Instructions for Use

03.816.700 Reusable Light, for INSIGHT™ Lateral Access System

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

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Instructions for Use

03.816.700 Reusable Light, for INSIGHT™ Lateral Access 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.

The Reusable Light for INSIGHT Lateral Access System is a glass fiber optic device intended for lighting into deep surgical sites. The Reusable Light is intended for use with a max. 300 Watt Xenon illuminator, using a 3.6 mm fiber optic cable (or smaller) and the corresponding adaptor to the light machine. The Reusable Light fits with a female ACMI connector.

Materials

Materials:	Standards:
Stainless Steel	ASTM F899
Glass Fiber	Glass (Schott Type D1)
Polyetheretherketone (PEEK)	
Epoxy Adhesive	2K epoxy adhesive

Intended use

The light system is intended to illuminate the surgical site in minimally-invasive surgeries. It is intended to be used with access systems containing corresponding interfaces such as the INSIGHT Lateral Access System and an appropriate light source (max. 300 Watt Xenon illuminator).

Indications/Contraindications

The light system is to be used in combination with access systems such as the INSIGHT Lateral Access System. For indications and contraindications please refer to the respective implant surgical techniques.

Precautions and Warnings

- Do not bend reusable light.
- Do not use higher wattage than indicated for reusable light.
- The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the Synthes brochure "Important Information".
- Do not place the light-transmitting end on skin or soft tissue.
- Do not embed the reusable light in soft tissue.
- Exchange reusable light if it collects fluid inside, appears broken or damaged.
- Depending on light source, temperature of Reusable Light (03.816.700) and Adapter (optional, 03.816.709) may exceed 43°C. Therefore avoid contact to user and patient with these parts for longer duration.
- Do not touch the open end of the Reusable Light or optical fiber cable. The emitted intense light energy can lead to burns. Avoid longer contact between metal parts and tissue during surgeries. To prevent burns, never place the open end of a connected optical fiber cable on the patient or near the patient. Allow for cooling before disassembly.
- Never place the Light or the open end of a connected optical fiber cable near flammable materials such as textiles (curtains) or near cotton swabs or pads that have been soaked with flammable fluids (e.g. disinfectants). The heat generated by the intense light emission can ignite these materials.
- When in operation, the lamp emits strong UV/IR radiation. Never look directly into the highly intense light since this could cause severe injuries to the eyes.
- Regardless of the condition and output of the light source and the light cable, combinations can occur which lead to excessive heat development at the light source end of the light cable and which can damage the light cable. In this case contact the manufacturer.
- Never leave the light system unattended when light is being transmitted from a light source.

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis occuring during usage of the light system.

Combination of medical devices

The Reusable Light is connected to an adapter for a light cable (03.816.709). The Reusable Light has a male ACMI interface.
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance environment

MR Unsafe: The medical device 03.816.700 is MR unsafe according to ASTM F 2052, ASTM F 2213, ASTM F 2182.

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, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For the reusable light 03.816.700, Synthes recommends steam sterilization in fractionated vacuum at 132 °C for 4 minutes.

Do not decontaminate and clean the Reusable Light in an ultrasonic bath.

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