Date: XX.XX.XXXX

Olympus reference: QIL FY26-EMEA-05-FY26-901-F BF Scope IFU Update

URGENT FIELD SAFETY NOTICE

RE: OLYMPUS BRONCHOFIBERSCOPE, BRONCHOVIDEOSCOPES (See Appendix 1 – List of Affected Devices)

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

Reason for Action:

Olympus previously issued Field Corrective Actions 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 2 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 your facility has purchased one or more affected Bronchoscopes. **Olympus requests you take the following action:**

1. Carefully read the content of this notification.
2. Inspect your inventory for the referenced devices and identify any device with the model names specified in the Appendix 1.
3. Ensure all personnel are completely knowledgeable and thoroughly aware of the **updates to the IFU contained in this letter when using the affected scopes.**

   For products which are actively sold, please obtain the updated IFU through web portal www.olympus-europa.com. All updates to the IFU are enclosed with this letter. Discard any copies of the previous IFU and the addendum issued in 2023.

   If an updated IFU is not available, include a copy of this letter with your existing IFU. Discard any copies of the addendum issued in 2023.

For products which have been discontinued, please include a copy of this letter (including Appendix 1 and Appendix 2) with your existing IFU. Discard any copies of the addendum issued in 2023. Refer to Appendix 1 for information regarding discontinued models in your region.

4. Olympus requests that you acknowledge receipt of this letter through the enclosed response form.
5. If you have further distributed the affected product, please identify your customers, and forward them this notification.

Olympus requests that you report any complaints, to [local facility complaint reporting contact]. Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

Olympus fully appreciates your prompt cooperation in addressing this situation. If you have any questions or concerns, please do not hesitate to contact [phone number] or [e-mail] [Regions to revise to reflect their operations]

Sincerely,

[SIGNATORY]

[Contact Name]

Appendix 1 - List of Affected Devices

Model/Catalog Number	Serial Number(s)	UDI DI
BF-1TH1100	All	4953170424199
BF-1TH1200	All	N/A
BF-1TH190	All	4953170434778
BF-1TH190-U	All	4953170434778
BF-1TQ170	All	4953170342943
BF-1TQ290	All	N/A
BF-F260	All	N/A
BF-H1100	All	4953170424229
BF-H1200	All	N/A
BF-H190	All	4953170335174
BF-H190-U	All	4953170335174
BF-H290	All	N/A
BF-P190	All	4953170342110
BF-P190-U	All	4953170342110
BF-PE2	All	4953170339974
BF-Q170	All	4953170342912
BF-Q190	All	4953170335198
BF-Q190-U	All	4953170335198
BF-Q290	All	N/A
BF-TE2	All	4953170339998
BF-XT190	All	4953170402470
BF-XT190-U	All	4953170402470
BF-P290	All	N/A
BF-1T150*	All	4953170308185
BF-1T180*	All	4953170339325
BF-1T260*	All	N/A
BF-1T60*	All	4953170339264
BF-1TQ180*	All	4953170339349
BF-260*	All	N/A
BF-6C260*	All	N/A
BF-MP60*	All	N/A
BF-P150*	All	4953170308178
BF-P180*	All	4953170339288
BF-P260F*	All	N/A
BF-P60*	All	4953170339196
BF-Q180*	All	4953170339301
BF-Q180-AC*	All	4953170340086
BF-XT160*	All	4953170340147
BF-XT40*	All	N/A

[Model Numbers- Regions to customize scope models based on their regulatory clearance]

**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
4.3. Using Endo Therapy accessories **4.2** Using Endo Therapy accessories (all scopes in the above chart with an asterisk) High-frequency cauterization treatment: Warning	Do not perform high-frequency cauterization while supplying oxygen. This may result in combustion during cauterization.	- Consult the instructions as described in the instruction manuals provided by the high frequency cauterization equipment manufacturer when performing high-frequency cauterization treatment. -Use caution when performing high-frequency cauterization while supplying oxygen as this may potentially result in combustion. -Avoid applying excessive energy to one spot as this may potentially result in combustion and/or charring of the tissue. - Use suction when there is smoke to secure visibility on bronchoscope and remove potential combustible materials from the treatment area. - 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. - 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. - 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.
	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.	Removed and further clarified above
4.3. Using Endo Therapy accessories **4.2** Using Endo Therapy accessories (all scopes in the above chart with an asterisk) Argon plasma coagulation (APC): Warning *This does not apply to BF-F260	-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. -Before and during APC, do not feed oxygen or other combustible gases and liquids into the tracheobronchial system.	-Consult the instructions as described in the instruction manuals provided by the Argon Plasma Coagulation (APC) equipment manufacturer when performing APC treatment. -Use caution when performing APC treatment while supplying oxygen as this may potentially result in combustion. -Avoid applying excessive energy to one spot as this may potentially result in combustion and/or charring of the tissue. -Use suction when there is smoke to secure visibility on bronchoscope and remove potential combustible materials from the treatment area. -Based on recommendation of clinicians and published literature, the oxygen concentration typically needs to be lower than 40% before performing APC treatment. If the oxygen concentration is too high, combustion may potentially occur which could cause patient burns.

Category & Section	Old IFU/Addendum	Revision
		-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. -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.
4.3. Using Endo Therapy accessories **4.2** Using Endo Therapy accessories (all scopes in the above chart with an asterisk) Laser cauterization: Warning	-Do not perform laser cauterization while supplying oxygen. This may result in combustion during cauterization. -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.	-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. -Consult the instructions as described in the instruction manuals provided by the laser equipment manufacturer when performing laser cauterization. -Use caution when performing laser cauterization while supplying oxygen as this may potentially result in combustion. -Avoid applying excessive energy to one spot as this may potentially result in combustion and/or charring of the tissue. -Use suction when there is smoke to secure visibility on bronchoscope and remove potential combustible materials from the treatment area. -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. -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. -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. -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.
2.2 Specifications **2.3** Specifications (BF-F260, BF-PE2 & BF-TE2)	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 with the indicated bronchoscope models.	Compatible; Nd:YAG laser system only

REPLY FORM: QIL FY26-EMEA-05-FY26-901-F BF Scope IFU Update

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

I acknowledge receipt of this notification. I confirm that I have communicated further to any affected departments.

Completed By:		
		Click or tap to enter a date.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to *XXX* by *XX.XX.XXXX*