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# 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.

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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

Material: Polymers

### Intended Purpose

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. It 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.

### General Warnings

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 manual before making any attempt to use the product clinically. Instructions should be followed specifically, with special attention given to warnings and cleaning instructions. This manual 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.

### Fire hazard

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

Safety precautions must always be exercised when using electrical equipment to prevent operator/patient shock, fire hazard, or equipment damage.

### Symbols

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



Consult instructions for use



Brightness



Type CF Equipment



Type BF Equipment

### Cable Care

You can prolong the life span by following a few guidelines.

- Avoid stretching your 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 your 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.

### Maintenance

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

### Cleaning

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.

### Sterilization

Your fibre optic cable has been specifically designed to withstand repeated sterilization in the following types of sterilizers:

- 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 your 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 your 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.

### 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.



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