Date

URGENT: Field Safety Notice

FSCA identifier: Product Field Action #1739180

Type of Action: Field Safety Corrective Action: Recall

Legal Manufacturer Stryker Leibinger GmbH & Co. KG, Boetzingerstrasse 41, 79111 Freiburg, Germany

Description: QuikFlap Neuro Implants: potential for compromised sterile barrier

Catalog #: see attached list

Lot Code: see attached list

Dear customer:

Stryker Leibinger GmbH & Co KG, Division Craniomaxillofacial, 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
During laboratory testing, Stryker became aware that for products of more than 3 years of shelf life there is a potential for the peel pouch (sterile barrier) to become compromised due to transportation forces. A compromised sterile barrier could result in the surgeon selecting a back-up device or, if not recognized, an unintended implantation of a potentially non-sterile device.

Potential Hazards
A compromised sterile barrier could potentially cause:
- Additional time under anesthesia due to prolongation of surgery
- Implantation of potentially non-sterile device

Mitigating Factors
- The initial sterilization remains effective
- Per the IFU, 'Sterile products are sterile only if the package is not damaged or opened.' Compromised packaging results in the loss of vacuum inside the peel pouch.
- A breach of the outer peel pouch has been only seen on packages at shelf life end after 5 years and after an excessive transportation testing.
- Packaging evaluations reveal that a contamination due to the described issue is considered unlikely. Any contaminate to remain viable and cause infection would require several unfavorable circumstances to occur.

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. Therefor 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 …. 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.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be cause. We would like to reassure you, that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

Yours Sincerely,

First Name, Second Name
Title

Attachment: <List all attachments>

PFA#1739180: PFA ACKNOWLEDGMENT FORM

FSCA identifier: Product Field Action #1739180

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Description: QuikFlap Neuro Implants: potential for compromised sterile barrier due to transportation forces

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

I acknowledge receipt of the Field Safety Notice for PFA#1739180, 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.