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stryker®
UK

«Contact_Name_»
«Customer_Name_»
«Address_1»
«Address_2»
«Town_»
«Postal_code_»
«Country_»

URGENT Field Safety Notice: RA 2012-067 EXT

5th July 2012

FSCA identifier: Product Field Action RA 2012-067 EXT

Type of Action: Field Safety Corrective Action

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

Catalog Nos: Refer to the attached list on pages 4 and 5

Lot Nos: All lot numbers

Dear Customer,

As communicated by a Field Safety Notice (FSN) dated 20th May 2012, Stryker Orthopaedics had previously initiated a product field action correction (reference RA 2012-067) 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 RA 2012-067 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

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RS 11877

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 Daniel Rana by fax (01635 262 464) or by e-mail (daniel.rana@stryker.com).

   (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 faithfully,

Daniel Rana
Quality Assurance and Regulatory Affairs

RA 2012-067 EXT Affected Product Codes

ABGII Modular	
Femoral Components	
4845-4-101	ABG™II Modular Cementless Hip Stem HA Coated # 1 - Right
4845-4-102	ABG™II Modular Cementless Hip Stem HA Coated # 2 - Right
4845-4-103	ABG™II Modular Cementless Hip Stem HA Coated # 3 - Right
4845-4-104	ABG™II Modular Cementless Hip Stem HA Coated # 4 - Right
4845-4-105	ABG™II Modular Cementless Hip Stem HA Coated # 5 - Right
4845-4-106	ABG™II Modular Cementless Hip Stem HA Coated # 6 - Right
4845-4-107	ABG™II Modular Cementless Hip Stem HA Coated # 7 - Right
4845-4-108	ABG™II Modular Cementless Hip Stem HA Coated # 8 - Right
4845-4-201	ABG™II Modular Cementless Hip Stem HA Coated # 1 - Left
4845-4-202	ABG™II Modular Cementless Hip Stem HA Coated # 2 - Left
4845-4-203	ABG™II Modular Cementless Hip Stem HA Coated # 3 - Left
4845-4-204	ABG™II Modular Cementless Hip Stem HA Coated # 4 - Left
4845-4-205	ABG™II Modular Cementless Hip Stem HA Coated # 5 - Left
4845-4-206	ABG™II Modular Cementless Hip Stem HA Coated # 6 - Left
4845-4-207	ABG™II Modular Cementless Hip Stem HA Coated # 7 - Left
4845-4-208	ABG™II Modular Cementless Hip Stem HA Coated # 8 - Left
Modular Necks	
4845-4-410	ABG™II Modular V40™ Neck Straight Grey Neck Short
4845-4-411	ABG™II Modular V40™ Neck Varus-Valgus Green Neck Short
4845-4-412	ABG™II Modular V40™ Neck Antre-Retro Brown Neck Short
4845-4-413	ABG™II Modular V40™ Neck Antre-Retro Varus-Valgus NeckShort
4845-4-414	ABG™II Modular V40™ Neck Antre-Retro Valgus-Varus Blue Neck Short
4845-4-415	ABG™II Modular V40™ Neck Straight Grey Neck Long
4845-4-416	ABG™II Modular V40™ Neck Varus-Valgus Green Neck Long
4845-4-417	ABG™II Modular V40™ Neck Antre-Retro Brown Neck Long
4845-4-418	ABG™II Modular V40™ Neck Antre-Retro Varus-Valgus Yellow Neck Long
4845-4-419	ABG™II Modular V40™ Neck Antre-Retro Valgus-Varus Blue Neck Long

RA 2012-067 EXT Affected Product Codes

Rejuvenate Implants	
Modular Stems	
SPT-070000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 7
SPT-080000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 8
SPT-090000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 9
SPT-100000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 10
SPT-110000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 11
SPT-120000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 12
Modular Necks	
NLS-300000B	LRG TAP PRI MOD NCK 0DEG 30MM
NLV-300800Y	LRG TAP PRI MOD NCK 8DEG 30MM
NLV-300800G	LRG TAP PRI MOD NCK 8DEG 30MM
NLS-301600P	LRG TAP PRI MOD NCK 16DEG 30MM
NLS-340000B	LRG TAP PRI MOD NCK 0DEG 34MM
NLV-340800Y	LRG TAP PRI MOD NCK 8DEG 34MM
NLV-340800G	LRG TAP PRI MOD NCK 8DEG 34MM
NLS-341600P	LRG TAP PRI MOD NCK 16DEG 34MM
NLS-380000B	LRG TAP PRI MOD NCK 0DEG 38MM
NLV-380800Y	LRG TAP PRI MOD NCK 8DEG 38MM
NLV-380800G	LRG TAP PRI MOD NCK 8DEG 38MM
NLS-381600P	LRG TAP PRI MOD NCK 16DEG 38MM
NLS-420000B	LRG TAP PRI MOD NCK 0DEG 42MM
NLV-420800Y	LRG TAP PRI MOD NCK 8DEG 42MM
NLV-420800G	LRG TAP PRI MOD NCK 8DEG 42MM
NLS-421600P	LRG TAP PRI MOD NCK 16DEG 42MM

RA 2012-067 EXT PFA ACKNOWLEDGMENT FORM

Please complete this form even if you do not have any product to return. This will preclude the need for future notices

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I acknowledge receipt of the Field Safety Notice for RA 2012-067 EXT and can confirm that:

PLEASE TICK APPROPRIATE SECTION

❑ WE HAVE PHYSICALLY CHECKED ALL HOSPITAL LOCATIONS AND WE DO NOT HAVE THE AFFECTED DEVICES.

❑ PLEASE ARRANGE COLLECTION AND REPLACEMENT FOR THE FOLLOWING DEVICES THAT WE HAVE IDENTIFIED.

Product Code	Lot Code	Qty to be returned

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital/ Organisation		Address	
Contact Name			
Contact Title			
Contact Signature			
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO DANIEL.RANA@STRYKER.COM