Date: *XX.XX.XXXX*

Olympus reference: QIL FY26-EMEA-20-FY26-043-F MAJ-210 Fragment Detachment

URGENT FIELD SAFETY NOTICE

RE: Single Use Biopsy Valve

Attention: Respiratory Department, Otorhinolaryngology Department, Endoscopy Department, Risk Management

Catalogue Number	Material Description	Lot Number(s)	UDI
NGL2167	MAJ 210 Single Use Biopsy Valve (Sterile)	All unused/unexpired	14953170152433
N6210355			14953170452069
028988			N/A

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Safety Notice pertaining to the MAJ-210 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 or could occur due to the failure mode associated with this FCA. We have received 126 complaints involving MAJ-210 and their compatible scopes, of which 88 were serious injuries.

Reason for Action:

Olympus is currently investigating an increase in complaints associated with rubber fragment detachment in the slit of MAJ-210 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 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.

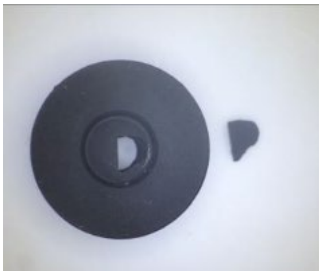
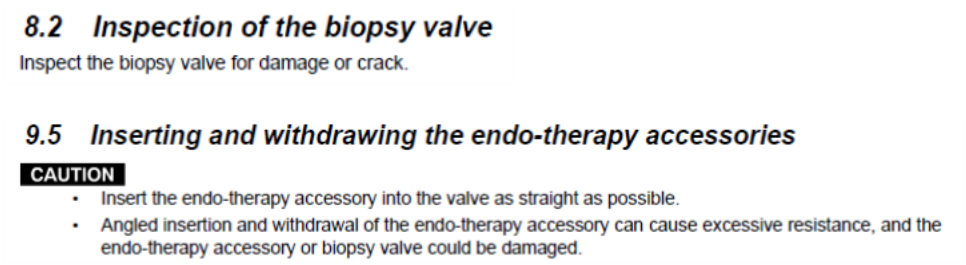


Figure 1: MAJ-210 slit fragment detachment.

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.

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

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

Risk to Health:

Potential consequences associated with detachment of fragment(s) from the MAJ-210 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, 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. Olympus requests 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.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative *XXX* latest by *XXX*.
5. If you have further distributed this product, identify your customers, and forward this notification to them.

[If applicable:] [competent authority] is aware of the actions described in this letter.
Olympus requests that you report any complaints, to *[local facility complaint reporting contact]. [If applicable:]*

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact *[me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].*

Sincerely,
Name
Olympus title

Attachment 1 – Compatible Devices to MAJ-210

Category	Series	Model	Catalogue Number(s)
Video Bronchoscope	1100 series	BF-H1100	N6130950, N6130960, E0420983S, N6130930, N6130940
		BF-1TH1100	N6130650, N6130660
	1200 series	BF-H1200	N6131050, N6131030
		BF-1TH1200	N6130750, N6130730
	190 series	BF-H190	N3828750, N3828730
		BF-1TH190	N3828850, N3828830, N3828844
		BF-Q190	N3828950, N3828930
		BF-P190	N4503950, N4503930
		BF-MP190F	N5768650
		BF-XP190	N4504050
		BF-XT190	N5784850, N5784860
	290 series	BF-H290	N3829050, N3829060
		BF-1TQ290	N3829150, N3829160
		BF-Q290	N3829250, N3829260
		BF-P290	N4506550, N4506560
		BF-MP290F	N5768550
		BF-XP290	N4506650
	180 series	BF-P180	N3820660, N2117530, N2117560, N3630560, N3820630
		BF-Q180-AC	N4498660, N2117360, N3630660, E0425410, E0425411
		BF-1TQ180	N3631060. N3820960, N3499460, N3820930
		BF-Q180	N3630760, N3820760, N2117430, N2117460
		BF-1T180	N3820860, N2117630, N2117660, N3630960, N3820830
	160 series	BF-3C160	N4498160, 020583, 6877830
		BF-XT160	N4499260, 6877930, 020584, N4499340, N4499130
		BF-XP160F	N4498830, N4498960, N1383960, N3631160
	260 series	BF-260	N3821130, N3821160, N1051360
		BF-1T260	N3821030, N3821060, N1026160
		BF-6C260	N3821230
		BF-F260	N3821350, N3821360, N2549860, N3631860, N3821330

Category	Series	Model	Catalogue Number(s)
		BF-P260F	N3821530
		BF-XP260F	N3821630
	170 series	BF-Q170	N4504150, N4504130, N4504160
		BF-1TQ170	N4504250, N4504230, N4504260, N4504233
Pleuroscope	290 series	LTF-H290	N6011950, E0420982S, E0420983S, N6011960
	160 series	LTF-260	N4500850, N4500830
	260 series	LTF-160	N4500660, N3634160, N1067120, N1030060
Fiber Bronchoscope	PE/TE series	BF-PE2	N4497760, N4497750, 687723020275, N4497630,20275
		BF-TE2	N4497960, N4497950, 6877330, 020276, N4497830
	60 series	BF-XP60	N3820260, N3820250, N1414360, N1414330
		BF-P60	N3819960, N3819950, N3630060, N1414260, N3819930
		BF-MP60	N3821460, N1414530, N1414560, N3630360
		BF-1T60	N3820360, N1414430, N1414460 N3630160, N3820350, N3820330
	40 series	BF-3C40	N4498160, 020396, 4622030
Mobile Airway Fiber scope	MAF series	MAF-TM	N3629630, E0425235, N3058930
	MAF-2 series	MAF-TM2	N5994050
Flexible tracheal intubation fiberscope	LF series	LF-GP	020299,5795570,7055554,N4500030,WA95530A,N4500170
		LF-TP	020298,N1003630,WA93630A,N1003670,1112233
		LF-DP	020297,WA93730A,N4499970,N4499830,N1003770
Video Rhinolaryngoscope	ENF series	ENF-T3	N3823530, N6006430, E11ENT-T3, N6006450, 020287
		ENF-VT2	E0497453, E0497646, E0497647, N6007150, N6007160, N5408430, N3824180
		ENF-VT3	N5779850, N5779860, N6007260, N6007250, K23009470, K23009358

REPLY FORM: QIL FY26-EMEA-20-FY26-043-F MAJ-210 Fragment Detachment

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*