21/08/2015

URGENT: Field Safety Notice

FSCA identifier:	Product Field Action RA2015-032
Type of Action:	Field Safety Corrective Action: Recall
Legal Manufacturer	Stryker Leibinger GmbH & Co. KG, Boetzingerstrasse 41, 79111 Freiburg, Germany
Description:	Disposable paper filter for sterilization containers
Catalog #:	29-10911, 29-10912, 29-10913, 29-10915
Lot Code:	all lots

Dear customer:

Stryker CMF has initiated a Product Field Action for the devices identified above. The purpose of this letter is to list the hazards potentially associated with the Product Field Action.

Issue
Stryker has become aware that the inhomogeneity of the filter paper might potentially compromise the ability of the filter to maintain a sterile barrier during post-sterilization shelf-life.

Figure 1 : Disposable paper for sterilization container 49 x 21 cm, REF 29-10913 & Disposable paper for sterilization cases 21x21 cm, REF 29-1091

Potential Hazards
No injuries or complaints have been reported to Stryker related to these product anomalies. If the paper filter for sterilization container is not able to maintain a sterile barrier, it could result in contamination of surgical instruments and supplies within the container during post-sterilization shelf-life.

Mitigating Factors

- The initial sterilization of the affected products remains effective.
- As per "Instructions for Cleaning, Sterilization, Inspection and Maintenance" – 90-3333 Rev. A, containers and trays should be double wrapped.
- The transfer of bacteria has been observed only at a wet paper. Post-sterilization drying time and dry and dust-free storage conditions are standard.
- Contaminating fluid that may have come in contact with the white filter paper might cause discoloration, which might be evident at the time of surgery A potential contamination fluid.

Type of Action

Recall of subject devices

Immediate Action

Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending to scrap all affected products at your location or return to Stryker.

2. Circulate this Field Safety Notice internally to all interested/affected parties.

3. Maintain awareness of this notice internally until all required actions have been completed within your facility

4. Inform Stryker if any of the subject devices have been distributed to other organizations.

    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.

5. Please inform Stryker of any adverse events concerning the use of the subject devices. Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.

6. 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 longer have any of the subject devices in your physical inventory.

7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA.On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt. The target date for completion of this action is 29 October 2015 and your timely response will enable us to ensure that we meet this target.

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:
Telephone:

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.

We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

Yours Sincerely,

<First Name>, <Last Name>
<Title>

Attachment: <List all attachments>

RA2015-032: PFA ACKNOWLEDGMENT FORM

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Lot Code: all lots

All affected products can be scrapped at your location or returned to Stryker.

I acknowledge receipt of the Field Safety Notice for RA2015-032, and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*				
We have located the following devices:				
Product description	**Product Reference**	**Qty**	**Qty scrapped**	**Qty quarantined, to be returned**
We have further distributed subject devices to the following organisations:				
Facility Name				
Facility Address				
Form completed by:				

Contact Name _____ **Contact Facility** _____

Contact address _____ **Contact Position** _____

_____ **Contact Tel No** _____

_____ **Contact Fax No** _____

_____ **Contact e-mail** _____

PLEASE COMPLETE AND FAX THIS FORM TO X
OR EMAIL TO X.