Reference: 2026-001M

4 February 2026

URGENT - FIELD SAFETY NOTICE

To all users of **Single Use Biopsy Valve**

Product Name	Model/Catalog Number	Serial/Lot Number(s)
Single Use Biopsy Valve (Sterile)	MAJ-210	All unused/unexpired

Re: Olympus Emphasis on Strict Adherence to Instructions for Use (IFU)

Attention: **Endoscopy Department, Risk Management**

Dear Health Care Professional:

Olympus is writing to inform you of a Field Safety Notice pertaining to the MAJ-210 and *MAJ-1218 Single use Biopsy Valves. These products are intended to be attached to the instrument channel port of compatible endoscopes and prevent reflux or leakage of body fluids.

Serious injuries have occurred and serious injuries and/or deaths could occur due to the failure mode associated with this FCA. We have received 126 complaints involving MAJ-210, *MAJ-1218 and their compatible scopes, of which 88 were serious injuries.
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Reason for Action:
Olympus is currently investigating an increase in complaints associated with rubber fragment detachment in the slit of MAJ-210 and *MAJ- 1218 Single use Biopsy Valves as shown below in Figure 1. While the investigation regarding the cause of the issue is ongoing, Olympus is highlighting the importance of strictly adhering to the 'Inspection of the Biopsy Valve' and 'Inserting and Withdrawing the Endo-therapy accessories' sections in the IFU related to the detachment of fragment from the slit part of rubber, as shown below in Figure 2 and Figure 3 below.

Olympus will share an updated customer notification by mid-2026.

Users are reminded of following instructions:

- Inspect the valves for damage or cracks
- Insert endo-therapy accessories as straight as possible
- Angled Insertion and withdrawal of endo-therapy accessories can cause resistance and could cause damage to the valve.

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Figure 1: MAJ-210 slit fragment detachment.

MAJ-210

8.2 Inspection of the biopsy valve

Inspect the biopsy valve for damage or crack.

9.5 Inserting and withdrawing the endo-therapy accessories

CAUTION

- Insert the endo-therapy accessory into the valve as straight as possible.
- Angled insertion and withdrawal of the endo-therapy accessory can cause excessive resistance, and the endo-therapy accessory or biopsy valve could be damaged.

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Figure 2: MAJ-210 Instructions and cautions are present in the Instructions for Use (IFU)

MAJ-1218

8.2 Inspection of the biopsy valve

Inspect the biopsy valve for damage or cracks. Do not use it if it is damaged; use a spare instead.

9.5 Inserting and withdrawing the endo-therapy accessories

CAUTION

- Slowly insert the endo-therapy accessory into the valve as straight as possible.
- Angled insertion and withdrawal of the endo-therapy accessory can cause excessive resistance, and the endo-therapy accessory or biopsy valve could be damaged.

Figure 3: *MAJ-1218 Instructions and cautions are present in the Instructions for Use (IFU)

Olympus would like to remind customers who have purchased scopes with MAJ-210 and *MAJ-1218 devices co-packaged to also adhere to the IFU points highlighted above. Scopes which are compatible with MAJ-210 and *MAJ-1218 are listed in Attachment 1.

Risk to Health:

Potential consequences associated with detachment of fragment(s) from the MAJ-210 or *MAJ-1218 biopsy valve include several possible patient harms. The most common harm is the presence of a foreign body in the patient's tracheobronchial tree, which may require intervention for removal. In all reported cases, the detached fragment(s) was identified immediately during the bronchoscopy procedure, with the majority successfully removed using bronchoscopic suction or standard bronchoscopic tools. However, some cases noted unconfirmed retrieval,

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unsuccessful retrieval, or fragments displaced to the gastrointestinal tract following patient coughing. Although not reported, unintended retention of device fragments could potentially lead to an inflammatory response in the patient. Additional risks include a potential decrease in suction capability during the procedure due to a detached fragment, which could result in accumulation of patient secretions, potentially leading to hypoxia and further extending procedure duration.

Actions Required:
Our records indicate that your facility has received one or more of the affected products. Therefore, **Olympus requires you to take the following actions:**

1. Carefully read the content of this notification.
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this notification. This is not a product removal action. You may continue to use the device as per this letter and the instruction for use.
3. Olympus is highlighting the importance of strictly adhering to the 'Inspection of the Biopsy Valve' and 'Inserting and Withdrawing the Endo-therapy accessories' sections in the IFU related to the detachment of fragment from the slit part of rubber, as listed above in Figures 2 and 3.
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
Hideki Nagai (Feb 4, 2026 13:19:57 GMT+8)

Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd

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Attachment 1 – Compatible Devices to MAJ-210 and *MAJ-1218

Category	Series	Model	MAJ-210 Compatible	*MAJ-1218 Compatible
Video Bronchoscope	1100 series	BF-H1100	X	
		BF-1TH1100	X	
	190 series	BF-H190	X	
		BF-1TH190	X	
		BF-Q190	X	
		BF-P190	X	
		BF-MP190F	X	
		BF-XP190	X	
		BF-XT190	X	
	290 series	BF-H290	X	
		BF-1TQ290	X	
		BF-Q290	X	
		BF-P290	X	
		BF-MP290F	X	
		BF-XP290	X	
	180 series	BF-P180	X	
		BF-Q180-AC	X	
		BF-1TQ180	X	
		BF-1T180	X	
	160 series	BF-3C160	X	
		BF-XT160	X	
		BF-XP160F	X	
	260 series	BF-260	X	
		BF-1T260	X	
		BF-6C260	X	
		BF-F260	X	
		BF-P260F	X	
		BF-XP260F	X	
	170 series	BF-Q170	X	
		BF-1TQ170	X	

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Pleuroscope	290 series	LTF-H290	X	
	160 series	LTF-260	X	
	260 series	LTF-160	X	
Fiber Bronchoscope	PE/TE series	BF-PE2	X	
		BF-TE2	X	
	60 series	BF-XP60	X	
		BF-P60	X	
		BF-MP60	X	
		BF-1T60	X	
	40 series	BF-3C40	X	
Mobile Airway Fiber scope	MAF series	MAF-TM	X	
	MAF-2 series	MAF-TM2	X	
Flexible tracheal intubation fiberscope	LF series	LF-GP	X	
		LF-TP	X	
		LF-DP	X	
Video Rhinolaryngoscope	ENF series	ENF-T3	X	X*
		ENF-VT2	X	X*
		ENF-VT3	X	X*
*MAJ-1218 is not available in Malaysia.				

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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 : 2026-001M

URGENT - FIELD SAFETY NOTICE

Re: Olympus Emphasis on Strict Adherence to Instructions 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

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2026-001M Customer Letter.r1

Final Audit Report 2026-02-04

Created:	2026-02-04 (Korean Standard Time)
By:	Rohaya Binti Asib (rohaya.asib@olympus.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA30_wU-UI3BolXxuUrsa7DB9cEAni5x1j

"2026-001M Customer Letter.r1" History

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