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DePuy Synthes
COMPANIES OF Johnson & Johnson

To all customers using Synthes SynFix-LR Implant Holder

14 October 2013

Urgent: Field Safety Notification / Medical Device Notification SynFix-LR Implant Holder

Part Description	Part Number	Lot Number
SynFix-LR Implant Holder	03.802.039	ALL
		

Dear Sir/Madam:

Synthes is initiating a Field Safety Notification related to the SynFix-LR Implant Holder.

Reason for Notification: Complaints have been received which describe the SynFix LR implant holder breaking at the interface between the implant and holder. If an unretrieved device fragment remains threaded into the plate, it will not be possible to properly attach the SynFix Aiming Device to the implant (plate). Proper attachment of the Aiming Device to the plate is required for accurate insertion of the four SynFix screws into the SynFix implant (plate) and vertebral bodies. If the tip holder should break, the potential exists for an unretrieved device fragment (URDF) to be left in the SynFix-LR Implant.

Potential Hazard: There is the potential for delay to the surgical procedure while the device is retrieved and exchanged which may expose patients to greater than expected amounts of anesthesia and the associated risk of this exposure. Forceps are provided to facilitate the removal of the SynFix implant; however, the surgeon may decide to leave the device implanted with the embedded broken fragment if removal and replacement of the implant is likely to cause damage to the surrounding structures. The implant holder is composed of non-implant grade material so any unretrieved fragment presents the potential risk of galvanic corrosion due to contact of dissimilar metals, potentially resulting in an adverse tissue reaction. If the patient is exposed to MRI at a later date, the retained fragment's presence may elicit a reaction. The fragment may heat up during MRI exposure however, since the fragment is threaded into the implant and subsequently broken off, the chance of migration during MRI exposure is deemed unlikely.

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Action: **Synthes is not requesting the return of this product - this notification is intended to highlight the potential patient risks of unretrieved device fragments only.** However, if your hospital owns this device and wishes to return it, please contact your local DePuy Synthes Spine Sales Consultant.

Please take the following actions:

- Review, complete, sign and return the attached reply form to your local DePuy Synthes sales organisation in accordance with the directions on the form.
- Forward this Field Safety Notification to anyone in your facility that needs to be informed.
- Maintain awareness of this Field Safety Notification & maintain a copy.

To **return** any of the identified devices, please take the following steps:

- Please prepare the list of affected part and lot numbers and contact your local DePuy Synthes Spine Sales Consultant.
- Complete the Verification Section at the end of this letter by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found. Please include your name, title, telephone number and signature in the spaces provided.

If you **DO NOT have** the identified product or **do not wish to return** the product, please take the following steps:

- Complete the attached Verification Section at the end of this letter by checking the appropriate box indicating that no affected product has been located. Please include your name, title, telephone number and signature in the spaces provided. This return documentation acknowledges your receipt of medical device removal information.

The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

If you have any questions, please contact your Synthes Trauma consultant.

Thank you for your attention to this issue.

Sincerely,

Synthes GmbH

Claudia Allemann
Field Action Manager

i.V. Stephan Müller
Markus Wien
Director Quality Assurance Operations

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FIELD SAFETY NOTICE FSN2013042

Synthes SynFix-LR Implant Holder

Verification Section

Part Description	Part Number	Lot Number
SynFix-LR Implant	03.802.039	ALL

☐ We have identified the product and wish to return it. The returned quantity is documented below.

☐ We acknowledge receipt of this information but do not have the SynFix-LR Implant Holder or do not wish to return it.

RETURNED DEVICES (including quantity) and/or COMMENTS:

_____

_____

_____

_____

_____

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____