stryker
Orthopaedics

April 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.

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:

- Ensuring that copies of this FSN are circulated internally to all affected users.
- Displaying the notice prominently until all required actions have been completed within the facility.
- Completing the attached customer response form to confirm acknowledgement of this notice and disposition of subject devices.

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 contact your local Sales Representative.

Yours Sincerely,

_____

STRYKER® ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

April XXXX, 2012

SURGEON

ADDRESS

CITY, STATE ZIP

FSCA identifier: Product Field Action **RA2012-067**

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

Catalog #: See attached list

Lot Code: All

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

RA2012-067 – scope of devices covered

ABG II Modular Components

Catalog No.	Description
4845-4-101	ABGII. Modular Stem
4845-4-102	ABGII. Modular Stem
4845-4-103	ABGII. Modular Stem
4845-4-104	ABGII. Modular Stem
4845-4-105	ABGII. Modular Stem
4845-4-106	ABGII. Modular Stem
4845-4-107	ABGII. Modular Stem
4845-4-108	ABGII. Modular Stem
4845-4-201	ABGII. Modular Stem
4845-4-202	ABGII. Modular Stem
4845-4-203	ABGII. Modular Stem
4845-4-204	ABGII. Modular Stem
4845-4-205	ABGII. Modular Stem
4845-4-206	ABGII. Modular Stem
4845-4-207	ABGII. Modular Stem
4845-4-208	ABGII. Modular Stem
4845-4-410	ABGII Modular short neck
4845-4-411	ABGII Modular short neck
4845-4-412	ABGII Modular short neck
4845-4-413	ABGII Modular short neck
4845-4-414	ABGII Modular short neck
4845-4-415	ABGII Modular long neck
4845-4-416	ABGII Modular long neck
4845-4-417	ABGII Modular long neck
4845-4-418	ABGII Modular long neck
4845-4-419	ABGII Modular long neck

RA2012-067 – scope of devices covered (continued)

Rejuvenate Modular Components

Catalog No.	Description
SPT070000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 7
SPT080000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 8
SPT090000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 9
SPT100000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 10
SPT110000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 11
SPT120000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 12
NLS-301600P	LRG TAP PRI MOD NCK 16DEG 30MM
NLS-300000B	LRG TAP PRI MOD NCK 0DEG 30MM
NLS-341600P	LRG TAP PRI MOD NCK 16DEG 34MM
NLS-340000B	LRG TAP PRI MOD NCK 0DEG 34MM
NLS-381600P	LRG TAP PRI MOD NCK 16DEG 38MM
NLS-380000B	LRG TAP PRI MOD NCK 0DEG 38MM
NLS-421600P	LRG TAP PRI MOD NCK 16DEG 42MM
NLS-420000B	LRG TAP PRI MOD NCK 0DEG 42MM
NLV-300800Y	LRG TAP PRI MOD NCK 8DEG 30MM
NLV-300800G	LRG TAP PRI MOD NCK 8DEG 30MM
NLV-340800Y	LRG TAP PRI MOD NCK 8DEG 34MM

Rejuvenate Modular Components

NLV-340800G	LRG TAP PRI MOD NCK 8DEG 34MM
NLV-380800Y	LRG TAP PRI MOD NCK 8DEG 38MM
NLV-380800G	LRG TAP PRI MOD NCK 8DEG 38MM
NLV-420800Y	LRG TAP PRI MOD NCK 8DEG 42MM
NLV-420800G	LRG TAP PRI MOD NCK 8DEG 42MM

Product Correction Bulletin

ABGII Modular and Rejuvenate Modular Hip Systems

stryker®

Orthopaedics

April 25, 2012

This Bulletin 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. Below outlines the potential hazards associated with fretting and/or corrosion, the factors which may increase the risk of the potential hazards, as well as the updated language that will be added to the IFU.

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.

Factors which may increase the risk of the above Potential Hazards

Several factors may contribute to increased metal ion and/or metal debris generation. These include, but are not limited to the following:

1. **Additional femoral offset.** Applying the same load through the head center with additional offsets will result in greater bending moments at the taper junctions. This may result in greater relative motion between the neck and stem at the taper junction.[1] Additional weight or excessive patient weight can also contribute to this phenomenon.
2. **Solution Chemistry.**[2,3] The local chemistry around an implant may vary considerably from patient to patient. Factors such as diabetes and infection may play a role in potential corrosion of an implant as these conditions may affect the pH of the tissue surrounding the implant. Local pH levels may also influence corrosion.
3. **Inadequate locking or assembly of the tapers may lead to increased mechanically assisted corrosion (note: this has not been demonstrated in a bench top setting).**
4. **Inadequate cleaning of the neck taper may lead to increased debris generation.**

Risk Mitigation

The Instructions for Use (IFU) for the ABGII Modular and Rejuvenate Modular Systems have been updated to include the following information on the potential for fretting and/or corrosion at or about modular neck junctions:

WARNINGS

- Patient post-operative pain. Inherent to all joint replacement is the risk that a patient will develop post-operative pain; pain is a commonly reported symptom regardless of the device implanted. The clinical literature reveals numerous potential causes of pain not directly related to the implant performance including, but not limited to, prior history of trauma and natural disease progression.

  For patients who present with pain following implantation with a modular stem containing a modular junction, physicians should consider potential causes of the symptoms, including common sources of pain identified in the clinical literature, for example infection and soft tissue impingement. Causes of pain which are less frequently reported in the literature, including pain related to wear and/or corrosion, should not be discounted. Accurate diagnosis of the source of pain and directed, timely intervention is essential to ensuring effective treatment of pain

- Modular Junctions: Mate modular components firmly to prevent dissociation. Machined taper surfaces must be clean, dry and firmly mated to ensure proper seating and assembly. Repeated assembly/disassembly or failure to clean, dry and firmly mate the components could compromise the taper lock and potentially lead to fretting/corrosion.

ADVERSE EFFECTS

- Corrosion and/or wear at junction of metal implants. Corrosion and/or wear may occur whenever two metal surfaces are in contact. The literature identifies a small number of cases involving wear-related corrosion at modular junctions formed by modular heads (neck/head interface) and modular necks (neck/stem interface). Local joint chemistry and/or other patient-specific conditions such as diabetes or infection may affect the potential for in vivo corrosion.

  A modular junction may release metal debris and may be affected by duration of service life and the forces acting on the modular junction. A small number of cases report corrosion at modular junctions and/or corrosion of wear-related debris in the implant vicinity, resulting in adverse local soft tissue reactions and potentially, increased metal ion levels in the blood and/or urine. Affected patients may present with symptoms similar to those associated with infection, including pain (most likely during weight-bearing) and swelling at the local joint site. Corrosion and/or wear at the modular junction may result in early revision surgery. Patients with a heightened sensitivity to these ions may experience a hypersensitivity/allergic reaction which may result in the need for revision surgery.

References

1. Brown, Stanley et. al, Effects of Neck Extension, Coverage, and Frequency on the Fretting and Corrosion of Modular THR Bore and Cone Interface, Modularity of Orthopedic Implants, ASTM STP 1301, American Society for Testing and Materials, 1997.

2. Messer RL, Tackas G, Mickalonis J, Brown Y, Lewis JB, Wataha JC. Corrosion of machined titanium dental implants under inflammatory conditions. J Biomed Mater Res B Appl Biomater. 2009 Feb;88(2):474-81.

3. Katharine Merritt, Stanley A. Brown. Effect of proteins and pH on fretting corrosion and metal ion release. Journal of Biomedical Materials Research Volume 22, Issue 2, pages 111–120, February 1988.

Please contact your local Stryker Sales Representative or Lauren Venekas (Mellides), Global Brand Manager - Hip Marketing Team at (201) 953-3217 with any questions regarding this Bulletin.

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