Surgical Innovations

URGENT FIELD SAFETY NOTICE

FSN Reference Number:

22-001 (Issue 2 – Update)

RECALL

Date: 10 June 2022

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	Part Number	Lot number
YelloPort Elite Universal Seal	EA512US	All

Description of the problem:

Surgical Innovations have identified that, during the manufacturing process, there is a risk of the formation of a hole in the sterile packaging which typically forms near the pre-sealed area at the bottom of the sterile packaging of the YelloPort Elite Universal Seals.

The device in question is not in direct patient contact, but indirect contact exists. The possible health consequence would be an infection caused by non-sterile devices transferring bioburden to an instrument and then this being transferred by the instrument to a patient

An initial internal investigation has been conducted, a series of drop tests in accordance with ASTM 7386-16 were conducted without any failures. A simulation of the internal manufacturing processes was able to replicate the failure therefore Surgical Innovations are confident that this failure occurs during the manufacturing process and not during the external distribution of the devices.

The IFU (479-5002 Rev. 9) contains the following statement: The Universal Seal and 5mm single use seal: *Contents sterile unless package has been opened or damaged. Sterile packaging should be inspected for integrity prior to use.* The following symbol below which is included on the product packaging: *Do not use if package is damaged.*

In order to minimise the impact on patients, including the disruption of surgical procedures, Surgical Innovations is requesting that the following steps are taken for **stock located at the distributor warehouse and any stock that has be distributed onwards to customers**:

1. Distributor to confirm receipt of this Field Safety Notice (Recall Notice).
2. Identify the devices held in stock at the Distributor and quarantine all stock.
3. Issue this Field Safety Notice (Recall Notice) to each end user (Hospital) that the Distributor has supplied.
4. All product still in stock at end users must be returned to the Distributor.
5. Confirmation that all such stock has been returned and that any other product has been successfully used must be obtained by the Distributor.
6. Confirmation using the attached form of the disposition of all stock.
7. The distributor shall inform Surgical Innovations of the quantities and an RMA will be provided by Surgical Innovations for return of all of the product to Surgical Innovations.
8. The devices shall then be returned to Surgical Innovations for disposition and the Distributor compensated for the carriage fees.
9. Replacement devices, as appropriate, which do not have this issue, will be provided by Surgical Innovations.

This applies to all shipments received of Universal Seal therefore we also require confirmation of any devices that have already been used successfully.

Surgical Innovations Limited

Part of the **Surgical** Innovations Group Plc

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Type of Action to mitigate the risk	
Action to be Taken by the User	
☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other Confirm all devices either returned or already used. ☐ None	
By when should the action be completed?	Devices must be returned to Surgical Innovations for inspection, the devices must be returned by 04 July 2022.
Is customer Reply Required?(If yes, form attached specifying deadline for return)	Yes
Actions Being Taken by the Manufacturer	
☒ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	

General Information	
FSN Type	Update
For updated FSN, reference number and date of previous FSN	N/AFSN 22-001 (initial issue), 07 Jun 2022
For Updated FSN, key new information as follows:	
We are now recalling all devices shipped before 07-Jun-2022 for inspection at our premises	
Further advice or information already expected in follow-up FSN?	No
If follow-up FSN expected, what is the further advice expected to relate to:	
N/A	
Anticipated timescale for follow-up FSN	N/A
Manufacturer information	
a. Company Name	**Surgical Innovations Ltd**
b. Address	**Clayton Wood House, 6 Clayton Wood Bank, Leeds, LS16 6QZ, United Kingdom**
c. Website address	**www.surginno.com**
d. Email	**quality@surginno.co.uk**
e. Telephone	**+44(0)1132307597**
The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	

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Transmission of this Field Safety Notice

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

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

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

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 your consideration.

Stephen Seed
Chief Compliance Officer

10 - JUN - 2022
Date

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