



Osteosynthesis

## URGENT FIELD SAFETY NOTICE

Date:

HOSPITAL  
ADDRESS  
CITY STATE ZIP

Recall #: RA 2009-357

Description: T2 Ankle Arthrodesis Nail  
Catalog No.: 18181030S 18181130S 18181230S  
18191030S 18191230S 18191230S  
Lot Codes: see attached list

Dear Hospital Risk Management:

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

The potential harms associated with this issue being moderate to severe infection and elongation of surgery time (time under anesthesia).

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.

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
- Placing the concerned products immediately in quarantine
- Returning the concerned products to Stryker
- Informing Stryker if products have been distributed to other users
- Informing Stryker if products have been discarded in the meantime
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- Completing the attached Customer Response Form and returning it to us

We sincerely regret the inconvenience caused to you by this action, however we know that you share the 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 us on .....phone number.

Yours faithfully,

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Name  
Position

**Enclosures:**  
Distribution List  
Customer Reponse Form