

Surgical Tray Corner Protectors

INTENDED USE:

Key Surgical® Tray Corner Protectors are made from medical-grade silicone and intended for use with surgical trays to prevent the tearing of the sterilization wrap and to protect the corners of the trays from damage.

PRECAUTIONS:

- Prior to subsequent re-use, the corner protectors should be cleaned following the instructions below
- Visually inspect the corner protectors before use to ensure that they are free from visible contaminants.

INSTRUCTIONS FOR USE:

1. Tray Corner Protectors do not need to be cleaned or disinfected prior to initial use.
2. Place the corner protectors on the top and bottom corners of the tray before wrapping with sterilization wrap. Once in place, wrap the tray according to standard wrapping procedures.
3. Appropriate sterilant contact will occur on the surface of the corner protectors as well as the tray surface under the corner protectors.

MANUAL CLEANING:

1. Pre-rinse under cold tap water for one (1) minute to remove gross debris
2. Soak for a minimum of two (2) minutes in a pH neutral detergent, prepared in accordance with the manufacturer's instructions for use.
3. Rinse under cold tap water for one (1) minute.
4. Ultrasonically clean for a minimum of five (5) minutes in a neutral pH detergent, prepared in accordance with the manufacturer's instructions for use.
5. Rinse under cold tap water for one (1) minute.

AUTOMATED CLEANING:

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

1. Load in a mesh wire tray with concave surface facing downward to facilitate draining.
2. Run the automatic wash cycle – minimum cycle parameters:
 - 1 minute cold pre-rinse
 - 5 minute enzyme wash at 43° C minimum temperature
 - 1 minute cold rinse
 - 7 minute dry at 90° C minimum temperature

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 corner protectors.

STERILIZATION:

Tray corner protectors have been validated for sterilization according to applicable international process standards and guidance for the following methods and parameters:

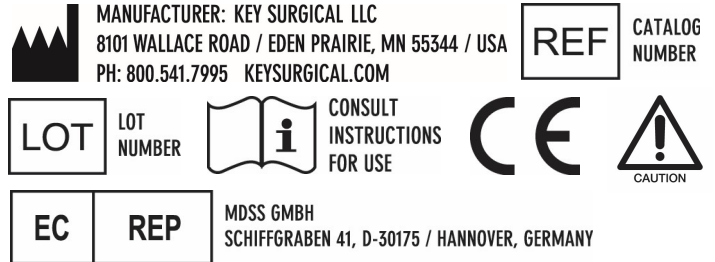
Cycle Type (Steam)	Temperature	Minimum Time – Full Cycle	Minimum Validated Dry Time
Gravity	121° C (250° F)	30 minutes	20 minutes
Pre-Vacuum	132° C (270° F)	4 minutes	20 minutes
Pre-Vacuum	134° C (273° F)	3 minutes	20 minutes

STERRAD® System and Cycle within the United States	STERRAD® System and Cycle outside United States
STERRAD® 50	STERRAD® 50
STERRAD® 200	STERRAD® 200 Short cycle
STERRAD® 100S	STERRAD® 100S Short cycle
STERRAD® NX Standard cycle	STERRAD® NX Standard cycle
STERRAD® NX Advanced cycle	STERRAD® NX Advanced cycle
STERRAD® 100NX Standard cycle	STERRAD® 100NX Standard cycle

It remains the responsibility of the processor to ensure that the processing, as actually 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.

DISPOSAL:

The corner protectors have been tested to withstand a minimum of 15 sterilization cycles with no impact to the fit, form or function; however, the corner protectors have a life span and will require replacing if there are any signs of deterioration or loss of functionality. Dispose of product following facility policy for disposal.



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LOT LOT NUMBER **CONSULT INSTRUCTIONS FOR USE**

EC **REP** MDSS GMBH
 SCHIFFGRABEN 41, D-30175 / HANNOVER, GERMANY

REF CATALOG NUMBER

CE CAUTION

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