Document ref **IFU-030aa** rev 2 (CRN 1493) 27/07/2026	**INSTRUCTIONS FOR USE FOR THE CARE, HANDLING AND REPROCESSING OF RE-USABLE LEAD HANDS (HAND FIXATORS)**	BOLTON SURGICAL of SHEFFIELD

DEVICE(S)	• **These instructions apply to re-usable Lead Hands (hand fixators) supplied by Bolton Surgical Limited.**	**INSTRUMENT CLASSIFICATION**	**Class 1**
INTENDED USE	• A flexible, semi-rigid device, intended for use during hand surgery procedures to temporarily restrain a patient's hand in the open position, restrict movement and facilitate patient positioning and stabilization.		
HOW SUPPLIED	 Bolton Surgical re-usable Lead Hands are latex free, including their packaging.	 Bolton Surgical re-usable Lead Hands are supplied non-sterile and must be cleaned and sterilised prior to each use. Lead Hands are made from Lead sheet conforming to BS EN 12588:2006 (PB810M).	
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.** • **This device is 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 damage or inadequate decontamination. • Oxidation of lead is a normal process. Consideration should be given to the minimisation of risk of surgical wound contamination or foreign body reaction resulting from the transfer of lead particles to surgical wounds via the surgeon's gloves or other surgical instruments (eg. by covering the lead hand with an impervious sterile drape, or consider using *Mitt-Mat®* (11-7070-00) to eliminate the risk). • Follow the 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. • **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 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. • Lead hands are re-usable for several uses but have limited service life due to the natural effects of metal fatigue with repeated use and need to be replaced at the first signs of unacceptable functionality loss.		

INSTRUCTIONS:

PREPARATION FOR FIRST USE	• Before first use Lead Hands must be cleaned, inspected for any possible damage and sterilised in accordance with the Instructions below. Until that point, the Lead Hands must not be used for any medical treatment. • A damaged or defective Lead Hand should not be used or processed. For replacement contact us directly or through your local sales representative, agent or distributor.
FROM POINT OF USE	• For best results and to maximise service life of Lead Hands we recommend removal of gross soil using absorbent wipes or rinsing immediately after use to minimise the potential for biological residues to dry and become encrusted. • If transfer to reprocessing is likely to take time it is best to keep Lead Hands moist after use. Consider covering with a damp cloth or, use an enzymatic foam spray cleaner to help prevent soil from drying. • Avoid damage to Lead Hands during transportation to the processing area (do not mix heavy devices with delicate items). Keep Lead Hands apart from other instruments during cleaning to avoid damage by sharp items and to minimise the risk of damaging other items under the weight of Lead Hands. • Avoid unnecessary contamination or cross contamination risk by transporting used instruments for reprocessing in closed or covered containers
PRE-CLEANING (OPTIONAL)	• Remove gross contaminants with a steady stream of lukewarm/cool water (below 40°C). • Do not use saline or chlorinated solutions. Where necessary, remove blood and general grime by washing the lead hand in water and a neutral detergent (at or near 7.0pH) and rinse thoroughly. • Ultrasonic cleaning can be used. • Disinfection and sterilisation must follow pre-cleaning.
AUTOMATED CLEANING	• Whenever possible, automated cleaning is recommended to provide greater process reliability and repeatability as well as reducing risks associated with staff exposure to contaminated devices and 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.** • Keep Lead Hands separate from other instruments to avoid surface and/or mechanical damage during processing and to minimise the risk of transfer of lead particles to other items. • It is recommended that neutral cleaning agents (at or near 7.0 pH) are used for Lead Hands. • Lead Hands can withstand thermal disinfection at 90°C to 95°C for a minimum of 1 minute. • Load Lead Hands carefully and so that they can drain. • Place heavy instruments with care into the bottom of containers, taking care not to overload wash baskets. • 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 the Lead Hand 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	• **Manual cleaning is only advised using the following process if an automatic washer-disinfector is not available:** 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 Lead Hand submerged, with an autoclavable brush, apply suitably approved cleaning solution to all surfaces until all soil has been removed. Always brush away from the body. - Care must be taken to ensure cleaning agents are used in accordance with the manufacturer's instructions. - To minimise abrasion damage to the soft lead surface use only soft brushes or non-abrasive scouring pads. - Do not use steel wool, wire brushes, or abrasive detergents. 3. In the second sink, rinse the Lead Hand in running, soft, high purity water which is controlled for bacterial endotoxins or, mains supplied potable tap water so that water reaches all surfaces of the Lead Hand until all traces of cleaning solution are removed. Allow to drain on absorbent wipes or transfer immediately to inspection step.

DRYING	• Care must be taken to ensure that the Lead Hand is dried thoroughly before storage. When drying is achieved as part of a washer disinfector cycle, do not exceed 127°C.
INSPECTION	• Before each use, inspect for any damage and the effects of wear and tear. If the lead hand is nicked, cracked or severely corroded it should not be used and must be replaced. For replacement, contact your Bolton Surgical Sales Consultant. ***Note:*** *If a used Lead Hand is returned for any reason, it* ***must*** *be decontaminated and sterilised and be accompanied with the relevant documented evidence.*
PACKING FOR STERILISATION	• All instruments to be packed following local protocol or in accordance with ISO11607-1
STERILISATION	• Ensure Lead Hands are dry before sterilisation. • It is recommended that Lead Hands are wrapped separately as supplementary items during sterilisation to minimise the risk of cross-contamination caused by transfer of lead particles. • **Use suitably authorised vacuum autoclave operating at 134°C to 137°C, with a minimum holding time of 3 minutes or 121°C to 124°C for a minimum holding time of 15 minutes - (see 'Additional Information' below for alternative sterilising parameters).** • 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. ***Note:*** *Sterilisation times are for exposure and do not include ramp up times or drying cycle times needed. Follow the manufacturer's instructions for loading and operation of steam autoclaves.* ***Note:*** *The responsibility for validation of sterilisation techniques and equipment lies with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilisation chambers, wrapping methods and/or load configurations.*
STORAGE	• Ensure instruments are dry before storage and stored in dry, clean conditions at an ambient room temperature.
⚠ **GENERAL CLEANING PRECAUTIONS**	• **Avoid using chemical cleaners as they can cause severe corrosion of the lead surface.** • **Lead Hands should be cleaned separately to other instruments to minimise the risk of transfer of lead particles.** • **Chemical Sterilisation should not be used** as this can result in severe corrosion of the lead surface. • Lead Hands must not be sterilised/disinfected by exposure to formaldehyde, glutaraldehyde, ethylene oxide or hydrogen peroxide (H202). • Prolonged immersion in chlorohexidine should be avoided. • 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 Lead Hand.
ADDITIONAL INFORMATION	• Alternative sterilising parameters** - vacuum autoclave operating at 132°C to 135°C, with a minimum holding time of 4 minutes or, 121°C - 124°C with a minimum holding time of 15 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	• Lead Hands cannot be economically repaired. If returned to Bolton Surgical for inspection/replacement, a certificate of decontamination must be supplied. Failure to supply evidence of decontamination will result in the products being returned untouched for reprocessing.
LIMITED WARRANTY	• Lead hands are re-usable for several uses but have limited service life due to the natural effects of metal fatigue with repeated use and need to be replaced at the first signs of unacceptable functionality loss. As such, Lead Hands are excluded from our standard terms of guarantee.
RETURNED GOODS POLICY	• 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	• End of service life disposal: Lead Hands must be decontaminated before disposal. The product should be disposed of in accordance with your local policy for the disposal of hazardous waste. • Alternatively, Lead Hands may be returned to Bolton Surgical Limited for material recycling providing that a certificate of decontamination is provided for each item returned. Failure to supply evidence of decontamination will result in the products being returned to sender untouched for reprocessing.
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.
UK CA	• Please note that the UK CA mark for these devices is applied to the original packaging label & this IFU document only.
EXPLANATION OF SYMBOLS USED ON LABELS	 Manufacturer  Manufacturer's Product Code  Serial Number  Supplied Non- Sterile  Supplied Latex Free  Caution  Consult Instructions for Use **Scan for other related downloads**

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MEDILINK MEMBER

NHS Supply Chain

UK CA

Manufactured under an ISO 13485 registered Quality Management System

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