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.

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each manual is always available online.
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DePuy Synthes
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Instructions for Use

03.816.710S Disposable Light, for INSIGHT™ Lateral Access System
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.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials
Medical and optical grade fiber optic cable, Polymers.

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
In case Disposable Light (03.816.710S) is used in combination with implants or instruments, please refer to the respective instructions for use for indications and contraindications and additional surgical steps.

Patient Target Group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

The patient target group is based upon the implant devices rather than the instruments. Specific patient target group for the Implants can be found in the respective implant instructions for use.

Intended User
This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the Instructions for use and, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the Implants can be found in the respective Synthes implant instructions for use.

Sterile Device

Sterilized using ethylene oxide

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.


Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.


Do not resterilize

Re-sterilization of Disposable Light (03.816.710S) can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single Use Device


Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical 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.

Warnings and Precautions

- 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.
- Do not bend fiber optic light under a radius of 5 cm.
- Do not apply pressure on the light using a sharp object.
- Do not use higher wattage than indicated for Disposable Light.
- 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.
- The disposable light should only be used with the associated light cables.
- 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.

For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.
The Disposable Light (03.816.710S) is intended for use with a max. 300 Watt Xenon light source, using a 3 mm fiber optic cable (or smaller) with a corresponding connection/adaptor (female ACMI).
Please, follow the light source manufacturers' operating manuals and safety instructions.

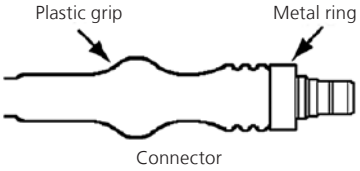
Magnetic Resonance Environment
MR Unsafe: The medical device 03.816.710S is MR unsafe according to ASTM F 2052, ASTM F 2213, ASTM F 2182.

Treatment before Device is Used
Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile 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.

Disposal
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Special Operating Instructions



– Screw the appropriate light source adapter onto the appropriate light cable and screw the light adapter(s) to the other end(s) of the cable.
– Slide the disposable light into the light slots. Secure light underneath the provided hooks.
– Connect the light cable to the light source. Turn on the light source. Body fluids or debris collecting on the surface of the Light Devices may be irrigated or wiped away.

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.

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