



Sku	Description
10-5000	SILICONE STER BAND RED 2"
10-5001	SILICONE STER BAND BLUE 2.5"
10-5002	SILICONE STER BAND GREEN 2.75"
10-5003	SILICONE STER BAND YELLOW 3.25"
10-5004	SILICONE STER BAND PURPLE 3.5"
10-5005	SILICONE STER BAND MIXED 3.5"

Symbols on Products and Packaging	
	CAUTION
	NON-STERILE

INTENDED USE

SKLAR SURGICAL INSTRUMENT STERILIZATION BANDS are designed to keep the joints and jaws of forceps and other instruments "open" during the cleaning and sterilization process.

INSTRUCTIONS FOR USE

1. Open the instrument to the required width for proper cleaning
2. Place appropriate band over instrument handles/shaft
3. Clean and Sterilize instruments according to guidelines provided/recommended by manufacturer
4. Clean the sterilization bands immediately after use. If cleaning must be delayed, soak in a neutral pH (7) enzymatic solution or deionized water to prevent drying and encrustation of surgical residue
5. Remove any excess residue with a disposable wipe

CONTRAINDICATIONS

No known contraindications and/or adverse effects.

SAFE HANDING AND PREPARATION

CAUTION

- Read, follow, and keep the "Instructions for Use"
- Use the product only in accordance with its intended use, see "intended use"
- Remove the transport packaging and clean the new product, either manually or mechanically, prior to its initial sterilization. Store any new or unused products in a dry, clean, and safe place
- Prior to each use, inspect the product for any loose, bent, broken, cracked, worn, or fractured components
- DO NOT use the product if it is damaged or defective. Set the product aside if it is damaged.

GENERAL SAFETY INSTRUCTIONS

CAUTION

- Adhere to national statutory regulations, national and international standards and directives, and local, clinical hygiene instructions for sterile processing.
- Mechanical processing should be favored over manual cleaning as it gives better and more reliable results.
- Successful processing of this medical device can only be ensured if the processing method is first validated. The operator/sterile processing technician is responsible for this.
- Products are subject to bending/breaking if misused.
- Misuse and improper insertion technique are the primary causes of product damage/deformation.

CLEANING/DISINFECTION

POINT OF USE

- If applicable, rinse non-visible surfaces preferably with deionized water using a disposable syringe
- Remove any visible surgical residue to the extent possible with a damp, lint free cloth

MANUAL CLEANING/DISINFECTION

1. Pre-rinse under cold tap water for one (1) minute to remove gross debris.
1. Visually inspect each part. Discard if cracked, bent, worn, torn, or damaged. Soak using a neutral pH (7) enzymatic cleaning agent for two (2) minutes.
2. Rinse with warm deionized water.
3. Ultrasonically clean for a minimum of five (5) minutes using a neutral pH (7) solution according to guidelines provided/recommended by manufacturer.
4. Thoroughly rinse with cold tap water for one (1) minute.

AUTOMATED CLEANING/DISINFECTION

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

- Run the automatic wash cycle - minimum cycle parameters include:
- One (1) minute cold pre-rinse
- Five (5) minute enzyme wash at 109°F/43°C minimum temperature
- One (1) minute cold rinse
- Seven (7) minute dry time at 194°F/90°C minimum temperature
- Visually inspect each part. Discard if cracked, bent, worn, torn, or damaged.

STERILIZATION

Surgical Instrument Sterilization Bands are supplied NON-STERILE and MUST be sterilized prior to each use. Material compatible with sterilization according to following parameters:

Steam Sterilization		
Cycle Type	Temperature	Cycle Time
Gravity	Up to 250°F/121°C	Max. 30 minutes
Pre-Vacuum	Up to 250°F/121°C	Max. 20 minutes
Pre-Vacuum	Up to 273°F/134°C	Max. 18 minutes

100% Ethylene Oxide (EtO)	
Concentration	735mg/L
Temperature	131°F/55°C
Exposure Time	Sixty (60) Minutes
Humidity	50-70%

Disclaimer

These pre-cleaning cleaning & sterilization guidelines are provided as guidelines only, and should not be used in place of the guidelines or standards otherwise followed by a given Operating Room Supervisor, Surgeon, Facility, Hospital, or institution.

FDA Draft Guidance for Industry and FDA Staff - Processing and Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, 2011.

ANSI/AAMI TIR 30 and TIR12

EN ISO 11607 (ANSI/AAMI ISO 11607): Packaging for Terminally Sterilized Instruments (replaced EN 868-1 and ISO 11607)

EN ISO 17665 (ANSI/AAMI ISO 17665): Sterilization of Health Care Products, Moist Heat (replaced EN 554 and ISO 11134)

ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities

EN ISO 17664: Sterilization of Medical Devices - Information to be provided by the Manufacturer for the Processing of Resterilizable Medical Devices

Exclusion of Warranty

Sklar makes no warranty, express or implied, regarding the Surgical Instrument Sterilization Bands, including without limitation any warranty of merchantability or fitness for any particular purpose. The purchaser is solely responsible for determining the suitability of this product for any particular use or procedure.