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DePuy Synthes

To all customers using Synthes SynFix-LR Implant Holder **FSN 20149998**

22 April 2014

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:

We are writing to inform you that Synthes GmbH is initiating a Field Safety Notification related to the SynFix-LR Implant Holder. **This notification is to inform you of the follow-up actions related to the notification FSN2013042** issued in October 2013 with which your facility was notified of the potential for SynFix-LR Implant Holder breaking at the interface between the implant and the 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-LR Aiming Device to the implant (plate). Proper attachment of the Aiming Device to the plate is required for accurate insertion of the four SynFix-LR screws into the SynFix-LR implant (plate) and vertebral bodies. If the tip of the 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

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exposure: however, since the fragment is threaded into the implant before the breakage occurs, the chance of migration during MRI exposure is deemed unlikely.

Root Cause for Breakage of Implant Holder:
It was determined that two or more of the following factors in combination might potentially lead to the Implant Holder breaking:

A. A loose connection between Implant Holder and implant due the incorrect assembly of the three component parts of the Implant Holder.
B. A loose connection between Implant Holder and Implant due to the implant being inadequately attached.
C. The jamming of the Implant Holder to the implant leading to excessive loading.
D. Excessive torque from over-tightening while attaching the implant to the Implant Holder.

Implemented Measures
The updated disassembly and assembly instructions (SE_431098 AB) clarify and reinforce the importance of using two wrenches for correct Implant Holder assembly and address root cause A.

To address the root causes A to D the revised surgical technique for SynFix-LR (0x6.000.915 AH):

1. Includes the updated assembly and disassembly instructions (SE_431098 AB) of the Implant Holder to assure correct assembly in the operating room.
2. Reflects the addition of two (2) wrenches (E5211-3) to each set to ensure the correct assembly and disassembly, especially with regard to the counter-torqueing of the cap and bolt on the tip of the Implant Holder.
3. Clarifies the appropriate tightening forces between Implant Holder and implant.
4. Update to ensure a firm attachment of the Implant Holder to the implant is maintained during insertion and final positioning.
5. Clarifies the correct disengagement of the Implant Holder from the implant and adds a precaution to remove the construct if difficulties removing the Implant Holder from the implant are encountered.
6. Adds a precaution that implant should be removed using the Holding Forceps (388.407) if the aiming device cannot be attached to the implant.

Action:

1. **Please update your current SynFix-LR surgical technique guide with the updated technique guide (0x6.000.915 AH) provided with this notice.**

2. **Please update your current SynFix-LR assembly/disassembly instructions with the updated assembly/disassembly instructions (SE_431098 AB) provided with this notice.**

Additionally, please note, DePuy Synthes has updated the Vario Case design to incorporate two additional wrenches to facilitate correct assembly/disassembly and an additional Implant Holder to facilitate continuation of the surgery.

Furthermore, please be reminded that an alternative to the implant holder, the SQUID instrument, (03.802.121) can be used for the insertion of the implant in suitable cases.

Any steps necessary to further mitigate the potential risk of instrument breakage and un-retrieved device fragments will be considered as a result of our post market surveillance of this product in concert with our trending of product complaints received through our routine complaint handling process. Furthermore, in accordance.with DePuy Synthes ISO 13485 accreditation and the company's own commitment to continuous improvement, all feedback received on our products is reviewed on an ongoing basis to identify potential design and functional improvements which might

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be applicable to our current products as well as those under development.

We would like to request that you please also take the following actions:

- Review, complete, sign and return the attached reply form to your local DePuy Synthes sales consultant 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 & retain a copy for your reference.

If you **DO NOT have** the identified surgical technique guide specifically the surgical technique guide and assembly/disassembly instructions, 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 labelling has been located. Please include your name, title, telephone number and signature in the spaces provided. This return documentation acknowledges your receipt of this Field Safety Notification.

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

If you have any questions, please contact your DePuy Synthes Spine sales consultant.

Thank you for your attention to this issue.

Sincerely,

Synthes GmbH

[redacted]

Field Action Manager

[redacted]

Director Quality Assurance Operations

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FIELD SAFETY NOTICE FSN20149998

Synthes SynFix-LR Implant Holder

Verification Section

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

☐ We have received the updated labelling for SynFix-LR and will discard the previous versions.

☐ We acknowledge receipt of this information but do not have SynFix-LR labelling at this facility.

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____