534, is described on the cover of the new TJF-160F/VF Reprocessing Manual. The new Reprocessing Manual has version number C3100_02 on the back cover, lower left corner.



Action Steps:

Our records indicate your facility has purchased a TJF-160F/VF duodenoscope. OAI requires you to take the following immediate action:

1. Olympus has discontinued previously distributed copies of the TJF-160F/VF Reprocessing Manual. **Inspect** your inventory of Reprocessing Manuals and **discard** any existing inventory of TJF-160F/VF Reprocessing Manuals.
2. Implement use of the enclosed TJF-160F/VF Reprocessing Manual, which contains new brushing and flushing steps for the TJF-160F/VF's elevator mechanism and the forceps elevator recesses. **Meticulous** cleaning of the TJF-160F/VF 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-160F/VF Reprocessing Manual can be obtained by contacting our Technical Assistance Center at 1-800-848-9024, option 1, or by requesting a copy via the enclosed questionnaire. OAI will mail additional Reprocessing Manuals directly to your facility upon request.
 - a. If you prefer to download a copy of the new TJF-160F/VF Reprocessing Manual, please visit our OlympusConnect customer website: at <https://www.OlympusConnect.com> New users will need to register. Once registered select [Product Support] on the left navigation bar, then select [Reprocessing Manuals], locate the TJF-160F/VF Reprocessing Manual and select the [Download] option.
5. 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.

If you require additional information about the new flushing steps or new reprocessing procedures, you can obtain additional information as follows:

- You can contact our Technical Assistance Center (TAC) at 1-800-848-9024, option 1 Monday - Friday between 7AM EST - 8 PM EST. The TAC department can assist you in answering questions on the new TJF-160F/VF reprocessing procedures and new flushing and brushing steps.
- OAI has dedicated field personnel, called Endoscopy Support Specialists (ESSs), who visit customer sites to observe customer reprocessing methods and to provide reprocessing training and education. If you would like an ESS to visit your facility to review and train on the new TJF-160F/VF reprocessing procedures and new flushing and brushing steps, please request a site visit by calling our TAC department at 1-800-848-9024, option 1. This site visit is free of charge to your facility.

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 Monday - Friday from 8AM to 6PM 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



OLYMPUS URGENT SAFETY NOTIFICATION

Affected Models: TJF-160F and TJF-160VF Duodenoscopes (TJF-160F/VF)

Serial Numbers - all serial numbers

By submitting this reply form I acknowledge that I have received the Urgent Safety Notification for the TJF-160F/VF duodenoscopes referenced above.

I understand that I need to inspect my inventory of reprocessing manuals and discard any existing inventory of TJF-160F/VF Reprocessing Manuals. I understand that I need to implement as soon as possible the new reprocessing procedures described in the attached new Reprocessing Manual and implement use of the new cleaning brushes enclosed with this letter.

Facility: (Please do not abbreviate)

Address:

City:

State: _____

Postal Code: _____

Your Name: _____

Your Phone Number: _____

_____ I would like additional copies of the new TJF-160F/VF Reprocessing Manual mailed to my facility.

_____ Number of Reprocessing Manual(s)

Please fax this completed reply form to Olympus Regulatory Affairs Department at facsimile 484-896-7128

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