Document ref **IFU-016** rev 0 01/06/2022	**INSTRUCTIONS FOR USE FOR THE CARE, HANDLING AND REPROCESSING OF RE-USABLE ELECTROSURGICAL CABLES**	BOLTON SURGICAL of SHEFFIELD

DEVICE(S)	• **These instructions apply to re-usable Electrosurgical Cables (Monopolar and Bipolar) supplied or distributed by Bolton Surgical Limited.** • **Materials used in Manufacture:** Connectors - Thermoplastic Elastomer (Medical Grade) Cable - Silicone insulated tinned copper wire. Contacts - Nickel-plated brass or Stainless Steel	**INSTRUMENT CLASSIFICATION**	**Class 1**
INTENDED USE	• Electrosurgical Cables are intended for use only during electrosurgery procedures for the purpose of connecting compatible electrosurgical instruments to the mono or bipolar output, as appropriate, of a compatible electrosurgical generator unit and control system (ESU).		
HOW SUPPLIED	 Bolton Surgical re-usable electrosurgical cables are **LATEX FREE**, including their packaging.	 Bolton Surgical re-usable electrosurgical cables are supplied non-sterile and must be cleaned and sterilised (Except Footswitches & Plate cables) prior to each use.	
WARNINGS AND CONTRAINDICATIONS	 • **WARNING: If this device is/was used on a patient with, or suspected of having Creutzfeld Jakob Disease (CJD), the device cannot be re-used and must be destroyed due to the inability to reprocess or sterilise to eliminate cross-contamination risk.** • **Electrosurgical cables are intended for use only by appropriately qualified surgical practitioners.** • Misuse of an electrosurgical cable for tasks other than those for which it is intended may result in serious, unnecessary harm to the patient or user as well as damage or failure of the instrument and equipment. • Do not use the cable if, in the opinion of the surgical practitioner, patient safety risks outweigh the benefits. • Before undertaking electrosurgery on patients with pacemakers or other active implants, consult a cardiologist or appropriate medical specialist in case special requirements apply (e.g. low HF-current, patient monitoring) • Risk of infection – Do not use any electrosurgical cable showing signs of inadequate decontamination. • Do not use any electrosurgical cable showing signs of damage or corrosion to connectors or damage to insulation. • Follow recommended guidelines for power set up & connection to the ESU. • Make sure that the connectors of the selected electrosurgical cable match both the instrument and ESU connectors. • To avoid risk of injury or electrical shock to patient or operating room personnel, ensure the ESU is in 'off' or 'standby' mode before connecting the cable and/or the instrument, and, that the instrument is isolated from the patient or user. • Do not use the cable if its connector does not fit securely to either the instrument terminal or the socket on the ESU or, if there are exposed metal portions of the terminal pins after plugging in (i.e. the plug is not fully inserted). • Fire risks are associated with improper use and handling of electrosurgical instruments and accessories. Do not place them in contact with or near to flammable or explosive substances (e.g. drapes, gauze, and oxygen sources). • Observe the use and safety instructions supplied by the manufacturer of the ESU to be used. • Do not allow an electrosurgical cable to lay parallel in close proximity to the cables of other electrosurgical devices. • Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents. • **When handling biologically contaminated instruments and reprocessing medical devices always handle with care wearing appropriate protective gloves, eyewear and clothing in accordance with local Health & Safety procedures.**		
LIMITATIONS OF USE AND REPROCESSING	• Repeated use and reprocessing does limit the service life of electrosurgical cables. The MHRA has therefore recommended (MDA Safety Notice MDA/2003/037) that electrosurgical cable usage is monitored and recorded. All Electrosurgical Cables supplied by Bolton Surgical are fitted with a tagging system to make traceability straightforward and to provide the means to maintain a count of the number of times the cable has been reprocessed for use. • Cables should be returned to Bolton Surgical after 50 reprocessing cycles for a full test and inspection or sooner if any fault is found or suspected. (See also 'INSPECTION' below)		
REPROCESSING INSTRUCTIONS:			
PREPARATION FOR USE	• Before every use, re-usable cable(s) covered by this IFU must be cleaned, inspected and sterilised in accordance with the Instructions below.		
FROM POINT OF USE	• At point of use, remove gross soil using absorbent wipes. Wherever possible, do not allow blood, surgical debris or bodily fluids to dry on the cables. • For best results and to maximise their service life reprocess cables immediately after use to minimise the potential for drying before cleaning. • If transfer to reprocessing is likely to take time, consider covering the cables with a damp cloth or use an enzymatic foam spray cleaner to help prevent soil from drying or, soak in an enzymatic solution (prepared according to the manufacturer's instructions) to help facilitate cleaning. • Do not leave cables soaking in saline or chlorinated solutions. • Avoid mechanical damage during transportation to the processing area (e.g. do not mix heavy devices with delicate items). Pay particular attention whenever sharp instruments are present to avoid injury or damage to the cable by the instrument. Separate cables from sharp instruments. • Avoid unnecessary contamination or cross contamination risk by transporting used instruments for reprocessing in closed or covered containers		
AUTOMATED CLEANING	• Whenever possible automated cleaning methods are preferable to manual methods to provide a more consistent and reliable process and, reduce staff exposure to contaminated devices and the cleaning agents used. • **Use suitably authorised washer-disinfector machines and low foaming, non-ionising cleaning agents and detergents following the manufacturer's instructions for use, warnings, concentrations and recommended cycles.** • Cables covered by these instructions can withstand alkaline cleaning agents up to 10.5 pH. • Cables covered by these instructions can withstand thermal disinfection at 90°C to 95°C for 1 minute minimum. • Place heavy instruments with care into the bottom of containers, taking care not to overload wash baskets. make sure heavy objects are not placed on the cables during processing and whilst cooling down. • Avoid contact between devices if movement during washing could cause damage or impair the washing action. • Soft, high purity water which is controlled for bacterial endotoxins or mains supplied potable tap water is suitable for use in the final rinse stage. • On completion of the cleaning cycle, visually inspect each device for dryness and any remaining soil. If soil remains, repeat the cleaning process. • Remaining wetness may be removed with medical grade compressed air or by heating in an oven below 110°C		
MANUAL CLEANING	• **Manual cleaning only advised using the following process if an automatic washer-disinfector is not available:** 1. Use a double sink system (wash/rinse) dedicated for instrument cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35°C. 2. In the first sink, keeping the cable submerged, apply a suitably approved mild detergent to all surfaces until all soil has been removed. Always brush away from the body. DO NOT use solvents of any kind as this might affect plastic parts. 3. In the second sink, rinse the cable with soft, high purity water which is controlled for bacterial endotoxins or, mains supplied potable tap water so that water reaches all parts of the cable, then carefully hand dry or use a drying cabinet.		

CLEANING INSPECTION	• After cleaning, visually inspect *all* surfaces paying particular attention to connectors for removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.
INSPECTION	• Electrosurgical cables must be inspected in accordance with local/hospital protocol, points to inspect are: - ▪ Check metal contacts, these should be bright without corrosion. ▪ Connectors should be free from damage or distortion and fit firmly to mating connectors. ▪ Cable insulation must be checked periodically to make sure the product is safe for use, pay special attention to the exit point on the connectors as excessive flexing can cause failure in this area. • All electrosurgical cables and instruments must be regularly checked for electrical continuity by the Medical Physics Department to prevent possible failure whilst being used in surgery. Flex the connectors whilst checking continuity, this will isolate conductors that may be breaking inside the insulation. • ***Remove for replacement any cables failing any of the above inspection criteria.*** **Note:** *Used cables returned to Bolton Surgical for any reason **must** be decontaminated and sterilised and be accompanied with the relevant documented evidence.*
PACKING FOR STERILISATION	• All instruments to be packed following local/hospital protocol or in accordance with ISO11607-1
STERILISATION	• **Use suitably authorised vacuum autoclave operating at 134°C to 137°C, with a minimum holding time of 3 minutes (see 'Additional Information' below for alternative sterilisation parameters)** • **Always follow the instructions of the machine manufacturer.** • Ensure cables are dry before sterilisation. • Sterilisation cases should be loaded just prior to the sterilisation step. • When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.
STORAGE	• Ensure cables are dry before storage and stored in dry, clean conditions at an ambient room temperature.
GENERAL CLEANING PRECAUTIONS	• Do not soak electrosurgical cables in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution. • DO NOT use solvents of any kind as this might affect plastic parts. Non-flammable agents should be used for cleaning and disinfection where possible. • Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents. • The quality of the water used for diluting cleaning agents and for rinsing medical devices should be carefully considered. Mineral residues from hard water can result in staining of the cable or prevent effective cleaning and decontamination. • Electrosurgical cables require careful handling to prevent damage. Use caution during cleaning and sterilisation. A non-fibrous sponge should be used to wipe off all blood and debris.
ADDITIONAL INFORMATION	• Other forms of cleaning** (i.e. Ultrasonic) and sterilisation (i.e. Low temperature steam and Formaldehyde, Ethylene Oxide and Gas Plasma) are available. However, always follow the instructions for use as issued by the equipment manufacturer and always consult with them if in any doubt over the suitability of any process used. • Alternative sterilising parameters** - vacuum autoclave operating at 132°C to 135°C, with a minimum holding time of 4 minutes, or, 121° - 124°C with a minimum holding time of 20 minutes. • Cleaning and sterilising guidelines are available in UK Health Technical Memorandum - HTM01-01 and ISO17665-1 ** *Products covered by this IFU have not been validated for these forms of cleaning and sterilisation.* ***Note:*** *It is the responsibility of the reprocessor to ensure that the reprocessing that is actually carried out, using the equipment, materials and personnel in the reprocessing facility, achieves the desired results. This requires validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.*
MAINTENANCE AND REPAIR	• Re-usable electrosurgical cables have no user serviceable parts and cannot be repaired. Proper handling, cleaning, sterilisation and storage will maximise their useful life. • If you have any question regarding the fitness for purpose of a used cable, contact Bolton Surgical Ltd or your medico-technical department.
LIMITED WARRANTY	• Bolton Surgical re-usable electrosurgical cables are guaranteed for a period of one (1) year from the date of purchase (terms & conditions apply) against product failure resulting from defective materials and workmanship, when used by appropriately qualified persons with the required specialist knowledge and training, for the purpose for which the device is intended and, properly maintained in accordance with this IFU. • Liability is refused for products which have been modified as compared to the originally supplied product, misused, incorrectly handled or, used for a purpose that differs in any way from product's stated Intended Use.
RETURNED GOODS POLICY	• Customers wishing to return goods for any reason must do so in accordance with Bolton Surgical's Returns Policy (ref. POL 009) a copy of which is supplied with each order or, is available online by visiting www.boltons.co.uk • Determination of a product defect will be made by Bolton Surgical Ltd.
DISPOSAL	• End of service life instruments must be decontaminated and sterilised prior to disposal. • Disposal should be in accordance with local/hospital waste management protocols.
INCIDENT REPORTING	• Report any serious incident that has occurred in relation to the use of the device to the manufacturer and the competent authority of the country in which the user and/or patient is established and in accordance with the reporting rules applicable in that country.
VALIDATION	• Except where indicated (**), these instructions have been independently validated using a washer-disinfector operated in accordance with the recommendations included in this IFU, following the HTM 01-01 guidelines.

EXPLANATION OF SYMBOLS USED ON LABELS						
 Manufacturer	 Manufacturer's Product Code	 Manufacturer's Batch Code	 Supplied Non- Sterile	 Supplied Latex Free	 Caution	 Consult Instructions for Use

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MEDILINK MEMBER

NHS Supply Chain

UK CA

Manufactured under an ISO 13485 registered Quality Management System

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