



Band Clamps

INTENDED USE:

Key Surgical® band clamps are designed to keep the joints and jaws of bone forceps and other instruments open during the cleaning and sterilization process.

CONTRAINDICATIONS:

There are no known contraindications and/or adverse effects.

INSTRUCTIONS FOR USE:

1. Open instrument to appropriate width for cleaning.
2. Place band clamp over instrument handles.
3. Clean/sterilize instrument according to instrument manufacturer guidelines.

POINT OF USE CARE:

Clean band clamps as soon as possible after use. If cleaning must be delayed, immerse in an enzymatic solution or water to prevent drying and encrustation of surgical soil. Avoid prolonged exposure to saline to minimize the chance of corrosion. Remove excessive soil with a disposable wipe.

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. 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 band clamps.

STERILIZATION:

Band Clamps are provided non-sterile and 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
Gravity	121° C (250° F)	30 minutes
Pre-Vacuum	132° C (270° F)	4 minutes

100% Ethylene Oxide (EtO)	
Concentration	735 mg/L
Temperature	55° C
Exposure Time	60 minutes
Humidity	50-70%

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:

Band clamps 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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