4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700
www.stryker.com

stryker®
Instruments

URGENT MEDICAL DEVICE RECALL NOTIFICATION

RE: STRYKER SMARTLIFE® ASEPTIC HOUSINGS

ATTENTION: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

October 8, 2014

Dear Customer,

The purpose of this letter is to advise you that Stryker Instruments is voluntarily recalling the following Stryker SmartLife® Aseptic Housings.

Stryker Product	Product Description	Lot Numbers Affected by Recall	Dates of Distribution
7126-120-000	SmartLife® Large Aseptic Housing	All Lot Numbers from 13027 to 14093	Apr 9, 2013 – May 2, 2014
7222-120-000	SmartLife® Small Aseptic Housing	All Lot Numbers from 13027 to 14093	Apr 9, 2013 – Apr 29, 2013

Reason for the Voluntary Recall:

The SmartLife® Aseptic Housings are being recalled because intended testing was not conducted and products may have a potentially insufficient weld which could result in the top section of the housing separating from the bottom section of the housing. As part of the manufacturing, periodic testing to verify the consistency of the welds between the two sections of the housing was not conducted. Therefore, changes in the quality of the weld may not have been detected and may be less effective than intended.

Photos have been provided, on page 2, to show the location of the weld, product number, and lot number. On page 3, photos show a comparison between a weld with deterioration/cracking and a weld without deterioration/cracking.

Product Description:

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.

Risk to Health:

Separation of the two sections of the housing could lead to product being unavailable for surgery, delay in surgery of <15 minutes while a backup is prepared, loss of surgical control due to loss of mechanical connection between the handpiece and the battery, intra-operative complications and/or breach of the sterile field. These situations could result in additional anesthesia (<15 minutes), bone fracture, additional surgical steps, soft tissue injury or infection.

For questions regarding this recall please contact Stryker Instruments:

Kara Spath
269-389-4518
kara.spath@stryker.com

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Photo 1: The weld line is illustrated by a *yellow line* in the photo and continues around the exterior of the smaller portion of the housing. The *yellow line* does not exist on the product. It has been added to the photo to identify the location of the weld.

Photo 2: Product Number is on the exterior of the lid in white. The *yellow box* does not exist on the product. It has been added to the photo to identify the location.

Photo 3: Lot Number is etched on the interior of the lid. The *yellow box* does not exist on the product. It has been added to the photo to identify the location.

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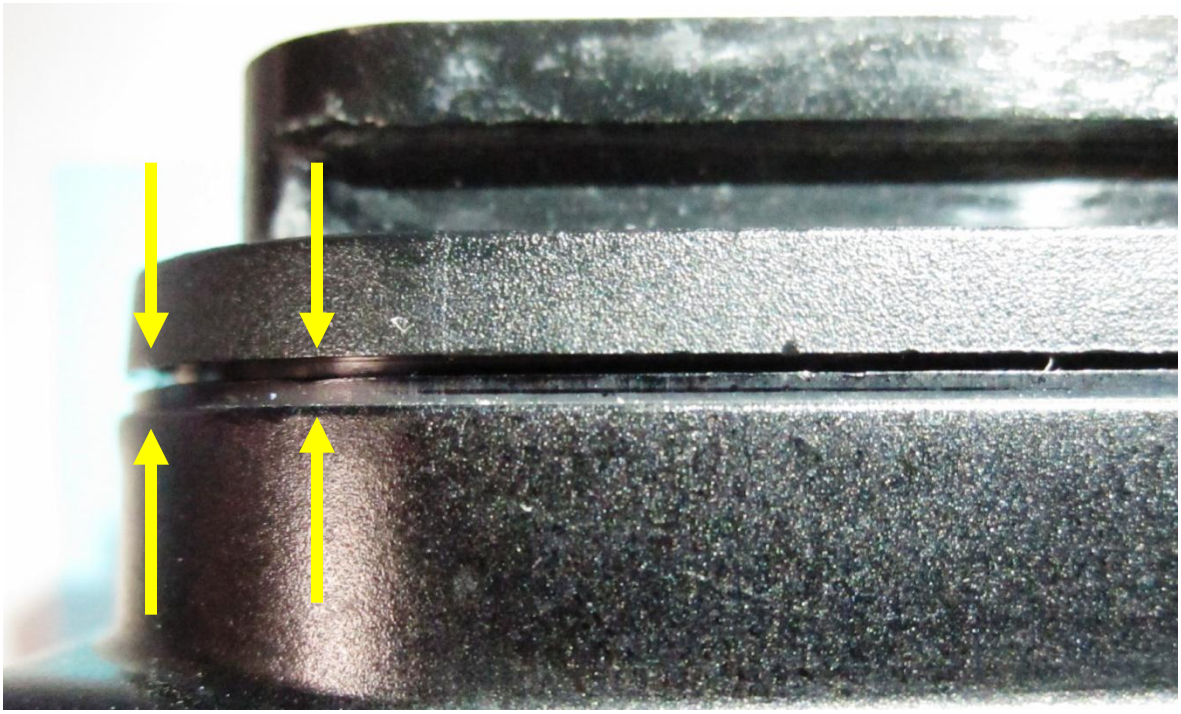

Photo 4: The weld line in Photo 4 shows signs of deterioration and cracking that can be visually detected. During inspection, look for cracking or separation of the solid weld line. If any damage is noticed, the battery housing should be removed from use.

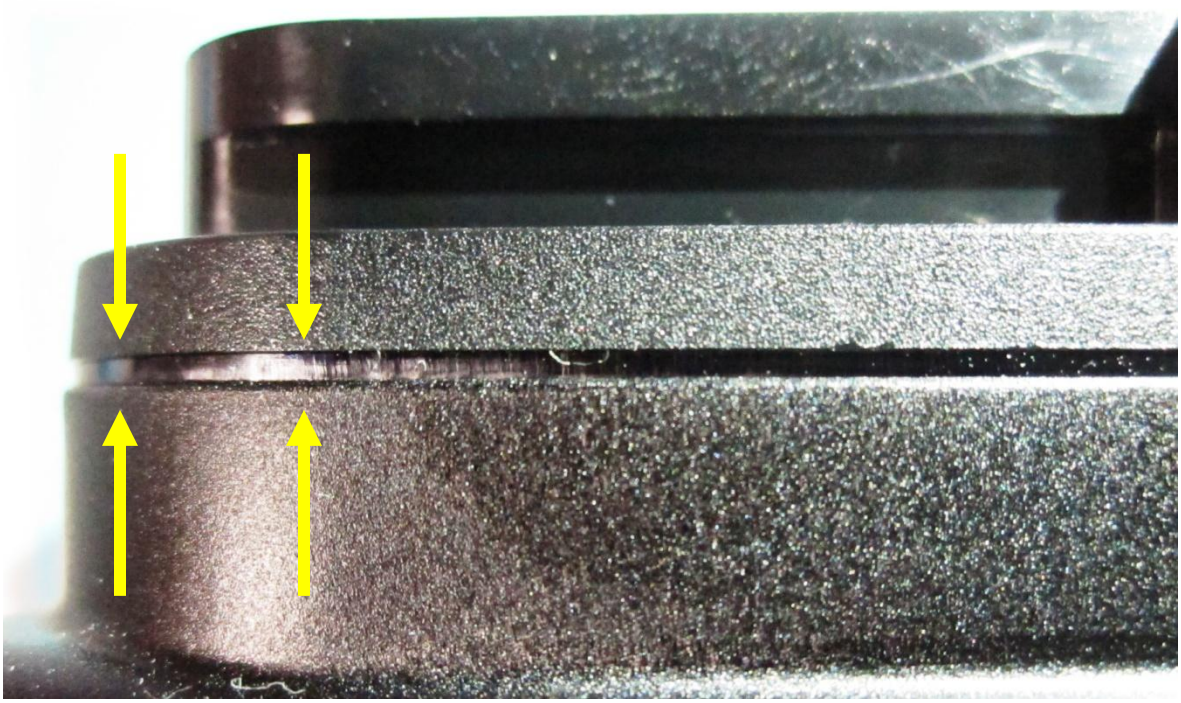

Photo 5: This photo shows the weld line with no damage, deterioration, or cracking.

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Inspection Required Prior To Each Use:

Please reiterate, with all relevant staff members, the importance of conducting this inspection prior to every use. Signs of cracking in the welded area are an indication that there is a potential for separation. Immediately discontinue use of any SmartLife® Aseptic Housing that exhibits cracking at the weld.

Page 5 of the Instructions for Use (User/Patient Safety, WARNINGS, bullet three) indicates: Upon initial receipt and before each use, operate the equipment and inspect each component for damage. Damage may include, but is not limited to, bent contacts and cracks in the housing. DO NOT use any equipment if damage is apparent or the inspection criteria are not met.

All SmartLife® Aseptic Housings (parts 7126-120-000 and 7222-120-000) distributed prior to May 3, 2014, will be replaced. Many facilities require uninterrupted use of this equipment. While replacement product is being manufactured and distributed, you may continue to use your SmartLife® Aseptic Housings if they show no sign of cracking at the weld. Replacement product will be provided to your facility as quickly as possible.

Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification. Advise all OR staff, product cleaning and sterilization staff, and anyone else who may use these products to inspect all SmartLife® Aseptic Housings prior to every use and to discontinue use of any product which shows signs of cracking or separation at the weld line.

2. Check all stock areas and/or operating room storage to determine how many SmartLife® Aseptic Housings, with lot numbers in the indicated range, are at 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. If you have further distributed this product, please forward this letter and the attached Business Reply Form (BRF) to all affected locations. Please indicate each location on the BRF.

5. Fax the completed Business Reply Form to Stryker Instruments Regulatory Department, 866-521-2762, or scan and email a copy to kara.spath@stryker.com.

6. 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. This email will also include a FedEx shipping label that can be used to return recalled product.

7. Upon receipt of the replacement product, remove all recalled SmartLife® Aseptic Housing(s) from use and replace them with the new SmartLife® Aseptic Housing(s).

8. Return all recalled product to Stryker, via FedEx. Please use the shipping label which will be provided to you via email. (See step 6, above.)

Report any serious adverse events or product quality problems to Stryker Instruments: 1-800-253-3210Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, or by fax or phone.
Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm
Fax: (800) FDA-0178 Phone: (800) FDA-1088
We apologize for any inconvenience this action may cause your facility. Please forward a copy of this letter to any other personnel within your facility that you deem appropriate.

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