

Reference: 2023-005M

9 August 2023

URGENT - FIELD SAFETY NOTICE

To all users of Olympus LF Series Tracheal Intubation Scopes (All serial numbers)

RE: TRACHEAL INTUBATION FIBERSCOPE, TRACHEAL INTUBATION VIDEOSCOPE

Models: Olympus LF-TP, LF-DP, LF-GP, LF-V and LF-P

Attention: **Endoscopy Department, Risk Management**

Dear Health Care Practitioner,

Olympus has become aware of a matter that requires your attention. This Safety Notice pertains to the above-referenced Olympus tracheal intubation scope models. These tracheal intubation scopes are intended for airway management which includes endoscopic observation to access airway anatomy, endotracheal/endobronchial intubation and management. Our records indicate that your facility has purchased one or more of these models.

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

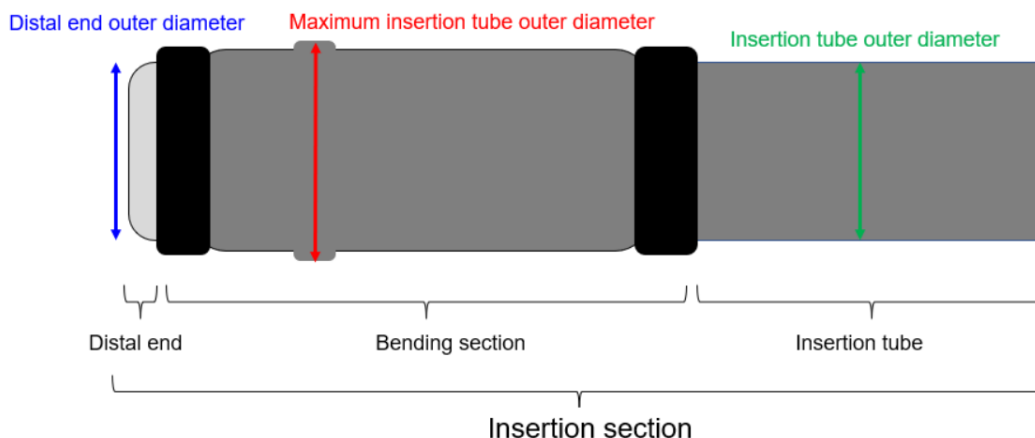
Selection of an endotracheal tube where the size is incompatible with the Olympus tracheal intubation scope can result in delayed procedures, foreign body obstruction, failure to ventilate the patient, hemorrhage, upper airway tract injury, esophageal perforation, and/or tracheal intubation scope damage.

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 tracheal intubation scope with an endotracheal tube into the patient, slide the tube along the entire length of the tracheal intubation scope insertion section to confirm that the insertion section of the tracheal intubation scope can be inserted smoothly into the endotracheal tube. If it cannot be inserted smoothly, the covering material of the bending section of the tracheal intubation scope 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 tracheal intubation scope, 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.
3. Ensure all personnel, including clinical staff, are completely knowledgeable and thoroughly aware the contents.
4. Olympus requests that you acknowledge receipt of this letter return the ‘Response Form’ to us.
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 complaints, including adverse events experienced with the use of this product to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact us for any additional information or support concerning this matter.

Contact for enquiries

Quality Affairs & Regulatory Affairs Department

Email : mes-ra.oml@olympus.com

Tel : (603) 7650 8990

Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

Hideki Nagai

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Hideki Nagai

Managing Director

Olympus (Malaysia) Sdn. Bhd.

Response Form

Please send the complete and signed Response Form to Quality Affairs & Regulatory Affairs Department at:

To : Olympus (Malaysia) Sdn. Bhd, Quality Affairs & Regulatory Affairs
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.: _____
Date : _____
Ref : 2023-005M

URGENT - FIELD SAFETY NOTICE

RE: TRACHEAL INTUBATION FIBERSCOPE, TRACHEAL INTUBATION VIDEOSCOPE

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I understand that I need to undertake the action(s) listed in the FSN.

Check the applicable boxes below:

- I DO NOT have affected devices remaining. All have been used or discarded.
- I DO have the affected devices, which I will adhere to the FSN.

Name: _____

Designation: _____

.....
Signature & Company Stamp

.....
Date






2023-005M LF- FSN - Customer Letter

Final Audit Report

2023-08-09

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