

Silicone Clamp Covers – Non-Sterile

EN - INTENDED USE: Key Surgical® Silicone Clamp Covers are single-use accessories to medical devices intended for transient-term (less than 60 minutes) use in surgical procedures requiring grasping and clamping. The silicone clamp covers are not intended to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body and are not intended for use in direct contact with the central circulatory or central nervous system.

PRECAUTION: Provided non-sterile but must be sterilized if used in a sterile environment. Single use only; reuse may lead to patient cross contamination.

CONTRAINDICATIONS: No known contraindications and/or adverse effects.

INSTRUCTIONS FOR USE:

1. Remove from bag.
2. Package in a sterile packaging device (e.g., pouch, wrapped tray, closed container).
3. Ensure the sterile packaging device has a complete seal.
4. Sterilize according to the parameters detailed in the Sterilization section below.
5. After sterilization, move the packaged covers to sterile storage area for storage or transport to point of use location.
6. Remove from sterile packaging device.
7. May be trimmed to desired length. Ensure cut does not impede functionality.
8. Single use and can be sterilized only once.

CLEANING AND DISINFECTION: Does not need to be cleaned or disinfected prior to sterilization.

STERILIZATION: Validated for sterilization according to the following parameters:

Steam Sterilization		
Cycle Type	Temperature	Minimum Time – Full Cycle
Pre-Vacuum	132° C (270° F)	4 minutes
Pre-Vacuum	134° C (273° F)	3 minutes

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: Dispose after use according to facility protocol. Do not reuse.

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 CONSULT INSTRUCTIONS FOR USE

 REF CATALOG NUMBER

 LOT LOT NUMBER

 CAUTION

 MEDICAL DEVICE

 DO NOT RE-USE

 NON-STERILE

 USE-BY DATE

 MANUFACTURER FOR US: MANUFACTURED FOR

 UDI UNIQUE DEVICE IDENTIFIER

 STERIS®