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INSTRUCTIONS FOR USE FOR THE CARE, HANDLING AND REPROCESSING OF RE-USABLE HOLDERS AND POSITIONERS

DEVICES:

These instructions apply to the following re-usable surgical Holding and Positioning devices supplied by Bolton Surgical Limited – see below:

INSTRUMENT CLASSIFICATION **Class 1**

Articulated Arms with Quick Release Head and Mounting Posts

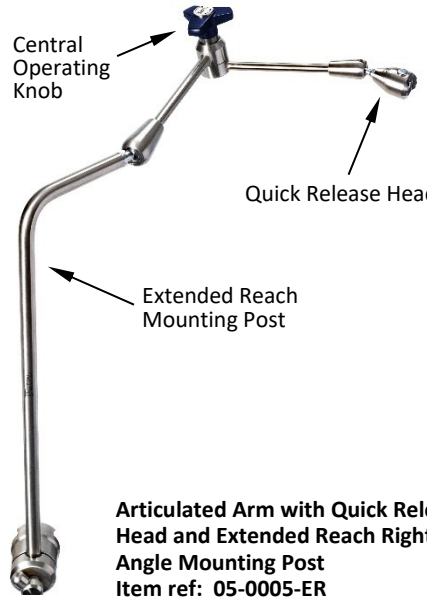

Fig. 1 **Articulated Arm with Quick Release Head and Extended Reach Right Angle Mounting Post**
Item ref: 05-0005-ER

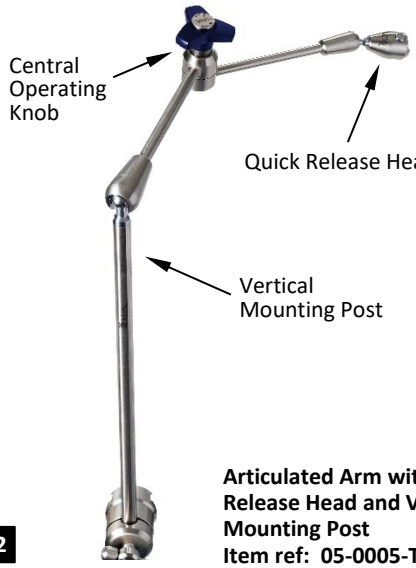

Fig. 2 **Articulated Arm with Quick Release Head and Vertical Mounting Post**
Item ref: 05-0005-TM

Table Rail Clamps

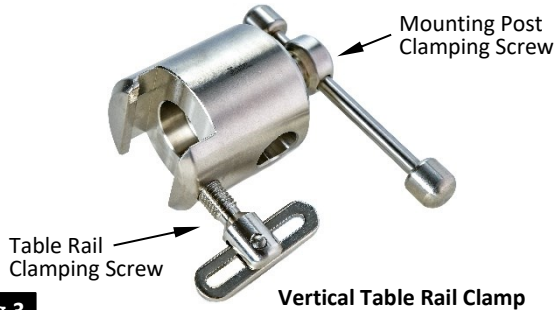

Fig.3 **Vertical Table Rail Clamp**
Item ref: 05-0020-01

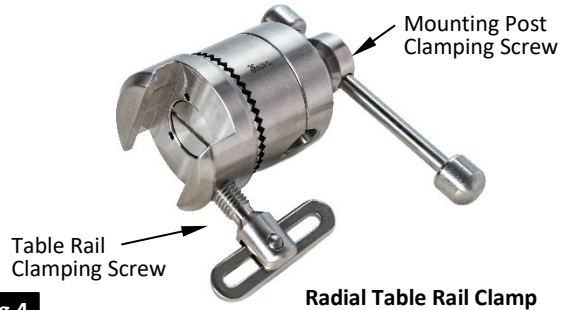

Fig.4 **Radial Table Rail Clamp**
Item ref: 05-0020-02

Instrument Holders

Fig.5 **Endoscope Holder**
Item ref: 05-0015-01

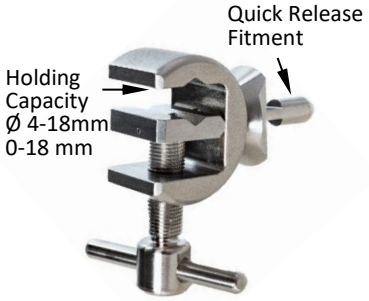

Fig.6 **Instrument Holding Clamp**
Item ref: 05-0015-02

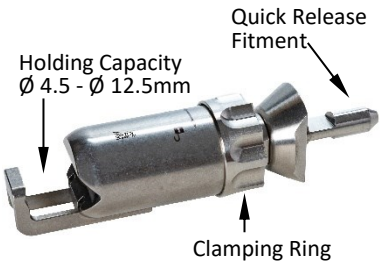

Fig.7 **Variable Instrument Holder**
Item ref: 05-0015-03

INTENDED USE

The Bolton Holding and Positioning System product range comprises a Table Rail Clamp, Post with Articulated Arm and Instrument Holder is re-usable and is intended for use to hold and position instruments, endoscopes, and other devices according to the needs of appropriately trained medical personnel during surgical procedures.

Mounting Post and Articulated arm (Figs.1 & 2) - Is intended to be secured to the operating table rail using either a Vertical or Radial Table Rail Clamp to support and maintain the set height and orientation of the Mounting Post. The Articulated Arm is intended to be fitted with one of the Head Attachments to suit the instrument to be clamped and can be fixed in any desired orientation according to the requirements of the surgeon.

Table Rail Clamp (Figs.3 & 4) **-** Is intended for use to secure the Mounting Post (up to 16mm diameter) to the operating table rail at the desired position, height and orientation. Suitable for all common rail types (EU, US, JP, CH etc.)

Endoscope Holder (Fig. 5) **-** Is intended to securely clamp endoscopes of 5mm or 10mm diameter without harm to the endoscope.

Instrument Holding Clamp (Fig.6) **–** Is attached to the Articulated Arm and is intended to securely clamp a surgical instrument such as a Nathanson Liver Retractor or other instrument during a surgical procedure.

Variable Instrument Holder (Fig.7) **-** Is attached to the Articulated Arm and is intended to securely clamp a round surgical instrument during a surgical procedure.

HOW SUPPLIED	The Bolton Surgical re-usable Holding and Positioning System is **LATEX FREE**, including its packaging.	The Bolton Surgical re-usable Holding and Positioning System is supplied non-sterile and must be cleaned and sterilised prior to each use.
RECEIVING INSPECTION	• Check the product immediately after receipt for potential transport damages and completeness. Complaints can only be considered if Bolton Surgical and/or freight forwarder is immediately notified. See also 'Return of Goods' section below.	
GENERAL	• Please read these instructions carefully and keep them in a safe place.	
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.** • **These devices are intended for use only by appropriately qualified surgical practitioners.** • **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.** • Do not use the device if, in the opinion of the surgical practitioner, patient safety risks outweigh the benefits. • Risk of infection – Do not use any surgical instrument or device showing signs of corrosion or inadequate decontamination. • Do not use damaged Instruments or devices. • Special care should be taken when if these devices are used together with electro-surgical applications. Contacts between the product and the electro-surgical device must be avoided. • 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. • The assembly and handling of the products must be done manually and without additional tools.	
LIMITATIONS OF USE AND REPROCESSING	• Off-label use of any part of this device for tasks other than those for which it is intended may result in serious damage or failure of the device as well as unnecessary stress to the patient. • Improper handling, or misuse can result in harm to the patient or over-stressing the device causing misalignment, loss of functionality or other irreparable damage. Repeated reprocessing has minimal effect on the service life of the Bolton Holding and Positioning System. End of useful service life is normally determined by wear and damage in use. (See 'INSPECTION' below)	
INSTRUCTIONS:		
PREPARATION FOR FIRST USE	• **Before first use, the re-usable devices covered by this IFU must be cleaned, inspected and sterilised in accordance with the Instructions below.**	
AT POINT OF USE	• It is recommended to first attach the Table Rail Clamp to the operating table rail and secure it by tightening the Table Rail Clamping Screw (Figs.3 & 4) from below, ensuring that the Table Rail Clamp is fully engaged with the table rail. • Insert the Mounting Post in the Table Rail Clamp and secure it by tightening the Mounting Post Clamping Screw (Figs.3 & 4). • Attach the selected Instrument Holder (Figs.5, 6 & 7) to the Articulated Arm by pushing it into the quick release head. • To detach the Instrument Holder, press the quick release button and pull out the Instrument Holder.  • When using the Vertical Table Rail Clamp (Fig.3), the Mounting Post height can be adjusted by loosening and then re-tightening the Mounting Post Securing screw. • When using the Radial Table Rail Clamp (Fig.4), the Mounting Post height and angle can be adjusted simultaeneously by loosening and then re-tightening the securing screw. • All Articulated Arm joints are fixed or released simultaeneously by tightening or loosening the Central Operating Knob (Figs.1 & 2). • Endoscope Holder (Fig.5) - Can hold Ø5mm or Ø10mm Endoscopes. Secure or release the endoscope by turning the Wing Nut by hand only, taking care not to over-tighten. • Instrument Holding Clamp (Fig.6) - Has a holding capacity of 0 - 18 mm, round items Ø4mm - Ø18mm. Secure or release the required instrument by turning the Securing Screw by hand only. • Variable Instrument Holder (Fig.7) - Has a holding capacity for round items of Ø4.5mm - Ø12.5mm. Secure or release the required instrument by turning the Clamping Ring by hand only.	
	• **Important:** When adjusting the Mounting Post or the Articulated Arm, hold it with one hand before loosening the securing screw with the other hand. When the desired position is reached, re-tighten the securing screw. • During use, avoid damage to the Holding and Positioning System and/or the surgical instrument being secured by applying the minimum force necessary, by hand only! • Clamping of the articulated arm is based on friction. Changing the position without loosening the clamping mechanism can cause damage and will shorten the lifespan of the articulated arm. • Ensure the Mounting Post is fully secured in the Table Rail Clamp, especially if using a non-Bolton Surgical table rail clamp.	

FROM POINT OF USE	• Immediately after use, remove the surgical instrument from the Instrument Holder and remove gross soil using absorbent wipes. Wherever possible, avoid blood, surgical debris or bodily fluids drying on the devices. • For best results and to maximise their service life reprocess immediately after use to minimise the potential for drying before cleaning. • If transfer to reprocessing is likely to take time, consider covering 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 lumens, joints, blind holes and cannulas. • Do not leave any parts of the Holding and Positioning System 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. Keep holders and positioners separate from sharp and delicate surgical instruments. • Avoid unnecessary contamination or cross contamination risk by transporting used instruments for reprocessing in closed or covered containers
PREPARATION FOR DECONTAMINATION	• Mounting Posts, Articulated Arms, Quick Release Heads are permanently assembled and cannot be dismantled. • Ensure the Instrument Holder is detached from the Quick Release Head and that the instrument has been removed from the Instrument Holder to expose all surfaces to the cleaning and disinfection process. • Remove the Table Rail Clamping Screw from the Table Rail Clamp before cleaning and disinfection. • Take care to retain all parts to facilitate reassembly. • Tighten the operating handle of the articulated arm by turning the Central Operating Knob and place it under running water or an approved disinfection liquid. The disinfecting agent should be aldehyde-free (otherwise blood soiling will set).
	 • The central operating handle (Figs.1 & 2) of the articulated arm must be tightened during pre-treatment so that impurities cannot enter the arm. • With the exception of the central operating handle on the articulated arm, all handles of the products must be in the open position during pre-treatment. • The Instrument Holders (Figs.5, 6 & 7) must be removed from the Quick Release Head (Figs.1 & 2 during pre-treatment. • The Articulated Arm must not be immersed in liquid.
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 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.** • The use of neutral/enzymatic cleaning agents is preferred. • If using alkaline cleaning agents, these devices can withstand alkaline cleaning agents up to 10.5pH. • Surgical instruments covered by these instructions can withstand thermal disinfection at 90°C to 95°C 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 orientated downwards to assist drainage and 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, 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 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 **Note**: Automated cleaning may not be fully effective for features, in which case clean manually (see below) and then pass the device 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. The detergent used was 10.5pH.*
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. The Central Operating Knob of the articulated arm must remain tightened throughout pre-treatment so that water and/or impurities cannot enter the arm. 3. In the first sink, keeping the device submerged, with an autoclavable brush, apply 'CE' marked cleaning solution to all surfaces until all soil has been removed. Always brush away from the body and avoiding splashing. Ensure instrument holders are thoroughly cleaned in both open and closed positions. 4. In the second sink, rinse with soft, high purity water which is controlled for bacterial endotoxins, RO water or mains supplied potable tap water so that water reaches all parts of the device, 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 for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.
MAINTENANCE	• Proper cleaning, handling, sterilisation and standard routine maintenance ensure that these devices perform as intended and will maximise their useful life.
INSPECTION	• Visually inspect and check: - all parts for completeness, damage, excessive wear, staining and corrosion. Ensure instrument holder jaws align correctly; articulated arms have a smooth movement without excess play; locking mechanisms fasten securely and smoothly; quick release mechanism assembles and releases correctly. • ***Remove for repair or replacement any worn out or damaged instruments.*** **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.*

PACKING FOR STERILISATION	• The product should be packed following local protocol, and according to ISO11607-1
STERILISATION	• **Use either 'CE' marked or validated 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 instruments are dry before sterilisation. • The Central Operating Knob of the articulated arm must be in the open (loosened) position during sterilization**. • The Instrument Holder must be removed from the Quick Release Head during sterilization. • The Mounting Post Clamping Screw of the Radial Table Rail Clamp must be loosened during sterilization. • 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.
	 • ** By releasing the Central Operating Knob the articulated arm may suddenly rotate downwards and can cause injury or damage. To avoid this put the articulated arm down, hold it with one hand and with the other hand release the central handle. • Never use the flash-sterilization procedure. Additionally, do not use hot air sterilization, irradiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.
DRYING	• The required drying time depends directly on parameters which are in the sole responsibility of the user (configuration and density of the loading, condition of the steam-sterilization apparatus etc) and must be determined therefore by the user. Nevertheless, drying times below 20 min. should be avoided.
STORAGE	• Ensure instruments are dry before storage and stored in dry, clean conditions at an ambient room temperature.
GENERAL CLEANING PRECAUTIONS	• Do not soak these devices 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. • These devices 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 at pivots and joints.
ADDITIONAL INFORMATION	• Alternative sterilising parameters** - vacuum autoclave operating at 132°C to 134°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	• These devices 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 of defects in workmanship and parts used to carry out the repair when used normally for their 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 Holding and Positioning products are guaranteed for a period of 5 years from the date of purchase (terms & 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. • 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 Ltd'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 waste management protocols. • All materials used in the manufacture of Bolton Surgical Holders and Positioners are fully recyclable.
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	• 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 10.5pH.

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

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MEDILINK MEMBER

NHS Supply Chain

Manufactured under an ISO 13485 registered Quality Management System

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