Instructions for Use
03.615.004S Light Clip for Insight Retractor, sterile

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.
Printed on: Mär 26, 2020

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

 SE_297285 AE 12/2019

Instructions for Use

03.615.004S Light Clip for Insight Retractor, sterile
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.

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 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
In case Light Clip (03.615.004S) 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 Light Clip (03.615.004S) 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 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 overheating, 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.

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 Light Clip (03.615.004S) 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.

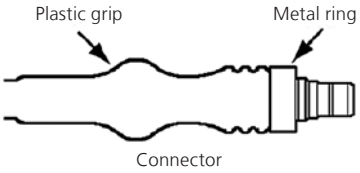
Magnetic Resonance Environment
MR Unsafe: The medical device 03.615.004S is MR unsafe according to ASTM F 2052, ASTM F 2213, ASTM F 2182.

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



– 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.

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedicaldevices.com