



Your Vision, Our Future

Reference: 2016-005M

Cc: Chairman Medical Board and relevant Head of Departments

5<sup>th</sup> April 2017

**IMPORTANT SAFETY NOTICE**

**IMPORTANT UPDATED LABELING INFORMATION:**

**NEW REPROCESSING INSTRUCTIONS FOR THE OLYMPUS TJF-145 and TFJ-150 DUODENOSCOPE**

Dear Sir/Mdm,

Olympus Singapore Pte. Ltd. ("OSP") is writing to inform you that we are issuing validated, new reprocessing instructions for Olympus TJF-145 and TJF-150 duodenoscopes, 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.

After the enclosed brushes are consumed, 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 (MAJ-1534), the new TJF-145 and TJF-150 reprocessing procedures require additional flushing and forceps elevator raising/lowering steps during pre-cleaning 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:

**Pre-cleaning:**

- 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

**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  
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is required for further cleaning of this area. Enclosed with this letter is a quantity of MAJ-1534 brushes.

- The revised brushing steps of the TJF-145 and TJF-150 and brush models required for each step are as follows. Please follow the detailed steps instructed in new reprocessing instructions for TJF-145 and TJF-150.

Step	Brushing Point	Brush models to be used
1	<ul style="list-style-type: none"> <li>• Forceps elevator</li> <li>• Forceps elevator recess</li> <li>• Instrument channel outlet</li> </ul>	Channel-opening cleaning brush (MH-507)
2	<ul style="list-style-type: none"> <li>• Forceps elevator</li> <li>• Forceps elevator recess</li> </ul>	Channel cleaning brush (BW-20T)
3	<ul style="list-style-type: none"> <li>• Distal end of the endoscope except the forceps elevator and the forceps elevator recess</li> </ul>	Channel-opening cleaning brush (MH-507)
4	<ul style="list-style-type: none"> <li>• Instrument channel</li> <li>• Suction channel</li> </ul>	Channel cleaning brush (BW-20T)
5	<ul style="list-style-type: none"> <li>• Suction cylinder</li> <li>• Instrument channel port</li> </ul>	Channel-opening cleaning brush (MH-507)
(Aspirate detergent solution through the instrument channel and the suction channel)		
6	<ul style="list-style-type: none"> <li>• Forceps elevator</li> <li>• Forceps elevator recess</li> <li>• Elevator wire</li> </ul>	The cleaning brush (MAJ-1534)

- 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 Manuals are distinguished from the prior Reprocessing Manual versions as illustrated in the images below. Specifically, the new cleaning brush, MAJ-1534, is described on the cover of the new TJF-145 and TJF-150 Reprocessing Manuals. The new Reprocessing Manuals have version number "RC3953 01" on lower left corner of back cover for TJF-145, and version number "RC3955 01" on lower left corner of back cover for TJF-150.

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# OLYMPUS®

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## OLYMPUS®

REPROCESSING MANUAL



Cleaning brush (MAJ-1534)

## INSTRUCTIONS



### EVIS EXERA DUODENOVideoscope OLYMPUS TJF TYPE 145

#### Accessories:

- Water resistant cap (MH-553)
- Suction valve (MH-443)
- Mouthpiece (MB-142)
- Channel plug (MH-944)
- Injection tube (MH-946)
- AW channel cleaning adapter (MH-948)
- Cleaning brush (MAJ-1534)
- Biopsy valve (MB-358)
- Air/water valve (MH-438)
- Suction cleaning adapter (MH-856)
- Channel cleaning brush (BW-20T)
- Channel-opening cleaning brush (MH-967)
- Washing tube (MH-974)



Refer to the endoscope's companion manual, the "OLYMPUS TJF TYPE 145 OPERATION MANUAL" for inspection and operation information.

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

Image 1: Front Cover of TJF-145 Reprocessing Manual

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## OLYMPUS®

REPROCESSING MANUAL



Cleaning brush (MAJ-1534)

## INSTRUCTIONS

### DUODENOVideoscope OLYMPUS TJF TYPE 150

#### Accessories:

- Water resistant cap (MH-553)
- Suction valve (MH-443)
- Mouthpiece (MB-142)
- Channel plug (MH-944)
- Injection tube (MH-946)
- AW channel cleaning adapter (MH-948)
- Cleaning brush (MAJ-1534)
- 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)
- Washing tube (MH-974)



Refer to the endoscope's companion manual, the "OLYMPUS TJF TYPE 150 OPERATION MANUAL", for operation information.

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Image 2: Front Cover of TJF-150 Reprocessing Manual

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# OLYMPUS®

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## OLYMPUS®

Manufactured by



**OLYMPUS MEDICAL SYSTEMS CORP.**

2561 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan  
 Fax: (042)646-2429 Telephone: (042)642-2111

Distributed by

**OLYMPUS AMERICA INC.**

3650 Corporate Parkway, P.O. Box 810, Center Valley, PA  
 18034-0810, U.S.A.  
 Fax: (484)896-7128 Telephone: (484)896-5000

**OLYMPUS LATIN AMERICA, INC.**

5301 Blue Lagoon Drive, Suite 290 Miami, FL 33126-2067, U.S.A.  
 Fax: (305)261-6421 Telephone: (305)266-2332



**OLYMPUS EUROPA SE & CO. KG**

(Premises/Goods delivery) Wendenstrasse 14-18, 20097 Hamburg, Germany  
 (Lithers) Postfach 10 49 08, 20034 Hamburg, Germany  
 Fax: (049)23773-4666 Telephone: (049)23773-0

**KEYMED (MEDICAL & INDUSTRIAL EQUIPMENT) LTD.**

KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, United Kingdom  
 Fax: (01702)465677 Telephone: (01702)616333

**OLYMPUS MOSCOW LIMITED LIABILITY COMPANY**

117071, Moscow, Malaya Kaluzhskaya 19, bld. 1, fl.2, Russia  
 Fax: (095)958-2277 Telephone: (095)958-2243

**OLYMPUS (BEIJING) SALES & SERVICE CO., LTD.**

ABF, Ping An International Financial Center, No. 1-3, Xinyuan South Road,  
 Chaoyang District, Beijing, 100027 P.R.C.  
 Fax: (86)10-5976-1299 Telephone: (86)10-5919-9000

**OLYMPUS KOREA CO., LTD.**

Olympus Tower 9F, 446, Bongeunse-ro, Gangnam-gu, Seoul, Korea 136-509  
 Fax: (02)6255-3494 Telephone: (02)6255-3210

**OLYMPUS SINGAPORE PTE LTD**

491B, River Valley Road #12-01/04, Valley Point Office Tower, Singapore 248373  
 Fax: 6834-2438 Telephone: 6834-0010

**OLYMPUS AUSTRALIA PTY LTD**

3 Acacia Place, Notting Hill, VIC 3168, Australia  
 Fax: (03)9543-1350 Telephone: (03)9265-5400

RC3953 01

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Image 3: Back Cover of TJF-145 Reprocessing Manual

**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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## OLYMPUS®

Manufactured by



**OLYMPUS MEDICAL SYSTEMS CORP.**

2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan  
Fax: (042)646-2428 Telephone: (042)642-2111

Distributed by

**OLYMPUS AMERICA INC.**

3500 Corporate Parkway, P.O. Box 810, Center Valley, PA  
18034-0810, U.S.A.  
Fax: (484)896-7128 Telephone: (484)896-5000

**OLYMPUS LATIN AMERICA, INC.**

5301 Blue Lagoon Drive, Suite 290 Miami, FL 33128-2007, U.S.A.  
Fax: (305)261-4421 Telephone: (305)266-2332



**OLYMPUS EUROPA SE & CO. KG**

(Premises/Goods delivery) Wendenstrasse 14-18, 20097 Hamburg, Germany  
(Letters) Postfach 10 49 08, 20034 Hamburg, Germany  
Fax: (040)23773-4698 Telephone: (040)23773-0

**KEYMED (MEDICAL & INDUSTRIAL EQUIPMENT) LTD.**

KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, United Kingdom  
Fax: (01702)465677 Telephone: (01702)616333

**OLYMPUS MOSCOW LIMITED LIABILITY COMPANY**

117071, Moscow, Malaya Kaluzhskaya 18, bld. 1, fl. 2, Russia  
Fax: (095)958-2277 Telephone: (095)958-2245

**OLYMPUS (BEIJING) SALES & SERVICE CO., LTD.**

ABF, Ping An International Financial Center, No. 1-3, Xinyuan South Road,  
Chaoyang District, Beijing, 100027 P.R.C.  
Fax: (86)10-5976-1289 Telephone: (86)10-5919-9000

**OLYMPUS KOREA CO., LTD.**

Olympus Tower 1F, 44B, Bongsurae-ro, Gangnam-gu, Seoul, Korea 135-509  
Fax: (02)6255-3494 Telephone: (02)6255-3210

**OLYMPUS SINGAPORE PTE LTD**

491B, River Valley Road #12-01/04, Valley Point Office Tower, Singapore 248373  
Fax: 6834-2438 Telephone: 6834-0010

**OLYMPUS AUSTRALIA PTY LTD**

3 Acacia Place, Notting Hill, VIC 3108, Australia  
Fax: (03)9543-1350 Telephone: (03)9265-5400

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Image 4: Back Cover of TJF-150 Reprocessing Manual

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Our records indicate that your facility has purchased one or more TJF-145 and/or TJF-150 duodenoscope. Olympus requires you to take the following immediate action:

1. Olympus has discontinued previously distributed copies of the TJF-145 and TJF-150 Reprocessing Manuals. **Inspect** your inventory of Reprocessing Manuals and **discard** any existing inventory of TJF-145 and TJF-150 Reprocessing Manuals.
2. Implement use of the enclosed TJF-145 and TJF-150 Reprocessing Manuals, which contain new brushing and flushing steps for the TJF-145 and TJF-150's elevator mechanism and the forceps elevator recesses. **Meticulous** cleaning of the TJF-145 and TJF-150 elevator mechanism and the forceps elevator recesses are required. In the new Reprocessing Manuals, the inside cover page lists the revision history and all changes in the new Reprocessing Manuals. The new cleaning brush should be used for cleaning the devices.
3. Ensure all reprocessing personnel are completely knowledgeable and **thoroughly** trained on the new reprocessing instructions in the new Reprocessing Manuals.
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 new Reprocessing Manuals and new cleaning brushes (MAJ-1534).

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 TJF-145 and/or TJF-150 reprocessing procedures, or if you would like our Service personnel to visit your facility to train on the new TJF-145 and/or TJF-150 reprocessing procedures, 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.

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Contact for enquires

Regulatory Affairs Department

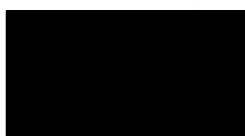
Email: [mes-ra.osp@olympus-ap.com](mailto:mes-ra.osp@olympus-ap.com)

Tel: 6833 4214

Fax: 6834 2438

Thank you for your patience and support.

Sincerely,



Loh E Thei

Deputy Division Manager

Medical Systems Business Division

Olympus Singapore Pte. Ltd.

**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  
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