
Instructions for Use

- 387.343 SynFrame Guiding Tube
- 387.344 SynFrame Angled Rod
- 387.336 SynFrame Holding Ring

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

Instructions for Use

387.343	SynFrame Guiding Tube, for Angled Rod No. 387.344, for Basic System
387.344	SynFrame Angled Rod, for Basic System
387.336	SynFrame Holding Ring Ø 300 mm, two-part, complete, for Basic System

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.

Materials

Materials:	Standards:
Stainless Steel (SS)	ASTM F 899, ASTM A 276, ISO 7153-1
Nitronic 60 (SS)	ASTM F 899, ASTM A 276

Intended use

SynFrame is a surgical approach and retraction system. It consists of a basic system (basic construction) and modules that are specially designed for the respective requirements and needs of various indications and/or approach techniques (eg. anterior lumbar approach for total disc replacement).

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".

Processing/reprocessing of the device

Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "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

The SynFrame System is insulated by the SynFrame Universal Holder for OR Table (387.342) from the grounded OR table, in compliance with the safety standards IEC 60601-1 and IEC 60602-2, VDE 0750 part 2 and VDE 0753 on grounding-free patient positioning.

Synthes can only guarantee grounding-free patient positioning if SynFrame is used in combination with the SynFrame Universal Holder for OR Table (387.342), which must be in perfect condition.

For instructions concerning the handling of the Universal Holder refer to the SynFrame surgical technique (DSEM/SPN/0616/0530).



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