Instructions for Use
03.612.031 Fibre Optic Cable for Light Clip/Light Strip

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
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE

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Instructions for Use

03.612.031 Fibre Optic Cable for Light Clip/Light Strip
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

Intended Use
This fibre optic light cable is designed to deliver illumination from a high intensity light source to a surgical instrument for surgical site illumination, either standard or minimally invasive.

Indications/Contraindications
In case fibre optic light cable (03.612.031) 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 instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implants and associated access systems used rather than the light cable. Specific adverse events/ side effects for can be found in the respective instructions for use.

Warnings and Precautions
The user of this product should be thoroughly familiar in the use and care of this product.

- Use care not to point the light cable directly at the eye while in operation. The brilliant light output can cause severe eye discomfort.
- The user should carefully study this Instructions for Use before making any attempt to use the product clinically. Instructions should be followed specifically, with special attention given to warnings and cleaning instructions. This Instructions for Use should also be available to the surgical team during a procedure.
- Follow the instructions in the operating manuals of other manufacturers' equipment when they are used in conjunction with this product.
- Before every procedure, carefully inspect the light cable to ensure it has been properly maintained, cleaned and sterilized, and that it is fully functional.
- Light sources use high intensity lamps, which produce heat as well as brilliant light. The high brightness produced by the light source and the light output of the light cable can cause burns.
- Care should be taken to follow the maintenance and cleaning instructions.
- Excessive bending of the cable should be avoided.
- Do not drape or cover the light source or the light cable while it is operating.
- Do not place the light cable on a drape while it is operating.
- Safety precautions must always be exercised when using electrical equipment to prevent operator/patient shock, fire hazard, or equipment damage.

You can prolong the life span by following a few guidelines.
- Avoid stretching the cable, forming configurations involving sharp angles or kinks, or contact with sharp or pointed objects. The internal light fibres are made of glass, a material that breaks under stress. Fibre breakage will result in diminished light output.
- Do not use the fibre optic cable with any alterations to its original design or fabrication. Bundle size (aperture) of the fibre optic cable should be matched to the aperture of the instrument to obtain maximum light output.
- A larger aperture fibre optic cable will not increase light output of a smaller aperture instrument. It may cause overheating in the instrument and may lead to patient injury.
- Keep the optical faces from contacting the floor or other hard surfaces. The resulting scratches will diminish light output. Store the cables in sterilization trays for additional protection.
- Any inadvertent cut or puncture to the silicone tube will render the cable unsafe. It should be taken out of service immediately.

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 fibre optic light cable is compatible for use with light sources made with the following: Xenon with lamp power rating of up to 300 Watts, Halogen with lamp power rating of up to 250 Watts, or Metal Halide with lamp power rating of up to 100 Watts. Any light source used with this cable should have a minimum of 90% infrared (IR) filtering to prevent cable damage during use.

Magnetic Resonance Environment
MR Unsafe: The medical device 03.612.031 is MR unsafe according to ASTM F 2052, ASTM F 2213, ASTM F 2182.

Treatment before Device is Used

Non-Sterile Device:
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".

Clinical Processing of the Device

Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Maintenance:
Follow all applicable bloodborne pathogen procedures as indicated by local regulations and/or hospital requirements when cleaning, disinfecting, and sterilizing instruments and accessories.

Cleaning:
- Cleaning can be done manually or mechanically with pre-clean.
- The device is not recommended for ultrasonic cleaning process.
- Lukewarm water with mild detergent is recommended to remove all blood and debris. (Do not use synthetic detergents or oil-based soap, as these chemicals may be absorbed into the cable and could subsequently leak out and cause tissue reactions.)
- Rinse thoroughly with distilled water, taking care to rinse the face of glass fibre at both ends of the cable.

Disinfecting:
- Cables may be soaked briefly in disinfecting solutions without damage.
- Refer to the time specifications of the disinfecting solutions; however, avoid soaking cables for more than 10 minutes.
- Disinfection cycle: For automated thermal disinfection: 93°C for a minimum of 2 minutes and 30 seconds.
- Disinfection cycle: Other: Thermal disinfection using the A0-Value-System

Sterilization:
- The fibre optic cable has been specifically designed to withstand repeated sterilization in the following type of sterilizer: Steam autoclave (pre-vacuum) wrapped at 132 °C for 4 minute cycle with a 20 minute dry time.
- Meticulous care should be taken to avoid cable contact with sharp or pointed objects.
- Ensure the autoclave is operating correctly for effective sterilization. Consult your autoclave manual for specific instructions, conditions and exposure periods.
- The pressure differential, which occurs during steam autoclaving, may cause small bubbles in the tubing. These bubbles will not affect the fibre optic cable and will dissipate in time.
- Following sterilization of the fibre optic cable, allow it to cool very slowly to room temperature.
- Do not immerse or rinse in a cold liquid, as this will cause fibre breakage and extensive light transmitting losses.

Additional Device-Specific Information
The symbols listed below identify those symbols that can be found on a medical grade light source and other illumination related equipment.

 Brightness

 Type CF Equipment

 Type BF Equipment

Notes BF: (1) B = Body, (2) F = Floating
Notes CF: (1) C = Cardial, (2) F = Floating

Indications for replacement
Note: Do not perform this check while the light cable is attached to an operating light source. The brilliant light output can cause severe eye discomfort.

- When a fibre optic cable shows 30% loss of light transmission of its fibres, the cable needs to be replaced. This can be determined while holding both ends of the cable: point one cable end toward a light while looking at the other end.
- When there is separation of the cable components that can be seen with a visual inspection, such as strain relief and sheath or endfittings.
- When a cable has been excessively stretched or cut.

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

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