Document ref **IFU-003b** rev 0 01/06/2022	**INSTRUCTIONS FOR USE FOR THE CARE, HANDLING AND REPROCESSING OF RE-USABLE SURGICAL RETRACTORS – HAND-HELD**	BOLTON SURGICAL of SHEFFIELD

DEVICE(S)	• **These instructions apply to re-usable hand-held Surgical Retractors including Tongue Depressors and re-usable hand-held Surgical Retractors fitted with Fibrelight Stems, supplied by Bolton Surgical Limited.**	**INSTRUMENT CLASSIFICATION**	**Class 1**
INTENDED USE	• **Retractor -** A hand-held, manual, non-self-retaining surgical instrument intended for use during surgical procedures to retract (separate/draw aside) the margins of a wound/incision, manipulate tissue or, expand a natural body opening. Some models are equipped with mounts for attachment of a fibrelight stem to provide targeted illumination of surgical sites typically during deep open surgical procedures. • **Tongue Depressor -** A hand-held surgical instrument designed to displace and maintain the tongue in a fixed position, usually by depressing it towards the floor of the mouth, during oral surgery.		
HOW SUPPLIED	 Bolton Surgical re-usable surgical instruments are **LATEX FREE**, including their packaging.	 Bolton Surgical re-usable surgical instruments are supplied non-sterile and must be cleaned and sterilised prior to each use.	
WARNINGS AND CONTRA-INDICATIONS	• **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.** • **These devices are intended for use only by appropriately qualified surgical practitioners.** • Do not use the instrument if, in the opinion of the surgical practitioner, patient safety risks outweigh the benefits. • Risk of infection – Do not use any surgical instrument showing signs of corrosion or inadequate decontamination. • Do not use damaged Instruments. • Never look into the optical end of a fibrelight stem that is connected to a light source. Always turn off the light source prior to removing the cable. • The light source connectors (where fitted) may become hot during use. Never rest the cable on a patient or bedding. • 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. • No part of the process to exceed 140ºC. • **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	• The use of a retractor or fibrelight stem for tasks other than those for which it is intended may result in serious damage or failure of the instrument as well as unnecessary stress to the patient. • Bolton Surgical Fibrelight Stems (where fitted) are compatible with light sources with a power rating up to 300-watt Xenon. To prevent cable damage any Xenon light source used should have a minimum of 90% IR rating. • Repeated reprocessing has minimal effect on the service life of surgical instruments. End of useful service life is normally determined by wear and damage in use. (See 'INSPECTION' below) • Misuse can result in over-stressing the retractor or, where applicable, the optical fibres causing loss of performance, misalignment or cracks or other irreparable damage.		

REPROCESSING INSTRUCTIONS:

PREPARATION FOR FIRST USE	• **Before first use, the re-usable device(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 instruments.
	• For retractors fitted with fibrelight stems:
	  ○ Ensure the fibrelight stems cable is correctly connected at both ends with the appropriate proximal and distal fittings.
	  ○ Handle the cable by the strain relief collar when removing it from a light source.
	  ○ During procedures it is recommended that the distal tip of the fibrelight stem 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. It is recommended that this is checked before it is passed to the Cleaning and Sterilisation Department as solidified blood debris is difficult to remove once dry.
	• For best results and to maximise their service life reprocess instruments immediately after use to minimise the potential for drying before cleaning. If transfer to reprocessing is likely to take time, consider covering the instruments with a damp cloth or use an enzymatic foam spray cleaner to help prevent soil from drying.
	• Do not leave instruments or fibrelight stems 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 cutting edges are present to avoid injury and damage to or by the instrument. Separate sharp and delicate surgical instruments.
	• Avoid unnecessary contamination or cross contamination risk by transporting used instruments for reprocessing in closed or covered containers

AUTOMATED CLEANING	• Where appropriate, detach the fibrelight stem and cable end fittings before cleaning. Retain all parts to facilitate reassembly. • 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 validated washer-disinfector machines and low foaming, non-ionising cleaning agents and detergents following the manufacturer's instructions for use, warnings, concentrations and recommended cycles.** • It is recommended to use cleaning agents with a medium pH (between neutral and 12.5 pH) • Surgical instruments covered by these instructions can withstand thermal disinfection at 90ºC to 95ºC for a minimum of 1 minute. • Place heavy instruments with care into the bottom of containers, taking care not to overload wash baskets. • Place instruments with concave surfaces facing down to prevent pooling of water. • 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	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 instrument submerged, with an autoclavable brush, apply suitably approved marked cleaning solution to all surfaces until all soil has been removed, Always brush away from the body. 3. In the second sink, rinse with soft, high purity water which is controlled for bacterial endotoxins or, mains supplied potable tap water and then thoroughly dry.
INSPECTION	• After cleaning, visually inspect *all* surfaces for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination. • Visually inspect and check: - all instruments for completeness, surface damage, excessive wear, staining and corrosion; edges are free from nicks and that instruments are not distorted. • To check a fibrelight stem, hold one end to a dim light (theatre environment light is fine) and observe the other end. If black specs appear, the light guide is damaged. If the specs appear to cover more than approximately 20% of the area of the end of the fibre light, the light guide should not be used. • For fibrelight stem testing or replacement, contact Bolton Surgical Ltd (or your local agent if outside the UK). **Note:** *If a used instrument is returned to the manufacturer / supplier for any reason, the instrument **must** be decontaminated and sterilised and be accompanied with the relevant documented evidence.*
MAINTENANCE	• Proper cleaning, handling, sterilisation and standard routine maintenance will ensure that instruments perform as intended and will maximise their useful life.
PACKING FOR STERILISATION	• All instruments to be packed following local 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. Always follow the instructions of the machine manufacturer. (see 'Additional Information' below for alternative sterilisation parameters) • Before sterilisation 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). • Ensure instruments are dry before sterilisation. • After sterilisation, allow the fibrelight stem to cool slowly to room temperature. Do not immerse or rinse in cold liquid, as fibre breakage may occur.
STORAGE	• Ensure instruments are dry before storage and stored in dry, clean conditions at an ambient room temperature.
GENERAL CLEANING PRECAUTIONS	• Do not soak instruments 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 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 device or prevent effective cleaning and decontamination. De-scaling agents, if used, will not harm the devices. • If practicable, avoid processing instruments of different metallic composition close together to minimise risk of electrolytic action between the metals that can result in corrosion. • Delicate instruments 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 at 132°C to 135°C, with a minimum holding time of 4 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	• Instruments can be returned to Bolton Surgical for repair but ***must*** be decontaminated and sterilised and be accompanied with the relevant documented evidence. Failure to supply decontamination/sterilisation certification will result in products being returned untouched for re-processing and delayed repairs. • Repairs carried out by Bolton Surgical are guaranteed for 12 months to be free from defects in workmanship, materials and parts used to carry out the repair providing the instrument is used normally for its intended surgical purpose. Any repair parts or workmanship proving to be defective will be replaced or repaired, at our discretion, at no charge to the customer.
LIMITED WARRANTY	• Bolton Surgical re-usable surgical instruments are guaranteed for a period of 15 years from the date of purchase (terms & conditions & exclusions of guarantee apply) against product failure resulting from defective materials and workmanship, when used by 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 Returns Policy (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 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	

Bolton Surgical Limited
Churchill House, 16 Churchill Way, Chapeltown, Sheffield, S35 2PY, UK
T: +44 (0) 114 240 44 F: +44 (0) 114 257 6555
E: sales@boltons.co.uk W: www.boltons.co.uk

MEDILINK MEMBER | NHS Supply Chain | UKCA

Manufactured under an ISO 13485 registered Quality Management System

This document is approved for use: Sig. Date: 01/06/2022