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SYNTHES®

To all customers using
Synthes' Soft Tissue Retractor small and large,
extendible

13 June 2013

Urgent: Field Safety Notification / Medical Device Labelling Correction
Synthes Soft Tissue Retractor

Part Description	Part Numbers
Technique Guide "**Plate Insertion Instruments.** For minimally invasive plate osteosynthesis (MIPO)."	0X6.000.127

Dear Sir/Madam:

Synthes is initiating a Medical Device Labelling Correction related to the Surgical Technique Guide (0X6.000.127) "Plate Insertion Instruments. For minimally invasive plate osteosynthesis (MIPO)". This action has been initiated as a result of the recall of the Soft Tissue Retractor, small, extendible (325.010) due to locking nut (clamping sleeve) malfunction.

The revised surgical technique guide contains a precaution (instead of a note) on page 3 stating **"Do not overtighten the clamping sleeve as this could lead to breakage"**.

This correction requires that you review the new technique guide provided in this mailing. Please note that the new Technique Guide will no longer be available as printed hardcopy.

Please take the following actions:

- Exchange the old surgical technique guide with the new guide version AD provided with this notification.
- Review the revised surgical technique guide.
- Forward this Field Safety Notification to anyone in your facility that needs to be informed.
- If the technique guide has been forwarded to another facility, contact that facility.
- Maintain awareness of this notice until all technique guides have been exchanged.
- Maintain a copy of this notice.

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

[redacted]

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

Thank you for your attention to this issue.

Sincerely,

Synthes GmbH

[redacted]

Field Action Manager

[redacted]

Director Quality Assurance Operations

[redacted]