stryker
Orthopaedics

May XX, 2012

URGENT: Field Safety Notice

FSCA identifier: Product Field Action RA2012-067

Type of Action: Field Safety Corrective Action:

Description: ABGII Modular Stems and ABGII Modular Necks
Rejuvenate Modular Stems and Rejuvenate Modular Necks

Catalog #: See attached List

Lot Code: All

Dear Distributor/ Risk Management/Surgeon:

On April XX 2012 Stryker® Orthopaedics initiated a product field action for the products and lot ID referenced above. The intent of this letter is to list all known potential hazards associated with the below noted issue and list the risk mitigation factors associated with the use of the product.

Issue:

This communication is intended to inform implanting and/or treating surgeons and other healthcare professionals that Stryker has updated the Instructions for Use (IFU) for the ABGII Modular and Rejuvenate Modular Hip Systems. This is based on a reported rate of less than one percent for revisions potentially associated with fretting and/or corrosion at or about the modular neck junction.

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 Instructions for Use (IFU) for the ABGII Modular and Rejuvenate Modular Systems have been updated to include information on the potential for fretting and/or corrosion at or about modular neck junctions. In addition to listing the above potential hazards, as well as factors which may increase the risk of these hazards to occur, a Product Correction Bulletin, attached, also identifies specific text updates to the IFUs. In order to provide surgeons with additional background on this issue, Stryker commissioned the preparation of a White Paper on this matter, also attached.

There is no requirement for any additional patient monitoring or follow up outside of what is usually performed for patients who have undergone joint replacement surgery. Additional follow-up would neither avoid nor lead to early diagnosis of any potential problems relating to this situation. Symptomatic patients would present to their operating surgeon for treatment.

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. Circulate this Field Safety Notice internally to all interested/affected parties.
    a. Include any personnel responsible for the allocation/maintenance of equipment.
2. Maintain awareness of this notice internally until all required actions have been completed within your facility.
3. 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).*
4. 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.
5. 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,

_____

STRYKER® ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

May XXXX, 2012

SURGEON

ADDRESS

CITY, STATE ZIP

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Type of Action: Field Safety Corrective Action

I have received the notification from Stryker® Orthopaedics dated April 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