Grena Biomed Ltd.
Chelsea House, Chelsea Street, Nottingham, Nottinghamshire, NG7 7HP, United Kingdom Tel./ Fax +44 115 9704 800

Nottingham, 30.12.2022

FSN Reference Number: 001/2022

Urgent Safety Notice

Our records indicate that your facility received one or more of the products subject to this Field Safety Notice. The table below gives a full list of the affected products.

Affected product	Product Reference Number	Lot Number
NE'X Glue Surgical Adhesive 2ml	0206-NX2	Z/220701
NE'X Glue Surgical Adhesive 5ml	0206-NX5	Z/220701
NE'X Glue Surgical Adhesive 10ml	0206-NX10	Z/220701

Description of the problem:
The Manufacturer has identified that, there is a risk of incorrect syringe plunger packing during manufacturing process. In an unspecified amount of 2 ml products there is a larger plunger intended for larger capacities of the product and in certain amount of 5 and 10 ml the packed plunger is compatible only with 2 ml capacity. The incorrect size of the plunger excludes the usage of the product. The product is packed in a sterile foil pouch and there is no possibility to open the package to check the plunger.

In order to minimize the impact on patients, including the disruption of any surgical procedure, the Manufacturer is requesting that the following steps are taken for stock located at the distributor warehouse and any stock that has been distributed onwards to customers:

1. Distributor is to confirm receipt of this Filed Safety Notice (Recall Notice).
2. Identify the device held in stock at the Distributor's warehouse and quarantine the stock.
3. Make this Filed Safety Notice (Recall Notice) available to each end user (Hospital) that the Distributor has supplied.
4. All products still in the end user's stock must be returned to the Distributor.
5. Confirmation that all such stock has been returned and that no other affected product is left at end user's stock must be obtained by the Distributor.
6. Confirmation using the attached Filed Safety Notice Respond Form of the disposition of all stock should be sent to Manufacturer.
7. The Distributor shall inform The Manufacturer of the quantities to be returned and exchanged.

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8. The device shall then be returned to the Manufacturer for disposition and the Distributor will be compensated for the carriage fees.
9. Replacement products, as appropriate, free of the fault, will be provided by the Manufacturer.

We request that you respond to this notice via Filed Safety Notice Response Form as a matter of urgency a not later than within one week from the date of receipt. We appreciate your cooperation, and we recognize any inconvenience that may have been caused to you.

If you need any support concerning this notice, please contact below reference departments:
International Customer Service:
Mail: sales@grena.co.uk
Quality Assurance Department:
Mail: quality@grena.co.uk

The Competent (Regulatory) Authority of your country was informed about this notice.

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected device have been transferred. (As appropriate)

Please transfer this notice to any other organizations impacted by this action. (As appropriate)

Please maintain awareness of this notice and resulting actions for an appropriate period to ensure effectiveness of the corrective actions.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority, if appropriate, as this provides important feedback.

Thank you for consideration.

Iwona Michalska
Quality Director

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Filed Safety Notice Response Form

Field Safety Notice (FSN) information	
FSN Reference number	FSN 001/2022
FSN Date	30.12.2022
Product/ Device name	NE`X Glue Surgical Adhesive
Product Reference Number	0206-NX2 0206-NX5 0206-NX10
Batch/Lot(s)	Z/220701
Customer Details	
Distributor/Importer Organization Name*	
Healthcare Organisation Name*	
Organisation Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	
Customer action undertaken on behalf of Healthcare Organization	
I confirm receipt of the Field Safety Notice and that I read and understood its content *(Customer to complete or enter N/A)* ☐ YES ☐ N/A	
The information and required actions have been brought to the attention of all relevant users and executed. *(Customer to complete or enter N/A)* ☐ YES ☐ N/A	

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No affected devices are available for return/ destruction *(Customer to complete or enter N/A)*

☐ YES ☐ N/A

Product(s) listed below will be returned:

Product reference number	Product name	Batch /LOT	Qty
0206-NX2	NEXGlue Surgical Adhesive 2 ml		
0206-NX5	NEXGlue Surgical Adhesive 5 ml		
0206-NX10	NEXGlue Surgical Adhesive 10 ml		
Print Name			
Signature			
Date			

**Choose as appropriate*