[Cover Letter]

URGENT: FIELD SAFETY NOTICE

ATTENTION: Endoscopy Department, Risk Management

Re: OLYMPUS [Reminding the WARNINGS within Olympus bronchoscope's Operation Manual]

Dear Health Care Professional:

By letter dated 29th May 2023, Olympus informed you that Olympus is conducting a voluntary corrective action for 32 bronchoscopes[1] to inform users on combustion events associated with these models during procedures using lasers and Argon Plasma Coagulation (APC) devices and to update labeling to include specific about laser compatibility. That letter informed you that only Nd:YAG laser or 810 nm diode lasers may be used with Olympus laser compatible bronchoscopes.

Olympus is now informing you of a different voluntary corrective action associated with Olympus bronchoscopes and endobronchial combustion during therapeutic procedures using high-frequency equipment. The attached Field Safety Notice informs you of an adverse event associated with use of Olympus bronchoscopes and high-frequency equipment and reminds you of Warnings within Olympus bronchoscope Operation Manuals for use of the subject bronchoscopes with high-frequency equipment.

Please see attached Field Safety Notice for further details and actions. Olympus fully appreciates your cooperation in this matter.

[1] Product availability is dependent upon country

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

Reference: 2023-012M

25 October 2023

URGENT - FIELD SAFETY NOTICE

To all users of Olympus BF Series Bronchoscopes (All serial numbers)

Re: Reminding the WARNINGS within Olympus bronchoscope's Operation Manual

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 below-referenced Olympus bronchoscopes models and our records indicate that your facility has purchased one or more of these models. These bronchoscopes are intended for use in endoscopic diagnosis and treatment within the airways, the tracheobronchial tree.

The specific models relevant to this alert include the following:

Affected BF Series Bronchoscopes

BF-1T150	BF-1TQ170	BF-H1200	BF-P60
BF-1T180*	BF-1TQ180*	BF-H190	BF-Q170
BF-1T260*	BF-1TQ290	BF-H290	BF-Q180-AC*
BF-1T60	BF-260*	BF-P150*	BF-Q190
BF-1TH1100	BF-6C260*	BF-P180*	BF-Q290
BF-1TH1200	BF-F260	BF-P190	BF-XT160*
BF-1TH190	BF-H1100	BF-P290	BF-XT190

*Sales discontinued

Note: Product availability is dependent upon country

Olympus has received four (4) adverse event complaints of endobronchial combustion during therapeutic procedures with the Olympus bronchoscope model BF-XT190, of which one (1) involved High-frequency therapy equipment. The other three (3) adverse events involved unknown energy therapy equipment. There are a total of 28 models of the BF series endoscopes that can be used in combination with High-frequency therapy equipment. The 28 bronchoscope models indicated above are listed as High-frequency therapy equipment compatible in the respective model's Operation Manuals.

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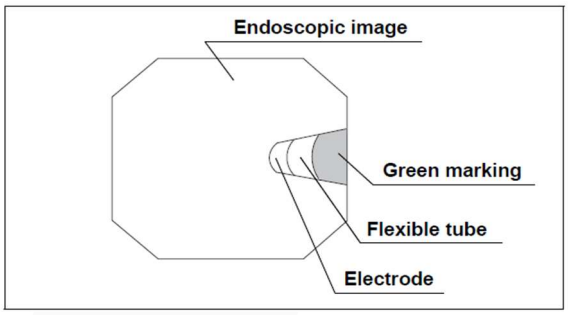
Risk to Health

There is a risk of endobronchial combustion if high-frequency cauterization is performed while supplying oxygen [and/or] the electrode section of the electrosurgical accessory is too close to the distal end of the endoscope.
If endobronchial combustion occurs, patients may suffer critical internal burns to the airway or lungs that may result in a requirement for additional medical intervention, prolonged procedure, extended hospitalization or ICU care, and death. Combustion can also result in damage to or breakage of device components that may injure or remain unintendedly in the patient and/or may require retrieval or surgical removal.

In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus is notifying users of these complaints and **reminding** them of the following Warnings, found in the affected bronchoscopes' Operation Manual(s), related to the use of high-frequency therapy equipment:

- Do not perform high-frequency cauterization while supplying oxygen. This may result in combustion during cauterization.

- Always confirm that the electrode section of the electrosurgical accessory is at an appropriate distance from the distal end of the endoscope. Confirm that the entire green marking (in case of WLI observation mode) at the distal tip of the electrosurgical accessory can be observed on the endoscopic image. If the electrode is used when it is too close to the distal end of the endoscope, the endoscope and/or ancillary equipment may be damaged. Patient injury, burns, bleeding, perforation, and/or equipment damage may result.



- Only utilize the Olympus bronchoscopes with high-frequency therapy equipment that is listed as compatible with the bronchoscope in the operation manual.

Actions to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected bronchoscopes.
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. Ensure all personnel are completely knowledgeable and thoroughly **aware of the Warnings in affected bronchoscope's Operation Manual for use with high-frequency devices and that Olympus high-frequency compatible bronchoscopes are compatible only with Combination equipment list in operation manual.**
3. Olympus requests that you acknowledge receipt of this letter return the 'Response Form' to us.
4. If you have further distributed this product, identify your customers, forward them this notification, and appropriately document your notification process.

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Olympus requests that you report complaints, including any injuries associated with procedures involving energy devices used with Olympus bronchoscopes and 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.
Regulatory Affairs and Quality Assurance 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
……
Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd.

Response Form

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

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2023-012M

URGENT - FIELD SAFETY NOTICE

Re: Reminding the WARNINGS within Olympus bronchoscope's Operation Manual

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 condemned or discarded.

☐ I DO have the affected devices, which I will adhere to the FSN.

Name: _____

Designation: _____

....
Signature & Company Stamp Date

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2023-012M FSN - Customer Letter.r1

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