

URGENT MEDICAL DEVICE RECALL

OLYMPUS ViziShot 2 FLEX (19G)

Model/Catalog Number	UDI-DI	Lot Numbers
NA-U403SX-4019	00821925043060	All

Attention: Respiratory Department, Risk Manager or Materials Manager

Dear Healthcare Professional / Provider:

Olympus is writing to inform you of a Product Removal action for all 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.

Background:

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.

Reason for Action:

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. Since the previous field safety notice in August 2025, internal investigations have identified additional contributing factors to hypotube component ejection including device heat-shrink material degradation and use errors. 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.

Risk to Health:

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.

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4. Please contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will arrange for the return of your device to Olympus. Olympus will issue a credit to your facility upon receipt of your affected product(s).
5. Olympus requests that you acknowledge receipt of this letter. Acknowledge receipt of this letter through the Olympus web portal:
 - a. Go to <https://olympusamerica.com/recall>
 - b. Enter the recall number "0486"
 - c. Complete the form as instructed.
6. If you have further distributed this product, identify your customers, and forward this notification to them.

Olympus requests you to report any complaints, including breakages and detaching components, to our Technical Assistance Center (TAC) at 1-800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me by phone at (647) 999-3203 or by email at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Sr. Manager
Field Corrective Action, Americas