325 Corporate Drive
Mahwah, NJ 07430
201-831-5000

stryker®

Orthopaedics

URGENT UPDATE
FIELD SAFETY NOTICE

January X 2013

Product Remediation #: RA 2012-067 EXT_1

Description:	ABGII Modular Stems and ABGII Modular Necks
Catalog No.:	See attached list
Lot Codes:	All

Description:	Rejuvenate Modular Stems and Rejuvenate Modular Necks
Catalog No.:	See attached list
Lot Codes:	All

Dear XX,

On June 28, 2012, Stryker Orthopaedics issued a Product Recall communication (Product Remediation reference # RA2012-067ext) for the above products. Since initiating this product field action, Stryker continued to work with the medical community to better understand this matter. The purpose of this letter is to provide updated information regarding the medical follow-up of patients with the ABGII Modular and Rejuvenate Modular Hip Systems:

Updated Patient Follow-up

The following information is applicable to patients with ABGII Modular and Rejuvenate Modular Hip Systems:

- 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.
- Repeat 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

Potential Hazards

The Potential Hazards identified in the June 28, 2012 Product Recall communication remain unchanged and are reprinted below.

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 Mitigation identified in the June 28, 2012 Product Recall communication remains unchanged and is reprinted below.

The risk was mitigated by the product recall.

Please continue to report to Stryker all adverse events related to the products.

Our records indicate that you have received and/or used the above referenced product(s). It is Stryker®'s responsibility as the manufacturer to ensure that customers who may have received and/or used these affected products also receive this important communication. Please assist us in meeting our regulatory obligation by faxing back the attached Product Recall Acknowledgement Form at your earliest convenience to 1-855-251-3635.

Please note that your signature on the following form only confirms that you received this notification and does not obligate you to take any additional action beyond what is called for in this notification letter.

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact me at [redacted], or [redacted], Director, Global Femoral Brand at 201-831-[redacted]

Sincerely,

[redacted]

[redacted]
Manager, Divisional Regulatory Compliance

RA2012-067 EXT 1 – 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

January X 2013

«ShipTo_Customer_Name»
«ShipTo_Address_1»
«ShipTo_Address_2_»
«ShipTo_Address_3_»
«SHIPTOCITY», «SHIPTOST» «SHIPTOZIP»

Product Remediation #: RA 2012-067 EXT_1

Description:	ABGII Modular Stems and ABGII Modular Necks
Catalog No.:	See attached list
Lot Codes:	All

Description:	Rejuvenate Modular Stems and Rejuvenate Modular Necks
Catalog No.:	See attached list
Lot Codes:	All

I have received the notification from Stryker® Orthopaedics dated January X 2013 stating that they have provided an update to the product recall notice of the above described products.

_____ _____

Risk Manager
(Signature)

Date

_____

Risk Manager
(Print)

Please fax this signed and dated form to [redacted] at 1-855-251-3635

325 Corporate Drive
Mahwah, NJ 07430
201-831-5000

stryker®

Orthopaedics

January X, 2013

Dear <INSERT CONTACT>,

We have some important information to share with you about Stryker's recall of its Rejuvenate and ABG II modular-neck femoral hip systems.

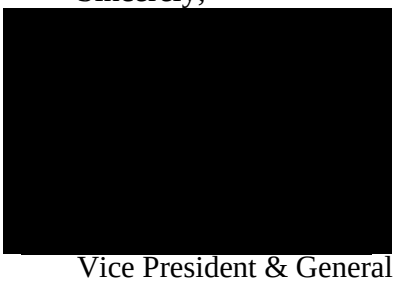
We have been working with the medical community to better understand this matter since the recall was initiated in June 2012. As a result, we are announcing two important developments.

First, surgeons should consider performing a clinical examination, such as blood work (including infection screen and metal ion levels) and cross sectional imaging on all patients who received a Rejuvenate or ABG II modular-neck hip stem regardless of whether a patient is experiencing pain and/or swelling. Repeat follow-up examination, such as blood work and cross section imaging, should be considered even in the presence of normal initial findings. For further information regarding patient follow-up please refer to the enclosed Product Recall Update.

Second, as part of our commitment to support patients and surgeons affected by this matter, Stryker will be reimbursing for testing, treatment, revision surgery, if necessary, and other costs relating to this voluntary recall. Stryker is partnering with Broadspire Services, Inc., a leading third-party claims administrator, to manage requests for reimbursement of costs relating to the voluntary recall of the Rejuvenate and ABG II modular-neck hip stems. Broadspire are in the process of establishing call centers in each market and we anticipate they will be fully operational within 60 days. Additional information will follow.

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

Sincerely,



Vice President & General Manager, Global Hip Reconstruction Business Unit

March X, 2013

Dear <INSERT CONTACT>,

We have some additional information to share with you about Stryker's voluntary recall of its Rejuvenate and ABG II modular-neck femoral hip systems.

In our recent communication we announced two important developments.

First, surgeons should consider performing a clinical examination, such as blood work (including infection screen and metal ion levels) and cross sectional imaging on all patients who received a Rejuvenate or ABG II modular-neck hip stem regardless of whether a patient is experiencing pain and/or swelling. Repeat follow-up examination, such as blood work and cross section imaging, should be considered even in the presence of normal initial findings.

Second, as part of our commitment to support patients and surgeons affected by this matter, Stryker will be reimbursing for testing, treatment, revision surgery, if necessary, and other costs relating to this voluntary recall. Stryker is partnering with Broadspire (a Crawford company), a leading third-party claims administrator, to manage requests for reimbursement of costs relating to the voluntary recall of the Rejuvenate and ABG II modular-neck hip stems. Broadspire have established call centers in each market and are fully operational from 1st February 2013.

In order to review and process the reasonable costs incurred, Broadspire will need access to some aspects of the patient's medical records that specifically relate to their hip implant and subsequent treatment. Broadspire takes great efforts to manage sensitive records securely and comply with all relevant data privacy laws. Before accessing and processing their medical data, Broadspire will ask patients to sign a form granting their consent to access and process sensitive data. Once the patient has consented to this access, Broadspire will be able to validate claims for reimbursement of medical costs and process payments more quickly.

Patients that have previously submitted claims with Stryker will now work directly with Broadspire. 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 any questions, please contact <INSERT LOCAL/COUNTRY CONTACT>.

Dear Customer

We wrote to you, on (date xxx), notifying you of additional actions requested by Stryker Orthopaedics relating to a Product Field Action that was originally initiated in (insert date) Details of the devices subject to this action are referenced above.

We have noted that your facility have already completed and returned the customer response form, acknowledging receipt of the Field Safety Notice that was distributed on (date). Our records have been updated to reflect this and we thank you sincerely for responding so quickly on this matter.

In the notification of (date) it was explained that the manufacturer had completed further investigations into the performance of the devices subject to this action and had determined that there was a need for additional patient monitoring. The letter also indicated that call centers and websites would be set up to support healthcare practitioners in this process and that an additional communication would be sent out with the contact details for these centers. This information is now available and a copy of the letter issued by the manufacturer is attached for your information. Please do not hesitate to contact these centres should you have any queries or concerns concerning this process.

Should you have any immediate queries and wish to speak directly with a Stryker Representative please contact:

Name: Position: E-mail:

Please note that this Product Field Action has been reported to the Competent Authority and they have been notified of this additional communication.

Once again on behalf of Stryker we thank you for your help and support in this process. It is very much appreciated.

Yours,