17 September 2018

URGENT Field Safety Notice: #1875982

FSCA identifier:	Product Field Action #1875982
Type of Action:	Field Safety Corrective Action: Recall
Legal Manufacturer	Stryker Leibinger GmbH & Co. KG, Boetzingerstrasse 41, 79111 Freiburg, Germany
Description:	HydroSet Injectable HA Bone Substitute
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

Our Supplier informed Stryker about an incorrect expiration date that had been documented on several batches of Hydroset products. The expiration date information on the product label indicates a longer shelf life than validated.

Potential Hazards

A longer expiration date than validated could potentially cause:

- Use of expired product that indicates compromised sterility
- Compromised stability of the product

Mitigating Factors

- Stryker and hospitals logistic rules should minimize the probability to use a product (HydroSet) which is expired
- HydroSet is the predicate device to the bone cement product, DirectInject, where the functionality has been verified to a 3-year shelf life. It can be inferred with a high level of confidence that the functionality of the calcium phosphate species in HydroSet formulation is unaffected in the 11-day extended labelling period

Type of Action

Recall of subject devices

Stryker UK
Stryker House, Hambridge Road, Newbury, Berks. RG14 5AW | P +44 1635 262400 | F +44 1635 580300| stryker.com

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 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 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.

5. Please inform Stryker of any adverse events concerning the use of the subject devices.

6. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

7. 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.

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

We request that you respond to this notice within 07 calendar days from the date of receipt. The target date for completion of this action is 26 October 2018 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: Nina Goddard
Position: RAQA Specialist
Telephone: 01635 262 476
E-mail: nina.goddard@stryker.com

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 caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours faithfully,

Nina Goddard
Regulatory Affairs and Quality Assurance

PFA #1875982: Affected products

Manufacturer Part Number	Manufacturer Part Name	Lot Numbers
397010	HydroSet Injectable HA Bone Substitute	IC02608 IC02617 IC02652

PFA #1875982: Acknowledgement Form

FSCA identifier: Product Field Action #1875982

Type of Action: Field Safety Corrective Action: Recall

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

Description: HydroSet Injectable HA Bone Substitute

Catalog #: see attached list

Lot Code: see attached list

I acknowledge receipt of the Field Safety Notice for PFA#1875982 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	Lot Number	Qty implanted	Qty to return
We have further distributed subject devices to the following organisations:				
Facility Name				
Facility Address				

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 580300
OR EMAIL TO nina.goddard@stryker.com