
Instructions for Use

387.346 SynFrame Holding Base for OR Table, insulated, dark blue

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

Instructions for Use

387.346 SynFrame Holding Base for OR Table, insulated, dark blue

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.

The SynFrame Holding Base for OR Table (387.346) allows grounding-free patient positioning. This product must therefore be handled with care. Any damage to this component, especially to its insulating material, may lead to loss of insulation or injury to the patient.

Material

Materials	Standards
Stainless Steel (SSt)	ASTM F899 / A276 / ISO 7153-1
Nitronic 60 (SSt)	ASTM F899 / A276
Aluminium Alloy (Al 6082)	ASTM B221M / DIN EN 573
Polyphenylsulfone (PPSU)	

Grounding-free patient positioning

The SynFrame System is insulated by the SynFrame Holding Base for OR Table (387.346) from the grounded OR table, in compliance with the safety standards IEC 60601-1 and 2-2, VDE 0750 part 2 and VDE 0753 on grounding-free patient positioning.

Synthes can only provide grounding-free patient positioning if SynFrame is used in combination with the SynFrame Holding Base for OR Table (387.346), which must be in perfect condition.

Stable construction of SynFrame

The SynFrame Holding Base matches the dimensions of the SynFrame Guiding Tube for Basic System (387.343) and provides a stable construction.

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".

Disinfection and cleaning

Use mild cleaning and disinfectant solutions to remove impurities.

If a cleaning agent is used together with the disinfectant, it is advisable to use both disinfectant and cleaning additive from the same manufacturer. Make sure the solutions are mutually compatible and strictly follow the manufacturer's instructions with regard to concentration and soaking time.

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".

Note: Do not plasma sterilize.

Dismantling

Under no circumstances must the SynFrame Holding Base be dismantled, as this can cause damage and impair its insulating properties.

Combination of medical devices

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

Warning

Check the SynFrame Holding Base for possible damage prior to each medical application, especially with regard to damages of the insulating plastic surface such as breakage or stress cracks.

Damaged SynFrame Holding Bases may not be used again. When in doubt, please consult your local Synthes representative.

The SynFrame Holding Base must not be used after the expiry date.

For further information on the handling of the SynFrame Holding Base refer to the surgical technique SynFrame (DSEM/SPN/0616/0530).



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