Instructions for Use

03.816.705 Bifurcated Light Cable
03.816.706 Light Cable

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

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE

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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.

Materials:

Materials:	Standards:
Silicone	
Glass Fiber	Glass (Schott Type D1)
Polypropylene	
Aluminium	
Stainless Steel	ASTM F 899

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 technique guides.

Precautions and Warnings
- Do not bend fiber optic cables under a radius of 5 cm.
- Do not apply pressure on the light cable using a sharp object.
- Do not modify the light cable or adapters. The light cable is designed to provide an optimal light output level when delivered.
- Avoid damaging the fiber surfaces at the ends of the light cable, as this will reduce the light output level.
- Do not use higher wattage than indicated for the light cables.
- 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".
- Never leave the light cable unattended when light is being transmitted from a light source.
- 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.
- When connected to a light source, do not place the light cable end into the surgical field. Danger of over-heating! (>43°C)
- Do not embed the light cable in soft tissue.
- In case of conspicuous mechanical damage (e.g. silicone hose is damaged), the light cable must not be used since sterility can no longer be ensured.
- Do not touch the open end of the 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 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.

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
03.816.705 and 03.816.706 are combined with 03.816.709 to connect to the light devices and 03.816.701; 03.816.702; 03.816.703; 03.816.704 to connect to the corresponding light source.

When connecting the light cable to the light devices ensure that the cross sections of the glass fibers are the same for both components; otherwise an unwanted (excessive) heating of the coupling points may result.

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 03.816.705 and 03.816.706 are 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".

Function control of light cables can be downloaded from:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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 light cables 03.816.705 and 03.816.706, Synthes recommends steam sterilization in fractionated vacuum at 132 °C for 4 minutes.

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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.depuysynthes.com