

Reference: 2025-003M

9 September 2025

URGENT - FIELD SAFETY NOTICE

To all users of **Olympus Bronchofiberscope, Bronchovideoscope**
(See Appendix 1 – List of Affected Devices)

Re: Olympus to Provide Updates to the Instruction For Use (IFU)

Attention: **Respiratory Department, Operating Room Manager, Risk Management**

Dear Health Care Professional:

Olympus is notifying you about a Medical Device Correction pertaining to the Olympus bronchoscopes models (listed in the appendix). These bronchoscopes are intended for use in endoscopic diagnosis and treatment within the airways, the tracheobronchial tree.

Reason for Action:

Olympus previously issued a Field Corrective Action in 2023, after investigating complaints of endobronchial combustion during therapeutic bronchoscopy. Olympus provided details on ablation device compatibility, provided additional recommendations regarding patient preparation, and reiterated warnings in the Instruction for Use about injury and death resulting from improper device use.

Since the Field Corrective Action in 2023, as a part of continued investigation activities, Olympus conducted additional assessment on the use of compatible bronchoscopes with laser, argon plasma coagulation, and high-frequency therapy equipment. Through these investigations, Olympus has determined that additional IFU updates are necessary to provide further clarification on safe and effective use of the bronchoscopes when used in conjunction with these instruments. This Correction supersedes the IFU addendum provided in 2023.

Summary of updates to the IFU:

Olympus has added additional warnings to the IFU to provide further clarification for safe and effective use of the bronchoscopes:

- **Using Endo Therapy accessories- Laser**

- Through the 2023 letter, Olympus previously issued clarification on endoscope compatibility with a Nd:YAG laser system. This updated compatibility table has been added to the revised IFU.

Notes:

- Olympus conducted bench testing using Nd:YAG laser; as such compatibility statements cannot be made for other laser systems (please refer to the Appendix for details).
- After further market assessment, Olympus learned that the 810nm diode laser type is not commonly used in the market. As a result, Olympus did not include this laser type in the additional benchtop testing and the laser type is no longer included in the IFU.

- **High-frequency cauterization treatment, Argon plasma coagulation (APC) and Laser cauterization.**

- Consult the instructions as described in the instruction manuals provided by the energy equipment manufacturer when performing high-frequency cauterization, argon plasma coagulation, or laser cauterization.
- Avoid applying excessive energy to one area as this may potentially result in combustion related to charring of the tissue.
- Use suction to evacuate smoke to secure visibility of bronchoscope and remove potential combustible materials from the treatment area.
- Based on recommendations of clinicians and published literature, the oxygen concentration needs to be lower than 40% before performing high-frequency cauterization, argon plasma coagulation, or laser cauterization treatment. If the oxygen concentration is too high, combustion may potentially occur which could cause patient harm.
- Based on recommendations of clinicians and published literature, the energy output level typically needs to be lower than 40 Watts when performing high-frequency cauterization, argon plasma coagulation, or laser cauterization treatment. If the output level is too high, combustion may potentially occur which could cause patient harm.
- Ensure that there is separation of >4cm between the endoscope and the tracheal tube when performing the procedure. Otherwise, there is a risk of accidentally damaging the tracheal tube during the procedure, or of the fire generated by the airway ignition spreading to it, which could potentially cause harm to the patient or damage to the equipment.

Note:

Olympus advises users to consult the respective compatible device IFUs that may be used in conjunction with Olympus bronchoscopes.

Risk to Health:

Since 2022, Olympus has received reports of 9 serious injuries and 1 death. As Olympus previously indicated in our communications, the risks associated with combustion during ablation procedures as follows:

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.

Actions Required:

Our records indicate that your facility has received one or more of the affected units. **Olympus requests you to take the following actions:**

1. Carefully read the content of this notification.
2. Inspect your inventory for the referenced devices and identify with the model names specified in the appendix.
3. Ensure all personnel are completely knowledgeable and thoroughly aware of the **updates to the IFU contained in Appendix 2 of this letter when using the affected scopes listed in Appendix 1. Please include a copy of this letter with your existing IFU. Discard any copies of the addendum issues in 2023.**
4. Olympus requests that you acknowledge receipt of this letter and return the 'Response Form' to us.
5. If you have further distributed this product, identify your customers and forward them this letter.

Olympus requests that you report any complaints and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

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

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Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd

Appendix 1 – List of Affected Devices

| Model/Catalog Number | Serial Number(s) |
|----------------------|------------------|
| BF-1TH1100 | All |
| BF-1TH1200 | All |
| BF-1TH190 | All |
| BF-1TH190-U | All |
| BF-1TQ170 | All |
| BF-1TQ290 | All |
| BF-F260 | All |
| BF-H1100 | All |
| BF-H1200 | All |
| BF-H190 | All |
| BF-H190-U | All |
| BF-H290 | All |
| BF-P190 | All |
| BF-P190-U | All |
| BF-PE2 | All |
| BF-Q170 | All |
| BF-Q190 | All |
| BF-Q190-U | All |
| BF-Q290 | All |
| BF-TE2 | All |
| BF-XT190 | All |
| BF-XT190-U | All |
| BF-P290 | All |
| BF-1T150* | All |
| BF-1T180* | All |
| BF-1T260* | All |
| BF-1T60* | All |
| BF-1TQ180* | All |
| BF-260* | All |
| BF-6C260* | All |
| BF-MP60* | All |
| BF-P150* | All |
| BF-P180* | All |
| BF-P260F* | All |
| BF-P60* | All |
| BF-Q180* | All |
| BF-Q180-AC* | All |
| BF-XT160* | All |
| BF-XT40* | All |

**IFU will not be updated for this product as it is discontinued*

Appendix 2 – Summary Table of IFU updates

| Category & Section | Old IFU/Addendum | Revision |
|--|--|--|
| <p>4.3. Using Endo Therapy accessories</p> <p>4.2 Using Endo Therapy accessories (all scopes in the above chart with an asterisk)</p> <p>High-frequency cauterization treatment: Warning</p> | <p>Do not perform high-frequency cauterization while supplying oxygen. This may result in combustion during cauterization.</p> | <p>- Consult the instructions as described in the instruction manuals provided by the high frequency cauterization equipment manufacturer when performing high-frequency cauterization treatment.</p> <p>-Use caution when performing high-frequency cauterization while supplying oxygen as this may potentially result in combustion.</p> <p>-Avoid applying excessive energy to one spot as this may potentially result in combustion and/or charring of the tissue.</p> <p>- Use suction when there is smoke to secure visibility on bronchoscope and remove potential combustible materials from the treatment area.</p> <p>- Based on recommendations of clinicians and published literature, the oxygen concentration typically needs to be lower than 40% before performing high-frequency cauterization treatment. If oxygen concentration is too high, combustion may potentially occur which could cause patient burns.</p> <p>- Based on recommendation of clinicians and published literature, the energy output level typically needs to be lower than 40 Watts when performing high-frequency cauterization treatment. If the output level is too high, the endoscope's and/or accessory's insulation may be damaged and could potentially cause operator and/or patient burns. Also, combustion may potentially occur which could cause patient burns.</p> <p>- Ensure that there is separation of >4cm between the endoscope and the tracheal tube when performing the procedure. Otherwise, there is a risk of accidentally damaging the tracheal tube during the procedure, or of the fire generated by the airway ignition spreading to it, which could potentially cause harm to the patient or damage to the equipment.</p> |
| | <p>Set the electrosurgical unit to the minimum necessary output level. If the output level is too high, the endoscope's and/or accessory's insulation may be damaged and cause operator and/or patient burns.</p> | <p>Removed and further clarified above</p> |
| <p>4.3. Using Endo Therapy accessories</p> <p>4.2 Using Endo Therapy accessories (all scopes in the above chart with an asterisk)</p> <p>Argon plasma coagulation (APC): Warning</p> | <p>-The argon gas itself is neither combustible nor a promoter of combustible substances, but the argon plasma is very hot and could ignite combustible substances. Flammable substances burn easily when argon is irradiated in the presence of combustible gas such as high-concentration or pure oxygen. Be sure to observe the following cautions.</p> | <p>-Consult the instructions as described in the instruction manuals provided by the Argon Plasma Coagulation (APC) equipment manufacturer when performing APC treatment.</p> <p>-Use caution when performing APC treatment while supplying oxygen as this may potentially result in combustion.</p> <p>-Avoid applying excessive energy to one spot as this may potentially result in combustion and/or charring of the tissue.</p> <p>-Use suction when there is smoke to secure visibility on bronchoscope and remove potential combustible materials from the treatment area.</p> <p>-Based on recommendation of clinicians and published literature, the oxygen concentration typically needs to be lower than 40% before performing APC</p> |

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| <p>*This does not apply to BF-F260</p> | <p>-Before and during APC, do not feed oxygen or other combustible gases and liquids into the tracheobronchial system.</p> | <p>treatment. If the oxygen concentration is too high, combustion may potentially occur which could cause patient burns.</p> <p>-Based on recommendation of clinicians and published literature, the energy output level typically needs to be lower than 40 Watts when performing APC treatment. If the output level is too high, the endoscope's and/or accessory's insulation may be damaged and could potentially cause operator and/or patient burns. Also, combustion may potentially occur which could cause patient burns.</p> <p>-Ensure that there is separation of >4cm between the endoscope and the tracheal tube when performing the procedure. Otherwise, there is a risk of accidentally damaging the tracheal tube during the procedure, or of the fire generated by the airway ignition spreading to it, which could potentially cause harm to the patient or damage to the equipment.</p> |
| <p>4.3. Using Endo Therapy accessories</p> <p>4.2 Using Endo Therapy accessories (all scopes in the above chart with an asterisk)</p> <p>Laser cauterization: Warning</p> | <p>-Do not perform laser cauterization while supplying oxygen. This may result in combustion during cauterization.</p> <p>-To avoid patient injury, burns, bleeding, perforation and/or damage to the endoscope, never emit laser radiation before confirming that an appropriate distance between the target and the endoscope's distal end is maintained and the tip of the laser probe is surely in the correct position in the endoscopic image.</p> | <p>-Olympus has only determined the compatibility of this endoscope with a Nd:YAG laser system. Therefore, it is only recommended to use this endoscope with a Nd:YAG laser system.</p> <p>-Consult the instructions as described in the instruction manuals provided by the laser equipment manufacturer when performing laser cauterization.</p> <p>-Use caution when performing laser cauterization while supplying oxygen as this may potentially result in combustion.</p> <p>-Avoid applying excessive energy to one spot as this may potentially result in combustion and/or charring of the tissue.</p> <p>-Use suction when there is smoke to secure visibility on bronchoscope and remove potential combustible materials from the treatment area.</p> <p>-Based on recommendation of clinicians and published literature, the oxygen concentration typically needs to be lower than 40% before performing laser cauterization. If the oxygen concentration is too high, combustion may potentially occur which could cause patient burns.</p> <p>-Based on recommendation of clinicians and published literature, the energy output level typically needs to be lower than 40 Watts when performing laser cauterization. If the output level is too high, combustion may potentially occur which could cause patient burns.</p> <p>-Ensure that there is separation of >4cm between the endoscope and the tracheal tube when performing the procedure. Otherwise, there is a risk of accidentally damaging the tracheal tube during the procedure, or of the fire generated by the airway ignition spreading to it, which could potentially cause harm to the patient or damage to the equipment.</p> <p>-To avoid patient injury, burns, bleeding, perforation and/or damage to the endoscope, never emit laser radiation before confirming that the endoscope's distal end is away from the target and the tip of the laser probe is surely in the correct position in the endoscopic image.</p> |
| <p>2.2 Specifications</p> <p>2.3 Specifications (BF-F260, BF-PE2 & BF-TE2)</p> | <p>2023 Addendum: Only Nd:YAG laser or 810nm diode lasers may be used with Olympus laser compatible bronchoscopes. Olympus has not evaluated any other lasers for compatibility</p> | <p>Compatible; Nd:YAG laser system only</p> |

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| | with the indicated bronchoscope models. | |
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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 : 2025-003M

URGENT - FIELD SAFETY NOTICE

Re: Olympus to Provide Updates to the Instruction For Use (IFU)

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

- I DO NOT have affected product remaining. Product has been condemned or discarded.
- I DO have the affected product, which I will adhere to this FSN letter.

Additional Customer Requests:

(Indicate if you have any additional requests to support this action)

Name: _____

Designation: _____

.....
Signature & Company Stamp

.....
Date






2025-003M FSN Customer Letter

Final Audit Report

2025-09-09

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|-----------------|---|
| Created: | 2025-09-09 (Australian Western Standard Time) |
| By: | Seo Ching Yeoh (seoching.yeoh@olympus.com) |
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