



Your Vision, Our Future

Reference: 2016-007M

Cc: Chairman Medical Board and relevant Head of Departments

5<sup>th</sup> April 2017

**URGENT SAFETY NOTICE**  
**IMPORTANT UPDATED LABELING INFORMATION**  
**NEW OPERATION INSTRUCTIONS FOR OLYMPUS ENDOSCOPE REPROCESSOR OER-AW**

Dear Sir/Mdm,

Olympus Singapore Pte. Ltd. ("OSP") has been informed by our manufacturer, Olympus Medical Systems Corp., on issuance of new operation instructions for Olympus Endoscope Reprocessor OER-AW. The purpose of the new operation instructions is to inculcate a routine of precleaning and manual cleaning of JF-20, JF-140F, TJF-M20, TJF-30, TJF-145, TJF-140F, TJF-150, TJF-160F, TJF-160VF and TJF-Q180V, as detailed in each duodenoscope's reprocessing manual, before setting these duodenoscopes into OER-AW.

Specifically, "Operation Manual" and "List of Compatible Endoscope/Connecting Tubes <OER-AW>" in the new operation instruction for OER-AW have been revised to include the following warning statement:

- When reprocessing the following non-detachable distal cover type duodenoscopes using OER-AW, conduct precleaning and manual cleaning as detailed in each duodenoscope's reprocessing manual.
  - JF-20, JF-140F, TJF-M20, TJF-30, TJF-145, TJF-140F, TJF-150, TJF-160F, TJF-160VF and TJF-Q180V

Please refer to attached annexes for location of the newly added warning statement in the new operation instruction for OER-AW. The new operation instruction should be implemented as soon as possible.

The new "Operation Manual" has version number "RA1526 01" on the back cover, lower left corner. The new "List of Compatible Endoscopes/Connecting Tubes <OER-AW>" has version number "GT8362 08" or "GT7884 04" on the back cover, lower left corner. Please note that version number "GT8362 08" is for 190 series and earlier scope user, while version number "GT7884 04" is for 180 series and earlier.

Our records indicate that your facility has purchased an Endoscope Reprocessor OER-AW. Olympus requires you to take the following immediate actions:

1. Olympus has discontinued previously distributed copies of OER-AW "Operation Manual" and "List of Compatible Endoscope/Connecting Tube <OER-AW>". **Inspect** your inventory of manuals and **discard** any existing inventory of OER-AW "Operation Manual" and "List of Compatible Endoscope/Connecting Tube <OER-AW>".

**OLYMPUS SINGAPORE PTE. LTD.**

Business Regn No. 198900566E

491B River Valley Road #12-01/04 Valley Point Office Tower Singapore 248373 Tel: (65) 6834 0010 Fax: (65) 6834 2438

[www.olympus.com.sg](http://www.olympus.com.sg)



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2. Implement use of enclosed OER-AW "Operation Manual" and "List of Compatible Endoscope/Connecting Tube <OER-AW>".
3. Ensure all reprocessing personnel are completely knowledgeable and **thoroughly** trained on the new reprocessing instruction in the new Reprocessing Manual.
4. Please complete "Response Form" to indicate that you have received this safety notice.
5. Please complete "Collection Form" to show that you have obtained the new OER-AW "Operation Manual" and "List of Compatible Endoscope/Connecting Tube <OER-AW>".

Please ensure that information in this safety notice is made available to all relevant personnel within your facility.

If you have questions on the new reprocessing instruction, or if you would like our Service personnel to visit your facility to train on the new reprocessing instruction, please feel free to contact us for a discussion.

Olympus regrets any inconvenience from this action and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact us for any additional information on this matter.

Contact for enquires

Regulatory Affairs Department

Email: [mes-ra.osp@olympus-ap.com](mailto:mes-ra.osp@olympus-ap.com)

Tel: 6833 4214

Fax: 6834 2438

Thank you for your patience and support.

Sincerely,



Loh E Thel  
Deputy Division Manager  
Medical Systems Business Division  
Olympus Singapore Pte. Ltd.

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**Annex 1: Location of new warning statement on Chapter 4 of "Operation Manual"**

## ***Chapter 4 Basic Endoscope Reprocessing Operations***

### **○ Precleaning (bedside cleaning) and modified manual cleaning**

**WARNING**

- When reprocessing the following non-detachable distal cover type duodenoscopes using OER-AW, conduct precleaning and manual cleaning as detailed in each duodenoscope's reprocessing manual.
  - JF-20, JF-140F, TJF-M20, TJF-30, TJF-145, TJF-140F, TJF-150, TJF-160F, TJF-160VF, and TJF-Q180V

**Annex 2: Location of new warning statement on Section 4.3 of "Operation Manual"**

### **4.3 Endoscope precleaning and manual cleaning**

#### ***Modified manual cleaning process or preparing Olympus endoscopes for processing in the OER-AW***

Endoscopes must be subject to cleaning by the user prior to reprocessing in the OER-AW. However, when using the OER-AW, the endoscope can be reprocessed according to the modified procedure described below.

**WARNING**

- The cleaning steps for external surfaces, the forceps elevator, and reusable parts must be performed according to the reprocessing instructions provided in the endoscope manual. Failure to preclean may compromise the effectiveness of the reprocessing.
- Valves and accessories must be manually cleaned as per the endoscope manual prior to placement in the OER-AW. Otherwise, effectiveness of the reprocessing may be compromised.
- Ultrasonic probes must be manually cleaned as per the ultrasonic probe manual prior to placement in the OER-AW. Otherwise, effectiveness of the reprocessing may be compromised.
- When reprocessing the following non-detachable distal cover type duodenoscopes using OER-AW, conduct precleaning and manual cleaning as detailed in each duodenoscope's reprocessing manual.
  - JF-20, JF-140F, TJF-M20, TJF-30, TJF-145, TJF-140F, TJF-150, TJF-160F, TJF-160VF, and TJF-Q180V

