

Silicone Clamp Covers
Non-Sterile

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:

- This product is provided non-sterile and must be sterilized before use.
- Do not re-use. Re-use of silicone clamp covers may cause a risk of infection and/or compromise functionality.

CONTRAINDICATIONS:

There are no known contraindications associated with the Silicone Clamp Covers.

INSTRUCTIONS FOR USE:


1. Remove silicone clamps covers from bag.
2. Package clamp covers in a sterile packaging device (e.g., pouch, wrapped tray, closed container). Silicone clamp covers do not need to be cleaned or disinfected prior to sterilization.
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 silicone clamp covers from sterile packaging device.
7. Clamp covers may be trimmed to desired length. Ensure cut does not impede functionality of the clamp cover.
8. Use during surgical procedure.

STERILIZATION:

<i>Cycle Type</i>	<i>Temperature</i>	<i>Minimum Time – Full Cycle</i>
Pre-Vacuum	132° C (270° F)	4 minutes
Pre-Vacuum	134° C (273° F)	3 minutes

DISPOSAL:

Upon completion of procedure, dispose of both used and unused clamp covers according to facility protocol. There are no special disposal instructions.

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REF CATALOG NUMBER **LOT** LOT NUMBER  **CONSULT INSTRUCTIONS FOR USE**

 NON-STERILE  DO NOT RE-USE  CAUTION **CE 2797**