



August X, 2018  
Olympus reference: QIL 151-005

## URGENT FIELD SAFETY NOTICE

### IMPORTANT UPDATED LABELING INFORMATION NEW REPROCESSING INSTRUCTIONS FOR THE OLYMPUS PJF-160 DUODENOSCOPE

#### ATTENTION: Endoscopy Department, Risk Management and Reprocessing Units

Model	Serial Number(s)
OLYMPUS PJF-160 DUODENOSCOPE	[to be completed] (please insert all Serial Numbers per customer) all products distributed so far are affected

Dear Health Care Professional:

Olympus is updating the reprocessing procedure for the Olympus PJF-160 duodenoscopes ("PJF-160"), consisting of revised manual cleaning and high level disinfection procedures to further increase hygienic safety.

Olympus did not receive any customer complaint in the past concerning the PJF-160 duodenoscope associated with patient infections following an endoscopic procedure. As the previous cleaning and disinfection procedure had been validated, Olympus believes that there is no additional risk to patients who were treated before with a PJF-160.

The updated reprocessing procedure should be implemented immediately. The new cleaning procedure requires additional recess flushing and forceps elevator raising/lowering steps during pre-cleaning, manual cleaning and manual disinfection using the two new cleaning brushes (MAJ-1534 & MAJ-1888), which you can find enclosed with this letter together with the updated reprocessing Manual.

The reusable MAJ-1534 is used for brushing around distal end recess. Handling and reprocessing instructions for the MAJ-1534 can be found in the enclosed reprocessing Manual of the PJF-160 section "*Brush the elevator wire and the forceps elevator recess*" starting on page 81.

The single use MAJ-1888 is used for brushing around the forceps elevator recess. Handling instructions for the MAJ-1888 can be also found in the enclosed reprocessing Manual of the PJF-160 section "*Brush the forceps elevator*" starting on page 67.

Below is a summary of the updated reprocessing procedure: (please refer to *Chapter 5 "Reprocessing the Endoscope (and related reprocessing accessories)"* of the attached Reprocessing Manual for detailed instructions)

**a) Precleaning:**

- During immersion, raise and lower the elevator three times

**b) Presoaking:**

- Presoaking the endoscope in detergent solution before manual cleaning.
- Using smaller size syringe (3ml) for flushing the elevator wire channel.
- During immersion, fill detergent solution in the elevator wire channel.
- During immersion, flush the distal end by detergent solution followed by raising/lowering the forceps elevator.
- During immersion, flush the air/water and suction channel at least three times.

**c) 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 with three different-sized brushes. In addition to the brush that is currently used to clean the elevator forceps area, the MAJ-1888 and MAJ-1534 brush will be provided for further cleaning of this area.
- Using smaller size syringe (3ml) for flushing the elevator wire channel.
- Additional flushing of the elevator wire channel and the forceps elevator recess area
- Additional raising/lowering the forceps elevator

**d) Manual High Level Disinfection:**

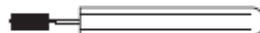
- Additional manual flushing steps and increased flushing volume of each endoscope channel, as well as the elevator recess area
- Additional raising/lowering the forceps elevator
- Repeating entire manual high-level disinfection process.

The updated Reprocessing Manual is distinguished from the prior versions as illustrated in the image below. The new cleaning brushes, MAJ-1534 and MAJ-1888, are described on the manual cover . It has the version number **18** on the back cover in the lower left corner.

# OLYMPUS®

**REPROCESSING MANUAL**


Cleaning brush (MAJ-1534)



Single use soft brush (MAJ-1888)

## INSTRUCTIONS



### EVIS EXERA DUODENOVideoscope OLYMPUS PJF TYPE 160

#### 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)
- Channel-opening cleaning brush (MH-507)
- Single use soft brush (MAJ-1888)
- Washing tube (MH-974)
- AW channel cleaning adapter (MH-948)
- 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)
- Cleaning brush (MAJ-1534)



MH-553



MB-358



MH-438



MH-856



BW-20T



MH-507



MAJ-1888



MH-974



MH-948



MH-443



MB-142



MH-944



MH-946



MAJ-1339



BW-412T



MAJ-1534

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.

**Advice on actions to be taken by the user:**

Our records indicate your facility has purchased a PJF-160 duodenoscope. Therefore Olympus requires from you to take the following immediate actions:

- a) **Inspect** your inventory of PJF-160 reprocessing Manuals and **discard** the existing ones.
- b) Exchange them with the updated PJF-160 Reprocessing Manual. (Revision #18)
- c) Implement the updated reprocessing process in your facility.
- d) Ensure you train your reprocessing personnel on the updated reprocessing instructions.
- e) Indicate on the enclosed questionnaire that you have received this notification.
- f) Send the completed form back to your Olympus representative (xxx)
- g) If you have further distributed this product, identify your customers, forward them this FSN including the attachments, and appropriately document your notification process.

Your National Competent Authority has been informed of this Field Safety Notice.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information or on-site support, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday till Friday or by e-mail at XXX.

Sincerely,

## REPLY FORM – QIL 151-005

<b>OLYMPUS URGENT FIELD SAFETY NOTICE NEW REPROCESSING INSTRUCTIONS FOR THE OLYMPUS PJF-160 DUODENOSCOPE</b>
<b>[Name &amp; Address of Hospital/Medical Facility]</b>
<b>[Dept/Attn]</b>
<b>[Date]</b>

I herewith acknowledge the receipt of your Field Safety Corrective Action, a new Reprocessing Manual of the PJF-160 and a sample of MAJ-1534 and MAJ-1888 brushes. Further I confirm that I have discarded any existing inventory of the PJF-160 Reprocessing Manuals and transferred the content of the attached FSN to all affected departments on which this action has an impact.

Name (Signature) \_\_\_\_\_

Name (Print) \_\_\_\_\_

Position \_\_\_\_\_

Please fax this completed reply form to Olympus at [contact number] latest by XXXX