
Instructions for Use

387.362

SynFrame Light-transmitting Rod

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

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387.362 SynFrame Light-transmitting Rod

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.

A thorough understanding of the principles and methods used in laser endoscopy and electro-surgical procedures is necessary to avoid shock or burn risks to patients and users as well as damages to other equipment and instruments.

Material(s)

Material: Stainless Steel (SSt) Standard: ASTM F 899, ASTM A 276, ISO 7153-1

The SynFrame Light-transmitting Rod (387.362) is used to illuminate deep cavities in the human body.

The light cable connection corresponds to the ACM Standard. Adapters for Wolf and Storz are included.

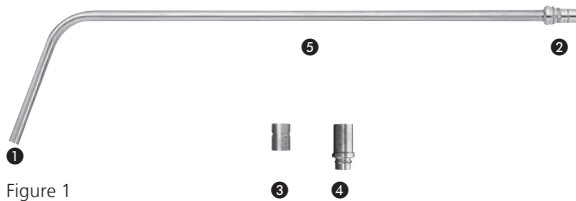


Figure 1

- ① Light exit
- ② Light cable connection ACM Standard
- ③ Adapter for Wolf
- ④ Adapter for Storz
- ⑤ Fixation area for SynFrame Clamp (387.347) and Holder for Optics (387.365)

The SynFrame Clamp for Holding Rings (387.347) and Holder for Optics (387.365), which is used to connect the Light-transmitting Rod to the SynFrame Holding Ring (387.336) and the SynFrame Half-Ring (387.337), can be attached to the SynFrame Light-transmitting Rod on the entire length of the shaft of the Light-transmitting Rod (see figure 1, ⑤).

For further instructions concerning the handling of the SynFrame Light-transmitting Rod refer to the surgical technique for SynFrame, (DSEM/SPN/0616/0530).

General safety instructions

Prior to each use, check the SynFrame Light-transmitting Rod and its accessories for any possible optical and mechanical defects, both of the surface and of the distal and proximal fiber optical end faces, to avoid the risk of injury.

To prevent the Light-transmitting Rod from being damaged, avoid bending stress. This can lead to damages to the optical components and result in malfunctioning of the equipment. The SynFrame Light-transmitting Rod is not sterile on delivery and has to be cleaned and sterilised prior to each use. Do not use damaged or defective Light-transmitting Rods. In case of doubt, please contact your Synthes representative.

Combination with other medical devices

There are numerous therapeutic vistas open for combinations with laser and HF surgery, pneumatic or electro-hydraulic lithotriptors. In such cases, please follow the manufacturers' operating manuals and safety instructions of devices and accessories used.

While using the SynFrame Light-transmitting Rod with electro-medical devices, ensure that the BF conditions (insulated, earth-free part) are maintained.

The simultaneous use of NMR (Nuclear Magnetic Resonance) and the SynFrame Light-transmitting Rod can be dangerous and lead to artefacts. Please follow the corresponding manufacturers' guidelines and safety instructions.

The use of the SynFrame Light-transmitting Rod in combination with electro-medical devices and/or power-driven accessories for light transmitters can lead to an addition of leakage currents. Failure of one of the light sources can lead to risks for the patient or hinder the surgical procedure. Keep an additional operational light source at hand or use light sources with a substitute lamp.

In combination with high performance light sources, the temperature of the light source and the instruments can reach levels which can cause burns. Light of high radiance energy can lead to an increased temperature in the tissue. Hence, avoid direct contact with tissue and make sure the distance of the distal end of the SynFrame Light-transmitting Rod and the tissue is at least 10 mm.

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.

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.

Note:

Do not decontaminate and clean the SynFrame Light-transmitting Rod in an ultrasonic bath.

Cleaning

Cleaning can be done manually or mechanically.

Manual cleaning

- Use only mild cleaning substances for dissolving the impurities. These cleaning agents have to be approved of by the manufacturer for cleaning endoscopes.
- For manual cleaning, use a soft cloth, cotton and special brushes.
- Remove dirt on the optical surfaces (see figure 1, ① and ②) using cotton soaked in alcohol (70% Ethanol) or a neutral cleanser.
- After cleaning, rinse thoroughly with de-ionised (distilled) water and dry with cotton or a soft cloth to remove the last traces of impurities and residues of the cleaning agents.
- Finally dry the SynFrame Light-transmitting Rod and the individual accessories carefully using a tissue or soft absorbent cloth.

Special instructions for manual cleaning

- The fiberoptical surfaces must not be treated using sharp objects. Generally, the SynFrame Light-transmitting Rod must be cleaned with maximum care to avoid damage because of excessive pressure, impact, bending or letting it fall.

Mechanical cleaning

- Clean and disinfect the SynFrame Light-transmitting Rod in suitable rinsing machines fitted with special endoscope cleaning programs. It is also possible to use a thermodisinfector. For mechanical procedures, ensure that the SynFrame Light-transmitting Rod remains firmly on the instrument holder and is not damaged by other instruments.

Procedure

- Place the SynFrame Light-transmitting Rod and the disassembled accessories in a suitable instrument carrier as prescribed by the manufacturer of the rinsing machine. Ensure that there are no rinsing shadows.
- Select the appropriate endoscope cleaning program depending on the machine load and the instructions of the manufacturer. The cleaning solutions have to be recommended for light-transmitters by the manufacturers.
- In case of mechanical cleaning, clean all residues of the rinsing program thoroughly, as there could be decoloring and formation of patches, especially with regard to a subsequent sterilisation. For the last rinsing round, use de-ionised water. This can be supported by the use of a suitable neutralisation agent, which can improve the post-rinse results.

Special instructions for mechanical cleaning

- In case of extreme soiling and encrusting (e.g. coagulated blood or secretion residues), it may be necessary to further clean the SynFrame Light-transmitting Rod manually.
- Remove dirt residues on optical surfaces (see figure 1, ❶ and ❷) using cotton soaked in alcohol (70% ethanol) or a neutral cleaning agent.
- Check the water quality regularly to avoid formation of residues and corrosion.
- Do not use grease or washing agents; there may be problems with respect to compatibility with plastics or adhesives and compatible accessories (e.g. electrical wires).

Sterilisation

Before sterilisation, make sure the SynFrame Light-transmitting Rod and the optical surfaces in particular (see figure 1, ❶ and ❷) are clean and that testing the SynFrame Light-transmitting Rod does not lead to any findings that impose restrictions on the use.

Further detailed instructions for reprocessing reusable devices 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>

Checking the fiber optics

- Hold one side of the fiber optic (e.g. the distal end) in the direction of a bright ceiling lamp. For this test, do not use any cold light source. View the other side (light cable connection) holding it relatively close to the eye. The individual fibers now appear to be bright. Move the side held against the lamp. The brightness of the fibers now changes. If certain fibers remain dark, this is not a cause for concern. The intensity of illumination of the SynFrame Light-transmitting Rod decreases with an increasing rupture rate of the fibers.
- The surfaces of the light inlets and outlets must be smooth and clean. If the surfaces show certain deposit layers, or if rough fibers can be felt or are withdrawn, illumination might be inadequate. If the SynFrame Light-transmitting Rod is used or prepared in this condition, it is likely to be further damaged.

Send the SynFrame Light-transmitting Rod to the manufacturer for an inspection if the fiber optics is damaged.

Trouble shooting

Defect	Possible cause	Possible solution
Too little illumination	– dirty fiber-optic surfaces (figure 1, ❶ and ❷)	– clean the fiber-optic surfaces as per instructions (manual cleaning)
	– stubborn residue, encrusting on the fiber-optic surfaces	– remove residues as per instructions/ check water quality
	– wrong light cable connection	– check whether light cable connection sits well and is connected properly
	– defective fiber optic	– check fiber optic as per instruction
Yellowish light	– defective light cable or light source	– check light cable connection and light source
	– dirty fiber optic	– clean fiber-optic surfaces (figure 1, ❶ and ❷). If required, send the SynFrame Light-transmitting Rod in for servicing
Corrosion, formation of patches, decoloring	– dirty or defective light cable connection	– check light cable connection (e.g. by illuminating a white surface)
	– inadequate cleaning (e.g. protein residue)	– subsequent cleaning up, if required by thorough rubbing
	– inadequate rinsing of the SynFrame Light-transmitting Rod between different preparation phases (especially before sterilisation)	– ensure adequate rinsing between the individual preparation phases
	– high chloride concentration	– check water quality
	– heavy metal ions and/or silicates, increased content of iron, copper manganese in water or sterilisation steam	– check water quality, only use de-ionised (distilled) water
	– high concentration of mineral substances (e.g. calcium) or organic substances	– check water quality, only use de-ionised (distilled) water
	– infected or too frequently used disinfection or cleaning solutions	– regularly replace the disinfection and cleaning solutions
– outside rust (e.g. through steam or preparation along with damaged or rust-prone instruments)	– check maintenance systems; in case of preparation with other materials, check for material compatibility, existing damages and avoid mutual contact	
– contact corrosion	– avoid mutual contact with other metal components	



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