

Reference: 2018-003M

07-Dec-2018

FIELD SAFETY NOTICE

REVISED OPERATION MANUAL FOR VARIOUS OLYMPUS ENDOSCOPE MODELS

Dear Sir/Madam,

OLYMPUS is implementing a Field Safety Corrective Action for the devices listed below. These endoscopes are intended for use in endoscopic diagnosis and treatment within the airways, the tracheobronchial tree, or the thoracic cavity.

Model Name	Model Number
Olympus Airway Mobilescope	MAF-TM
Ultrasonic Bronchofiberscope	BF-UM40
Ultrasonic Bronchofibervideoscope	BF-UC160F-OL8, BF-UC180F, BF-UC260FW, BF-UC260F-OL8
Bronchofiberscope	BF-XP40, BF-3C40, BF-P40, BF-40, BF-1T40, BF-XT40, BF-XP60, BF-MP60, BF-P60, BF-1T60
Bronchovideoscope	BF-XP160F, BF-3C160, BF-MP160F, BF-P160, BF-160, BF-1T160, BF-XT160, BF-P180, BF-Q180-AC, BF-Q180, BF-1T180, BF-1TQ180, BF-P240, BF-240, BF-6C240, BF-1T240, BF-1T240R, BF-1T150, BF-P150, BF-260, BF-1T260, BF-6C260, BF-P260F, BF-XP260F, BF-F260
Rhino-Laryngo Videoscope	ENF-VT, ENF-VT2
Affected Serial Number(s)	
All serial range	

Olympus America received a complaint claiming that patients were infected after a bronchoscopy procedure in which a BF-1T180 bronchoscope with a loosened biopsy port was used. As a result of Olympus's investigation, it was discovered that the attachment of non-Olympus accessories to the bronchoscope's biopsy port may have resulted in more applied force than expected and lead to loosening of the biopsy port.

The IFU already warns using incompatible equipment can result in patient or operator injury and/or equipment damage. Please refer to the IFU of the accessories or endoscopes for information about the compatibility. The use of the loosened biopsy port possibly results in insufficient reprocessing.

In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus is notifying users of this complaint and the need for careful inspection of the endoscope's biopsy port prior to use in accordance with the instructions provided below.

Below you can find a detailed description about the required inspection steps prior to every use. The required inspection steps can also be found in Chapter 3 "Preparation and Inspection" of the operation manuals.

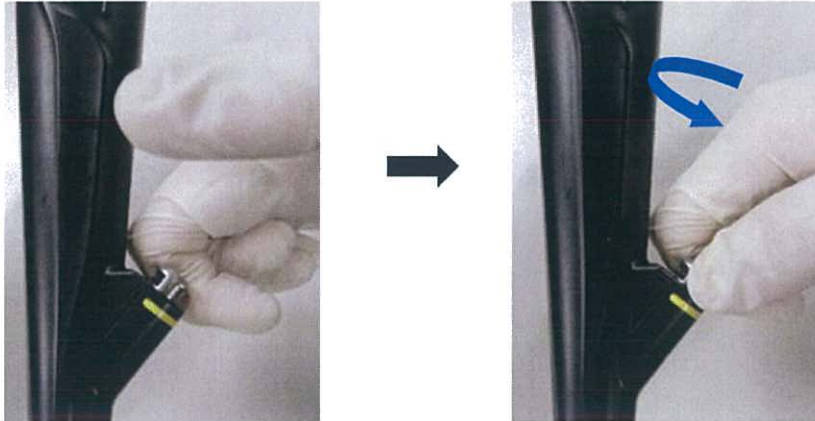
OLYMPUS SINGAPORE PTE LTD

Business Regn No. 198900566E

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Step 1:

Wearing sterile gloves, attempt to rotate or turn the biopsy port in counter-clock direction as shown in picture 01. If the biopsy port is able to be rotated or turned, do not use the endoscope and return it to Olympus for repair. If the biopsy port does not rotate or turn, go to step 2.



Picture 01: Counter-clock rotation

Step 2:

Visually inspect the rubber part around the biopsy port of the referenced endoscope. If the rubber part is in a normal condition as shown in picture 02, the endoscope can be used in a patient procedure. If the rubber part is lifted from the molding parts as shown in picture 03, do not use the endoscope and return it to Olympus for repair.



Picture 02: Normal Condition



Picture 03: The rubber part lifted

If you have any questions about how to conduct this important inspection or you are not sure of the results of your inspection, you should contact Olympus prior to using the device again.

Action(s) to be taken by end user

Our records indicate that you have purchased the affected product(s) and we requests you to take the following action(s):

1. Inspect your inventory of operation manuals for the referenced Olympus models and review the manual together with the addendum.
2. Implement the described inspection prior to every use.
3. Ensure you train your personnel on the updated operation instructions.
4. Indicate on the enclosed Response Form that you have received this notification.
5. Email the completed Response Form to the Regulatory Affairs Department at mes-ra.osp@olympus-ap.com, or you may return the completed form to your local Olympus representative.

OLYMPUS regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact us for additional information.

Contact information

Olympus Singapore Pte. Ltd.

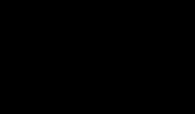
Regulatory Affairs Department

Email : mes-ra.osp@olympus-ap.com

Tel : (+65) 6833 4214

Fax : (+65) 6834 2438

Sincerely,



Loh E Thei

Division Manager

Medical Systems Business Division

Olympus Singapore Pte. Ltd.

Cc: Chairman Medical Board and relevant Head of Departments

OPERATION MANUAL ADDENDUM

FSCA Ref: 2018-003M

1 Instructions

The section below provides instructions and additional inspection points that need to be followed in connection with the control section of the endoscope described in "Inspection of the endoscope" of Chapter 3, "Preparation and Inspection" in the operation manual.

Other parts of the instructions in Chapter 3, "Preparation and Inspection" are not changed. Refer to the operation manual of each specific endoscope including the case when any irregularity is suspected.

▪ Prior to every use, inspect the instrument channel port according to the steps below

- 1 Wearing sterile gloves, confirm that the instrument channel port does not rotate or turn by attempting to rotate or turn the instrument channel port counterclockwise. If the instrument channel port is able to be rotated or turned, do not use the endoscope and return it to Olympus for repair.



Figure 1

- 2 Visually inspect the rubber part around the instrument channel port. Figure 2 depicts the rubber part is in a normal and abnormal condition. Lifting of the rubber part is abnormal. If the rubber part is lifted from the molding part as shown in Figure 2, (abnormal condition), do not use the endoscope and return it to Olympus for repair.

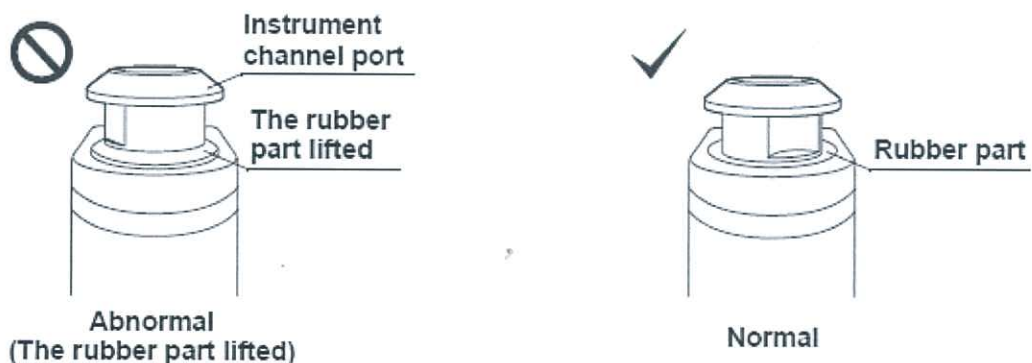


Figure 2