stryker
Orthopaedics

April XX, 2012

URGENT: Field Safety Notice

FSCA identifier: Product Field Action **RA 2012-062**

Type of Action: Field Safety Corrective Action: **Product Inspection/ Return to Supplier**

Description: Restoration Modular Cone Body Trials

Catalog #: 6278-1-019, 6278-1-021, 6278-1-023, 6278-1-025, 6278-1-027, 6278-1-029, 6278-1-031, 6278-1-119, 6278-1-121, 6278-1-123, 6278-1-125, 6278-1-127, 6278-1-129, 6278-1-131, 6278-1-219, 6278-1-221, 6278-1-223, 6278-1-225, 6278-1-227, 6278-1-229, 6278-1-231, 6278-1-319, 6278-1-321, 6278-1-323, 6278-1-325, 6278-1-337, 6278-1-329, 6278-1-331

Lot Code: Refer to Attachment 1distribution history

Dear Distributor/ Risk Management/Surgeon:

On April XX 2012 Stryker® Orthopaedics initiated a product recall for the products and lot ID referenced above. The intent of this letter is to initiate a product inspection of the above noted products.

Issue:

Stryker Orthopaedics has become aware that there is the potential for the presence of a burr in the last threaded feature of Restoration Modular Cone Body Trials. This threaded feature mates with the trial locking bolt. To date, no Product Experience reports were received with regard to this issue.

Technical and Medical Assessments are currently underway to determine the list of any potential hazards associated with the use of the product. An additional communication will be forwarded upon completion of the internal investigation of this issue.

Our records indicate that you have received the above referenced product. Please refer to the attached Bulletin for instructions on how to inspect the affected product. If a device is determined to be non-conforming, please continue to quarantine the device and return to the manufacturer.

All inspections must be completed immediately as per the provided Product Correction Bulletin. Please document the results of your inspection on the Tracking Log, indicating conforming devices as "Not Affected" and non-conforming devices as "To be returned." If the devices listed on your tracking log have previously been returned or are otherwise not on hand, indicate the appropriate disposition following our usual process.

- All trials both at your physical location and those on-site at hospital locations must be inspected.
- Trials which do not exhibit the non-conformance may continue to be used in surgery.
- As stated above, trials which exhibit the non-conformance must remain in quarantine and be returned to the manufacturer.
- Confirmation of inspection of all trials distributed to each region is required.

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 faxing back the attached Product Acknowledgment Form.

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

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Lot Code: Refer to Attachment 1distribution history

Type of Action: Notifiable Recall

I have received the notification from Stryker® Orthopaedics dated April XX, 2012 stating that they initiated a voluntary Field Safety Corrective Action of the above referenced product.

_____ _____

Surgeon (Signature) Date

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Surgeon (Print)

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Please fax this signed and dated form to XXXX