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# Instructions for Use

## 03.615.004S Light Clip for Insight Retractor, sterile

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

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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 Light Clip for Insight Retractor is a sterile, single use, plastic fiber optic device intended to bring lighting into deep surgical sites. The light is intended for use with a max. 300 Watt Xenon illuminator, using a fiber optic cable with a female ACMI connector.

## Intended use

The Light Clip (03.615.004S) matches with a 3 mm fiber optic cable.

The light is intended for the illumination of surgical procedures, particularly where deep cavities or adjacent tissues limit outside light in the surgical field. It is intended for use in less invasive Spine surgery.

## Indications/Contraindications


The Light Clip is to be used in combination with access systems. 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 re-used. Re-use or reprocessing (e.g. cleaning and re-sterilization) may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury, illness or death. Furthermore, re-use 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

The user should be familiar with the use of light sources and cables and should take precautions accordingly.

Do not operate the light source and cable without the Light Clip attached. Without the Light Clip, the output from the fiber optic cable is extremely bright, hot and may cause burns, ignite materials such as cotton swabs/drapes/gowns, or temporarily blind vision.

The light is designed for use with max. 300 Watt Xenon illuminators, using a fiber optic cable. Do not use light sources rated higher than 300 Watt, or cables with fiber optic bundles of more than 3 mm diameter. Use of higher watt sources or larger diameter cables could result in over heating, causing product failure and patient injury. Should the light become cut, collect fluid inside, appear broken or damaged in any manner, it must be replaced to minimize risk to the patient.

The Light Clip package contains one Light Clip assembly with an attached, protective paper shield. Prior to using it, the shield must be removed and discarded.

Light sources vary widely in emission of visible and infrared energy. As a precautionary measure, we recommend occasionally monitoring connector temperature during first time use with a new light source or lamp; thereafter if needed. As is common with fiber optic equipment, the metal portion of the connector can become hot to the touch. Depending on the light source, the temperature of the metal part of the Light Clip (03.615.004S) may exceed 43°C. Use the plastic grip as a handle. Refer to illustration. Do not place the metal ring portion of connector directly on the patient's skin.

Because light energy can be absorbed as heat, the entire lit portion (distal end) of the light should not be continuously embedded (i.e. lit surface should not be completely buried) in tissue and held fixed for more than a few minutes at one time.

Prior to closing the surgical site, all components must be accounted for.

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and local regulations.

## Directions for Use

Attach the Light Clip to the correct Synthes Insight Access System. The Light Clip should be clipped to the appropriate cranial/caudal retractor frame/tube.

The light connects to a light source used for head lamps or endoscopes. A fiber optic cable attaches the light source and the light. Make sure the light connector is securely attached to the cable. The cable should be in good repair with clean optics. Dirty optics or cables in need of repair can cause excessive heat at the connectors.

Turning down overhead lighting may improve visualization within the surgical site.

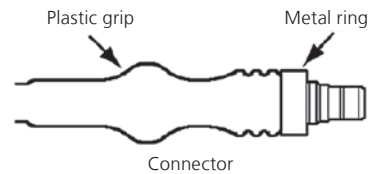
Body fluids or debris collecting on the surface of the light may be irrigated or wiped away.

## 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.

## Magnetic Resonance environment

MR Unsafe: The medical device 03.615.004S is MR unsafe according to ASTM F 2052, ASTM F 2213, ASTM F 2182.



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