Date: 8-Aug-2025

Olympus reference: QIL FY26-EMEA-04-FY25-077- Vizishot Flex

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)	Refer to Attachment 1	00821925043060

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.

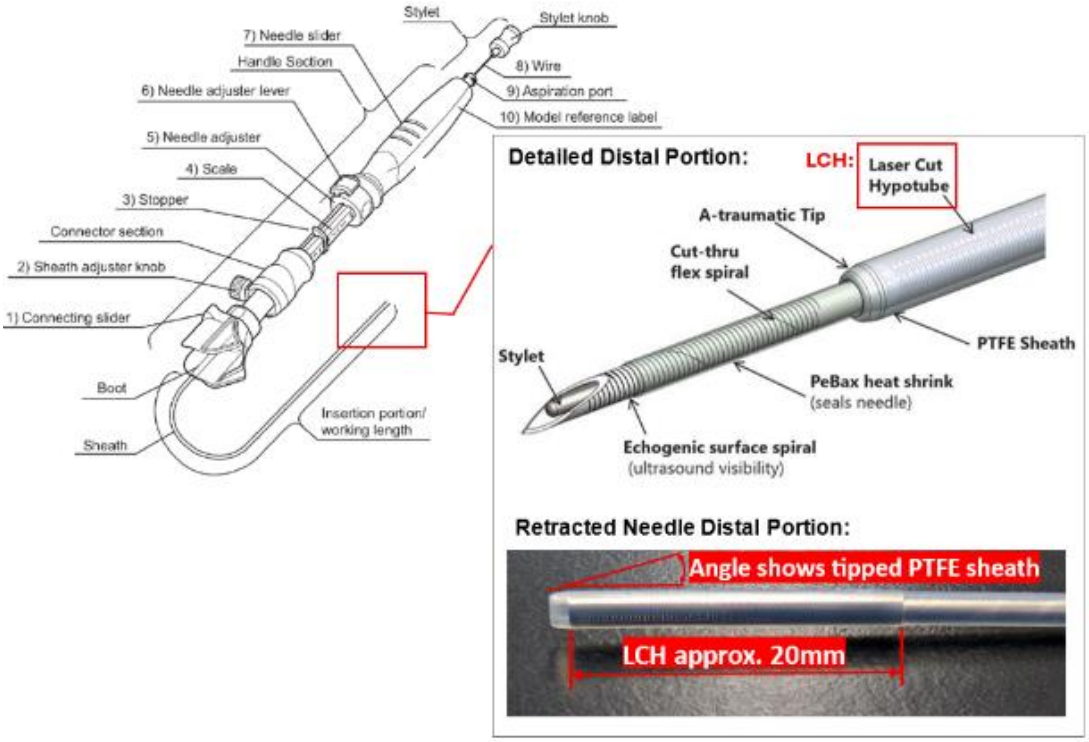

Figure 1: ViziShot 2 Flex Components

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:

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. 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: Affected Lot List

Expiration Date	Lot Number
14/07/2025	KR226916
21/07/2025	KR226970
21/07/2025	KR227360
21/07/2025	KR227381
28/07/2025	KR227711
28/07/2025	KR227717
28/07/2025	KR232952
04/08/2025	KR232959
04/08/2025	KR232972
04/08/2025	KR232979
04/08/2025	KR232985
04/08/2025	KR232986
12/08/2025	KR233098
19/08/2025	KR233127
15/09/2025	KR233176
15/09/2025	KR233210
19/09/2025	KR248635
26/09/2025	KR248694
29/09/2025	KR238875
29/09/2025	KR238880
29/09/2025	KR248654
29/09/2025	KR248678
29/09/2025	KR248686
03/10/2025	KR248697
03/10/2025	KR248699
03/10/2025	KR248708
05/10/2025	KR248724
13/10/2025	KR248709
13/10/2025	KR248749
24/10/2025	KR257485
25/10/2025	KR257487
25/10/2025	KR257488
25/10/2025	KR257489
25/10/2025	KR257490
01/11/2025	KR257491
17/11/2025	KR257486
23/12/2025	KR257486

Expiration Date	Lot Number
01/03/2026	KR285017
01/03/2026	KR315608
06/06/2026	KR315626
06/06/2026	KR315614
06/06/2026	KR315623
06/06/2026	KR315625
15/06/2026	KR315631
15/06/2026	KR315639
22/06/2026	KR315642
13/07/2026	KR315649
13/07/2026	KR315651
13/07/2026	KR315652
13/07/2026	KR315659
13/07/2026	KR315660
13/07/2026	KR315670
13/07/2026	KR315671
13/07/2026	KR315677
13/07/2026	KR315684
17/07/2026	KR315686
17/07/2026	KR315689
17/07/2026	KR315691
27/07/2026	KR315721
27/07/2026	KR315724
31/07/2026	KR315692
31/07/2026	KR315695
31/07/2026	KR315701
31/07/2026	KR315708
31/07/2026	KR315726
08/08/2026	KR315737
17/08/2026	KR315740
24/08/2026	KR315744
24/08/2026	KR315750
24/08/2026	KR315767
24/08/2026	KR315771
31/08/2026	KR383607
31/08/2026	KR383609
07/09/2026	KR383608

Expiration Date	Lot Number
07/09/2026	KR383610
07/09/2026	KR383611
07/09/2026	KR383612
07/09/2026	KR383613
07/09/2026	KR383614
13/09/2026	KR383615
02/10/2026	KR383616
02/10/2026	KR383624
02/10/2026	KR383625
05/10/2026	KR383630
05/10/2026	KR383631
05/10/2026	KR383632
09/10/2026	KR383626
09/10/2026	KR383627
09/10/2026	KR383628
09/10/2026	KR383629
25/10/2026	KR383634
01/11/2026	KR383633
01/11/2026	KR383635
01/11/2026	KR383637
08/11/2026	KR383638
08/11/2026	KR383639
08/11/2026	KR383640
22/11/2026	KR383641
22/11/2026	KR383642
20/12/2026	KR383643
22/12/2026	KR383636
19/01/2027	KR401622
26/01/2027	KR383644
26/01/2027	KR383645
26/01/2027	KR383646
26/01/2027	KR401017
26/01/2027	KR401056
26/01/2027	KR401070
26/01/2027	KR401621
26/01/2027	KR401624
26/01/2027	KR401627

Expiration Date	Lot Number
26/01/2027	KR405731
26/01/2027	KR429653
26/01/2027	KR429669
26/01/2027	KR429674
26/01/2027	KR433654
26/01/2027	KR433655
26/01/2027	KR435646
30/01/2027	KR435648
05/02/2027	KR435649
27/02/2027	KR435651
27/02/2027	KR435650
04/03/2027	KR435652
05/03/2027	KR435654
06/03/2027	KR435653
18/03/2027	KR442690
18/03/2027	KR442712
19/03/2027	KR442728
25/03/2027	KR442734
26/03/2027	KR442749
01/04/2027	KR443807
05/04/2027	KR443842
08/04/2027	KR443846
09/04/2027	KR451944
11/04/2027	KR442800
15/04/2027	KR452002
16/04/2027	KR452835
19/04/2027	KR443696
19/04/2027	KR452836
24/04/2027	KR452913
26/04/2027	KR452924
26/04/2027	KR452940
30/04/2027	KR452952
03/05/2027	KR452977
06/05/2027	KR452980
06/05/2027	KR453811
10/05/2027	KR453821
14/05/2027	KR453834
21/05/2027	KR462508
29/05/2027	KR453828

Expiration Date	Lot Number
19/06/2027	KR469783
20/06/2027	KR469800
27/06/2027	KR470017
11/07/2027	KR469779
17/07/2027	KR470993
17/07/2027	KR462514
17/07/2027	KR467945
17/07/2027	KR469750
17/07/2027	KR470025
17/07/2027	KR471679
18/07/2027	KR471005
30/07/2027	KR472669
30/07/2027	KR477649
31/07/2027	KR472671
01/08/2027	KR477646
07/08/2027	KR477647
13/08/2027	KR477648
14/08/2027	KR477650
21/08/2027	KR477653
21/08/2027	KR478094
22/08/2027	KR477652
27/08/2027	KR478095
03/09/2027	KR478096
03/09/2027	KR478097
04/09/2027	KR478098
05/09/2027	KR478099
09/09/2027	KR477651
12/09/2027	KR478127
10/10/2027	KR478172
16/10/2027	KR478194
16/10/2027	KR478202
17/10/2027	KR478836
17/10/2027	KR478837
24/10/2027	KR479646
06/11/2027	KR481873
12/11/2027	KR481913
12/11/2027	KR482117
05/12/2027	KR482125
18/12/2027	KR482128

Expiration Date	Lot Number
27/12/2027	KR482137
03/01/2028	KR485794
08/01/2028	KR485795
14/01/2028	KR488754
16/01/2028	KR488755
23/01/2028	KR488756
28/01/2028	KR488758
05/02/2028	KR488760
05/02/2028	KR488761
07/02/2028	KR488759
11/02/2028	KR488764
18/02/2028	KR488828
20/02/2028	KR488852
20/02/2028	KR493979
20/02/2028	KR493989
26/02/2028	KR489586
27/02/2028	KR489764
04/03/2028	KR495937
05/03/2028	KR495940
05/03/2028	KR495941
11/03/2028	KR496988
12/03/2028	KR497146
12/03/2028	KR497594
13/03/2028	KR497606
18/03/2028	KR497626
20/03/2028	KR497641
02/04/2028	KR497646
03/04/2028	KR497645
03/04/2028	KR497672
03/04/2028	KR497691
07/04/2028	KR497665
10/04/2028	KR497711
05/05/2028	KR497872
05/05/2028	KR498040
07/05/2028	KR497728
07/05/2028	KR497856
08/05/2028	KR497873
5/21/2027	KR462508

Attachment 2: REPLY FORM
QIL FY26-EMEA-04-FY25-077- Vizishot Flex

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests	

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

Model #	**Lot #**	**Date Shipped**	**Qty Shipped to your facility**	**Qty remaining in Stock**

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*