



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**>.



URGENT FIELD SAFETY NOTICE: RA2016-193
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)