stryker®

Osteosynthesis

URGENT
FIELD SAFETY NOTICE

January 13, 2012

HOSPITAL
ADDRESS
CITY STATE ZIP

Recall #: RA 2011-153

Description: T2 Arthrodesis Nail (left and right version)
Catalog No.: see list below

Catalogue # (left version)			Catalogue # (right version)		
18292004S	18291104S	18291304S	18292054S	18291154S	18291354S
18292008S	18291108S	18291308S	18292058S	18291158S	18291358S
18292012S	18291112S	18291312S	18292062S	18291162S	18291362S
18292016S	18291116S	18291316S	18292066S	18291166S	18291366S
18292020S	18291120S	18291320S	18292070S	18291170S	18291370S
18292024S	18291124S	18291324S	18292074S	18291174S	18291374S
18292028S	18291128S	18291328S	18292078S	18291178S	18291378S

Lot Codes: see attached list

Dear Hospital Risk Management:

Stryker® Osteosynthesis is initiating a Voluntary Product Recall of the T2 Knee Arthrodesis Nail from catalog numbers referenced above and lot codes identified in the attached list.

Issue
Stryker Osteosynthesis has become aware that there is a potential for breaching the sterile barrier of certain lots of T2 Knee Arthrodesis Nails upon transportation which might lead to loss of sterility.

Potential Hazards
The potential hazard associated with this product field action is unsterile product due to perforation of the sterile barrier. There are two associated potential harms. The first associated potential harm is infection. The risk to patient is severe. The second associated potential harm is prolongation of surgery time to find replacement product or re-sterilization of same product if replacement product not available. The risk to patient is limited.

Risk Mitigation
If the package is visibly damaged, the potential hazard of occurrence is minimal as the damage will be recognized by the user and the surgeon will use another devices instead.
As it is not indicated to accept the risk situation for the use of the devices affected we are therefore initiating a Field Safety Corrective Action. Any product remaining in the field will be returned to the manufacturer as part of this field safety corrective action and therefore will be not at risk of being implanted.

Increased patient follow up would neither result in early diagnosis nor early detection of clinical problems.
The implanting and treating physicians should have an increased awareness of this issue and follow patients according to the normal post-operative course of treatment.
We recognize that implanting and treating physicians are in the best position to exercise medical judgment for their patients and should make the final decision on this point.

Actions Needed
Our records indicate that you have received the above referenced product(s) and we are requesting that you assist us in this Field Safety Corrective Action by:

Passing this Field Safety Notice to all those who need to be aware of it within your organization.

If you have further distributed this product, please forward this letter and the attached Business Reply Form (BRF) to all affected locations. Please indicate each location on the BRF.

Immediately check all stock areas or operating room storage and quarantine any affected product(s) found.

Mark product as “RECALLED PRODUCT”.

Please indicate on the BRF the quantity of affected T2 Knee Arthrodesis Nails you are returning and fill in the form completely.

Sign the BRF (**even if you do not have any affected product**).
Note: *Your signature on the BRF indicates that you have received and understand this notification and are returning all affected product(s) from your facility.*

Return the Business Reply Form to Stryker Osteosynthesis Regulatory Department, (need fax number)

Upon receipt of the BRF, Stryker will contact you to coordinate the return of all affected product that you have on hand.

Send back all affected product using the pre-paid shipper provided to you by Stryker.

We sincerely regret any inconvenience caused to you by this action, however we know that you share our desire to ensure the highest quality standards in our products and reduce risks to patients. We would like to thank you for your co-operation in this matter. Should you require any further information or have any queries on the matter please do not hesitate to contact the undersigned..

Yours faithfully,

Name
Position
(address)
phone: xxxx-xxxx
fax: xxxx-xxxxxx
email: XXX.XXX@stryker.com

Enclosures:
Distribution List
Customer Response Form

STRYKER® OSTEOSYNTHESIS
Field Safety Corrective Action ACKNOWLEDGMENT FORM

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Lot Codes: see attached list

I have received the notification from Stryker® Osteosynthesis dated January 13, 2012 stating that they initiated a Field Safety Correction Action of the above referenced product.

_____ _____

Hospital Risk Management Representative (Signature) Date

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Hospital Risk Management Representative (Print)

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Please fax this signed and dated form to XX