Reference: 2026-X001M

12 January 2026

URGENT: MEDICAL DEVICE REMOVAL

Product: OLYMPUS ViziShot 2 Flex (19G)

Model/Catalog Number	Lot Numbers
NA-U403SX-4019	All

Attention: **Respiratory Department, Risk Manager**

Dear Healthcare Professional,

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>Background:</u>

In August 2025, Olympus issued a field safety notice requesting the partial product removal for specific lots of ViziShot 2 FLEX (19G) devices, manufactured prior to May 12, 2025. These lots received a manual and visual inspection during manufacturing, which may not have identified improperly formed a-traumatic distal needle components. These defects could result in hypotube component ejection, posing a risk during clinical use. The field safety notice also reinforced the existing device instructions for use to reduce the likelihood of the ViziShot 2 FLEX (19G) device becoming damaged during use, and/or reduce the likelihood of a damaged device continuing to be used.

This field safety notice supersedes the previous field safety notice.

<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.

Action Required:
Our records indicate that your facility has purchased one or more of the affected products.
Therefore, Olympus requests 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. Olympus will arrange for the return of your device to Olympus. When it is received, you will receive a credit for your affected device.
5. Olympus requests that you acknowledge receipt of this letter. Indicate on the Response Form that you have received and understand this notification by filling out and returning the completed enclosed Response Form to us.
6. If you have further distributed this product, identify your customers and forwards this notification.

Olympus requests that you report any complaints, including breakages and detaching components and adverse events experienced with the use of this product to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this matter. If you have any questions or concerns, please do not hesitate to contact us for additional information.

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 (Jan 12, 2026 11:18:06 GMT+8)

Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd

RESPONSE FORM

Medical Device Recall - Acknowledgement and Receipt

Response is required

[Name & Address of Hospital/Medical Facility]
[Dept/Attn]

Product: OLYMPUS ViziShot 2 Flex (19G)

Model/Catalog Number	Lot Numbers
NA-U403SX-4019	All

Please distribute this information to the appropriate personnel at your facility, including surgeons who may have received the product which is the subject of this recall notice.

I have read and understand the recall instructions provided in the **12 January 2026** letter.

Yes ☐ No ☐

Any adverse incidents associated with recalled product?

Yes ☐ No ☐

If yes, please explain: _____

Check the applicable boxes below:

☐ I DO NOT have affected device remaining. All have been used or discarded.

☐ I DO have the affected device, which I will return to Olympus.

Lot Number: _____ Quantity to be Returned (UOM): _____

Name: _____

Designation: _____

…… ……

Signature & Company Stamp Date

Please send the completed and signed Response Form to Regulatory Affairs and Quality Assurance Department to [Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com]

2026-X001M Recall - Customer Letter

Final Audit Report 2026-01-12

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