| Document ref **IFU-042** rev 1 (CRN 1432) 10/06/2025 | **INSTRUCTIONS FOR USE FOR THE CARE, HANDLING AND REPROCESSING OF RE-USABLE – *KIT-MAT* (Magnetic mat)** | BOLTON SURGICAL of SHEFFIELD |
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| **DEVICE(S)** | • **These instructions apply to the re-usable *Kit-Mat* supplied by Bolton Surgical Ltd.** | **DEVICE CLASSIFICATION** | **Class 1** |
| **INTENDED USE** | • A flexible magnetic instrument mat, intended for use during surgical procedures to provide a temporary safe retention zone for placement or transfer of surgical instruments. | | |
| **HOW SUPPLIED** |   Bolton Surgical ***Kit-Mat*** is latex free, including its packaging. |   Bolton Surgical ***Kit-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.**<br>• **This device is intended for use only by appropriately qualified surgical practitioners.**<br>• Do not use the ***Kit-Mat*** if, in the opinion of the surgical practitioner, patient safety risks outweigh the benefits.<br>• Risk of infection – Do not use a ***Kit-Mat*** showing signs of damage or inadequate decontamination.<br>• Take care to avoid placing the ***Kit-Mat*** in close proximity to electronic equipment or implants being worn by the patient to minimise the risk of magnetic interference, even though the magnetic flux level is low.<br>• **HEART PACEMAKERS –** Avoid placing the Kit-Mat on the patient's chest.<br>• Take care when placing sharp instruments on the ***Kit-Mat*****.** Do not cut, tear or pierce the silicone coating.<br>• Avoid exposing the ***Kit-Mat*** to temperatures over 140°C.<br>• 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.<br>• No part of the process to exceed 140°C.<br>• **When handling biologically contaminated instruments and accessories 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 a ***Kit-Mat*** for tasks other than those for which it is intended may result in serious damage to the ***Kit-Mat*** as well as unnecessary stress to the patient.<br>• Repeated reprocessing (in accordance with HTM 01-01) has minimal effect on the useful service life of the Bolton Surgical ***Kit-Mat*****.** End of useful service life is normally determined by wear and tear damage in use. (See also 'INSPECTION' and 'MAINTENANCE AND REPAIR' sections below) | | |
| ***INSTRUCTIONS:*** | | | |
| **PREPARATION FOR FIRST USE** | • **Before first use the *Kit-Mat* must be cleaned, inspected for any possible damage and sterilised in accordance with the Instructions below. Until that point, the *Kit-Mat* must not be used during any medical treatment.** | | |
| **FROM POINT OF USE** | • At point of use, remove gross soil by using absorbent wipes.<br>• For best results and to maximise its service life reprocess the ***Kit-Mat*** immediately after use to minimise the potential for drying before cleaning.<br>• If transfer to reprocessing is likely to take time it is best to keep the ***Kit-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.<br>• Keep the ***Kit-Mat*** apart from other instruments during transportation and cleaning to avoid damage to the silicone coating by sharp items and to minimise the risk of damaging other items under the weight of ***Kit-Mat.***<br>• Avoid unnecessary contamination or cross contamination risk by transporting used instruments and accessories 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.<br>• Remove gross contaminants with a steady stream of lukewarm/cool water (below 40°C). Rinse thoroughly.<br>• Ultrasonic cleaning can be used.<br>• 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.<br>• **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.**<br>• ***Kit-Mat*** can withstand cleaning agents with a medium pH (between neutral and 12.5 pH)<br>• ***Kit-Mat*** can withstand thermal disinfection at 90°C to 95°C for a minimum of 1 minute.<br>• It is recommended to wrap the ***Kit-Mat*** separately without rolling or folding the mat to avoid risk of impairing the cleaning process.<br>• 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.<br>• On completion of the cleaning cycle, visually inspect the ***Kit-Mat*** for dryness and any remaining soil. If soil remains, repeat the cleaning process.<br>• 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:**<br>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.<br>2. In the first sink, keeping the ***Kit-Mat*** submerged, with a soft autoclavable brush, apply a suitably approved cleaning solution to all surfaces until all soil has been removed. Always brush away from the body.<br>- Care must be taken to ensure cleaning agents are used in accordance with the manufacturer's instructions.<br>- Avoid abrasion damage to the silicone surface by using only soft brushes or non-abrasive cleaning pads.<br>- Do not use steel wool, wire brushes, or abrasive detergents.<br>3. In the second sink, rinse ***Kit-Mat*** thoroughly in running, soft, high purity water which is controlled for bacterial endotoxins, RO water or mains supplied potable tap water until all traces of cleaning solution are removed. Allow to drain on absorbent wipes then transfer to inspection step. | | |
| **DRYING** | • Care must be taken to ensure that the ***Kit-Mat*** is dried thoroughly before storage. When drying is achieved as part of a washer disinfector cycle, do not exceed 140°C. | | |

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| **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.<br>• Before each use, inspect for any damage and the effects of wear and tear. If the silicone coating is nicked or cracked whereby the encapsulated magnet is exposed the ***Kit-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).<br>**Note:** *If a used **Kit-Mat** is returned for any reason, it **must** be decontaminated and be accompanied with the relevant documented evidence.* |
| **PACKING FOR STERILISATION** | • Follow local protocol or in accordance with ISO11607-1<br>• It is recommended to wrap the ***Kit-Mat*** separately without rolling or folding the mat to avoid risk of impairing the sterilising process. |
| **STERILISATION** | • **It is recommended to sterilise the *Kit-Mat* in accordance with HTM 01-01 Guidelines using a 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).**<br>• Ensure the ***Kit-Mat*** is dry before sterilisation.<br>• It is recommended to wrap the ***Kit-Mat*** separately without rolling or folding the mat to avoid risk of impairing the sterilising process. Sterilisation cases should be loaded just prior to the sterilisation step.<br>• When sterilising multiple items in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.<br>***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.* |
| **STORAGE** | • Ensure the ***Kit-Mat*** is dry before storage and stored in dry, clean conditions at ambient room temperature. |
| ⚠ **GENERAL CLEANING PRECAUTIONS** | • Prolonged immersion in chlorohexidine should be avoided.<br>• When drying the Kit-Mat it is recommended to use a soft, absorbent, lint-free cloth or be sure the drying phase is sufficiently long enough.<br>• Cleaning or wiping with solvent-based solution may detrimentally affect the silicone coating.<br>• Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.<br>• 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 ***Kit-Mat***. |
| **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.<br>• Cleaning and sterilising guidelines are available in UK Health Technical Memorandum - HTM01-01 and ISO17665-1<br>***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.*<br>** Products covered by this IFU have not been validated for these forms of cleaning and sterilisation. |
| **MAINTENANCE AND REPAIR** | • The ***Kit-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** | • The Bolton Surgical ***Kit-Mat*** is guaranteed for a period of 1 year from the date of purchase (terms & conditions 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.<br>• 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.<br>• Determination of a product defect will be made by Bolton Surgical Ltd. |
| **DISPOSAL** | • *End of service life disposal:* The ***Kit-Mat*** must be decontaminated before disposal. The product contains Ceramic magnets within a silicone rubber encapsulation and should be disposed of in accordance with local protocols.<br>• Alternatively, the ***Kit-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<br>  Manufacturer's Product Code<br>  Serial Number<br>  Supplied Non- Sterile<br>  Supplied Latex Free<br>  Caution<br>  Consult Instructions for Use<br>**Scan for other related downloads**<br>  |


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