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XX May 2023

# URGENT: FIELD SAFETY NOTICE – SUR-23-4657

## Ventralight™ ST Mesh with Echo PS™ Positioning System

**REF:** See Table 1 **Lot Numbers:** See Table 1

**Type of Action**: Product Removal

### Attention: Healthcare providers, Procurement/Purchasing Managers

This letter contains important information which requires your **immediate** attention.

Dear customer,

BD is conducting a Field Safety Corrective Action to remove specific lots of **Ventralight™ ST Mesh with Echo PS™ Positioning System**. According to our distribution records your organisation may have received the impacted product in Table 1. Product was distributed between 3rd November 2022 and 29th November 2022.

Manufacturer's SRN: US-MF-000017971

| Product Code (REF) | Lot Number | Expiry Date | UDI |
|---|---|---|---|
| 5955450 (4.5" Circle) | HUGS2015 | 28 April 2024 | (01)00801741031717(17)240428(10)HUGS2015 |
| | HUGS2020 | 28 April 2024 | (01)00801741031717(17)240428(10)HUGS2020 |
| | HUGS2061 | 28 May 2024 | (01)00801741031717(17)240528(10)HUGS2061 |
| | HUGS2076 | 28 April 2024 | (01)00801741031717(17)240428(10)HUGS2076 |
| | HUGT1582 | 28 May 2024 | (01)00801741031717(17)240528(10)HUGT1582 |
| 5955460 (4"x 6" Ellipse) | HUGS2031 | 28 May 2024 | (01)00801741031724(17)240528(10)HUGS2031 |
| | HUGS2079 | 28 April 2024 | (01)00801741031724(17)240428(10)HUGS2079 |
| | HUGT1627 | 28 May 2024 | (01)00801741031724(17)240528(10)HUGT1627 |
| | HUGT1989 | 28 June 2024 | (01)00801741031724(17)240628(10)HUGT1989 |
| 5955460G (4"x 6" Ellipse) | HUGS2043 | 28 April 2024 | (01)00801741201967(17)240428(10)HUGS2043 |
| | HUGT1988 | 28 June 2024 | (01)00801741201967(17)240628(10)HUGT1988 |

**Table 1: Impacted product**

This product removal is limited to the product codes and lot numbers listed in Table 1. No other product codes or lot numbers are affected.

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## Description of the problem

BD has identified through customer complaints that the **Ventralight™ ST Mesh with Echo PS™ Positioning System** has the potential to exhibit failure to inflate the balloon component of the positioning system, due to an inadequate seal of the balloon material.

## Clinical risk

The **Ventralight™ ST Mesh with Echo PS™ Positioning System** balloon may not inflate as intended. If the balloon does not inflate during laparoscopic ventral hernia repair this may result in a delay or prolongation of the procedure, inadequate mesh placement, erosion/migration, pain and mesh infection.

If complications are encountered while using these products, the health consequences can be serious and may require additional procedures including transitioning to manual mesh placement and the placement of additional trocars. Long-term health consequences may occur and include, but not limited to, fistula formation, implant failure and recurrence of the hernia.

To date, BD has received 15 complaints in relation to this issue, none of which have resulted in adverse events.

## BD Actions:

BD is implementing actions to prevent recurrence of this product issue.

### Advice to Clinical Users

1. Healthcare facilities and providers are instructed to discontinue use of the impacted products and select an appropriate equivalent product for performing laparoscopic ventral hernia repair.
2. Patients who have undergone laparoscopic ventral hernia repair with the **Ventralight™ ST Mesh with Echo PS™ Positioning System** where the balloon has failed, do not require immediate explantation of the mesh however, these patients should be monitored at the discretion of the treating physician.

## Customer Actions:

- Identify and quarantine all unused affected **Ventralight™ ST Mesh with Echo PS™ Positioning System**.
- Make a note of the lot numbers and destroy all unused affected units.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 29th May 2023**.
- Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.
- If you experience any issues with **Ventralight™ ST Mesh with Echo PS™ Positioning System**, please report as a complaint as per your normal process.

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**Distributor Actions:**

- Cease distribution.
- Identify, quarantine, make a note of the lot numbers then destroy all unused affected **Ventralight™ ST Mesh with Echo PS™ Positioning System.**
- Identify the facilities where you have distributed affected product and notify them immediately of this notice.
    - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **29th May 2023**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- If you experience any issues with **Ventralight™ ST Mesh with Echo PS™ Positioning System**, please report as a complaint as per your normal process.

| | End User with Inventory | End User with ZERO inventory | Where to send completed form |
|---|---|---|---|
| Purchased **directly** from BD | Complete the form in its entirety.<br><br>Upon receipt, BD will process the response, and you will receive replacements for unused product | Complete form and check the box indicating "no inventory" | <<insert BD email address>> |
| Purchased from a **distributor/3rd party** | Complete all fields on the form and contact your distributor to arrange for replacements as available or credit. | Complete form and check the box indicating "no inventory" | Return the form to your distributor |

**Contact reference person**

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

[redacted]

[redacted]
Associate Director, Post Market Quality
EMEA Quality

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# Customer Response Form – SUR-23-4657

## Ventralight™ ST Mesh with Echo PS™ Positioning System

**REF:** See Table 1 **Lot Numbers:** See Table 1

Return to <*<insert fax/email address here>>* as soon as possible or **no later than the 29th May 2023.**

- **I confirm this Field Safety Notice has been read, understood and that all recommended actions have been implemented as required.**

*Tick the appropriate box below*

☐ We do not have any of the affected product as listed in **Table 1** in our facility. Affected product has been used.

***All product that is not available for destruction will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified.***

**OR**

☐ We have the following units of the affected product as listed in **Table 1** in our possession and I confirm that the units have been destroyed *(Please complete the table below with the lot number and the number of units destroyed. Replacement product will only be sent on completion and return of this form).*

| REF: | Lot Number/s: | Units destroyed *(insert quantity below)* |
|---|---|---|
| | | |
| | | |

| | |
|---|---|
| **Account/Organisation Name:** | |
| **Department** *(if applicable)*: | |
| **Address:** | |
| **Postcode:** | **City:** |
| **Contact Name:** | |
| **Job Title:** | |
| **Contact Telephone Number:** | **Contact E-mail Address:** |
| **Name of your supplier for this product** *(if not direct from BD)* | |
| **Signature:** | **Date:** |

*This form must be returned to BD before this action can be considered closed for your account.*If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*