

To: Operating Room Director or Risk Manager
From: Stryker Instruments, Post Market Regulatory Department
Date:
Subject: Stryker SmartLife Large Aseptic Housings

Dear Customer,

The purpose of this letter is to remind you of the recommended cleaning instructions for the Stryker SmartLife Large Aseptic Housings (7126-120-000). A small subset of customers have experienced product issues based on cleaning practices that are causing a deterioration of the housing. This letter is for your awareness only, as we have not seen a trend of these failures at your facility.

The SmartLife Aseptic Housings are designed to be used in conjunction with the SmartLife Non-Sterile Batteries for System 7 Handpieces, Cordless Driver 4 Handpiece, and Sabo2 Sagittal Saw Handpiece.

Several factors can adversely influence the structural integrity of the device. Below are some suggestions for you to review from the Heavy Duty Care Instructions/Instructions for Use to help reduce undue strain on the housing material:

- We recommend following sterilization/autoclaving instructions in the Care Instructions.
- We have identified that some customers are applying a pre-treatment to the device, please note that the Care Instructions advise the following that pertain to the application of pretreatments (Reference Page 12 of the Heavy Duty Care Instructions):

"ALWAYS make sure the detergent solution is completely rinsed from the interior and exterior of the equipment before drying the equipment."

"ALWAYS prepare the detergent solution according to the manufacturers' recommendations. Pay particular attention to the concentration used and the total dispersion."
- We recommend when using an auto-washer, assure the appropriate parameters (rinse time/settings) are used as instructed in the Care Instructions (Reference Page 21 of the Heavy Duty Care Instructions). Additionally:

"Unload the washer-disinfector and visually inspect the equipment for remaining soil or detergent solution. If soil or detergent solution remains, repeat the cleaning procedure using fresh detergent solution."

Utilizing cleaning practices outside of the IFU could lead to the housing separating at the weld. The health risk associated with the separation of the housing at the weld, is a potential breach in sterility, which may require medical or surgical intervention.

If you are already following the recommended cleaning instructions, no action is required of you at this time; this letter is for your awareness only. As a reminder, any failures or negative experiences with a Stryker product should be reported to Stryker <insert local complaint contact here>.

Thank you,

Stryker Instruments

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To: Operating Room Director or Risk Manager
From: Stryker Instruments, Post Market Regulatory Department
Date:
Subject: Stryker SmartLife Large Aseptic Housings

Dear Customer,

The purpose of this letter is to notify you that Stryker Instruments will be replacing your SmartLife Large Aseptic Housings (7126-120-000) due to a trend of weld failures identified at your facility. The SmartLife Aseptic Housings are designed to be used in conjunction with the SmartLife Non-Sterile Batteries for System 7 Handpieces, Cordless Driver 4 Handpiece, and Sabo2 Sagittal Saw Handpiece.

Utilizing cleaning practices outside of the IFU and outside instructions provided by cleaning agent manufacturers could lead to material degradation and the housing separating at the weld. The health risk associated with the separation of the housing at the weld, is a potential breach in sterility, which may require medical or surgical intervention.

Due to the trend of weld failures at your facility, we would like to replace your current supply of SmartLife Large Aseptic Housings with our System 6 Aseptic Housings or place you on a SmartLife Aseptic Housings replacement program. Your Stryker Sales Representative will be contacting you to determine the best solution for your facility.

Additionally, we would like to remind you of some of the cleaning recommendations in the IFU. Following these recommendations should further reduce the failures at your facility:

- We recommend following sterilization/autoclaving instructions in the Care Instructions.
- We have identified that some customers are applying a pre-treatment to the device, please note that the Care Instructions advise the following that pertain to the application of pretreatments (Reference Page 12 of the Heavy Duty Care Instructions):

"ALWAYS make sure the detergent solution is completely rinsed from the interior and exterior of the equipment before drying the equipment."

"ALWAYS prepare the detergent solution according to the manufacturers' recommendations. Pay particular attention to the concentration used and the total dispersion."
- We recommend when using an auto-washer, assure the appropriate parameters (rinse time/settings) are used as instructed in the Care Instructions (Reference Page 21 of the Heavy Duty Care Instructions). Additionally:

"Unload the washer-disinfector and visually inspect the equipment for remaining soil or detergent solution. If soil or detergent solution remains, repeat the cleaning procedure using fresh detergent solution."

Please refer to the instructions below to receive your replacement housings:

1. Immediately review this Customer Letter.
2. A Stryker representative will contact your facility to determine the best replacement solution for your facility.
3. Complete the enclosed Business Reply Form (BRF) to confirm receipt of this notification and identify how many, if any, affected items are currently in your inventory. Please complete and return the BRF even if you don't have any affected product on hand. **Note:** Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the Notification.
4. Fax the completed Business Reply Form to Stryker Instruments Regulatory Department, (insert Fax Number here), or scan and email a copy to (insert local contact here).



5. Upon the receipt of the completed, signed Business Reply Form, your facility will be placed on the list to receive replacement product. As soon as replacement product is available, you will be informed, via email, that the replacement product is being shipped.
6. Upon receipt of the replacement product, remove all affected SmartLife Large Aseptic Housing(s) from use and replace them with the new devices.
7. Return all product to Stryker. (Insert method of return here)

Thank you,

Stryker Instruments

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Stryker Instruments

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BUSINESS REPLY FORM

PRODUCT: Stryker SmartLife Large Aseptic Housings

Product Number	Quantity on Hand	Indicate Replacement Preference: "SmartLife" or "System 6"
7126-120-000		

If you don't have any affected SmartLife Large Aseptic Housings on hand, please indicate "0" in the "Quantity on Hand" box (above). A no charge replacement order will be generated for any affected units remaining in your inventory. **(No charge PO# (if applicable) _____)**

Please refer to the instructions below to receive your replacement housings:

1. Immediately review this Customer Letter.
2. A Stryker representative will contact your facility to determine the best replacement solution for your facility.
3. Complete this Business Reply Form (BRF) to confirm receipt of this notification and identify how many, if any, affected items are currently in your inventory. Please complete and return the BRF even if you don't have any affected product on hand. **Note:** Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the Notification.
4. Fax the completed Business Reply Form to Stryker Instruments Regulatory Department, (insert Fax Number here), or scan and email a copy to (insert local contact here).
5. Upon the receipt of the completed, signed Business Reply Form, your facility will be placed on the list to receive replacement product. As soon as replacement product is available, you will be informed, via email, that the replacement product is being shipped.
6. Upon receipt of the replacement product, remove all affected SmartLife Large Aseptic Housing(s) from use and replace them with the new devices.
7. Return all product to Stryker. (Insert method of return here)

Acct:

Account #:

Print Customer Name

Customer Title

Contact Phone Number

Customer Signature

Date

Email Address

Fax Number

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