325 Corporate Drive
Mahwah, NJ 07430
t: 201 831 5000

stryker®

Orthopaedics

IMPORTANT PRODUCT RECALL UPDATE
RA2012-067 EXT_2

Reference: RA 2012-067_EXT_2 (update of the action reference RA2012-067_EXT_1 dated on Jan 2013)
Description: ABGII Modular Stems and ABGII Modular Necks
Rejuvenate Modular Stems and Rejuvenate Modular Necks
Catalog No.: See attached list
Lot Codes: All

July XX, 2014

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Dear Surgeon,

At Stryker, patient health and well-being is our number one priority. Since initiating the voluntary recall of Rejuvenate and ABG II modular-neck femoral hip stems, Stryker committed to partnering with the medical community to better understand this matter and to provide updates when appropriate. To that end, Stryker would like to reiterate some important information and provide you with an update.

Previous Communications
In June 2012, Stryker voluntarily recalled Rejuvenate and ABG II modular-neck stems after post-market surveillance data indicated potential risks associated with fretting and corrosion at the modular neck junction. Stryker notified healthcare professionals and regulatory bodies of this voluntary recall and encouraged surgeons to follow-up with patients who received a Rejuvenate or ABG II modular-neck femoral hip stem.

In January 2013, Stryker issued a Product Recall Update which included the following recommendations:

- Surgeons should consider performing a clinical examination, such as blood work (including infection screen and metal ion levels) and cross sectional imaging, regardless of whether a patient is experiencing pain and/or swelling.
- Routine follow-up examination, such as blood work and cross section imaging, should be considered even in the presence of normal initial findings.
- When following up with patients, surgeons should continue to evaluate their patients for aseptic loosening and periprosthetic sepsis.
- If the surgeon's workup reveals an adverse response to metal wear debris, the surgeon should consider proceeding with a revision of the femoral component to a device without a modular neck.

Updated Information
Recent Publications
Recent publications regarding the Rejuvenate and ABG II modular neck stems have included treatment algorithms and revision rates: Pivec, Robert, Meneghini, Michael R., Hozack, William J., Westrich, Geoffrey H., Mont, Michael A., "Modular Taper Junction Corrosion and Failure: How to Approach a Recalled Total Hip Arthroplasty Implant." *Journal of Arthroplasty* Volume 29, Issue 1, Pages 1-6, January 2014. A full copy of this publication can be found by visiting http://literature.ortho.stryker.com/files/REJUV_AJA_1.pdf .

Patient Reimbursement
Stryker also reminds you that as part of its commitment to support patients and surgeons affected by this matter, it is reimbursing patients for out of pocket expenses directly arising from testing, treatment, revision surgery (if necessary), and other costs relating to this voluntary recall. Broadspire Services, Inc., a leading third-party claims administrator, is managing requests for reimbursement of costs relating to the recall of the Rejuvenate and ABG II modular-neck stems. Since January 2013, Broadspire has assisted patients through the claims and reimbursement process, and payments have been made to cover costs for medical treatment and patient out-of-pocket expenses including co-pays, deductibles, lost wages and travel costs.

If there is a need to submit a new claim, patients should contact Broadspire at toll-free number 0808 2381788 or +44(0)1908 302344. Additional information on this voluntary recall and claims process can be found at www.stryker.co.uk/modularneckstems.

In the meantime should you have questions, please contact <INSERT LOCAL/COUNTRY CONTACT>

RA2012-067 EXT_2 – 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

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
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

STRYKER® ORTHOPAEDICS
PRODUCT RECALL ACKNOWLEDGMENT FORM
RA2012-067_EXT_2

DATE

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I have received the notification from Stryker® Orthopaedics dated INCLUDE DATE stating that they have provided an update to the product recall notice of the above described products.

_____ _____ ___
Risk Manager Date
(Signature)

_____
Risk Manager
(Print)

Please fax this signed and dated form to INCLUDE THE CONTACT