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Field safety notice

Date: November 18, 2016

Product: MetaToe™ ReadyToUse Kit (FP90105S) – all LOTs

Dear valued User,

Our post-market surveillance data revealed that the absorbable MetaToe™ EndoSorb™ screw may fracture during implantation in narrow medullary cavities. The screw is not self-cutting or self-tapping within cortical bone and is only intended to be inserted into cancellous bone. Fracture risk is increased during insertion into narrow medullary cavities. Therefore, ensure a sufficient medullary cavity while using the named implant.

Merete will supply a tap for the treatment of patients with narrow medullary cavities as soon as possible free of charge. Until then please refrain from treating patients with narrow medullary cavities.

Potential problem: The implant may fracture in narrow medullary cavities if inserted into hard, cortical bone.

Clinical consequences: In case of fracture the in-situ fragment of the implant needs to be removed. Additionally, an alternative treatment needs to be applied which results in an increased surgery time.

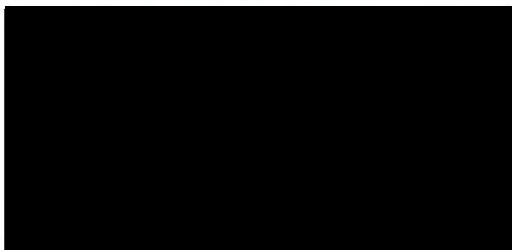
The risks for the surgeon and already implanted devices are unchanged.

Further measures:

- 1) Confirm the receipt of this notice by filling in the attached acknowledgment and return it to Merete until November 25, 2016.
- 2) Do not hesitate to contact the listed contact person or your sales representative with any further questions.
- 3) Only treat patients with narrow medullary cavities upon receipt of corresponding tap.

Contact Person: Dipl.-Ing. Susanne Kahl, skahl@merete.de, Tel.: +49(0)30 77 99 80 122

Thank you for your understanding.



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Acknowledgement of Field safety Notice

Please fill in the following page and send it back to Merete GmbH.

I/ We confirm the receipt of the field safety notice related to MetaToe ReadyToUse Kit (FP90105S) issued November 18, 2016. I/ We read the field safety notice and forwarded it to the relevant persons if necessary.

Institution

Name

Position

Location, Date, Signature

Please return this letter to:

Merete GmbH
Susanne Kahl
Alt-Lankwitz 102
12105 Berlin
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