Date: June 8, 2023

URGENT MEDICAL DEVICE CORRECTIVE ACTION

Attention: Operating Room Manager, Endoscopy Manager,
Risk Management Department
Products: Bronchofiberscope, Bronchovideoscope
Serial numbers: All Serial Numbers

Dear Health Care Provider:

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 for the US include the following:

Affected BF Series Bronchoscopes

Model	Name	UDI
BF-XT40**	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE XT40	04953170055980
BF-P60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE P60	04953170339288
BF-MP60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE MP60	04953170338394
BF-1T60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE 1T60	04953170339264
BF-PE2	BRONCHOFIBERSCOPE OLYMPUS BF TYPE PE2	04953170339974
BF-TE2	BRONCHOFIBERSCOPE OLYMPUS BF TYPE TE2	04953170339998
BF-P150*	BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P150	04953170288876
BF-1T150	BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T150	04953170288968
BF-XT160*	EVIS EXERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE XT160	04953170340147
BF-Q170	BRONCHOVIDEOSCOPE OLYMPUS BF-Q170	04953170342912
BF-P180*	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P180	04953170339288
BF-Q180**	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE Q180	04953170339301
BF-Q180-AC*	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE Q180-AC	04953170340086
BF-1T180*	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T180	04953170339325
BF-1TQ180*	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1TQ180	04953170339349
BF-H190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-H190	04953170434754
BF-Q190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-Q190	04953170335198
BF-XT190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	04953170402470
BF-1TH190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190	04953170434778

* Sales discontinued; ** Sales and Service discontinued; Note: Product availability is dependent upon country

Olympus has received complaints of endobronchial combustion during therapeutic procedures using lasers or argon plasma coagulation with the Olympus bronchoscope model BF-1TH190. Three (3) adverse event complaints with endobronchial combustion during laser or argon plasma coagulation procedures have occurred, of which one (1) complaint resulted in patient death. In the US, there are a total of 19 models of the BF series endoscopes (including BF-1TH190) that can be used in combination with laser therapy equipment. The 19 bronchoscope models indicated above are listed as laser compatible in the respective model's Operation Manuals.

Risk to Health

If endobronchial combustion occurs, patients may suffer internal burn in their airway or lungs, respiratory insufficiency, apnea, loss of consciousness, hospitalization or its prolongation, ICU care, or death.

In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus is notifying users of these complaints and the providing the following recommendations related in combination with laser therapy equipment:

- **Only Nd:YAG laser or 810 nm diode lasers may be used with Olympus laser compatible bronchoscopes.** Olympus has not evaluated any other lasers for compatibility with the indicated bronchoscope models.

- **Do not perform laser cauterization while supplying oxygen**. This may result in combustion during cauterization. This is included in the Warnings in the Operation Manual on laser cauterization with Olympus bronchoscopes.

- Never emit laser radiation before confirming that an appropriate distance between the target and the endoscope's distal end with the tip of the laser probe is in the correct position in the endoscopic image. This is essential to avoid patient injury (burns, bleeding, & perforation) or damage to the device.

Actions to be taken by the company:

The labelling will be updated to include specificity about laser compatibility, improved instructions regarding patient preparation, and warnings about patient injury and death resulting from incompatible laser use.

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. Carefully read the content of this Medical Device Correction Action as well as the attached "Addendum". The addendum provides compatible laser type.

3. Ensure all personnel are completely knowledgeable and thoroughly **aware that Olympus laser compatible bronchoscopes are compatible only with Nd: YAG laser or 810 nm diode lasers.**

4. Olympus requests that you acknowledge receipt of this letter through the Olympus recall portal.
    a. Go to https://olympusamerica.com/recall
    b. Enter the file (recall) number: **0427**

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 any injuries associated with laser procedures with Olympus bronchoscopes, to our 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

Addendum: Bronchofiberscope and Bronchovideoscope – Compatible laser type

x: compatible

Model name	Product name	Laser type	
		Nd: YAG	810 nm diode
BF-XT40	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE XT40	x	-
BF-P60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE P60	x	x
BF-MP60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE MP60	x	x
BF-1T60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE 1T60	x	x
BF-PE2	BRONCHOFIBERSCOPE OLYMPUS BF TYPE PE2	x	-
BF-TE2	BRONCHOFIBERSCOPE OLYMPUS BF TYPE TE2	x	-
BF-P150	BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P150	x	x
BF-1T150	BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T150	x	x
BF-XT160	EVIS EXERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE XT160	x	x
BF-Q170	BRONCHOVIDEOSCOPE OLYMPUS BF-Q170	x	x
BF-P180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P180	x	x
BF-Q180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE Q180	x	x
BF-Q180-AC	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE Q180-AC	x	x
BF-1T180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T180	x	x
BF-1TQ180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1TQ180	x	x
BF-H190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-H190	x	x
BF-Q190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-Q190	x	x
BF-XT190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	x	-
BF-1TH190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190	x	x