Reference: 2025-X001M

13 August 2025

URGENT: MEDICAL DEVICE REMOVAL

Product: OLYMPUS ViziShot 2 FLEX

Product Name	Model/Catalog Number	Lot Number(s)
ViziShot 2 FLEX (19G)	NA-U403SX-4019	KR257487, KR315608, KR315649, KR383614, KR383639, KR383643, KR433655, KR452836, KR452924, KR453834, KR469783, KR470993, KR471679, KR477649, KR477653, KR478095, KR478194, KR478202.

Table 1: Impacted product

Attention: **Respiratory Department, Risk Manager or Materials Manager**

Dear Healthcare Professional / Provider:

Olympus is writing to inform you of a Removal Action for 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.

Olympus is removing certain ViziShot 2 FLEX (19G) devices due to a potential patient safety issue. Devices manufactured before May 12, 2025, received a manual and visual inspection during manufacturing. Olympus is removing devices manufactured before May 12, 2025 due to the potential for undetected, deformed a-traumatic tips. These defects could lead to hypotube component ejection, posing a risk during use. The devices subject to this removal action are listed in Table 1.

Do not use any ViziShot 2 Flex (19G) device with a lot number listed in Table 1.

Devices manufactured after those listed in Table 1 received an automated inspection, which maximized the detection of deformed a-traumatic tips, and therefore these devices are not affected by this removal action.

In addition to the identified lots of ViziShot 2 FLEX (19G) devices being removed, as listed in Table 1, **Olympus is also reinforcing existing Warnings in the Instructions for Use (IFU)** as set forth in this letter.

This Medical Device Removal does not include any other ViziShot EBUS-TBNA needles, as they do not have the same materials and manufacturing processes that are specific to the ViziShot 2 FLEX.

Reason for Action:

Olympus has received a total of 91 complaints for the ViziShot 2 FLEX (19G) device, where the laser cut hypotube component has ejected from the device, or plastic components have detached. See illustration for identification of the hypotube component. Of these complaints, 43 were reported to regulators as malfunctions, 40 were reported as serious injury (or potential for serious injury), and 1 was reported for potential contribution to a patient death, though a causal relationship could not be determined due to insufficient information received regarding the event. The laser cut hypotube protects the sheath from the needle tip and provides stability during transit and insertion. If device damage occurs, whether detected or undetected and the device continues to be used, the hypotube component has the potential to eject from the device. In addition, if the a-traumatic tip of the ViziShot 2 FLEX (19G) device is improperly formed at the time of manufacturing, and if this is undetected during manufacturing, it could potentially contribute to the likelihood of the hypotube ejecting from the device during use.

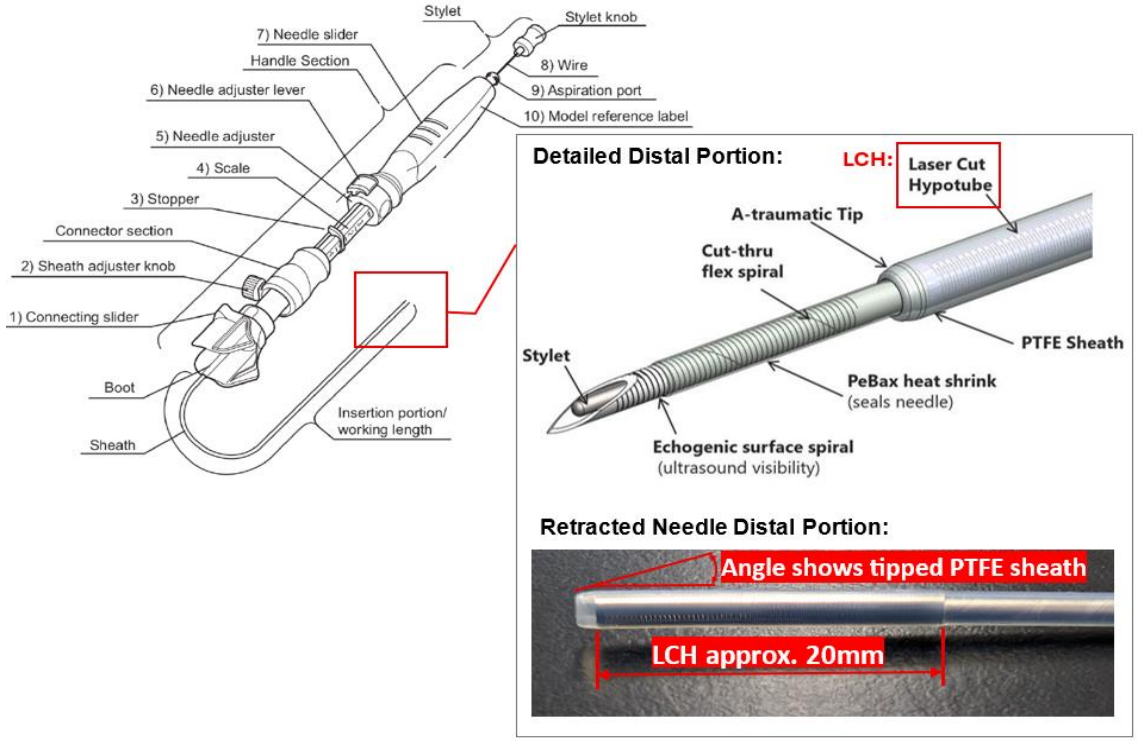

Figure 1: ViziShot 2 Flex Components

Reminder on Instructions for Use

If significant resistance is felt while using ViziShot 2 FLEX (19G) during a procedure and the force continues, this could contribute to the risk of device damage and potential patient injury. Therefore, in addition to identified lots of the ViziShot 2 FLEX (19G) devices being removed, **Olympus is also reinforcing the following existing Warnings** from Section 11 of the current instructions for use (IFU, ref: PN0008807_AH) for all users of the ViziShot 2 FLEX (19G):

- If you feel excessive resistance while operating the needle, do not push the needle slider forcibly.
- Do not force the instrument if resistance to insertion is encountered. Confirm the endoscope is straight and in the neutral position. Attempting to force the instrument could cause patient injury, such as perforation, bleeding, or mucous membrane damage. It could also damage the endoscope and/or the instrument.

To reduce the likelihood of an already damaged instrument being used, **Olympus is reinforcing the following Cautions and Warnings** from Section 6 and Section 11 of the IFU:

- If using the same instrument several times during an operation, confirm there is no irregularity of the instrument before inserting it into the endoscope.
- Prepare and inspect the instrument as instructed [in Section 11], should any irregularity be observed, do not use the instrument; use a spare instead. Damage or irregularity may compromise patient or user safety, such as posing an infection control risk causing tissue irritation, perforation, bleeding, or mucous membrane damage, and may result in more severe equipment damage.
- Do not use an aspiration needle that has an irregularly bent or deformed needle tube.

Risk to Health:

Potential consequences of an ejected Laser Cut Hypotube or detached plastic component of the ViziShot 2 FLEX 19G EBUS-TBNA needle includes the risk of unintended device components within the tracheobronchial tree that may require intervention for removal.

- In most reported cases, the detached component was noticed right away during bronchoscopy. These components were successfully removed using standard bronchoscopic tools, with no further complications.
- In some cases, the issue was not recognized during the procedure. A detached component was later found during routine follow-up imaging, often in patients who showed no symptoms. Most of these components were removed using flexible or rigid bronchoscopy. In rare cases, removal was not attempted or not successful, and alternative strategies (including surgery) were considered.
- There was one instance in which a patient with advanced lung cancer developed infections and empyema months after the procedure. Subsequently, imaging revealed a retained foreign body, which required intervention. The patient later passed away, but a direct link to the retained device could not be confirmed due to limited information.
- Additional Risks to Consider: Mucosal injury and bleeding may occur due to sharp edges or during retrieval. Though not reported, pneumothorax and hemoptysis are possible risks. Longer procedure times may result from needing to replace a damaged device or remove a foreign body.

Olympus does not provide recommendations for medical care in patients who were treated with the impacted devices beyond recommending the standard post-procedural care required of patients undergoing these types of procedures. However, users of this device should note that for patients with abnormal symptoms or image findings post-procedure, the potential for unanticipated retained device components should be assessed. It is notable that some of these components are not radiopaque.

Action steps to be taken by end user:

Our records indicate that your facility has purchased one of the affected products. **Olympus requests you to take the following actions:**

1. Examine your inventory and quarantine any identified devices with the affected lot numbers from Table 1. Refer to the below pictures for the location of the lot number:

Figure 2: Location of Lot Number on Shelf Box

Figure 3: Location of Lot Number on Sterile Tray

2. Ensure all users of the device carefully read the content of this notification, including the reinforced text from the IFU and the product removal information.
    a. If resistance is encountered, do not continue using the device and do not forcibly attempt to insert the device or push the needle slider forcibly.
    b. Confirm the device is free of any irregularity after each pass.
    c. Do not continue to use a device with any irregularity or deformity.
    d. In the event a device from an affected lot number was inadvertently used, ensure you inspect the device after use for any damage or missing components.
3. Olympus will arrange for the return of your device to Olympus. When it is received, you will receive a credit for your affected device(s).
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Response Form that you have received and understood this notification by filling out and returning the completed enclosed Response Form to us.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

Olympus requests that you report 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
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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 NAME: OLYMPUS ViziShot 2 FLEX

Product Name	Model/Catalog Number	Lot Number(s)
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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 **6 August 2025** 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: _____

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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]

2025-X001M Recall - Customer Letter

Final Audit Report 2025-08-13

Created:	2025-08-13 (Australian Western Standard Time)
By:	Seo Ching Yeoh (seoching.yeoh@olympus.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAs_81qs7SLAfL5n89l-ehu190jLzXDL8Y

"2025-X001M Recall - Customer Letter" History

Document created by Seo Ching Yeoh (seoching.yeoh@olympus.com)
2025-08-13 - 8:30:31 AM GMT+8- IP address: 167.103.64.86

Document emailed to Hideki Nagai (hideki.nagai@olympus.com) for signature
2025-08-13 - 8:31:13 AM GMT+8

Email viewed by Hideki Nagai (hideki.nagai@olympus.com)
2025-08-13 - 8:32:51 AM GMT+8- IP address: 104.47.51.126

Document e-signed by Hideki Nagai (hideki.nagai@olympus.com)
Signature Date: 2025-08-13 - 8:34:10 AM GMT+8 - Time Source: server- IP address: 136.226.234.98

Agreement completed.
2025-08-13 - 8:34:10 AM GMT+8