stryker
Orthopaedics

June XX, 2012

URGENT UPDATE: Field Safety Notice

FSCA identifier: Product Field Action RA2012-067 EXT

Type of Action: Field Safety Corrective Action

Description: ABG II Modular Stems and ABG II Modular Necks
Rejuvenate Modular Stems and Rejuvenate Modular Necks

Catalog #: See attached List

Lot Code: All

Dear Distributor/Risk Management/Surgeon:

As communicated by a Field Safety Notice (FSN) dated May XX, 2012, Stryker Orthopaedics had previously initiated a product field action correction (reference RA2012-067) for the products and lot ID referenced above. Please be advised that Stryker has now updated this action to a product recall. Please note, however, that the known potential hazards associated with Product Remediation RA2012-067 EXT have not changed from the previously communicated FSN (restated below for reference).

Issue:

Ongoing analysis of the global data following the Product Correction does not yield a significant increase in the global reported rate for Adverse Local Tissue Reaction (ALTR). However, the additional data, which includes variability in ALTR rates among sites, may potentially be predictive of an increased likelihood of this condition for both the Rejuvenate and ABG II Modular Hip Systems. Based on information received to date, a product field action to remove these products is being conducted.

Potential Hazards

1. Excessive metal debris and/or ion generation. Fretting and/or corrosion at or about the modular neck junction may lead to increased metal ion generation in the surrounding joint space.

   a. Contact between metal ions and tissues and structures during an implant's service life may result in an Adverse Local Tissue Reaction (ALTR), the inflammation of associated tissues experiencing immunological response (metallosis, necrosis, and/or pain). An ALTR may result in the need for revision surgery.

b. Patients with a heightened sensitivity to these ions may experience a hypersensitivity/allergic reaction which may result in the need for revision surgery.

2. Excessive fretting debris. Fretting may lead to increased metal debris in the joint space (concentration of debris exceeds individual patient threshold) resulting in osteolysis. Osteolysis may be asymptomatic and may result in the need for revision surgery.

Note: Stryker has not received any reports of modular neck fracture associated with fretting/corrosion.

Risk Mitigation

The risk is mitigated by the removal of products from use.

Follow-up

Surgeons should ensure that patients with ABG II Modular or Rejuvenate Modular Hip Systems are followed regularly and undergo clinical evaluation as per their surgeon and institutional protocol.

If a patient is experiencing pain and/or swelling involving the groin, buttock, lateral hip or thigh, the surgeon should rule out aseptic loosening or periprosthetic sepsis, common conditions following joint replacement surgery that are not related to an ALTR to metal wear debris. Once the surgeon has ruled out aseptic loosening and periprosthetic sepsis, the surgeon should evaluate the patient for an ALTR potentially related to metal wear debris. Testing includes blood work for metal ion levels (CR and CO levels over 7 ppb are commonly considered high) and either an MRI or ultrasound to look for soft tissue mass or fluid collection. If the results reveal an ALTR to metal wear debris, the surgeon should consider proceeding with a revision of the femoral component to a monolithic stem.

Our records indicate that you have received the above referenced product(s). It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication.

Please assist us in meeting our regulatory obligation by:

1. Immediately check your internal inventory. Locate and quarantine all subject devices pending return to your local Stryker Distributor.

2. Circulate this Field Safety Notice internally to all interested/affected parties.

   a. Include any personnel responsible for the allocation/maintenance of equipment.

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. 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.

6. Complete the attached customer response form and return to the address indicated. *(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)*

In line with the recommendations contained in the Meddev Vigilance Guidance document, Ref 2.12-1 we can confirm that this 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 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 and appreciate your assistance in meeting this objective.

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

Yours Sincerely,

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STRYKER ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

June XXXX, 2012

SURGEON

ADDRESS

CITY, STATE ZIP

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I have received the notification from Stryker Orthopaedics dated June XX, 2012 stating that they initiated a Field Safety Corrective Action of the above referenced product.

_____ _____
Surgeon (Signature) Date

_____
Surgeon (Print)

Please fax this signed and dated form to XXXX