

URGENT FIELD SAFETY NOTICE

RE: Recall of ViziShot 2 – Single Use Aspiration Needles NA-U401SX

Attention: Endoscopy Department, Pulmonology Department, Risk Management

Material ID	Model	Product Description	Lot Number
EGNA-U401SX4021	NA-U401SX-4021	ViziShot 2 Single Use Aspiration Needle, 21G	Please refer to Attachment 1
EGNA-U401SX4022	NA-U401SX-4022	ViziShot 2 Single Use Aspiration Needle, 22G	

Dear Health Care Provider,

Olympus has become aware of an issue that requires your attention. This letter pertains to certain lot numbers of ViziShot 2 Single Use Aspiration Needles. Please refer to Attachment 1 for a list of the affected lot numbers.

These instruments have been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract.

Olympus became aware of a manufacturing non-conformance pertaining to the angle of the needle in that it did not meet manufacturing specifications and remained unbent. Olympus assessed the situation and concluded that no patient harm is associated with this issue. To date, Olympus has not received any reported complaints or adverse events associated with this matter. Although there is no harm associated with this issue, due to non-conformance to manufacturing specifications, Olympus decided to initiate a recall of affected products.

Action steps to be taken by the end user:

Olympus has determined based upon our distribution records that your facility is in possession of one or more affected devices with a lot number listed in Attachment 1. Olympus requires you to take following actions:

1. Carefully read the content of this Field Safety Notice.
2. Immediately assess any product you have to identify ViziShot 2 Single Use Aspiration Needle 21G/22G with affected lot numbers listed in this communication, cease use of the product, and quarantine any affected product.
3. Contact your Olympus representative at [XXXXXXXX]. Olympus will issue a Return Material Authorization to return any affected product at no charge to you. Olympus will issue a credit to your facility for your affected product.
4. If you have further distributed this product, identify your customers and forward them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedbacks accordingly.
5. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative at [XXXXXXXX] latest by [XX.XX.XXX].

OLYMPUS

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me at **[phone number]** or **[e-mail address]**.

Sincerely,



URGENT FIELD SAFETY NOTICE
ViziShot 2 – Single Use Aspiration Needles NA-U401SX
Attachment 1 – Affected Models and Lots

Material ID	Model	Product Description	UDI	Lot
EGNA-U401SX4021	NA-U401SX-4021	ViziShot 2 Single Use Aspiration Needle, 21G	04953170388248	KR248648
				KR248785
				KR248808
				KR249160
				KR251593
				KR257313
				KR264697
				KR264708
				KR264726
				KR264732
				KR264746
				KR264751
				KR264778
EGNA-U401SX4022	NA-U401SX-4022	ViziShot 2 Single Use Aspiration Needle, 22G	04953170388286	KR248740
				KR248746
				KR253666
				KR260854
				KR260873
				KR260875
				KR260876
				KR260877
				KR260896
				KR260917
KR260937				



REPLY FORM – QIL FY23-EMEA-13

FIELD SAFETY NOTICE ViziShot 2 – Single Use Aspiration Needles NA-U401SX	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]	
[Inventory information (Model and Lot Number(s) of ViziShot 2 Single Use Aspiration Needle, 21G/22G)]	
Model	Lot Number
[Date]	

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity to follow the steps.

Name (Signature) _____
Name (Print) _____
Position _____

Please scan / email your completed paper form response to [XXXXXXXX] latest by [XX.XX.XXX].