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27th October 2022

**PRODUCT NOTIFICATION – SUR-22-4516**

**Genesis™ STERRAD® Reusable Rigid Sterilization Container Systems**

**REF:** See Table 1 **Lot Numbers:** All lot numbers

**Type of Action**: Product Removal

Dear Customer,

BD is issuing this product notification to remove the **Genesis™ STERRAD® Reusable Rigid Sterilization Container Systems**. According to our distribution records your organisation may have received the impacted product in table 1. Product was distributed between July 2011 and May 2017.

| Product Code (REF) | Product Name | Lot Number | UDI |
|---|---|---|---|
| CD0-3ST | Genesis™ STERRAD® Mini Container, PERF | All Lot numbers | 10885403018886 |
| CD1-4ST | Genesis™ STERRAD® Half Length Container, PERF | | 10885403018978 |
| CD1-5ST | Genesis™ STERRAD® Half Length Container, PERF | | 10885403019012 |
| CD3-7ST | Genesis™ STERRAD® Full Length Container, PERF | | 1088540301943 |
| CD5-3ST | Genesis™ STERRAD® Large, Shallow Container, PERF | | 10885403019562 |
| CD5-61ST | Genesis™ STERRAD® Large, Shallow Container, PERF | | 10885403019593 |

**Table 1: Impacted product**

This product removal is limited to the product codes listed in Table 1. No other product codes are affected. Appendix 1 demonstrates how to identify the product.

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**No other products within the Genesis™ Sterilization Containers portfolio are impacted by this product removal.**

## Description of the Problem

BD has determined that the **Genesis™ STERRAD® Reusable Rigid Sterilization Containers** have not consistently met the requirements for aerosol challenge testing. This could potentially result in a breach of sterility under conditions outside of normal use as indicated in the Instructions For Use, which might lead to transmission of infectious pathogens to the surgical patient. This could lead to clinical signs of localised and/or systemic infection including fevers/chills, abscess formation, mild-moderate sepsis, and further worsening if untreated.

There have been no reports of adverse events associated with this issue.

## Actions to be taken by BD

BD will issue credit to customers that purchased product directly from BD during the warranty period of May 2019 to August 2022, following receipt of the completed Customer Response Form.

## Actions to be taken by the DISTRIBUTOR/ PRODUCT SUPPLIER:

1. Inspect your inventory, locate and quarantine any units of the impacted product. Appendix 1 demonstrates how to identify the product.
    a. Make a note of the quantity quarantined, then destroy all affected product.
    b. Please note the following materials for each component and dispose of them accordingly:

| Component | Material |
|---|---|
| Container (bottoms, lids, retention plates) | Anodized aluminium 5000 and 1100 series, stainless steel 300 series |
| Gasket and handle grips | Silicone |
| Baskets (if applicable) | 304 Stainless Steel |

2. If you have further distributed the product, identify those facilities and notify them at once of this product notification and have them destroy the affected product.

3. If you experience any issues with the **Genesis™ STERRAD® Reusable Rigid Sterilization Containers**, please report as a complaint as per your normal process.

4. Complete and sign the Customer Response Form on page 5 and return it to **<<insert contact details here>> as soon as possible or no later 30th November 2022** indicating the following:
    - the number of units destroyed, **OR**

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- that your organisation does not have any impacted units left in inventory.

**Note**: If you no longer have the product in your possession, it is still important that you return the Customer Response Form for our reconciliation purposes.

**Actions for the END USER/ HEALTHCARE ORGANISATION:**

1. Inspect your inventory, locate and quarantine any units of the impacted product. Appendix 1 demonstrates how to identify the product.
   a. Make a note of the quantity quarantined, then destroy all affected product.
   b. Please note the following materials for each component and dispose of them accordingly:

| Component | Material |
|---|---|
| Container (bottoms, lids, retention plates) | Anodized aluminium 5000 and 1100 series, stainless steel 300 series |
| Gasket and handle grips | Silicone |
| Baskets (if applicable) | 304 Stainless Steel |

2. Circulate this product notification to all those within your organisation that may use the **Genesis™ STERRAD® Reusable Rigid Sterilization Containers.**

3. If you have further distributed the product, please identify those users and notify them at once of this product notification. Ensure they follow the instructions listed in this notice.

4. If you experience any issues with the **Genesis™ STERRAD® Reusable Rigid Sterilization Containers**, please report as a complaint as per your normal process.

5. Complete the customer response form on page 5 and return the **completed Customer Response Form to YOUR DISTRIBUTOR/ PRODUCT SUPPLIER as soon as possible or no later than 24th November 2022** indicating the following**:**
   - the number of units destroyed **OR**
   - that your organisation does not have any impacted units left in inventory

**Note**: If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

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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,

Lorna Darrock
Associate Director, Post Market Quality
EMEA Quality

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# Customer Response Form – SUR-22-4516

## Genesis™ STERRAD® Reusable Rigid Sterilization Container Systems

**REF:** See Table 1 **Lot Numbers:** All lot numbers

Return to <*<insert email address here>>* as soon as possible or **no later than the 30th November 2022**

- **I confirm this 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 possession.

**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 product code and the number of units destroyed).*

| **REF:** | **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 Product notification via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*

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# Appendix 1 – Product identification

The **Genesis™ STERRAD® containers** are unique in their appearance. The base of the container has fuchsia silicone handles and end plates. The containers include labels on the data block that identify the catalog number. The underside of the lid has a fuchsia gasket.

**No other products within the Genesis™ Sterilization Containers portfolio are impacted by this product removal.**


**Figure 1**: Front image of container with fuchsia silicone handles and end plate also showing product identification


**Figure 2**: Identification label on container includes catalog number, description, and lot information

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**Figure 3**: Image showing the underside of the lid with the fuchsia silicone gasket