














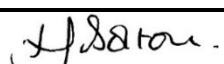


Document ref: IFU-002a rev 0 (CRN531) 01/06/2022	INSTRUCTIONS FOR USE FOR THE CARE, HANDLING AND REPROCESSING OF RE-USABLE ROUGH CUT UTILITY SCISSORS		
DEVICE(S)	<ul style="list-style-type: none">These instructions apply to re-usable Rough Cut Utility Scissors supplied by Bolton Surgical Limited.	INSTRUMENT CLASSIFICATION	Class 1
INTENDED USE	<ul style="list-style-type: none">ROUGH CUT UTILITY SCISSORS - A hand-held manually operated general purpose, non-surgical scissor intended for use in a surgical environment to cut a variety of materials associated with general clinical use (bandages, fabrics etc).		
HOW SUPPLIED	 Bolton Surgical re-usable surgical instruments are LATEX FREE , including their packaging.	 Bolton Surgical re-usable Rough Cut Scissors are supplied non-sterile and must be cleaned and sterilised prior to use.	
 WARNINGS AND CONTRAINDICATIONS	<ul style="list-style-type: none">WARNING: If this device is/was used in association with 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 scissors must not be used as a surgical scissor.Do not use the scissor if, in the opinion of a qualified practitioner, patient or user safety risks outweigh the benefits.Risk of infection – Do not use this device if it shows signs of corrosion or inadequate decontamination or damage.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 140°C.When handling biologically contaminated items always handle with care wearing appropriate protective gloves, eyewear and clothing in accordance with local Health & Safety procedures.		
LIMITATIONS OF USE AND REPROCESSING	<ul style="list-style-type: none">Use of the scissor for tasks other than those for which it is intended may result in harm to a patient or user as well as serious damage or failure of the scissor.Repeated reprocessing has minimal effect on the service life of these scissors. End of useful service life is normally determined by wear and damage in use. (See 'INSPECTION' below)Misuse can result in over-stressing the scissor causing misalignment or cracks or other irreparable damage.		
INSTRUCTIONS:			
PREPARATION FOR FIRST USE	<ul style="list-style-type: none">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	<ul style="list-style-type: none">At point of use, remove any gross soil using absorbent wipes. Wherever possible, do not allow blood, surgical debris or bodily fluids to dry on the instruments.For best results and to maximise service life reprocess the scissors 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 or, soak in an enzymatic solution (prepared according to the manufacturer's instructions) to help facilitate cleaning.Do not leave scissors soaking in saline or chlorinated solutions.Avoid 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.Avoid unnecessary contamination or cross contamination risk by transporting used instruments for reprocessing in closed or covered containers		
AUTOMATED CLEANING	<ul style="list-style-type: none">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.It is recommended to use cleaning agents with a medium pH (between neutral and 10.5 pH)Rough Cut Scissors covered by these instructions can withstand thermal disinfection at 90°C to 95°C for a minimum of 1 minute.Load scissors carefully with blades in the open position for cleaning so that they can drain.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, RO water or mains supplied potable tap water is suitable for use in the final rinse stage.On completion of the cleaning cycle, visually inspect the scissors 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	<ul style="list-style-type: none">Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following process: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 scissors submerged, with a soft brush, apply suitably approved cleaning solution to all surfaces until all soil has been removed. Clean the scissor joint in open and closed positions. Always brush away from the body.3. In the second sink, rinse thoroughly with soft, high purity water, RO water or, mains supplied potable tap water then carefully hand dry or use a drying cabinet.		
CLEANING INSPECTION	<ul style="list-style-type: none">After cleaning, visually inspect <i>all</i> surfaces, paying particular attention to blades and joints, for complete removal of soil. If ANY soil is still visible, return the instrument for repeat decontamination.		
MAINTENANCE	<ul style="list-style-type: none">It is recommended to apply a surgical grade lubricant to the scissor joints in accordance with the lubricant manufacturer's instructions.Proper cleaning, sterilisation and careful handling, will ensure the scissor perform as intended and will maximise their useful life.		
INSPECTION	<ul style="list-style-type: none">Visually inspect and check scissors for completeness, damage/distortion, excessive wear, staining and corrosion; cutting edges are free from damage and provide a continuous cut to the blade tip; joints should have a smooth movement without excess play.Remove for repair or replacement any worn out, cracked, fractured or otherwise damaged scissors.Note: If a used instrument is returned to the manufacturer / supplier for any reason, the instrument <i>must</i> be decontaminated and sterilised and be accompanied with the relevant documented evidence.		

PACKING FOR STERILISATION	<ul style="list-style-type: none"> All instruments to be packed following local protocol, in accordance with ISO11607-1 						
STERILISATION	<ul style="list-style-type: none"> 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 the scissors are dry before sterilisation. Sterilisation cases should be loaded just prior to the sterilisation step. When sterilising multiple items in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded. 						
STORAGE	<ul style="list-style-type: none"> Ensure the scissors are dry before storage and stored in dry, clean conditions at an ambient room temperature. 						
GENERAL CLEANING PRECAUTIONS	<ul style="list-style-type: none"> 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, or abrasive cleaners. 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 scissors or prevent effective cleaning and decontamination. De-scaling agents, if used, will not harm the scissors. 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. Handle the scissors carefully to prevent damage. Use caution during cleaning and sterilisation. A non-fibrous sponge should be used to wipe off all blood and debris. Do not apply excessive force at pivots and joints. 						
ADDITIONAL INFORMATION	<ul style="list-style-type: none"> Cleaning and sterilising guidelines are available in UK Health Technical Memorandum - HTM01-01 and ISO17665-1 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. <p>** Products covered by this IFU have not been validated for these forms of cleaning and sterilisation.</p> <p>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.</p>						
MAINTENANCE AND REPAIR	<ul style="list-style-type: none"> Rough Cut Utility Scissors are not repairable. 						
LIMITED WARRANTY	<ul style="list-style-type: none"> Bolton Surgical re-usable Rough Cut Utility Scissors are guaranteed for a period of 1 Year 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 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> End of service life instruments must be decontaminated and sterilised prior to disposal. Disposal should be in accordance with local waste management protocols. Bolton Surgical re-usable Rough Cut Utility Scissors are manufactured from stainless steel and Polypropylene and are fully recyclable. 						
INCIDENT REPORTING	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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						Manufactured under an ISO 13485 registered Quality Management System
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