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

stryker
Instruments

URGENT MEDICAL DEVICE RECALL NOTIFICATION

RE: STRYKER SYSTEM 6 ASEPTIC HOUSINGS

ATTENTION: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

Date

Dear Customer,

The purpose of this letter is to advise you that Stryker Instruments is voluntarily recalling the following Stryker System 6 Aseptic Housings.

Stryker Product	Product Description	Lot Numbers Affected by Recall	Dates of Distribution
6126-120-000	System 6 Aseptic Housing	13205, 13209, 13210, 13212	July 26, 2013 – Sept 12, 2013
Please note: In addition to being sold as individual housings (6126-120-000), recalled System 6 Aseptic Housings were also sold as part of a System 6 Aseptic Battery Kit (6126-000-000). The System 6 Aseptic Housing (6126-120-000) is the only component of the System 6 Aseptic Battery Kit that is being recalled.			

Reason for the Voluntary Recall:

The System 6 Aseptic Housings are being recalled because the Laser Welder may have failed to produce a continuous bond line for product manufactured under four specific lot numbers – 13205, 13209, 13210, 13212.

Product Description:

The System 6 Aseptic Housings are designed to be used, in conjunction with Stryker Non-Sterile Batteries, for System 6 Handpieces, System 7 Handpieces and Cordless Driver 3.

Risk to Health:

Lack of a continuous bond line could lead to separation of two sections of the housing, 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

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

stryker
Instruments

Photos below indicate the location of the Product Number and the Lot Number. Please note: Lot numbers 13205, 13209, 13210 and 13212 are the only lots affected by the recall.

Photo 1: 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 2: Lot Number is located inside the housing. The *yellow box* does not exist on the product. It has been added to the photo to identify the location.

For questions regarding this recall please contact Stryker Instruments:

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

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

stryker
Instruments

Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification.
2. Check all stock areas and/or operating room storage to determine how many System 6 Aseptic Housings, with lot numbers affected by the recall (13205, 13209, 13210, 13212), are at your facility. Discontinue use of any System 6 (6126-120-000) Aseptic Housings with these lot numbers.
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.
    a. ***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, replacement housings will be overnighted to your facility, pending product availability. You will receive an email confirming the shipment of replacement product. In addition, the email will include a FedEx shipping label that can be used to return recalled product.
7. 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.)

If discontinuing use of these specific housings will cause disruption at your facility, please contact Kara Spath, at mobile number 269-365-7849.

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.

For questions regarding this recall please contact Stryker Instruments:

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

4100 E. Milham Avenue
Kalamazoo, MI 49001
www.stryker.com

stryker

Instruments

BUSINESS REPLY FORM

PRODUCT: Stryker System 6 Aseptic Housings

Quantity Shipped	Product Number	Lot Number of Recalled Product Shipped	Quantity On Hand (From Recalled Lots)	Lot Number(s) of Recalled Product On Hand
	6126-120-000			

If you don't have any affected System 6 Aseptic Housings (lots 13205, 13209, 13210, 13212) 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) _____***)***

1. Check all stock areas and operating room storage to determine how many System 6 Aseptic Housings, with lot numbers affected by the recall (13205, 13209, 13210, 13212), are at your facility. Discontinue use of System 6 (6126-120-000) Aseptic Housings with these lot numbers.
2. If you have further distributed this product, please forward the Notification and Business Reply Form (BRF) to all affected locations. Please indicate each location below.
3. Please fax this completed, signed form to 866-521-2762 or scan and email a copy to kara.spath@stryker.com
4. Upon receipt of this form, replacement products will be overnighted to your facility. You will receive an email confirming the shipment of replacement product. In addition, the email will include a FedEx shipping label that can be used to return recalled product.
5. Return all recalled product to Stryker, via FedEx. Please use the shipping label which will be provided to you via email. (See step 4, above.)

Please complete and sign this form. Your signature indicates that you have received and understand the notification. Please fax the completed form to 866-521-2762 or email a copy to kara.spath@stryker.com. **If discontinuing use of these housings will cause disruption at your facility, please contact Kara Spath, at mobile number 269-365-7849.**

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:

_____
Name Address City State Zip

_____
Contact Person Part Number(s) and Quantities

Stryker Instruments, Kara Spath
Phone: 269-389-4518
Fax: 866-521-2762 Email: kara.spath@stryker.com

*Note: Please keep a copy of this completed, executed form for your records.