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Instruction For Use
Kent Surgical Silicone Mats

Kent Surgical Industries L.L.C Plot No.12, 54th Street, Companies Camp, Al Ain, Abu Dhabi, United Arab Emirates	This IFU Cover The following products: Silicone Mat 520 x 220 (SM5222), Silicone Mat 380 x 220 (SM3822), Silicone Mat 460 x 220 (SM4622), and Silicone Mat 220 x 220 (SM2222).	Ph.: +971 3 753 2555 Email:support@kentsurgical.com Website: www.kentsurgical.com

Symbols Using in Labeling:

Symbol	Symbol Title	Description of symbol
	**Catalogue number**	Indicates the manufacturer's catalogue number.
	**Consult instructions for use.**	Indicates the need for the user to consult the instructions for use.
	**Date of manufacture**	Indicates the date when the medical device was manufactured.
	**Do not use if package is damaged**	Indicates a medical device that should not be used if the package has been damaged or opened.
	**Caution**	Indicates that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	**Manufacturer**	Indicates the medical device manufacturer.
	**Batch code**	Indicates the manufacturer's batch code.
	**Non-sterile**	Indicates a medical device that has not been subjected to a sterilization process.
	**Use-by date**	Indicates the date after which the medical device is not to be used.
	**Keep dry**	Indicates a medical device that needs to be protected from moisture.

	**Keep away from sunlight**	Indicates a medical device that needs protection from sunlight.

Intend of use for Silicon

- To protect delicate items to hold them in place and prevent damage.

Product Specification:

- Material: Silicone

General Safety Information:

- Read and follow these instructions and keep them accessible to the staff working with the device.
- All mats must be cleaned, disinfected, and sterilized each time they are used; this also applies particularly to the first time they are used after delivery, as all mats are supplied unsterile.
- Effective cleaning and disinfection are an indispensable prerequisite for effective sterilization.
- When using mats, please ensure that, as part of your responsibility for the sterility of products, only methods for cleaning/disinfection and sterilization, which have been adequately validated for the equipment and products, are implemented, that the equipment used (disinfector, sterilizer) is regularly maintained and tested, and that the validated parameters are maintained for each cycle.
- Please observe the legal regulations applicable in your country and the hygiene regulations of the medical practice or hospital.
- The sterilization parameters are only valid for devices that are adequately cleaned.
- The products must be used exclusively for the intended purpose by appropriately trained and qualified personnel.
- Visually inspect the mats before use.
- Discard damaged mats.

- The following information is only valid for properly installed, maintained, calibrated, and compliant reprocessing equipment.

Warning:

- Do not use steel wool, wire brushes, or abrasive cleaners.
- Possible danger to the life of patient, user, and third parties if these Instructions for Use are not observed.
- Possible danger to the life of others by shipping contaminated products.
- In case of return shipments, send only clean and disinfected products in sterile packaging.
- Non-sterile handling can result in danger to the life of the patient. Products supplied in non-sterile condition must be cleaned, disinfected, and sterilized before the first application.
- Do not exceed 137 ℃ (279 ℉).

Limits On Reprocessing:

- Repeated processing cycles that include mechanical washing, and sterilization have minimal effect on **Kent Surgical**® silicon mats.
- For silicone mats, the end of life is normally determined by wear and damage due to use.

Preparation:

- Mats are reusable and must be cleaned and disinfected before initial use and subsequent reuse.

Instructions For Use:

1. With fingers pointed upwards, place the appropriate size Silicone Finger Mat in the tray.

2. Place delicate items in a single layer with adequate spacing to prevent contacting each other.
3. Place the lid onto a tray to secure items.
4. Place the tray containing the instruments inside the chamber.
5. Read and follow the Instrument/device manufacturer's Instructions for Use (IFU) regarding immediate-use sterilization.
6. Clean and decontaminate instruments and devices per the manufacturer's instructions before sterilization.

Manual Cleaning:

1. Inspect the Silicone Finger Mats before processing.
2. Rinse with warm water to remove any residues.
3. Wash mats with detergents, and disinfectants ranging between 2 pH and 13 pH; enzymatic or biocide cleaners compatible with polypropylene material (see detergent manufacturer's guide).
4. Final Rinse with deionized Water.

Automatic Cleaning:

It may be necessary to manually clean before automated processing to improve the removal of adherent soil. Follow the previous instructions for manual cleaning.

1. Run the automatic wash cycle – minimum cycle parameters:

- 1-minute cold pre-rinse
- 5-minute enzyme wash at 43° C (109° F) minimum temperature
- 2-minute cold rinse
- 7-minute dry at 90° C (194° F) minimum temperature

2. Visually inspect to ensure complete removal of soil from surfaces. No visible soil should be observed.
3. If soil is still visible, repeat the above steps until free from visible soil.

Cleaning Inspection:

- Visually inspect before sterilization or storage to ensure the complete removal of soil from surfaces. If soil is still present, re-clean the mat.

Sterilization:

- The mat has been validated for sterilization efficacy according to applicable international process standards and guidance for the following methods and parameters:

Steam Sterilization			
Cycle Type	Temperature	Minimum holding time	minimum drying time
Pre-Vacuum	(134) ° C	3.5 minutes	10 minutes

- Dry times may be highly variable due to the differences in packaging materials (e.g. non-woven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance, and varying cool-down time.
- The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.

- **Other methods of Sterilization (eto):**
  Silicone mats can be used in eto provided they are fully dry before putting in the machines.

100% Ethylene Oxide (EtO)	
Concentration	725 mg/L
Temperature	55° C
Exposure Time	60 minutes
Humidity	50-80%
STERRAD® System and Cycle	
STERRAD® 100S/100S Short STERRAD® NX Standard STERRAD® 100NX Standard/Express/DUO/Flex	
STERIZONE® System	STERIZONE® VP4
MMM Hyper (TS-CSD System)	
Easy Classic Complex	

- It remains the responsibility of the processor to ensure that the processing, as performed using equipment, materials, and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

Maintenance:

1. Store in clean, dry conditions on the shelf in original packaging.
2. Inspection before each use.
3. Discard damaged mats.

Disposal:

- Mats have a life span and will require replacing if there are any signs of deterioration or loss of functionality.
- For disposal, country-specific laws and regulations must be observed.