Date

URGENT FIELD SAFETY NOTICE: RA2013-104

FSCA Identifier: Product Field Action RA 2013-104

Type of Action: Field Safety Corrective Action

Description: HydroSet Injectable HA Bone Substitute All Sizes

Catalogue Nos: Refer to the attached list on page 5

Lot Nos: Refer to the attached list on page 5

Dear Customer,

Please find attached details of a Product Field Action that has been initiated by Stryker Osteosynthesis concerning the above referenced devices.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. It may be that you no longer have any physical inventory on site.

This action has been taken to ensure that users are aware of important Information concerning the devices listed above. You are required only to read the attached Field Safety Notice and then sign and return the customer response form confirming that you have completed the actions requested by the manufacturer.

Completing the Customer Response 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.

We request that you respond to this notice within seven calendar days from the date of receipt. The target date for completion of this action is 30th Aug 2013 and your timely response will enable us to ensure that we meet this target and ensure that non conforming devices are removed from the market as quickly as possible.

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:	X
Position:	Regulatory Affairs Specialist
E-mail:	X
Tel:	X
Fax:	X

In line with the recommendations of the MEDDEV Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA (Field Safety Corrective Action) 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 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,

X
Quality Assurance and Regulatory Affairs

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Dear Customer,

Stryker® Osteosynthesis 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 received reports indicating the desiccant bag is leaking the silica gel granulate. The desiccant bag is packed in the powder blister to protect the product from moisture (see picture below). A leaking desiccant bag could result in the surgeon selecting a back-up or, if not recognized, an inadvertent implantation of silica gel granulate.

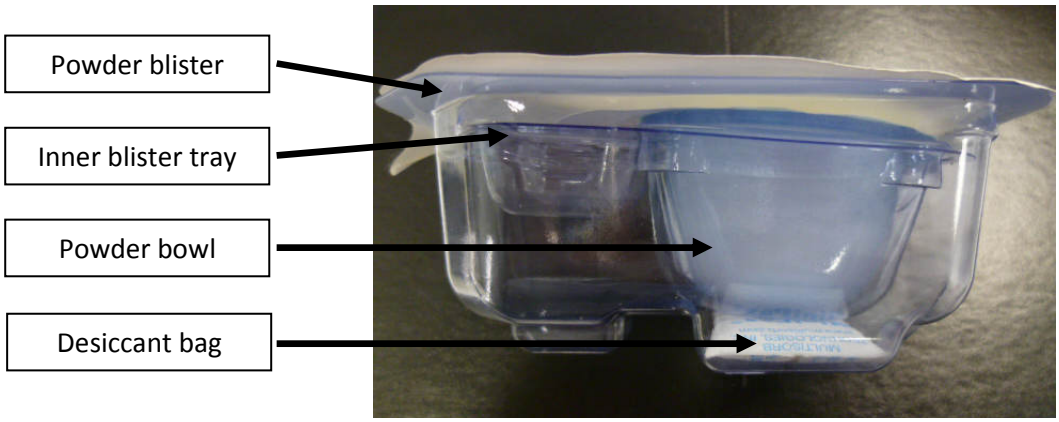

Figure 1: Example of powder blister

Potential Hazards
The usage of HydroSet with a leaking desiccant bag could potentially cause:

- Additional time under anesthesia due to prolongation of surgery, when recognized (less than 60 minutes).
- Foreign / inflammatory body reaction, if silica gel granulate is implanted, which in turn might lead to a revision surgery.

Mitigating Factors

1. Surgery planning with a back-up device.
2. Inspection of packaging prior to usage.

3. Since silica gel granulate (SiO2) is known to be biocompatible and is currently used in medical implants, the probability of a foreign body or other inflammatory reaction is considered remote.

Type of Action
Distribution of FSN including the Product Correction Bulletin.

Product Correction Instructions
1. Please plan HydroSet surgeries with a back-up device.
2. Please inspect the powder blister for loose silica gel granulate prior to usage.
3. Please use only products with verified intact packaging.

Immediate actions
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:

Our records indicate that you have received at least one of the subject devices listed above. We therefore request that you:

1. Please inform HydroSet users of this Medical Device Correction and pass this notice and the attached bulletin to all those individuals who need to be aware within your organization.
2. Please maintain awareness of this notice to ensure effective use of the product.
3. Please fax/email back the enclosed Business Reply Form within 5 days to acknowledge your receipt and understanding of this information (Fax to X or by email X).
4. Keep a copy of the completed and executed Business Reply Form for your records.

We sincerely regret any inconvenience that this action may cause you and on behalf of Stryker would like to thank you for your help and support in completing this action in a timely manner.

Should you have any queries on this matter please do not hesitate to contact the undersigned.

Yours faithfully

X
Quality Assurance and Regulatory Affairs

Appendix:
Affected Product and Lot Codes
Product Correction Bulletin
PFA Acknowledgment Form

RA2013-104 Affected Product and Lot Codes

Pos	Manufacturer Part Number	Manufacturer Part Name	Lot Numbers
1	79-43903	HydroSet Injectable HA Bone Substitute 3cc	IC01116, IC01130, IC01204, IC01233, IC01238
2	79-43905	HydroSet Injectable HA Bone Substitute 5cc	IC01084, IC01085, IC01086, IC01093, IC01123, IC01150, IC01166, IC01167, IC01168, IC01180, IC01188, IC01189, IC01190, IC01198, IC01199, IC01200, IC01213, IC01214, IC01229, IC01230, IC01239, IC01240, IC01245, IC01246, IC01270
3	79-43910	HydroSet Injectable HA Bone Substitute 10cc	IC01087, IC01090, IC01091, IC01153, IC01154, IC01163, IC01164, IC01165, IC01179, IC01183, IC01184, IC01201, IC01202, IC01203, IC01231, IC01243, IC01244, IC01248, IC01249, IC01261, IC01264
4	79-43015	HydroSet Injectable HA Bone Substitute 15cc	IC01100, IC01114, IC01161, IC01162, IC01182, IC01211, IC01212, IC01227, IC01228, IC01241, IC01242, IC01252, IC01253, IC01254, IC01267
5	397003	HydroSet Injectable HA Bone Substitute 3cc	IC01092, IC01101, IC01102, IC01103, IC01104, IC01105, IC01106, IC01107, IC01115, IC01127, IC01131, IC01205, IC01220, IC01232, IC01234
6	397005	HydroSet Injectable HA Bone Substitute 5cc	IC01088, IC01094, IC01095, IC01096, IC01097, IC01098, IC01110, IC01111, IC01118, IC01119, IC01120, IC01132, IC01133, IC01134, IC01135, IC01136, IC01137, IC01147, IC01148, IC01149, IC01158, IC01159, IC01160, IC01171, IC01172, IC01181, IC01193, IC01194, IC01195, IC01196, IC01223, IC01224, IC01247
7	397010	HydroSet Injectable HA Bone Substitute 10cc	IC01099, IC01108, IC01109, IC01112, IC01121, IC01138, IC01139, IC01140, IC01141, IC01151, IC01152, IC01155, IC01156, IC01157, IC01173, IC01174, IC01191, IC01192, IC01197, IC01210, IC01216, IC01219, IC01225, IC01226, IC01250, IC01251, IC01263, IC01266, IC01301
8	397015	HydroSet Injectable HA Bone Substitute 15cc	IC01113, IC01122, IC01124, IC01125, IC01142, IC01143, IC01144, IC01145, IC01146, IC01169, IC01170, IC01177, IC01178, IC01185, IC01186, IC01187, IC01206, IC01207, IC01208, IC01209, IC01217, IC01218, IC01221, IC01222, IC01265

RA2013-104: PRODUCT CORRECTION BULLETIN

HydroSet Injectable HA Bone Substitute All Sizes
Manufacturer Part Number: 79-43903, 79-43905, 79-43910, 79-43015, 397003, 397005, 397010, 397015

July 26, 2013

Issue:
Stryker received reports indicating that the desiccant bag is leaking the silica gel granulate. The desiccant bag is packed in the powder blister to protect the product from moisture (see picture below). A leaking desiccant bag could result in the surgeon selecting a back-up or, if not recognized, in an inadvertent implantation of silica gel granulate.

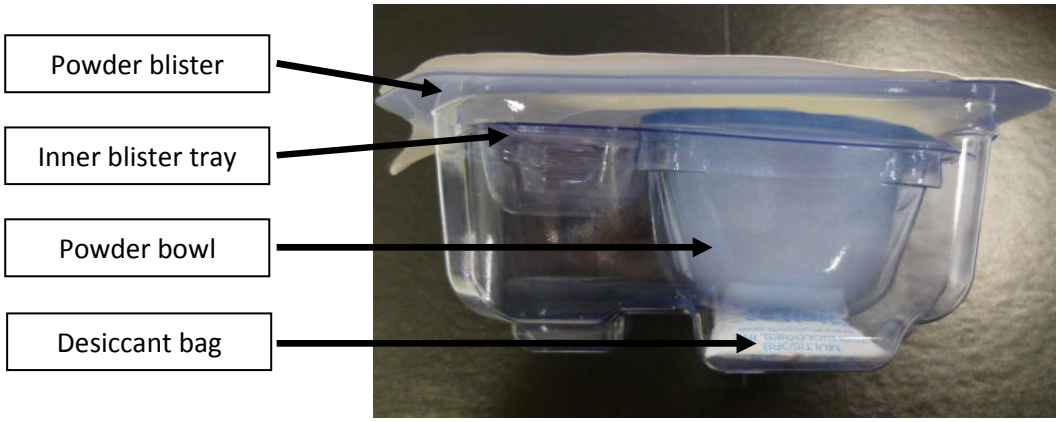

Figure 2: Example of powder blister

Potential Hazards:
The usage of HydroSet with a leaking desiccant bag could potentially cause:

- Additional time under anesthesia due to prolongation of surgery, when recognized (less than 60 minutes).
- Foreign / inflammatory body reaction, if silica gel granulate is implanted, which in turn might lead to a revision surgery.

Product Correction Instructions:

1. Please plan HydroSet surgeries with a back-up device.
2. Please inspect the powder blister for loose silica gel granulate prior to usage.
3. Please use only products with verified intact packaging.

Contact X, Regulatory Affairs Specialist, Stryker X, with any questions regarding this bulletin. Email: X; Phone: X.

RA2013-104: PFA ACKNOWLEDGMENT FORM

FSCA Identifier: Product Field Action RA 2013-104

Type of Action: Field Safety Corrective Action

Description: HydroSet Injectable HA Bone Substitute All sizes

Catalogue Nos: Refer to the attached list on page 5

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I acknowledge receipt of the Field Safety Notice for RA2013-104 and can confirm that (please circle):

1	**We have checked inventory and can confirm that we do not have any affected product at this location.**
2	**We have checked inventory and we have affected product at this location. We have informed all users of the Medical Device Correction Notification and will maintain awareness of the notice.**
3	**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.