stryker
Orthopaedics

September XXth, 2015

URGENT: Field Safety Notice

FSCA identifier: Product Field Action RA2015-119

Type of Action: Field Safety Corrective Action: **Return to supplier.**

Description: Exeter Small Tapered Pin Reamer and Exeter Large Tapered Pin Reamer

Catalog #: 0932-0-000 and 0932-2-000

Lot #: GW281208, GW284192, GW288907, GW282586, GW282310, GW298838, GX303720, GX302994, GX301732, GW288908, GW282454, and GW288485

Dear Distributor/ Risk Management/Surgeon:

On the XXth of September 2015 Stryker® Orthopaedics initiated a lot specific voluntary product recall for Exeter Small Tapered Pin Reamer and Exeter Large Tapered Pin Reamer devices as referenced above. The intent of this letter is to list all known hazards potentially associated with the use of the product and list the risk mitigation factors.

Issue:

Stryker® Orthopaedics has received a customer complaint which reported that during a total hip replacement the surgeon was using the Exeter small tapered pin reamer (0932-0-000 lot #GW281208) when the device fractured approximately 3 inches from the tip.

Potential Hazards:

1. Tip of the reamer detaches from the instrument.
2. Excessive metal ions (corrosion related).
3. Displacement from MRI.

The aforementioned potential hazards may result in one or more of the following potential patient harms:

1. Complications associated with a delay in surgery of ≤15 minutes.
2. Complications associated with a delay in surgery of 31-60 minutes.
3. Complications associated with a delay in surgery greater than 60 minutes.
4. Prolonged wound healing.
5. Inflammatory response to inert particulates.
6. Necrosis (local).
7. Pain.

Risk Mitigation

For potential hazard # 3 – Displacement from MRI. The Instructions for Use (IFU) for Total Hip Joint Replacement Prostheses for Cementless and Cemented Applications (Lit. # 96E112 Rev. G) included in the Exeter hip stem implant package provides necessary precautions and warnings to both the patient and the surgeon for potential risks of undergoing Magnetic Resonance Imaging (MRI) scans. This will mitigate instances of exposure to an MRI field that has the potential to cause movement/ translation of implanted stainless steel within the patient's femur.

Our records indicate that you have received the above referenced product. Please assist us in meeting our regulatory obligation by:

1. Immediately check your internal inventory and quarantine all subject devices.
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. *(Please provide contact details so that Stryker can inform the recipients appropriately).*
5. Complete the attached customer response form and return the form and any affected devices to your local Stryker Representative.
   (Please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notice)
6. Please inform Stryker of any adverse events associated with the use of the subject devices.
   a. Comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Safety Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours Sincerely,

_____

STRYKER® ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

September XX, 2015

SURGEON

ADDRESS

CITY, STATE ZIP

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Type of Action: **Return to Supplier**

I have received the notification from Stryker® Orthopaedics dated September XX 2015 stating that they initiated a Field Safety Corrective Action of the above referenced product.

_____ _____

Surgeon (Signature) Date

_____

Surgeon (Print)