October X, 2018
Olympus reference: QIL 151-006

URGENT FIELD SAFETY NOTICE

Attention: Operating Room Manager and Risk Management Department

	Model Name	
Olympus Airway Mobilescope	MAF-TM	All Serial Numbers
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-1T150, BF-P150, BF-260, BF-1T260, BF-6C260, BF-P260F, BF-XP260F, BF-F260,	
Rhino-Laryngo Videoscope	ENF-VT, ENF-VT2	

Dear Health Care Practitioner:

Olympus has become aware of a matter that requires your attention. This Field Safety Notice pertains to the above-referenced Olympus endoscope models and our records indicate that your facility has purchased one or more of these models. These endoscopes are intended for use in endoscopic diagnosis and treatment within the airways, the tracheobronchial tree, or the thoracic cavity.

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 Instruction for Use (IFU) of the affected models already warns that 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 an endoscope with a loosened biopsy port may possibly result 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 enclosed operation manuals.

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.

Advice on actions to be taken by the user:
Our records indicate that your facility has purchased one or more of the above-referenced endoscopes. Therefore Olympus requires from you to take the following immediate actions:

a) Inspect your inventory of operation manuals for the referenced Olympus models and discard the existing ones.
b) Exchange them with the updated operation manuals.
c) Implement the updated operation instructions in your facility and conduct the described inspection prior to every use.
d) Ensure you train your personnel on the updated operation 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 151-006

OLYMPUS URGENT FIELD SAFETY NOTICE **NEW OPERATION INSTRUCTIONS FOR VARIOUS OLYMPUS ENDOSCOPE MODELS LISTED BELOW:**
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[**Date]**
OLYMPUS Endoscopes affected Models (Please insert the quantities available in your facility in front of the Model Name)

	MAF-TM		BF-UM40		BF-UC160F-OL8		BF-UC180F		BF-UC260FW
	BF-UC260F-OL8		BF-XP40		BF-3C40		BF-P40		BF-40
	BF-1T40		BF-XT40		BF-XP60		BF-MP60		BF-P60
	BF-1T60		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-1T150		BF-P150		BF-260
	BF-1T260		BF-6C260		BF-P260F		BF-XP260F		BF-F260
	ENF-VT		ENF-VT2						

I herewith acknowledge the receipt of your Field Safety Corrective Action as well as the new operation manuals.
Further I confirm that I have discarded any existing inventory of operation manuals for the above referenced Olympus endoscopes and transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of inspection of the instrument channel port prior to every use of the referenced endoscopes.

Name (Signature) _____

Name (Print) _____

Position _____

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