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SYNTHES®

To the ATTENTION of:
Operating room manager

27 September 2012

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number: See attached list

Part Number	Part Description	Lot Number
04.004.XXXSAB	Expert Tibial Nail PROtect Ø 8.0 – 13.0 mm, cannulated, length 255 – 465 mm, Gentamicin Sulphate, Titanium Alloy (TAN), dark blue, sterile	all

Dear Sir/Madam

Synthes is initiating a Medical Device Product Removal related to the Synthes Expert Tibial Nail PROtect. This action is being initiated following the finding of a formal inconsistency in the instructions for use (IFU) delivered with every product of the mentioned family.

An inappropriate or incomplete indication statement in the IFU could lead to improper application of this device. Use of the Expert Tibial Nail PROtect in indications other than the specified and approved ones, as listed in the Technique Guide of the Expert Tibial Nail PROtect (036.000.380), may lead to a major health risk for patients. It is strongly recommended to carefully consult the Technique Guide prior to a surgical procedure. The approved indications for the Expert Tibial Nail PROtect are as follows:

The Expert Tibial Nail PROtect is indicated for fractures in the tibial shaft as well as for metaphyseal and certain intraarticular fractures of the tibial head and the pilon tibiale:

- *41-A2/A3*

- *All shaft fractures*
- *43-A1/A2/A3*
- *Combinations of these fractures*

For the following indications the Expert Tibial Nail PROtect should be used in combination with other implants.

- *41-C1/C2*
- *43-C1/C2*

The Expert Tibial Nail PROtect is particularly indicated in cases where there is an increased risk of local bone infections, for example, in polytraumatized or immunosuppressed patients, and in patients with open fractures. The purpose of the PDLLA + gentamicin sulfate coating is to reduce the risk of bacterial colonization on the nail's surface after it has been implanted. The effectiveness of the antibiotic coating should become apparent during the first few hours and days after implantation. The effectiveness of the PDLLA + gentamicin sulfate coating is restricted to gentamicin-sensitive bacteria[1].

Synthes has not received any complaints related to this issue and is acting in a purely preventive manner. If used according to the indications specified in the technique guide, the Expert Tibial Nail PROtect does not pose any kind of safety risk to the patients.

Synthes will exchange the mentioned IFU with an updated version and make the Expert Tibial Nail PROtect available again for clinical use as soon as possible.

Synthes is requesting that you immediately cease using the product and please examine your inventory for the above part numbers and remove them.

Your Synthes Sales Consultant will contact you to organize the return of the products.

If you have any questions, please contact your Synthes Sales Consultant.

We apologize for the inconvenience caused.

Thank you for your attention and cooperation.

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[1] **Remark:** In relation to PK/PD data, the indication is based on the results from in vitro and in vivo models that the investigated models adequately simulate the clinical situation and allow a reliable estimation of the behavior of antibiotic coated implants after implantation. The composition of the coating and the amount of coating per unit surface area on the implants used for the animal study is identical to the values specified for the coated IM nails. Although clinical PK data are preferred, the present data can be considered of indirect supportive value.

Synthes GmbH

[redacted]

Manager Complaint Handling Unit

[redacted]

Director Quality EMEA

Cc:

NOTICE: MEDICAL DEVICE RECALL

Synthes Expert Tibial Nail PROtect

Verification Section

Part Number	Part Description	Lot Number

☐ We have located the identified product in stock; returned quantity is documented below, and have retained a copy of this letter for our records.

☐ We do not have any identified product in stock; returned quantity is zero, and have retained a copy of this letter for our records.

RETURNED DEVICES (including quantity):

_____

_____

_____

_____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____