

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)

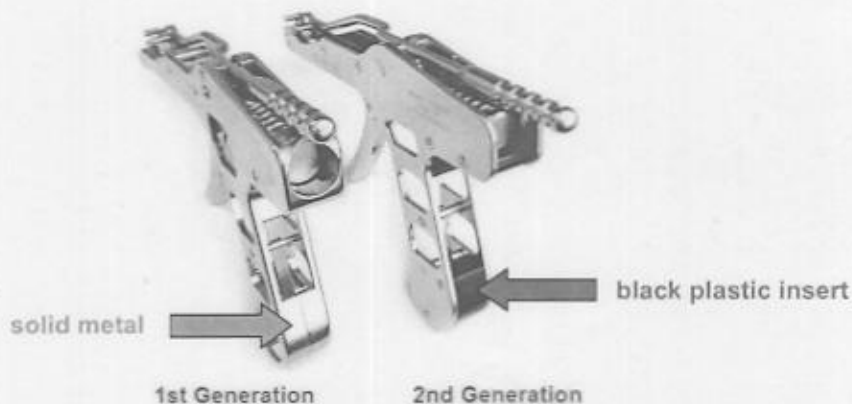
Dear Sir/Madam:

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:

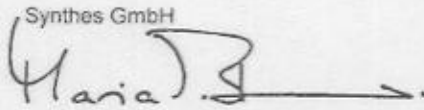
- Complete the attached Verification Section at the end of this letter by checking the appropriate box indicating that you do not have the CMF Sternal ZipFix™ System at this facility. Please include your name, title, telephone number and signature in the spaces provided. This return documentation acknowledges 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,

Synthes GmbH

Dr. med. Maria I. Behrens MDRA
Field Action Manager


Markus Wien
Director Quality Assurance Operations
Stephen Miller, UP QMS