GENERAL INSTRUCTIONS & RECOMMENDATIONS FOR THE USE, CARE AND MAINTENANCE OF **FIBRE LIGHT CABLES**

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INTENDED USE:	Transmission of illumination from a light source to an endoscope, surgical instrument or surgical headlight. The fibre light cable is compatible with light sources with a power rating up to 300-watt Xenon.
HOW SUPPLIED:	**Fibre Light Cables are supplied non-sterile** and must be cleaned and sterilised before each use according to the instructions and recommendations outlined below.
WARNINGS: 	• **Never look into the optical end while it is connected to a light source. Always turn off the light source prior to removing the cable. The light source connector may become hot during use. Never rest the cable end on a patient or bedding. To prevent cable damage any Xenon light source used should have a minimum of 90% IR filtering.** • **If this device is/was used on a patient with, or suspected of having Creutzfeld Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilise to eliminate cross-contamination risk.**

INSTRUCTIONS & RECOMMENDATIONS

Handling:	With proper treatment and care, a fibre light cable can have a long service life: • Avoid stretching the cable, forming configurations involving sharp angles or kinks, or contact with sharp objects. • Do not place objects on the fibre light cable that could crush it. Avoid the optical faces coming into contact with the floor and keep them free from fingerprints, foreign matter, and scratches.
Point of use:	• A xenon light source is strongly recommended for use with this product. This produces a pool of white light, as opposed to the less effective yellow light that a halogen system produces. • Ensure the fibre light cable is correctly connected to the light source generator with the appropriate proximal fitting. • Handle the cable by the strain reliever when removing it from a light source. Remove the cable from service immediately if a puncture is found in the outer sheathing. • During procedures it is recommended that the distal tip of the fibre light is wiped with a non-abrasive cloth. A small amount of heat will leak through the heat filter in the power source. If blood and debris are allowed to dry, the light transmission will be partially or totally obscured. Ask an appropriate member of staff to check this before it is passed to the Cleaning and Sterilisation Department as solidified blood debris is difficult to remove once dry.
Pre-Cleaning:	• If possible, do not allow blood and/or bodily fluids to dry on the fibre light. If necessary, consider covering with a damp cloth to avoid drying out of the soil. • Take care to avoid damage to the fibre light and/or other instruments during transportation for reprocessing (e.g. do not mix heavy devices with delicate items). Transport for reprocessing as soon as possible after use.
Cleaning:	Reference to Health Technical Memorandum HTM 01-01 is advised which provides guidance about the management, decontamination and sterilisation of reusable medical devices. • The product may be cleaned using an automatic washing and disinfecting unit using an alkaline (ie. neutral to 10.5 pH in dilution) detergent and thermal disinfection at 90°C to 95°C for a minimum of one minute with water. • For Manual Cleaning: – Remove gross contaminants with a steady stream of lukewarm/cool water (below 43°C). Rinse thoroughly. – A moist cloth or soft bristled brush moistened with a neutral pH enzymatic cleaner or mild soap and water is recommended to remove visible debris. Wipe or brush as necessary to remove the debris. Do not use synthetic detergents or oil-based soap, as the chemicals may cause skin irritation. – Care must be taken to ensure cleaning agents are used in accordance with the manufacturer's instructions. – Rinse thoroughly in warm tap water, followed by a distilled water rinse. – Visually inspect for any remaining soil and repeat the manual cleaning steps above if necessary. – Allow to drain on absorbent wipes or transfer immediately to inspection step.
Service Life, Inspection & Maintenance	• Before each use, inspect for any damage. If the outer sheathing is nicked or cracked and/or the connectors severely corroded the fibre light cable must be repaired or replaced. • Cables should always be checked prior to attaching to the connector. Always ensure the connector is correctly fitted. • To check a fibre light cable, hold one end to a dim light (theatre environment light is fine) and observe the other end. If black specs appear, the cable is damaged. If the specs appear to cover more than approximately 20% of the area of the end of the fibre light, the cable should not be used. Cable condition is paramount to the performance of the instruments attached to it. • Damaged or defective fibre light cables should not be used. For repair or replacement, contact your Bolton Surgical Sales Consultant (or your local agent if outside the UK). • If fibre light cables are returned to Bolton Surgical for any reason, a certificate of decontamination must be supplied. Failure to supply evidence of decontamination will result in the products being returned untouched for reprocessing.
Sterilisation:	Reference to Health Technical Memorandum HTM 01-01 is advised which provides guidance about the management, decontamination and sterilisation of reusable medical devices. • Before sterilisation commences make sure that any removable cable connector is detached. If it is left on, water and sterilisation debris can build up in this area and impair light transmission. (Do not forget to reattach the connector prior to use). • It is best to sterilize the cable separately. Place the cable in an approved sterilization tray. • Steam Autoclaving is recommended. Bolton Surgical Fibre Light cables are able to withstand repeated sterilisations for 3 minutes at 134°C with a 20 minute dry time. • **Note:** Sterilisation times are for exposure and do not include ramp up times needed. Follow the manufacturer's instructions for loading and operation of steam autoclaves. • After sterilization, allow the cable to cool slowly to room temperature. Do not immerse or rinse in cold liquid, as fibre breakage will occur. • **Note:** The responsibility for validation of sterilisation techniques and equipment lies with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilisation chambers, wrapping methods and/or load configurations.

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MEDILINK MEMBER

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Manufactured under an ISO 13485 registered quality management system.