Document ref **IFU-030a** rev 1 (CRN 1432) 10/06/2025	**INSTRUCTIONS FOR USE FOR THE CARE, HANDLING AND REPROCESSING OF RE-USABLE *Mitt-Mat*® (HAND FIXATOR)**	BOLTON SURGICAL of SHEFFIELD

DEVICE(S)	• **These instructions apply to re-usable *Mitt-Mat*® hand fixator 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 *Mitt-Mat*® is latex free, including its packaging.	 ***Mitt-Mat*®** is supplied non-sterile and must be cleaned and sterilised prior to each use.	
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. • 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 140ºC. • **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. • Although *Mitt-Mat*® is re-usable for multiple uses, it does have a limited service life due to the natural effects of metal fatigue on the encapsulated lead core with repeated use and must be replaced at the first signs of unacceptable functionality loss.		
INSTRUCTIONS:			
PREPARATION FOR FIRST USE	• Before first use *Mitt-Mat*® must be cleaned, inspected for any possible damage and sterilised in accordance with the Instructions below. Until that point, the *Mitt-Mat*® must not be used for any medical treatment • A damaged or defective *Mitt-Mat*® should not be used or processed. For replacement contact us directly or through your local sales representative, agent or distributor.		
FROM POINT OF USE	• At point of use, remove gross soil by using absorbent wipes. • For best results and to maximise its service life reprocess *Mitt-Mat*® immediately after use to minimise the potential for drying before cleaning. • If transfer to reprocessing is likely to take time it is best to keep *Mitt-Mat*® moist after use to avoid blood and/or bodily fluids drying on it. Consider rinsing, covering with a damp cloth or, use an enzymatic foam spray cleaner to help prevent soil from drying. • Avoid damage to *Mitt-Mat*® during transportation to the processing area (do not mix heavy devices with delicate items). Keep *Mitt-Mat*® apart from other instruments during cleaning to avoid damage to the silicone coating by sharp items and to minimise the risk of damaging other items under the weight of *Mitt-Mat®.* • Avoid unnecessary contamination or cross contamination risk by transporting used instruments for reprocessing in closed or covered containers		
PRE-CLEANING (OPTIONAL)	• Manual pre-cleaning with cold water, followed by manual cleaning with water at a maximum temperature of 40°C. • Remove gross contaminants with a steady stream of lukewarm/cool water (below 40°C). Rinse thoroughly. • Ultrasonic cleaning can be used. • Disinfection and sterilisation must follow pre-cleaning.		
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 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.** • *Mitt-Mat*® can withstand cleaning agents with a medium pH (between neutral and 12.5 pH) • *Mitt-Mat*® can withstand thermal disinfection at 90°C to 95°C for a minimum of 1 minute. • Load instruments 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 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		
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 *Mitt-Mat*® 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 silicone 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 instruments 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 *Mitt-Mat*® 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 *Mitt-Mat*® is dried thoroughly before storage. When drying is achieved as part of a washer disinfector cycle, do not exceed 150°C.		

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. • Before each use, inspect for any damage and the effects of wear and tear. If the silicone coating is nicked or cracked whereby the lead core is visible the *Mitt-Mat®* must no longer be used and must be replaced. For replacement, contact your Bolton Surgical Sales Consultant (or your local agent if outside the UK). **Note:** *If a used Mitt-Mat® 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	• **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 sterilising parameters).** • Ensure *Mitt-Mat® is* 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. ***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**	• *Mitt-Mat®* must NOT be sterilised/disinfected by exposure to formaldehyde, glutaraldehyde or ethylene oxide. • Prolonged immersion in chlorohexidine should be avoided. • Cleaning or wiping with solvent-based solution and exposure to rinse aids may detrimentally affect the silicone coating. • 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.
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	• *Mitt-Mat®* 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	• Bolton Surgical *Mitt-Mat®* is 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 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'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: Mitt-Mat®* must be decontaminated before disposal. The product contains a lead core within a silicone rubber encapsulation and should be disposed of in accordance with your local policy for the disposal of hazardous waste. • Alternatively, *Mitt-Mat®* may be returned to Bolton Surgical Limited for materials recycling providing that decontamination certification 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	• 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. The detergent used was 10.5pH.
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

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Manufactured under an ISO 13485 registered Quality Management System

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