Reference: 2023-001M (rev.01)

7 June 2023

URGENT - FIELD SAFETY NOTICE

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

Re: Bronchofiberscope, Bronchovideoscope

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-XT40**	BF-XT160*	BF-H190	BF-6C260*
BF-P60	BF-Q170	BF-Q190	BF-H290
BF-MP60	BF-1TQ170	BF-XT190	BF-Q290
BF-1T60	BF-P180*	**BF-1TH190**	BF-1TQ290
BF-PE2	BF-Q180**	BF-260*	BF-H1100
BF-TE2	BF-Q180-AC*	BF-F260	BF-1TH1100
BF-P150*	BF-1T180*	BF-P260F*	BF-H1200
BF-1T150	BF-1TQ180*	BF-1T260*	BF-1TH1200

* 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. There are a total of 32 models of the BF series endoscopes (including BF-1TH190) that can be used in combination with laser therapy equipment. The 32 bronchoscope models indicated above are listed as laser compatible in the respective model's Operation Manuals.

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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

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 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 return the 'Response Form' to us.
5. If you have further distributed this product, identify your customers, forward them this notification, and appropriately document your notification process.

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.

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Olympus requests that you report complaints, including any injuries associated with laser procedures 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 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.

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Addendum 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-1TQ170	BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ170	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
BF-260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 260	x	x
BF-F260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE F260	x	x
BF-P260F	EVIS LUCERA BRONCHOFIBERVIDEOSCOPE OLYMPUS BF TYPE P260F	x	x
BF-1T260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T260	x	x
BF-6C260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 6C260	x	x
BF-H290	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-H290	x	x
BF-Q290	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-Q290	x	x
BF-1TQ290	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ290	x	x
BF-H1100	BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	x	-
BF-1TH1100	BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100	x	-
BF-H1200	BRONCHOVIDEOSCOPE OLYMPUS BF-H1200	x	-
BF-1TH1200	BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1200	x	-

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Response Form

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

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2023-001M (rev.1)

URGENT - FIELD SAFETY NOTICE

Re: Bronchofiberscope, Bronchovideoscope

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 used 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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