

To the ATTENTION of:
Operating Room Manager

20 June 2014

Urgent: Field Safety Notification FSN20149997

Follow-up action for the Application Instrument of Sternal ZipFix™: Changes in the Surgical Technique Guide

| Part Description | Part Numbers | Lot numbers |
|--|--------------|---|
| Application Instrument for Sternal ZipFix™ | 03.501.080 | All 1st generation Application Instruments (Lots prior to 8100630) |

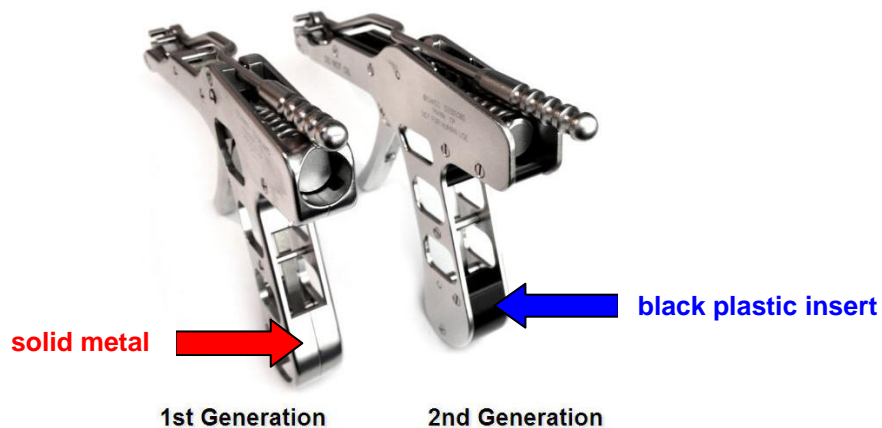
Dear Sir/Madam:

Synthes is issuing a Field Safety Notification for the CMF Application Instrument for Sternal ZipFix™ (03.501.080).

Our records indicate that your facility uses the CMF Sternal ZipFix™ System.

Reason for notification: While the Surgical Technique Guide includes a precaution that the trigger must be released before and during cutting and that no cutting should take place under tension, when using the 1st generation Application Instrument for Sternal ZipFix™, it is possible to cut the implant while the tensioning trigger is being squeezed (known as being cut under tension). This allows the ZipFix™ implants to become overly tensioned and possibly cut.

NOTE: This issue applies to the 1st generation Application Instrument only. The 1st generation instrument is distinguishable by the presence of an all stainless steel handle. Please see the figures below for 1st generation and 2nd generation instruments.



With the Field Safety Notification FSN2013022 issued in August 2013, your account was notified of the need not to cut under tension with the Application Instrument for Sternal ZipFix™.

This notification is to inform you of the follow-up actions related to the mentioned notification FSN2013022 of August 2013 about changes in the Surgical Technique Guide with regard to the Application Instrument for Sternal ZipFix™.

Potential hazard: The ZipFix™ implant can possibly loosen if the implant is cut while the tensioning trigger is being squeezed. The possibility also exists for the ZipFix™ implant to be compromised and loosen after implantation or during the post-operative recovery period.

A compromised implant may hold initially, and loosen or burst open during the postoperative period. In these cases, the risk to the patient can be medically severe. Loose or broken implants postoperatively can lead to the following issues including but not limited to:

- Sternal instability
- Patient complaints of irritation, discomfort and pain
- Malunion or nonunion of the sternum
- Revision
- Damage to vital organs leading to hemorrhage and/or patient death

If you have utilised the 1st generation Application Instrument for Sternal ZipFix™ in prior surgeries, additional medical or surgical intervention is not required in the absence of postoperative patient complications. Follow your normal postoperative patient treatment and monitoring regimen.

If you currently have a 1st generation ZipFix™ Application Instrument you **must** completely release the tensioning trigger before cutting the implant. Additionally, after cutting the implant, return the cutting lever to its originating (locked) position before using the Application Instrument to tension a subsequent implant.

Action:

Please remove the Surgical Technique Guide 036.001.285 (all versions) dated 10/2012 or earlier and replace it with the updated Technique Guide provided with this communication (Version 036.000.285 AE, Date 03/2014).

You can find the version number and date transversely positioned on the back cover of the Surgical Technique Guide called “Sternal ZipFix™ System“.

Please find a compilation of all changes in the Appendix (starting on page 4) of this communication.

Please also 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 provided 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 and keep a copy.

If you DO NOT have the identified Surgical Technique Guide called "Sternal ZipFix™ System", please take the following steps:

- Complete the attached Verification Section at the end of this letter by checking the appropriate box indicating that you do not have the CMF Sternal ZipFix™ System at this facility. 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 taking this action voluntarily.

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

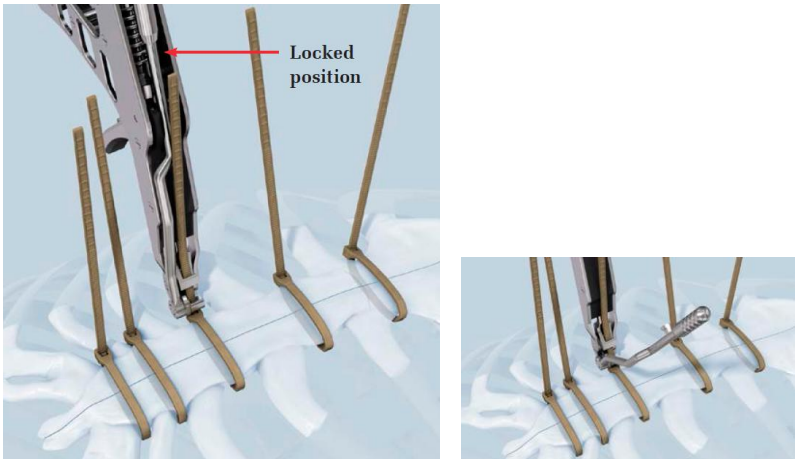
Thank you for your attention to this issue.

Sincerely,


| | |
|---|--|
| <p>Synthes GmbH  Dr. med. Maria I. Behrens MDRA Field Action Manager</p> | <p> Markus Wien Director Quality Assurance Operations</p> <p><i>Stephan Witten, VP QMS</i></p> |
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Appendix

Table 1: Updated version of the Surgical Technique Guide (036.000.285 AE) gives precise instructions how to avoid cutting the implant while tensioning with the application instrument .

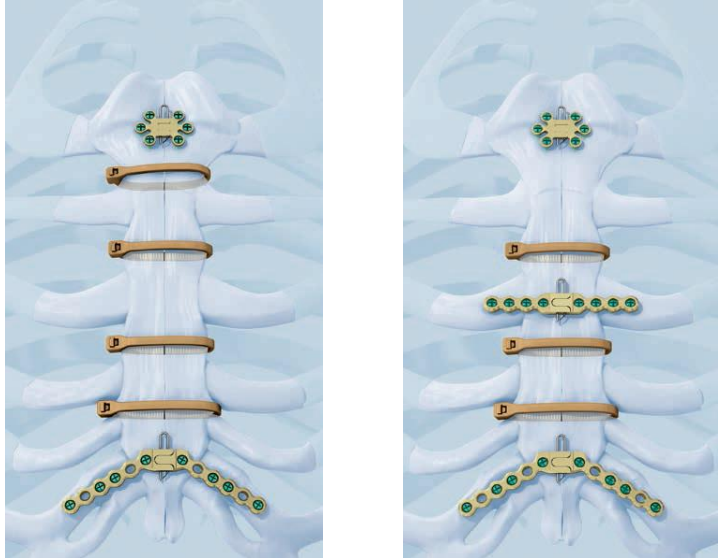
| Table 1 Updated Surgical Technique Guide on Sternal ZipFix™ | | | |
|--|------|--|------|
| New version | | Former version | |
| Version: 036.000.285 AE Date: 03/2014 | page | Version: 036.001.285 AD Date: 10/2012 | page |
| Part: Surgical Technique Chapter: Surgical Technique Section: 7 Remove excess material This chapter is newly constructed to ensure how to avoid cutting under tension. Newly added wording: “Warning: The tensioning trigger must be completely released before and during implant cutting. Cutting the implant while tensioning with the application instrument could compromise the implant lock and lead to implant failure. Do not cut the implant under tension. ...The excess material can also be removed with a wire/pin cutter.” | 14 | “Ensure the cutting lever is in the locked position. Precaution: The trigger must be released before and during cutting. Do not cut under tension.” | 14 |
| New: Detailed images show the position of the cutting lever locked and unlocked. An arrow indicates “Locked position” .  | 14 | | 14 |

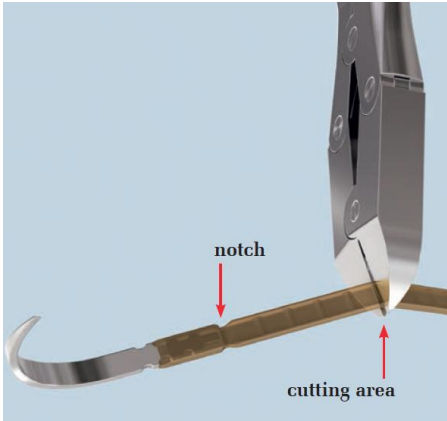
| Table 1 | | | |
|---|----|---|-------|
| Updated Surgical Technique Guide on Sternal ZipFix™ | | | |
| New version | | Former version | |
| Chapter: Surgical technique Section: 5 Secure Sternal ZIPFIX implants New: “Repeat for the remaining ZIPFIX. Remove forceps, if used.” In order to emphasize that it must not be cut under tension the following text has been added: “Prior to insertion of the cut end, ensure the ZIPFIX is properly oriented such that the toothed surface contacts the sternum. Avoid excessive force when tightening implant. Do not use forceps to tighten implant. Damage resulting from excessive force or forceps may cause implant failure.” | 12 | “Stainless steel needles must be removed before closing the Sternal ZipFix implants to avoid damage to the locking head.” | 11 |
| Chapter: Surgical technique Section: 6 Tension Sternal ZIPFIX implants New: Detailed advice is given on the relation between tension and cutting: “The cutting lever is locked when the lever is snapped into the latch. Insert the cut end of the implant into the front portion of the application instrument and slide the application instrument down to the locking head. If required, the ZIPFIX can be tensioned again to achieve the desired stability. Warning: Do not cut the implant until all implants have been fully tensioned. Implants cannot be tensioned once cut. Do not cut implants under tension.” | 13 | “Slide the application instrument over the loose end of the implant, down to the locking head. Squeeze the trigger to tension the implant. The implant should fit snugly to the bone.” | 12-13 |

| Table 1 Updated Surgical Technique Guide on Sternal ZipFix™ | | | |
|--|----|--|----|
| New version | | Former version | |
| <p>New: Overview illustrations provide orientation of the correct positioning of the cutting lever.</p>  | 13 | <p>Comment: The former image didn't present the cutting lever in full size, this has been changed in the updated version in order to give optimized orientation.</p> | 12 |

In order to improve the precision of the surgical technique, further explanations are given in the same Surgical Technique Guide. Though these are not directly related to the previous recall (FSN 2013022) they shall be presented in the following section as well.

| New version | | Former version | |
|--|---|----------------|---|
| <p>Part: Introduction Chapter: Sternal ZIPFIX System</p> <p>New: “Caution: The ZIPFIX with attached ferromagnetic needle cannot be placed in the vicinity of an MR scanner, anywhere in the MR procedure room, or used in an interventional MRI procedure.”</p> | 3 | No precaution | 3 |
| <p>New: Multiple closure options and combinations e.g. with the Titanium sternal fixation system are presented by two additional illustrations.</p> | 4 | | 3 |

| New version | | Former version | |
|--|--|----------------|---|
|  | | | |
| <p>New: The positive Cut-through-Test result is substantiated: “The ZIPFIX has larger implant-to-bone contact area compared to stainless steel wire to reduce risk of bone cut-through.”</p> | | 6 | 5 |
| <p>Part: Surgical Technique Chapter: Surgical technique Section: 1 Insert Sternal ZIPFIX implant</p> <p>New: In a list of 3 precautions a 4th precaution is added: “Avoid clamping of implant in the area of the teeth or excessive bending/twisting of the implant, as this may lead to implant failure.”</p> | | 9 | <p>Comment: 3 precautions were stated instead of 4</p> <p>8</p> |

| New version | | Former version | |
|--|----|--|---|
| <p>Chapter: Surgical technique Section: 2 Remove Sternal ZIPFIX needle</p> <p>10</p> <p>New: High precision is given by recommendations of the cutting technique and removal of the needle:</p> <p>“Cut needle off the ZIPFIX below the notch, using the cable cutter.</p> <p>Precautions:</p> <ul style="list-style-type: none"> • Do not cut the implant directly at the notch. • Removing the needle by bending or twisting will cause a deformed end that may damage the locking head during insertion. Always ensure that the implant end is cut and not deformed. If the implant is not cut, implant failure may occur. <p>Note: Needle can also be removed using a wire/pin cutter.”</p> | | <p>“Use standard cutters to create a clean cut along the implant medial to the needle.</p> <p>Precautions</p> <ul style="list-style-type: none"> – Do not cut the implant directly at the junction between the needle and the implant. – Do not remove the needle without the assistance of a cutter.” | 9 |
| <p>New: In the image showing a cable cutter and the area to be cut, 2 instructive pointers are added. Aim: to show precisely where to cut. An arrow indicates “notch”, and “cutting area”.</p>  | 10 | | 9 |

| New version | | Former version | |
|---|----|--|---------|
| Chapter: Surgical technique Section: 3 Insert remaining Sternal ZIPFIX implants and remove needles New: The adaption of the number of ZipFix binders and the additional use of plates and wires according to the patient's anatomy is recommended: “The number of ZIPFIX used in partial sternotomy is according to patient anatomy. Use 5 ZIPFIX to achieve stable fixation in a full midline sternotomy. ZIPFIX can be used with plates and/or wires or where ZIPFIX insertion is inhibited by patient anatomy.” | 11 | “It is recommended to use a minimum of five Sternal ZipFix implants to achieve stable fixation in a full midline sternotomy. ZipFix can be used with plates or wires according to surgeon preference. ” | 10 |
| Chapter: Surgical technique Section: 6 Tension Sternal ZIPFIX implants A slight change of the wording regarding potential hazards for patients with poor bone quality is made: “Care should be taken to control ZIPFIX tension in patients with poor bone quality to prevent additional injuries.” Maintenance recommendations to safeguard the instrument's long-term use are added: “Refer to "Maintenance of Application Instrument" section (page 22) for proper care instructions for the application instrument. Failure to lubricate the application instrument may result in instrument failure.” | 13 | “Care should be taken to control implant tension in patients with poor bone quality as excessive tension in this patient population could induce transverse fractures. ” | 12 - 13 |
| New: Advice is given on multiple sternum closure options, similar to page 4 (new – page 3 former) : “Note: A manubrium plate can be added if additional stability in the manubrium is desired. Refer to the <i>Synthes Titanium Sternal Fixation System Surgical Technique</i> for additional information.” | 15 | “Note: Sternal plating or other standard closure techniques can be combined if required.” | 15 |

FIELD SAFETY NOTICE FSN20149997

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Verification Section

| Part Description | Part Numbers | Lot numbers |
|--|--------------|--|
| Application Instrument for Sternal ZipFix™ | 03.501.080 | All 1st generation Application Instruments (Lots prior to 8100630) |

- We have received the updated Surgical Technique Guide called "Sternal ZipFix™ System" Version 036.000.285 AE Date: 03/2014 and will discard the previous version.
- We acknowledge the receipt of this information but do not have the Sternal ZipFix™ System at this facility.

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____