Date: October 12, 2023

URGENT MEDICAL DEVICE CORRECTIVE ACTION

Attention: Operating Room Manager, Endoscopy Department
Risk Management Department
RE: Bronchofiberscope, Bronchovideoscope

Serial numbers: All serial numbers

Dear Health Care Professional:

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; see Table 1 for models sold in the U.S. and UDI information

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. Please refer to Attachment 1 for the models applicable to the U.S.

Risk to Health

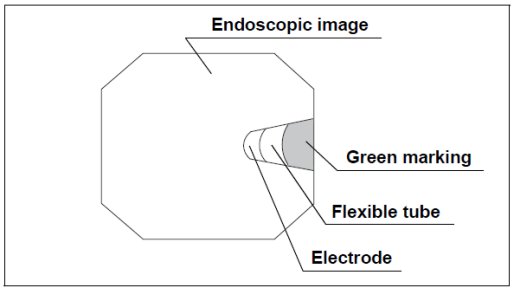
There is a risk of endobronchial combustion if high-frequency cauterization is performed while supplying oxygen [and/or] the electrode section of the electrosurgical accessory is too close to the distal end of the endoscope.

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 facility for the referenced devices and ensure all personnel are completely knowledgeable and thoroughly **aware of the Warnings in affected bronchoscope's Operation Manual for use with High-frequency therapy equipment and that Olympus high-frequency**

compatible bronchoscopes are compatible only with Combination equipment list in operation manual. You may continue to use the device according to the existing instructions and warnings contained in the Instruction for Use.

2. Complete the enclosed response form and return to our recall partner, Sedgwick, via Email (Olympus4907@sedgwick.com) or Fax (866-808-1177). For any questions about the acknowledgement form, please call the Sedgwick team at 855-215-5128.

3. If you have further distributed this product outside of your facility, forward them this notification and appropriately document your notification process.

Olympus requests that you report to Olympus complaints, including any injuries associated with procedures involving energy devices used with Olympus bronchoscopes. Please report complaints to the Olympus Technical Assistance Center (TAC) at 1-800-848-9024 (option 1). Adverse events experienced with the use of this product may also be reported to the Food and Drug Administration MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact me directly at (647) 999-3203 or at Cynthia.Ow@Olympus.com for any additional information or support concerning this matter.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Action Lead, Americas

MEDICAL DEVICE CORRECTIVE ACTION

Olympus Bronchovideoscope, Bronchofiberscope

Serial Numbers: All Serial Numbers

Attachment 1 – List of models distributed in the U.S. and UDI

Model	Device Description	UDI DI
BF-1T150	BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T150	4953170308185
BF-1T180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T180	N/A
BF-1T260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T260	Not sold and registered in US
BF-1T60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE 1T60	4953170339264
BF-1TH1100	BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100	Not sold and registered in US
BF-1TH1200	BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1200	Not sold and registered in US
BF-1TH190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190	4953170335181
BF-1TQ170	BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ170	4953170342943
BF-1TQ180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1TQ180	N/A
BF-1TQ290	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ290	Not sold and registered in US
BF-260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 260	N/A
BF-6C260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 6C260	Not sold and registered in US
BF-F260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE F260	Not sold and registered in US
BF-H1100	BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	Not sold and registered in US
BF-H1200	BRONCHOVIDEOSCOPE OLYMPUS BF-H1200	Not sold and registered in US
BF-H190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-H190	4953170335174
BF-H290	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-H290	Not sold and registered in US
BF-P150	BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P150	N/A
BF-P180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P180	N/A
BF-P190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-P190	4953170342110
BF-P290	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-P290	Not sold and registered in US
BF-P60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE P60	4953170339196
BF-Q170	BRONCHOVIDEOSCOPE OLYMPUS BF-Q170	4953170342912
BF-Q180-AC	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE Q180-AC	N/A
BF-Q190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-Q190	4953170335198
BF-Q290	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-Q290	Not sold and registered in US
BF-XT160	EVIS EXERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE XT160	N/A
BF-XT190	EVIS EXERA Ⅲ BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	4953170402470

Response Form

Please submit the complete form by e-mail to Olympus4907@sedgwick.com

or by fax to 866-808-1177

☐ I confirm that I have read and understood the instructions provided in the field corrective action letter dated October 12, 2023, regarding bronchoscopes and high-frequency therapy equipment.

☐ I confirm all personnel are completely knowledgeable and thoroughly aware of the contents of the letter.

☐ We have further distributed these products and this letter has been forwarded to those facilities.

☐ I no longer have this product at my facility.

Signature of Receipt

Date Form Completed:	
Name of Person Completing Form:	
Title/Department	
Facility Name:	
Address	
Phone #:	
e-mail:	
Signature:	