



URGENT FIELD SAFETY NOTICE: RA2016-193
Stryker SmartLife Large Aseptic Housings

ATTN: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

March 16, 2017

FSCA Identifier: RA2016-193

Type of Action: Field Safety Notice

Catalogue Numbers: 7126-120-000

Product description: 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**>.



We request that you read this notice carefully and complete the following actions:

1. Circulate this Field Safety Notice internally to all interested/affected parties.
2. Inform Stryker if any of the subject devices have been distributed to other organisations.
 - a) Please provide contact details so that Stryker can inform the recipients appropriately.
 - b) If you are a Distributor, note that you are responsible for notifying your affected customers.
3. Please inform Stryker of any adverse events concerning the use of the subject devices.
 - a) Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
4. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.
5. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA

We request that you respond to this notice within 7 calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours Sincerely,

XXXXXX



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Acknowledgement Form

FSCA Identifier: RA2016-193
Type of Action: Field Safety Notice
Catalogue Numbers: 7126-120-000
Product description: Stryker SmartLife Large Aseptic Housings

I acknowledge receipt of the Field Safety Notice for the RA2016-193, I have read this notice carefully and complete the actions.

Acct:

Account #:

Print Customer Name

Customer Title

Contact Phone Number

Customer Signature

Date

Email Address

Fax Number

**If you have further distributed any affected product, please indicate to whom below
(attach additional sheets as necessary):**

Name Address City State Zip Contact

Person

Product(s)