Craniomaxillofacial

750 Trade Centre Way, Suite 200
Portage, MI 49002

www.stryker.com

September 13, 2018

URGENT MEDICAL DEVICE RECALL

Attention: SURGEONS, OR STAFF, RISK MANAGER, DIRECTOR or MATERIALS MANAGER
cc: Chairman Medical Board and relevant Head of Departments

Voluntary recall

We are writing to communicate the details of a voluntary recall.

Product Recalled	HydroSet Injectable HA Bone Substitute
Part #s:	397010
Lot #s:	IC02608, IC02617, IC02652

Legal Manufacturer

Stryker Leibinger GmbH & Co. KG, Boetzinger Strasse 41, 79111 Freiburg, Germany

Reason for recall

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

Risk mitigation

- 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

Action to be taken

1. Please inform users of this Medical Device Removal and pass this notice to all appropriate individuals within your organization.
2. Return all affected products available at your location to:

Stryker CMF
Attn: Recall Coordinator
6300 Sprinkle Rd
Portage, MI 49002
REF: PFA #1739180

Or, Contact Stryker Customer Service and refer to PFA #1875982 with any questions about returning the product to us.

3. Complete and sign the enclosed Business Reply Form and fax a copy to: (877) 648-7114 or email a copy to CMF-custserv@stryker.com.
4. Keep a copy of the completed and executed Customer response Form for your records.

Please report any adverse events or product quality problems to Stryker CMF Customer Service: 1 (800) 962-6558.

Health care professionals and consumers may report 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, by regular mail, fax, or phone.

Online: www.fda.gov/MedWatch/report.htm
Forms for fax or email:
http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
Fax: 1-(800) FDA-0178
Phone: 1-(800) FDA-1088

We are committed to manufacturing products that meet your expectations for quality and reliability and regret any inconvenience associated with this voluntary recall. Please do not hesitate to contact us if you have any further questions or feedback.

Julie Brown
Senior Manager RAQA
[redacted]

stryker

CUSTOMER RESPONSE ON RECEIPT

Stryker Reference Number: RA #1875982

We have received notification of affected Lots of HydroSet Injectable HA Bone Substitute.
Completion instructions:

1. Complete product disposition table.
2. Return competed form to Customer Service as described below.
3. If returning any products, please ensure that package is labeled with Stryker Reference Number RA #1875982
4. Contact Customer Service with any questions.

Product Disposition (Completed by Customer)					
Part Number	Lot Number	Quantity to be Returned	Quantity Used/ Implanted	Quantity Disposed/ Destroyed	Quantity Not Located

Hospital: _____

Customer Name: _____

Signature: _____

Printed Name: _____

Date: _____

Please return this completed form to CMF's Customer Service Team by email, fax, or mail.

Email: CMF-custserv@stryker.com
Fax: 1 (877) 648-7114
Address: Stryker Craniomaxillofacial
Attn: Recall Coordinator
6300 Sprinkle Rd
Portage, MI 49002