

## 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

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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        |                |  |                |          |

