Instructions for Use 03.835.043 Torque-limiting Handle, straight with Ratchet Wrench, 3 Nm

This instruction for use is not intended for distribution in the USA.

Instructions for Use

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material(s)

Material(s): Standard(s):

Stainless Steel ASTM F899/A276/A564

Silicone

Intended use

The Torque-limiting Handle is intended to support the implantation of Synthes implants.

Indications and contraindications

In case the Torque-limiting Handle is used in combination with implants or instruments, please refer to the respective surgical techniques for indications and contraindications and additional surgical steps.

Combination of medical devices

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Treatment before device is used

Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Reprocessing of the device

Detailed instructions for reprocessing implants, instruments and cases are described in the Important Information. Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from: http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

Additional device-specific information

Important note on servicing

We recommend that torque-limiting instruments be serviced:

- Once every 6 months or after every 50 autoclave cycles, whichever occurs first
- If you suspect that the instrument is out of calibration

Servicing is handled through normal sales channels of the subsidiary in the respective country.





Synthes GmbH Eimattstrasse 3 4436 Oberdorf Switzerland Tel: +41 61 965 61 11 Fax: +41 61 965 66 00 www.depuysynthes.com

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