stryker
Orthopaedics

December XX, 2011

URGENT: Field Safety Notice

FSCA identifier: Product Field Action **RA2011-158**

Type of Action: Field Safety Corrective Action: **Return to Supplier**

Description: TRIDENT 10 Degree Poly Inserts

Catalog #: 620-10-22G, 620-10-32E, 620-10-32F, 620-10-32G, 620-10-32H and 620-10-32I

Lot Code: 27086201, 32961601, 33092201, 33653101, 33646401, 33950701, 34072501,34075101, 34576001, 34577101, 32825101, 33106101, 33468501, 33658501,33664301, 33667601, 33668901, 35601301, 35660101, 31643601, 33468601, 33521501, 34538201, 34549601, 27160801, 27157401, 27942101

Dear Distributor/ Risk Management/Surgeon:

On December XX, 2011 Stryker® Orthopaedics initiated a voluntary product recall for the product referenced above.

Issue
The Trident 10 Degree Inserts were removed from Stryker Orthopaedics's Design Dossier as part of the 2007 Medical Device Directive amendments and should have been obsoleted as a consequence to this change. No shipments to the EU should have occurred, however shipments continued until April 2011.

Potential Hazards
There are no potential hazards associated with this field safety corrective action.

Any product remaining in the field will be returned to the manufacture as part of this field safety corrective action and therefore runs no risk of being implanted.

Our records indicate that you have received the above referenced product and we are requesting that you assist us in this voluntary Field Safety Corrective Action by completing the attached Product Field Safety Corrective Action Acknowledgement Form.

It is Stryker's responsibility as the manufacturer to ensure that customers who have received this affected product also receive this important communication. Please assist us in meeting our regulatory obligation by faxing back the attached form at your earliest convenience.

In the occurrence that any of the affected Lots are unused, please follow the below advice:

1. Immediately check your internal inventory and quarantine all subject devices.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
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. Complete the attached customer response form.
   (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)
6. Please inform Stryker of any adverse events.
7. Return the completed form and any affected devices to your local Stryker Representative.

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
PRODUCT RECALL ACKNOWLEDGMENT FORM

December XX, 2011

SURGEON

ADDRESS

CITY, STATE ZIP

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I have received the notification from Stryker® Orthopaedics dated December XX, 2011 stating that they initiated a voluntary Field Safety Corrective Action of the above referenced product.

_____ _____

Surgeon (Signature) Date

_____

Surgeon (Print)

_____

Please fax this signed and dated form to XXXX