stryker
Orthopaedics

21/09/2015

URGENT: Field Safety Notice

FSCA identifier: Product Field Action RA2015-105

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

Description: Duracon Augments

Catalog #: 6630-6-105, 6630-6-110, 6630-6-125, 6630-6-130, 6630-6-150, 6630-6-155, 6630-6-170, 6630-6-175, 6630-6-205, 6630-6-210, 6630-6-225, 6630-6-230, 6630-6-250, 6630-6-255, 6630-6-270, 6630-6-275, 6630-6-305, 6630-6-310, 6630-6-325, 6630-6-330, 6630-6-350, 6630-6-355, 6630-6-370, 6630-6-375, 6630-6-405, 6630-6-410, 6630-6-425, 6630-6-430, 6630-6-450, 6630-6-455, 6630-6-470, 6630-6-475

Lot Code: Various as per distribution history

Dear Distributor/ Risk Management/Surgeon:

On the 21st of September 2015, Stryker initiated a lot-specific product recall for Duracon Augments devices as referenced above. The intent of this letter is to list all known hazards potentially associated with the use of the product and list the risk mitigation factors.

Issue:

Stryker has received two customer complaints regarding Duracon Tibial Wedge implants puncturing the packaging's Tyvek lid(s). In each case, the punctured Tyvek lid was recognized in the operating room and a new device was opened and used.

Potential Hazards:

1. Device is not utilized during surgery
2. Non-sterile implant

The aforementioned potential hazards may result in one or more of the following potential patient harms:

1. Delay in surgery <5 minutes while new device is obtained
2. Infection

Risk Mitigation

In all Stryker Instructions for Use (IFU) for the above referenced product, the end user is instructed to inspect the package for damage and, if present, to discard the device. Operating room staff should conduct this packaging inspection for any breach in the outer and inner packaging. Performing this inspection may mitigate this potential hazard.

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Our records indicate that you have received the above referenced product. Please assist us in meeting our regulatory obligation by:

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 and return the form and any affected devices to your local Stryker Representative.
   (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 associated with the use of the subject devices.
   a. Comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.

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 do not hesitate to contact the undersigned.

Yours Sincerely,

STRYKER® ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

September XX, 2015

SURGEON

ADDRESS

CITY, STATE ZIP

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Lot Code: Various as per distribution history

Type of Action: **Return to Supplier**

I have received the notification from Stryker® Orthopaedics dated September XX, 2015 stating that they initiated a Field Safety Corrective Action of the above referenced product.

_____ _____
Surgeon (Signature) Date

_____
Surgeon (Print)

Please fax this signed and dated form to XXXX