Instructions for Use
Torque Limiting Handles for Spinal Surgery

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

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each
manual is always available online.
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Torque Limiting Handles for Spinal Surgery

Devices in scope:

321.133	03.620.019	03.641.002
389.471	03.620.061	03.641.004
03.602.042	03.627.017	03.807.357
03.614.035	03.632.204	03.835.043
03.615.040		

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials
Stainless Steel, Aluminum, Nitrile Rubber, Silicone.

Intended Use
The Torque Limiting Handle is intended to support the implantation of Synthes implants.

Indications/Contraindications
In case the Torque Limiting Handle is used in combination with implants or instruments, please refer to the respective instructions for use for indications and contraindications and additional surgical steps.

Patient Target Group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

The patient target group is based upon the implant devices rather than the instruments. Specific patient target group for the implants can be found in the respective implant instructions for use.

Intended User
This IFU alone does not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.
This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the instructions for use, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the implants can be found in the respective implant instructions for use.

Warnings and Precautions
- Ensure the appropriate torque limiter is used for specific systems with the required torque value.
- Never use a fixed or ratcheting handle screwdriver for techniques where a torque limiting attachment is required. Breakage of the driver or implant may occur and could potentially harm the patient.
- To loosen the tightened screw/nut/cap from the construct, the loosening torque value may be higher than the torque value which was used during tightening. In such cases, use the respective system procedure to remove the tightened implant from the construct.
- If the system requires a counter torque for final tightening, counter torque instrument must be placed on each implant. If the counter torque is not used during final tightening, construct loosening may occur.
- For screw/rod constructs, do not orient the handle of the counter torque in line with the rod. This could cause misalignment of the rod with the screw head.

For more information, please refer to the Synthes brochure "Important Information".

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

Magnetic Resonance Environment
MR Unsafe: These devices are MR unsafe according to ASTM F 2052, ASTM F 2213, ASTM F 2182.

Treatment before Device is Used
Non-Sterile Device:
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".

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Additional Device-Specific Information

Important note on servicing
It is recommended that Torque Limiting instruments are 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.

Disposal
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

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