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DePuy Synthes
Companies of Johnson & Johnson

To all customers using Synthes' TomoFix System

25 September 2013

**Urgent: Field Safety Notification / Medical Device Labelling Correction**
**TomoFix System**

| Part Description | Part Number |
|---|---|
| TomoFix Medial High Tibia Plate, Technique Guide | 0X6.000.386 |
| TomoFix Application Notes | 0X6.000.385 |

Dear Sir/Madam:

Synthes is initiating a Medical Device Labelling Correction related to the Surgical Technique Guide (0X6.000.386) "TomoFix Medial High Tibia Plate, Technique Guide" and the "TomoFix Application Notes" (0X6.000.385).

The revised surgical technique guide and the revised application notes contain the following corrections:

| | Old Surgical Technique Guide (AB) | Revised Surgical Technique Guide (AC) |
|---|---|---|
| **p. 45 – Plate Dimensions** | 440.834S TomoFix Standard:<br><br>Sagittal angle proximal holes A, B, C (A) = 4° caudally | 440.834S TomoFix Standard:<br><br>Sagittal angle proximal holes A, B, C (A) = 10° caudally |
| **p. 45 – Plate Dimensions** | 440.83S TomoFix Small:<br><br>Thickness (T) = 3 mm | 440.83S TomoFix Small:<br><br>Thickness (T) = 3.2 mm |
| **p. 45 – Plate Dimensions** | 440.83S TomoFix Small:<br><br>Sagittal angle proximal holes A, B, C (A) = 6° caudally | 440.83S TomoFix Small:<br><br>Sagittal angle proximal holes A, B, C (A) = 11° caudally |

| | Old Application Notes (AB) | Revised Application Notes (AC) |
|---|---|---|
| **p. 12 – Implants, TomoFix MHT** | Thickness 2.8 mm | Thickness 3 mm |
| **p. 12 – Implants, TomoFix MHT** | Angle 4° | Angle 10° |

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**Please note that there was no change to the design of the TomoFix plates.** The plate design has not changed and the 11°/10° angulations have always been present in the product. The wrong dimensions (angulations and thickness) were included in the original surgical technique guide and in the application notes. All verification and validation actions which were performed during the development phase were based on the correct dimensions.

Potential patient impact:
There is no impact for patients previously successfully treated with these products.
There is a potential for surgical delay if the surgeon inserts the superior screws at a lesser angle (4 or 6 degrees) and is not aware that those angles are not present.

This correction requires that you review the new technique guide and application notes provided in this mailing.

Please take the following actions:

- Exchange the old surgical technique guide and the application notes version AA and AB with the new version AC provided with this notification.
- Review the revised surgical technique guide (p. 45) and application notes (p.12).
- Forward this Field Safety Notification to anyone in your facility that needs to be informed.
- If the technique guide and the application notes have been forwarded to another facility, contact that facility.
- Maintain awareness of this notice until all technique guides and application notes have been exchanged.
- Maintain a copy of this notice.

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

Markus Wien
Director Quality Assurance Operations