stryker

FIELD SAFETY NOTICE

RA2016-193

SmartLife Large Aseptic Housings

Attn: Risk Manager, Materials Manager, OR Director
Date

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

Dear Customer,

This letter is in follow up to the FSN issued in 2017, and 2019. The purpose of this letter is to provide information regarding the life expectancy for the Stryker SmartLife Large Aseptic Housings.

Product description:
The SmartLife Aseptic Housings are designed to be used in conjunction with the SmartLife Non-Sterile Batteries for System 7 Handpieces, System 8 Handpieces, Cordless Driver 4 Handpiece, and Sabo2 Sagittal Saw Handpiece.

Reason for this notice:
During the design of a device, verification and validation testing is conducted to ensure specified requirements are met and to confirm the device will perform as intended. As part of the design process for this product, the SmartLife Large Aseptic Housings are designed and tested for 100 uses.

Several factors can adversely influence the reliability of the device. The Heavy Duty Processing Instructions should be followed to reduce undue strain of the housing material and mitigate the risk of the housing separating at the weld. Utilizing cleaning practices outside of the Processing Instructions or continued usage exceeding 100 uses could lead to the potential of the housing separating at the weld.

Risk to health:
The health risk associated with weld-seperation includes the potential breach of sterility at the patient's surgical site, possible bone or soft tissue damage, and infection, which may require medical or surgical intervention.

Actions to be taken by the customer/user:
Routine and careful inspection are the best methods for determining the functional condition of the device. If the equipment fails to meet the inspection and testing criteria, contact your Stryker sales representative or your nearest Stryker subsidiary.

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

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.

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:

Sincerely,

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