Date: 07.08.2023
Olympus reference: QIL FY24-EMEA-12-FY24-OMSC-07

URGENT FIELD SAFETY NOTICE

Attention: Endosocopy Examination Room Manager, Operating Room Manager, Risk Management Department

RE: Bronchofiberscope, Bronchovideoscope, Ultrasonic Bronchofibervideoscope, Tracheal Intubation Fiberscope, Tracheal Intubation Videoscope, Airway Mobilescope

Serial numbers: all serial numbers

Dear Health Care Practitioner,

Olympus has become aware of a matter that requires your attention. This Field Safety Notice pertains to the below-referenced Olympus bronchoscopes/tracheal intubation scopes/airway mobilescopes models. Our records indicate that your facility has purchased one or more of these models.

BF Series Bronchoscopes

These bronchoscopes are intended for use in endoscopic diagnosis and treatment within the airways and the tracheobronchial tree.

BF-1T150	BF-260	BF-MP160F	BF-P290	BF-TE2	BF-UC180F
BF-1T180	BF-3C160	BF-MP190F	BF-P60	BF-XP160F	BF-UC260FW
BF-1T260	BF-3C40	BF-MP290F	BF-PE2	BF-XP190	BF-UC190F
BF-1T60	BF-6C260	BF-MP60	BF-Q170	BF-XP260F	BF-UC290F
BF-1TQ170	BF-F260	BF-P150	BF-Q180	BF-XP290	—
BF-1TQ180	BF-H190	BF-P180	BF-Q180-AC	BF-XP60	—
BF-1TQ290	BF-H290	BF-P190	BF-Q190	BF-XT160	—
BF-1TH190	BF-N20	BF-P260F	BF-Q290	BF-XT190	—

Note: Product availability is dependent upon country

LF Series tracheal intubation scopes

These tracheal intubation scopes are intended for airway management which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management.

LF-TP	LF-DP	LF-GP	LF-V	LF-P

Note: Product availability is dependent upon country

MAF Series airway mobilescopes

These airway mobilescopes are intended for airway management, which includes diagnosis and observation to access airway anatomy, endotracheal/endobronchial intubation and management.

MAF-TM	MAF-TM2	MAF-GM	MAF-GM2	MAF-DM2

Note: Product availability is dependent upon country

Olympus has received three complaints, including one that was associated with an injury, that upon trying to use an Olympus pulmonary endoscope model with an endotracheal tube, the tip became lodged (entrapped) inside the endotracheal tube connector. As a result of the complaint investigation, it was determined that the scope (bending section) was too large for the endotracheal tube connector.

Risk to Health

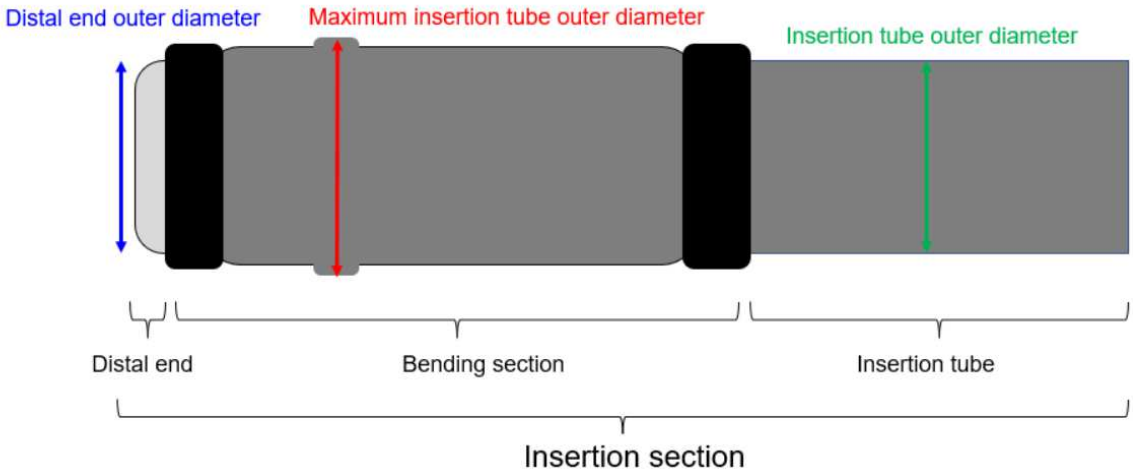
Selection of an endotracheal tube where the size is incompatible with the Olympus bronchoscope/tracheal intubation scope/airway mobilescope can result in delayed procedures, foreign body obstruction, failure to ventilate the patient, hemorrhage, upper airway tract injury, esophageal perforation, and/or bronchoscope damage.

In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus is providing the following information related to using an endotracheal tube:

- Before inserting the bronchoscope/tracheal intubation scope/airway mobilescope with an endotracheal tube into the patient, slide the tube along the entire length of the bronchoscope/tracheal intubation scope/airway mobilescope insertion section to confirm that the insertion section of the bronchoscope/tracheal intubation scope/airway mobilescope can be inserted smoothly into the endotracheal tube. If it cannot be inserted smoothly, the covering material of the bending section of the bronchoscope or the external surface of the insertion section may be damaged. When using a lubricant, make the above confirmation before applying the lubricant.

In the event the endotracheal tube cannot slide smoothly over the insertion section of the bronchoscope/tracheal intubation scope/airway mobilescope, please select another size tube, or inspect your scope for damage.

To mitigate the selection of incompatible endotracheal tubes, please refer to the Addendum which provides information on the maximum insertion tube outer diameter. Refer to the image below to identify the different sections of the insertion section:



Actions to be taken by the end user:

Olympus **requests you to take the following actions:**

1. Inspect your inventory for the referenced devices and identify any device with the model names specified above. Please check all areas of the hospital to determine if any of these devices remain in inventory.
2. Carefully read the content of this Field Safety Notice as well as the attached "Addendum". The Addendum provides information on the maximum insertion tube outer diameter for the affected bronchoscopes/tracheal intubation scopes/airway mobilescopes.
3. Ensure all personnel are completely knowledgeable and thoroughly aware of the contents.
4. Send the completed Reply Form back to your local Olympus representative at info@olympus.ie latest by 21 August 2023.
5. If you have further distributed this product, identify your customers, forward them this notification, and appropriately document your notification process.

Olympus requests that you report any complaints to Olympus. Please report complaints to concerns@olympus.co.uk.

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact me directly at 01 4260100 or at info@olympus.ie for any additional information or support concerning this matter.

Sincerely,

Niamh Billings

Niamh Billings
Olympus Ireland

REPLY FORM – QIL FY24-EMEA-12-FY24-OMSC-07

URGENT FIELD SAFETY NOTICE
Bronchofiberscope, Bronchovideoscope, Ultrasonic Bronchofibervideoscope, Tracheal Intubation Fiberscope, Tracheal Intubation Videoscope, Airway Mobilescope

[Name & Address of Hospital/Medical Facility]

[Dept/Attn]

[Inventory information]

Model	Serial Number

[**Date]**

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity to follow the steps.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to **info@olympus.ie**