Date: 12-Jan-2026

Olympus reference: QIL FY26-EMEA-19-FY26-077-F-1 ViziShot 2 FLEX (19G)

URGENT: FIELD SAFETY NOTICE

RE: OLYMPUS ViziShot 2 FLEX

Attention: Respiratory Department, Risk Manager or Materials Manager

Material ID	Model/Catalog Number	Product Name	Lot Number(s)	UDI DI
EGNA-U403SX4019	NA-U403SX-4019	ViziShot 2 FLEX (19G)	All	00821925043060

Dear Healthcare Professional / Provider:

Olympus is writing to inform you of a Product Removal action for <u>all</u> lots of the ViziShot 2 FLEX (19G), model: NA-U403SX-4019. The ViziShot 2 FLEX (19G) has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions of the tracheobronchial tree.

<u>Reason for Action:</u>
Olympus received complaints for the ViziShot 2 FLEX (19G) devices in which the hypotube component ejected from the device or plastic components detached during use. Investigation has identified that device heat-shrink material degradation and use errors can cause hypotube component ejection. Additionally, investigation has identified that the device heat-shrink material (which seals the needle) degrades during clinical use and may result in difficulty in extracting or expelling samples, fluid leakage, impaired needle deployment or retraction, or breakage of device components. To mitigate these risks, Olympus is removing all ViziShot 2 FLEX (19G) devices from the market.

<u>Risk to Health:</u>
Hypotube ejection and unintended detachment of plastic components within the tracheobronchial tree can result in a requirement for medical intervention for retrieval and removal.

- In most reported cases, the detached component was identified immediately during bronchoscopy and successfully removed using standard bronchoscopic tools, with no further complications.

- In other cases, the issue was not recognized during the procedure and detached components were later discovered during routine follow-up imaging, often in asymptomatic patients. Most instances of identified foreign body were removed via flexible or rigid bronchoscopy. In rare cases, removal was not attempted or was unsuccessful, and alternative strategies, including surgery, were considered.

- One patient with advanced lung cancer developed infections and empyema months after the procedure. Imaging performed revealed a retained foreign body requiring intervention. The patient

later passed away; however, a direct causal link to the retained device could not be confirmed due to limited information.

- Additional risks include the need for foreign body retrieval, prolonged procedure time, mucosal injury, and bleeding, which may occur due to sharp edges or during removal of the foreign body. Although not reported, pneumothorax and hemoptysis are also possible risks. Potential risks associated with inability to deploy and/or retract the needle include prolonged procedure time, damage to the echoendoscope, and risk of needle stick injury to users upon device withdrawal from the scope.

Olympus does not provide recommendations for medical care beyond standard post-procedural care for patients undergoing these procedures. However, clinicians should consider the potential for retained device components in patients presenting with abnormal symptoms or imaging findings post-procedure. It is notable that some components are not radiopaque, which may complicate detection.

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

1. Examine your inventory and quarantine any identified devices immediately.
2. **Immediately cease use of ViziShot 2 FLEX (19G) devices.**
3. Ensure all users of the device carefully read the content of this notification.
4. If you have affected products in your inventory, please contact Olympus with regard to return of affected products. Olympus will issue a credit to your facility upon return of your affected product.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understand this notification by filling out and returning the completed enclosed Reply Form to your local Olympus representative XXX.
5. If you have further distributed this product, identify your customers, and forward this notification to them.

Your National Competent Authority is aware of the actions described in this notification

Olympus requests that you report any complaints, including breakages and detaching components, to [local facility complaint reporting contact]. Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

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: REPLY FORM
QIL FY26-EMEA-19-FY26-077-F-1 ViziShot 2 FLEX (19G)

Facility Name	
Facility Address	
Contact Name	
Contact E-mail Address	
Contact Telephone Number	

Insert description of the product names and model numbers of the affected products

Catalogue Number	**Lot Number**	**Quantity**

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*