Prevation Preva	II	
NUMBER         RE-USABLE DRILLS, BURRS, AWLS AND REAMERS         SURGICAL           DEVICES)         • These Instructions apply to re-usable surgical fills, burrs, awk, reamers, drill chucks and LASSIFICATION         Instrument to be applied non-table surgical productions of mills be or transmission to house.         Instrument to be applied non-table surgical productions of mills be or transmission to house.           WOW SUPPLID         Image: Surgical re-usable surgical productions of mills be or transmission to house applied non-table is and multical productions of the surgical production of the surgical productions and productions of the surgical production of the surgical productions of the surgical productions of the surgical production of the surgical productions of the surgical		
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Image: Constraint in the device cannot be re-used and must be destroyed due to the inability to reprocess or serilise to eliminate cross contamination risks of infection - Do not use any surgical instruments showing signs of corrosion or inadequate decontamination.           WARNINGS         Buck of infection - Do not use any surgical instruments showing signs of corrosion or inadequate decontamination.           Buck of infection - Do not use any surgical instruments showing signs of corrosion or inadequate decontamination.           No part of the process to exceed 140°C.           When handling biologically contaminated instruments and reprocessing medical devices always handle with care wearing appropriate processing has minimal effect on the service life of surgical instruments. disinfectants and cleaning agents used. When went care wearing appropriate processing has minimal effect on the service life of surgical instruments. End of useful service life is Repeated reprocessing has minimal effect on the service life of surgical instruments. Howing agent of the instrument care wearing appropriate processing has minimal effect on the service life of surgical instruments. Howing agent of the instruments with a dama contance with the instructions below.           PREPARATION         Negle for first use, the re usel bio device(s) covered by this FU must be cleaned, inspected and sterilised in accordance with the instruments. Surgical devices always devices with complex of ability first or processing is likely to take the consider covering the instruments with a damp cloth or use an enymatic log or grave cleaner infinite the conside covering the instruments with a damp cloth or use an enymatic log or grave cleaner to evolution grave cleaner to evolution grave cleaner to evolution grepared alway devices with dedicate terms. Pay particular attenti		instruments are LATEX FREE, including supplied non-sterile and must be cleaned and their packaging.
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OF USE AND REPROCESSING         • 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 'NSPECTION' below)           PREPARATION POR 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.           PREPARATION POR 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         • A point of use, remove gross soil using absorbent wipes. Wherever possible, do not allow blood, surgical debris or booling fluids to dry on the instruments.           • From POINT OF USE         • A point of use, remove gross soil using absorbent wipes. Wherever possible, do not allow blood, surgical debris or booling fluids to dry on the instruments.           • From POINT OF USE         • A point of use, the re-usable device(s) covered by this IFU must be cleaned, inspected and sterilised in according to the manufacturer's instructions to help to failitate cleaning, especially for instruments with complex features such a drill flutes, lumens and blind holes.           • Do not leave instruments soaking in saline or chlorinated solutions.         • Avoid unnecessary contamination or cross contamination risk by transporting used instruments for reprocessing in cload or covered or chainers           • Disassemble the device, if it is intended to be disassemble dwithout the use of tools (unless these are specifically provide to espose al surfaces to the dening proceses.         • Avoid unnecesesare contalin	LIMITATIONS	
<ul> <li>Misuse can result in over-stressing the instrument causing misalignment or cracks or other irreparable damage.         INSTRUCTIONS     </li> <li>PREPARATION POR FIRST USE     <li>Before first use, the re-usable device(s) covered by this IFU must be cleaned, inspected and sterilised in accordance with the instructions below.     <li>At point of use, remove pross soil using absorbent wipes. Wherever possible, do not allow blood, surgical debris or bodily fluids to dry on the instruments.</li> <li>For best results and to maximise their service life reprocess instruments immediately after use to minimise the potential for drying before cleaning.</li> <li>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 mainfacturer's instructions) to help facilitate cleaning, especially for instruments with complex features such as drill flutes, lumens and blind holes.</li> <li>Do not leave instruments soaking in soline or choloniated solutions.</li> <li>Avoid mechanical damage during transportation to the processing area (e.g. do not mix heavy devices with the instrument. Separate sharp and delicate surgical instruments.</li> <li>Avoid unnecessary contamination or cross contamination risk by transporting used instruments for reprocessing in closed or covered and telcaning methods are preferable to maxima methods to provide a more consistent and reliable process and, reduce stiff exposure to contaminated devices and the cleaning agents and detergents following the manufacturer's instructions for use, warning, concentrations and recommended cycles.</li> <li>Surgical instruments covered by these instructions can withstand alkaline cleaning agents used.</li> <li>Surgical instruments;</li> <li>Surgical instruments;</li> <li>Surgical instruments;</li> <li>Surgical instruments;<th></th><td>Repeated reprocessing has minimal effect on the service life of surgical instruments. End of useful service life is</td></li></li></li></ul>		Repeated reprocessing has minimal effect on the service life of surgical instruments. End of useful service life is
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.           • AT point of use, remove gross soil using absorbent wipes. Wherever possible, do not allow bload, surgical debris or bodily fluids to dry on the instruments.           • For best results and to maximise their service life reprocess instruments immediately after use to minimise the potential for drying before cleaning to take time, consider covering the instruments with a damp cloth or use an encymatic foam spray cleaner to help prevent soil from drying or, soak in an enzymatic solution (prepared networks) as drill flutes, lumens and blind holes.           • Do not leave instruments soaking in saline or chlorinated solutions.         • Do not leave instruments soaking in saline or chlorinated solutions.           • Avoid mechanical damage during transportation to the processing are present to avoid injury and damage to or by the instrument. Separate sharp and delicate surgical instruments.           • Do samelbe the device, if it is intended to be disassembled without the use of tools (unless these are specifically provided) to expose all surfaces to the cleaning process. Retain all parts to facilitate reasenby.           • Ubassemble the device if it is intended to be disassembled without the use of tools (unless these are specifically provided) to expose all surfaces to the cleaning are preferable to manual methods to provide a more consistent and reliable process and, reduce staff exposure to containinated devices and the cleaning agents and detergents following the manufacturer's instructions for use, warnings, concentrations and recommended cycles.	REPROCESSING	
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AUTOMATED <ul> <li>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.</li> <li>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.</li> <li>Surgical instruments covered by these instructions can withstand alkaline cleaning agents up to 12.5 pH. (Not applicable to blackened instruments)</li> <li>Surgical instruments covered by these instructions can withstand thermal disinfection at 90°C to 95°C for a minimum of 1 minute.</li> <li>Load instruments carefully for cleaning so that any fenestrations in the instruments can drain.</li> <li>Place heavy instruments with care into the bottom of containers, taking care not to overload wash baskets.</li> <li>Avoid contact between devices if movement during washing could cause damage or impair the washing action.</li> <li>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.</li> <li>On completion of the cleaning process.</li> <li>Remaining wetness may be removed with medical grade compressed air or by heating in an oven below 110°C Note: These instructions have been validated for the products detailed above using a washer-disinfector operated in accordance with the recommendations included in this IFU. The detergent used was 12.6pH.</li> </ul> <li>MANUAL CLEANING</li> <li>MANUAL CLEANING</li> <li>MANUAL CLEANING</li> <li>MANUAL CLEANING</li> <li>MANUAL CLEANING</li> <li>MANUAL CLEANING</li> <li>Manual cleaning is no tadvised if an automatic washer-</li>		<ul> <li>or bodily fluids to dry on the instruments.</li> <li>For best results and to maximise their service life reprocess instruments immediately after use to minimise the potential for drying before cleaning.</li> <li>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, especially for instruments with complex features such as drill flutes, lumens and blind holes.</li> <li>Do not leave instruments soaking in saline or chlorinated solutions.</li> <li>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.</li> <li>Avoid unnecessary contamination or cross contamination risk by transporting used instruments for reprocessing</li> </ul>
MANUAL CLEANING       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 instrument submerged, with an autoclavable brush, apply suitably approved cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations and drill/reamer flutes. Always brushing away from the body. Ensure drill chucks are thoroughly cleaned in both open and closed positions.         3. In the second sink, rinse instruments 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 instrument, then carefully hand dry or use a drying cabinet         CLEANING       • After cleaning, visually inspect <i>all</i> surfaces for complete removal of soil and fluids. If ANY soil or fluid is still visible,		<ul> <li>provided) to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly.</li> <li>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.</li> <li>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.</li> <li>Surgical instruments covered by these instructions can withstand alkaline cleaning agents up to 12.5 pH.(Not applicable to blackened instruments)</li> <li>Surgical instruments covered by these instructions can withstand thermal disinfection at 90°C to 95°C for a minimum of 1 minute.</li> <li>Load instruments carefully for cleaning so that any fenestrations in the instruments can drain.</li> <li>Place heavy instruments with care into the bottom of containers, taking care not to overload wash baskets.</li> <li>Avoid contact between devices if movement during washing could cause damage or impair the washing action.</li> <li>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.</li> <li>On completion of the cleaning cycle, visually inspect each device for dryness and any remaining soil. If soil remains, repeat the cleaning process.</li> <li>Remaining wetness may be removed with medical grade compressed air or by heating in an oven below 110°C Note: These instructions have been validated for the products detailed above using a washer-disinfector operated in</li> </ul>
	CLEANING	<ul> <li>available, use the following process:</li> <li>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.</li> <li>2. In the first sink, keeping the instrument submerged, with an autoclavable brush, apply suitably approved cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations and drill/reamer flutes. Always brushing away from the body. Ensure drill chucks are thoroughly cleaned in both open and closed positions.</li> <li>3. In the second sink, rinse instruments 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 instrument, then carefully hand dry or use a drying cabinet</li> </ul>
		return the instrument for repeat decontamination.

MAINTENANCE	<ul> <li>Apply surgical grade lubricants to drill chucks in accordance with the lubricant manufacturer's instructions.</li> <li>Lubrication is essential every time instruments are processed. Only lubricate dry instruments.</li> <li>Proper cleaning, handling, sterilisation and standard routine maintenance (such as sharpening, if applicable) will ensure that instruments perform as intended and will maximise their useful life.</li> </ul>	
INSPECTION	<ul> <li>Visually inspect and check: - all instruments for completeness, damage, excessive wear, staining and corrosion; cutting edges are free from nicks and present a continuous edge; chuck jaws align correctly and have a smooth movement without excess play; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components.</li> <li><i>Remove for repair or replacement any worn out, cracked, fractured or otherwise damaged instruments.</i></li> <li>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.</li> </ul>	
PACKING FOR STERILISATION	All instruments to be packed following local protocol or in accordance with ISO11607-1	
STERILISATION	<ul> <li>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)</li> <li>Always follow the instructions of the machine manufacturer.</li> <li>Ensure instruments are dry before sterilisation.</li> <li>Sterilisation cases should be loaded just prior to the sterilisation step.</li> <li>When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.</li> </ul>	
STORAGE	• Ensure instruments are dry before storage and stored in dry, clean conditions at an ambient room temperature.	
GENERAL CLEANING PRECAUTIONS	<ul> <li>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.</li> <li>Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.</li> <li>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.</li> <li>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.</li> <li>Delicate instruments with cutting edges 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. Do not apply excessive force.</li> </ul>	
ADDITIONAL INFORMATION	<ul> <li>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.</li> <li>Alternative sterilising parameters** - vacuum autoclave operating at 132°C to 135°C, with a minimum holding time of 4 minutes.</li> <li>Cleaning and sterilising guidelines are available in UK Health Technical Memorandum - HTM01-01 and ISO17665-1</li> <li>** Products covered by this IFU have not been validated for these forms of cleaning and sterilisation.</li> <li>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 reprocess. Likewise, any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.</li> </ul>	
MAINTENANCE AND REPAIR	<ul> <li>Instruments can be returned to Bolton Surgical for repair but <i>must</i> 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.</li> <li>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.</li> </ul>	
LIMITED WARRANTY	<ul> <li>Bolton Surgical re-usable surgical instruments are guaranteed for a period of 15 years from the date of purchase (terms &amp; conditions 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.</li> <li>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.</li> </ul>	
RETURNED GOODS POLICY	<ul> <li>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 <u>www.boltons.co.uk</u>.</li> <li>Determination of a product defect will be made by Bolton Surgical Ltd.</li> </ul>	
DISPOSAL	<ul> <li>End of service life instruments must be decontaminated and sterilised prior to disposal. Disposal should be in accordance with local waste management protocols.</li> </ul>	
INCIDENT REPORTING	<ul> <li>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.</li> </ul>	
VALIDATION	<ul> <li>These instructions have been validated for the products detailed above using a washer-disinfector operated in accordance with the recommendations included in this IFU. The detergent used was 12.6pH.</li> </ul>	
EXPLANATION OF SYMBOLS USED ON LABELS	REF Manufacturer's Product CodeLOT Manufacturer's Batch CodeImage: Consult Supplied Non- SterileImage: Consult Supplied Latex FreeImage: Consult CautionImage: Consult Consult Instructions for Use	
Bolton Surgical Limited Churchill House, 16 Churchill Way, Chapeltown, Sheffield, S35 2PY, UK T: +44 (0) 114 240 44 E: sales@boltons.co.uk W: www.boltons.co.uk F: +44 (0) 114 257 6555 W: www.boltons.co.uk W: www.boltons.co.uk W: www.boltons.co.uk		
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