MDL 062P rev 3 25-01-2018	**GENERAL INSTRUCTIONS & RECOMMENDATIONS FOR THE USE, CARE AND MAINTENANCE OF** ***Mitt-Mat®*** (Surgical hand)	BOLTON SURGICAL of SHEFFIELD
INTENDED USE:	*Mitt-Mat®* supplied by Bolton Surgical Ltd is a re-usable device intended for hand fixation during hand surgery procedures.	
HOW SUPPLIED:	*Mitt-Mat®* is supplied non-sterile and must be cleaned and sterilised before each use according to the instructions and recommendations outlined below. *Mitt-Mat®* is **LATEX FREE**.	
⚠ **CJD - WARNING**	• **If this device is/was used on a patient with, or suspected of having Creutzfeld Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilise to eliminate cross-contamination risk.**	
BEFORE USE:	• Read the Instructions for Use and keep them in a safe place. • Before first use *Mitt-Mat®* must be cleaned and sterilised. Until that point, the *Mitt-Mat®* must not be used for any medical treatment • Inspect for any possible damage. • 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:	• *Mitt-Mat®* must be used only by appropriately qualified surgical practitioners. • We recommend immediate rinsing of *Mitt-Mat®* after use to prevent biological residues becoming encrusted. • It is best to keep *Mitt-Mat®* moist after use to avoid blood and/or bodily fluids drying on them. If necessary, consider covering with a damp cloth or use an enzymatic foam spray cleaner to help prevent soil from drying.	
CLEANING:	• Optional: Manual pre-cleaning with cold water, followed by manual cleaning with water at a maximum temperature of 40°C. Ultrasonic cleaning can be used. Disinfection and sterilisation must follow pre-cleaning. • Avoid damage to the *Mitt-Mat®* and other instruments during transportation for reprocessing (i.e. do not mix heavy devices with delicate items). Transport for reprocessing as soon as possible after use. • Remove gross contaminants with a steady stream of lukewarm/cool water (below 43°C). Rinse thoroughly. • Blood and general surgical debris can be removed by washing *Mitt-Mat®* in water and a detergent up to pH12.5 in dilution. • 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®.* • Manual or automated cleaning methods can be used although whenever possible, automated cleaning is recommended. This will provide greater process reliability and repeatability as well as reducing risks associated with staff exposure to contaminated devices and cleaning agents used. • Whichever cleaning method is used, suitable protective clothing and equipment (PPE) should be used at all times. • 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. • Rinse in running water until all traces of cleaning solution are removed. Visually inspect for any remaining soil and repeat the steps above if necessary • Allow to drain on absorbent wipes or transfer immediately to inspection step	
DISINFECTION:	• *Mitt-Mat®* can be thermally disinfected in accordance with HTM01-01 at 90° - 95°C for 1 minute using a standard wash and disinfection program.	
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.	
STERILISATION:	• Steam autoclaving is recommended: *Mitt-Mat®* should be sterilised in accordance with HTM01-01 at 134°C - 137°C with a minimum holding time 3 minutes or, 121°C - 124°C with a minimum holding time 15 minutes. ***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.*	
⚠ **STERILISATION**	• *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 could detrimentally affect the silicone coating.	
SERVICE LIFE, INSPECTION AND DISPOSAL:	• 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). • 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. As such, *Mitt-Mat®* is excluded from our standard terms of guarantee. • *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. • *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 untouched for reprocessing.	

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MEDILINK MEMBER

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Manufactured under an ISO 13485 registered quality management system.