

URGENT: MEDICAL DEVICE REMOVAL

OLYMPUS ViziShot 2 FLEX

Product Name	Model/Catalog Number	UDI-DI	Lot Numbers
ViziShot 2 FLEX (19G)	NA-U403SX-4019	00821925043060	Refer to Attachment 1

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 Attachment 1.

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

Devices manufactured after those listed in Attachment 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 Attachment 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.

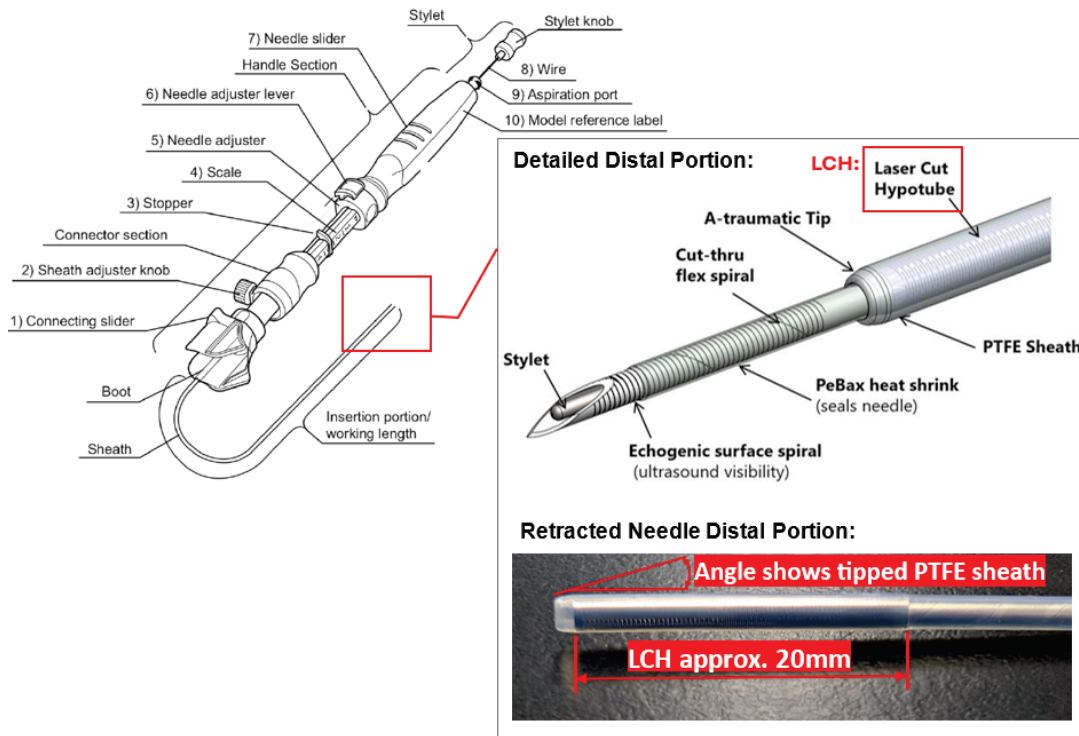


Figure 1: ViziShot 2 Flex Components

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.

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 with the affected lot numbers from Attachment 1. Refer to the below pictures for the location of the lot number:



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. Please contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will issue a credit to your facility upon return of your affected product(s).

4. 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 "0473"
 - c. Complete the form as instructed.
5. 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 e-mail at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Sr. Manager, Field Corrective Action, Americas



Attachment 1: Affected Lot List
US Product Distribution: 04-Aug-2022 to 25-Apr-2025
Expiry Date: 25-Mar-2028 or earlier*

Lot Number	Lot Number	Lot Number	Lot Number	Lot Number	Lot Number
KR226916	KR285017	KR383608	KR401624	KR453811	KR478836
KR226970	KR315608	KR383610	KR401627	KR453821	KR478837
KR227360	KR315626	KR383611	KR405731	KR453834	KR479646
KR227381	KR315614	KR383612	KR429653	KR462508	KR481873
KR227711	KR315623	KR383613	KR429669	KR453828	KR481913
KR227717	KR315625	KR383614	KR429674	KR469783	KR482117
KR232952	KR315631	KR383615	KR433654	KR469800	KR482125
KR232959	KR315639	KR383616	KR433655	KR470017	KR482128
KR232972	KR315642	KR383624	KR435646	KR469779	KR482137
KR232979	KR315649	KR383625	KR435648	KR470993	KR485794
KR232985	KR315651	KR383630	KR435649	KR462514	KR485795
KR232986	KR315652	KR383631	KR435651	KR467945	KR488754
KR233098	KR315659	KR383632	KR435650	KR469750	KR488755
KR233127	KR315660	KR383626	KR435652	KR470025	KR488756
KR233176	KR315670	KR383627	KR435654	KR471679	KR488758
KR233210	KR315671	KR383628	KR435653	KR471005	KR488760
KR248635	KR315677	KR383629	KR442690	KR472669	KR488761
KR248694	KR315684	KR383634	KR442712	KR477649	KR488759
KR238875	KR315686	KR383633	KR442728	KR472671	KR488764
KR238880	KR315689	KR383635	KR442734	KR477646	KR488828
KR248654	KR315691	KR383637	KR442749	KR477647	KR488852
KR248678	KR315721	KR383638	KR443807	KR477648	KR493979
KR248686	KR315724	KR383639	KR443842	KR477650	KR493989
KR248697	KR315692	KR383640	KR443846	KR477653	KR489586
KR248699	KR315695	KR383641	KR451944	KR478094	KR489764
KR248708	KR315701	KR383642	KR442800	KR477652	KR495937
KR248724	KR315708	KR383643	KR452002	KR478095	KR495940
KR248709	KR315726	KR383636	KR452835	KR478096	KR495941
KR248749	KR315737	KR401622	KR443696	KR478097	KR496988
KR257485	KR315740	KR383644	KR452836	KR478098	KR497146
KR257487	KR315744	KR383645	KR452913	KR478099	KR497594
KR257488	KR315750	KR383646	KR452924	KR477651	KR497606
KR257489	KR315767	KR401017	KR452940	KR478127	KR497626
KR257490	KR315771	KR401056	KR452952	KR478172	KR497641
KR257491	KR383607	KR401070	KR452977	KR478194	
KR257486	KR383609	KR401621	KR452980	KR478202	

* Update made on August 19, 2025, to correct/replace lot specific expiry dates with an expiry date range