Instructions for Use
03.816.710S
Disposable 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

03.816.710S Disposable 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.

Material
Medical and optical grade fiber optic cable
Polymers

The Disposable Light for INSIGHT Lateral Access System is a fiber optic device intended for lighting into deep surgical sites. The Disposable Light is intended for use with a max. 300 Watt Xenon illuminator, using a 3 mm fiber optic cable (or smaller) and the corresponding adaptor to the light machine. The Disposable Light fits with a female ACMI connector. Body fluids or debris collecting on the surface of the Light Devices may be irrigated or wiped away.

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).

Indication/Contraindication
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.

Sterile device

STERILE EO Sterilized using ethylene oxide

Store medical devices in their original protective packaging, and do not remove them from the packaging until immediately before use. Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged.

Single-use device

Do not re-use

Products intended for single-use must not be reused. Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

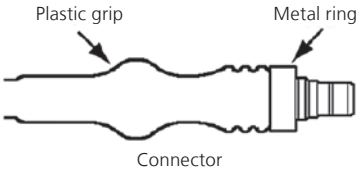
Precautions and Warnings
- Do not use higher wattage than indicated for Disposable Light.
- The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the Synthes brochure "Important Information".
- Do not place the light-transmitting end on skin or soft tissue.
- Do not embed the Disposable Light in soft tissue.
- Depending on light source, temperature of the metallic part of the Disposable Light (03.816.710S) and Adapter (optional, 03.816.709) may exceed 43°C. Therefore avoid contact to user and patient with these parts for longer duration. Use the plastic grip as a handle. See illustration.
- Do not touch the open end of the Disposable 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 which can damage the light cable. In this case, contact the manufacturer.
- The ends of the light guide can become hot during operation. Therefore, do not place the cable onto temperature-sensitive objects.
- Never leave the light system unattended when light is being transmitted from a light source.
- Sterile unless package is opened or damaged. Do not use if package is opened or damaged.
- Do not use if product appears damaged.
- After use, this product may be a potential biohazard. Handle and dispose of Disposable Light in accordance with accepted medical practice and local regulations.

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 occurring during usage of the light system.

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

Warranty
All warranty rights are lost if repairs or modifications are carried out by an unauthorized service center. The manufacturer does not take responsibility for any effects on safety, reliability or performance of the product if the product is not used in conformity with the instructions for use.

Magnetic Resonance environment
MR Unsafe: The medical device 03.816.710S is MR unsafe according to ASTM F 2052, ASTM F 2213, ASTM F 2182.



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