Manufactured By: PHEASANT	**MDL062C** Rev 6 (CRN503) 07/01/2022 **GENERAL INSTRUCTIONS FOR USE, CARE AND MAINTENANCE OF ELECTRO-SURGICAL INSTRUMENTS (Class IIb)**	Distributed By: BOLTON SURGICAL of SHEFFIELD

DEVICE(S):	• **These instructions are for Class IIb re-usable electro-surgical instruments manufactured by Pheasant Surgical Corporation and distributed by Bolton Surgical Limited unless stated otherwise with the packaging of the product.** • **Products covered by these instructions are: All stainless steel electro-surgical instruments including those containing 'Tufnol' or other plastic parts and coatings.** • **These instructions are intended for use only by persons with the required specialist knowledge or training.**
INTENDED USE:	• Electro-surgical instruments are intended for use in surgical procedures by appropriately qualified medical practitioners for the purpose of grasping, cutting and coagulating of selected tissue using high frequency electric current by connection of the instrument via specialised cable and connectors to an electro-surgical generator and control system.
HOW SUPPLIED:	• These instruments are **LATEX FREE**, including their packaging. • All instruments and accessories are supplied non-sterile and must be cleaned and sterilised prior to use.
	• **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.** • **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. Bolton Surgical medical devices are designed for use by appropriately qualified surgical practitioners.** • Careless or improper use of Electro-surgical instruments poses a risk of injury to the patient, operator or other theatre staff through shock, burn or explosion hazard. • Follow the instructions supplied by the manufacturer of the electro-surgical generator. • Test all instruments, accessories and equipment prior to each use. • Avoid touching or grounding electro-surgical instruments to non-insulated instruments or other conductive theatre equipment. • Do not use in the presence of flammable liquids or gasses. • 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 cleaning and sterilising process shall exceed 140°C. • Devices with long, narrow cannula, valves, lumens, hinges and blind holes require particular attention during cleaning.
LIMITATIONS OF USE AND REPROCESSING:	• The use of an instrument 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 and/or injury to the user. • Repeated reprocessing has minimal effect on the service life of electro-surgical instruments. End of useful service life is normally determined by wear, material fatigue and damage in use. • Products covered by and used in accordance with these instructions have been validated capable of 25 reprocessing cycles (in accordance with HTM 01-01) following which it is recommended to return the instruments to Bolton Surgical Limited for full inspection or replacement if necessary. • Misuse can result in over-stressing the instrument causing misalignment or cracks or other irreparable damage.

Instructions:

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 best results and to maximise their service life reprocess instruments immediately after use. 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 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 to cutting edges to avoid injury and damage to or by the instrument. Separate sharp and delicate surgical instruments.
PREPARATION FOR DECONTAMINATION:	• Reprocess all instruments as soon as is reasonably practicable after use. • Disassemble the device if the device is intended to be disassembled without the use of tools (unless these are specifically provided with the instrument). Retain all parts to facilitate reassembly.
AUTOMATED CLEANING:	• **Use only either 'CE' marked or 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.** • Surgical instruments covered by these instructions can be thermally disinfected at 90°C to 95°C for 1 minute. • Load instruments carefully with any box jointed or hinged instruments in the open position for cleaning and so that any fenestrations in the instruments can drain. • 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 obstruct the washing action. • Where available, use appropriate attachments to flush inside devices with lumens or cannulas. Arrange medical devices so that lumens or cannulas are oriented downwards to assist drainage. • Ensure that soft, high purity water which is controlled for bacterial endotoxins is used in the final rinse stage. • On completion, unload the washer disinfector. Visually inspect each device for remaining soil and dryness. 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 **Note**: *Automated cleaning may not be suitable for all lumens and cannula, in which case clean manually with a water jet gun, if available, and an appropriate brush (and stilette if provided) that reaches the depth of the feature. After manually cleaning, pass all devices through an automatic cleaning cycle to achieve disinfection.* **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 (HTM01-01). The detergent used was 12.6pH.*

MANUAL CLEANING:	• **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 instrument submerged, with an autoclavable brush, apply 'CE' marked cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations, teeth, ratchets and hinges, always brushing away from the body and avoiding splashing. Ensure hinged instruments 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, so that water reaches all parts of the instrument, then carefully hand dry or use a drying cabinet. **Note:** *Manual cleaning is NOT a disinfection process: when manual cleaning is used it may not be possible to disinfect the device prior to further handling.*
CLEANING INSPECTION:	• **After cleaning, visually inspect *all* surfaces, cannulations, ratchets, joints, holes and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.**
MAINTENANCE:	• Apply surgical grade lubricants to pivot joints and moving parts as per the lubricant manufacturer's instructions • Lubrication is essential every time instruments are processed. Only lubricate dry instruments. • 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.
INSPECTION AND FUNCTION TESTING:	• Visually inspect and check: - all instruments for damage, wear, staining and corrosion and ensure that insulation and all edges are free from nicks, jaws and teeth align correctly, articulated instruments have a smooth movement without excess play, locking mechanisms (such as ratchets) fasten securely and close easily, long slender instruments are not distorted and that any component parts fit and assemble correctly with mating components. • Close instruments with a ratchet lock in the first ratchet position only before sterilisation to avoid the risk of thermally-induced stress cracks in the joints. • It is recommended that insulation integrity is checked before each use. • ***Remove for repair or replacement any worn out, flaking, fractured or damaged instruments.*** **Note:** *If an instrument is returned to the manufacturer / supplier, the instrument **must** be decontaminated and sterilised and be accompanied with the relevant documented evidence.*
STERILISATION:	• **Either 'CE' marked or validated vacuum autoclave operating at 134 - 137°C, for a minimum holding time of 3 minutes – always follow the instructions of the machine manufacturer.** • Ensure instruments 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 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 damage. • Delicate instruments require special handling to prevent damaging the tips. Use caution during cleaning and sterilisation. A non-fibrous sponge should be used to wipe off all blood and debris. Do not apply excessive stress or strain at joints.
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 manufacturer and always consult with them if in any doubt over the suitability of any process used. • Cleaning and sterilising guidelines are available in Health Technical Memorandum - HTM01-01.
MAINTENANCE AND REPAIR	• Instruments returned to Bolton Surgical for inspection or repair ***must*** be decontaminated and sterilised and be accompanied with the relevant documented evidence. Failure to supply evidence of cleaning and disinfection 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 of defects in workmanship and parts used to effect the repair when used normally for their intended surgical purpose. Any workmanship or parts proving to be defective will be replaced or repaired, at our discretion, at no charge to the customer.
NOTE:	IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING AS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY ACHIEVE 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.

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