

Silicone Sleeve

IMPORTANT INFORMATION FOR USE OF THOMPSON SILICONE SLEEVES

This IFU is intended to assist health care personnel in safe handling practices and effective processing of Thompson Surgical Instruments, Inc.'s silicone sleeve accessory.

SILICONE SLEEVE IS A SINGLE-USE PRODUCT. All Thompson Retractor products and accessories are latex-free.



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IMPORTANT INFORMATION FOR USE OF THOMPSON SILICONE SLEEVES

PLEASE READ BEFORE USE

Failure to follow these instructions may render device unusable and may void product specific warranty.

INTENDED USE:

The Silicone Sleeve is intended for use with Thompson Surgical Instruments' retractors as noted in catalogs and brochures. The Silicone Sleeve is designed to fit around the perimeter of retractor blades to provide gentle, soft tissue retraction in conjunction with the retractor blades.

 Silicone Sleeves are supplied non-sterile. **Silicone Sleeves must be inspected, cleaned, and sterilized prior to use.**

CONTRAINDICATIONS:


None known.

LIMITATIONS ON REPROCESSING:

Silicone Sleeve is a single-use product and may not be re-sterilized.

WARNINGS AND PRECAUTIONS:

 **PPE (Personal Protective Equipment):** Should be worn, per individual hospital protocol, when handling or working with contaminated (or potentially contaminated) instruments.

 Do not reuse, Silicone Sleeve is a disposable, single-use product only.

 Do not re-sterilize, Silicone Sleeve is a single-use product and may not be re-sterilized.

- Medical professionals should be familiar with all product support literature and videos to perform procedures with this device before use.
- Many variables such as patient anatomy, pathology, and surgical techniques may influence the procedure's outcome. Patient, product, and procedure selection is the responsibility of the medical professional.
- Do not over-retract. Only use as much retraction as necessary to provide adequate exposure and access.
- Do not use if Silicone Sleeve appears to be damaged or torn.
- Do not puncture/cut Silicone Sleeve in vivo or when fully retracted around an open blade.
- Products are provided non sterile and must be cleaned and sterilized before use.
- Thompson Silicone Sleeves are only for use with other Thompson Retractor products.
- Use of the Silicone Sleeve for any purpose other than what is described here and in associated device user manuals, may cause damage or failure of the device which could result in serious patient injury or death.
- US Federal Law restricts this device to sale to or on the order of a physician.

PROPER CARE AND MAINTENANCE:

To ensure the Silicone Sleeve keeps a cylindrical shape, do not crush during sterilization. The Silicone Sleeve is made of medical grade translucent silicone elastomer. It can remain in storage for up to 5 years as described in the expiration date on the Silicone Sleeve label. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

STERILIZATION

- Arrange instruments in dedicated instrument trays to ensure sterilization can penetrate all surfaces.
- Wrap instruments or instrument tray in 2 layers of 1-ply polypropylene wrap, using sequential wrapping techniques.
- Place wrapped instruments in sterilizer, following validated parameters as indicated below.

Prevacuum Steam Sterilization Parameters Validated

Sterilizer Type: Prevacuum
Preconditioning Pulses: 4
Temperature: 132°C (270°F)
Exposure Time: 4 Minutes
Dry Time: 30 Minutes *

*The dry times were validated utilizing a 15 minute open door phase and 30 minute cool down phase.

Gravity Steam Sterilization Parameters Validated

Sterilizer Type: Gravity
Temperature: 121°C (250°F)
Exposure Time: 30 Minutes
Dry Time: 30 Minutes *

PRODUCT	METHOD	CYCLE	CYCLE TEMP	EXPOSURE TIME	MIN. DRY TIME
Thompson Retractor	Steam	Prevacuum	132°C (270°F)	4 Minutes	30 Minutes
Thompson Retractor	Steam	Gravity	121°C (250°F)	30 Minutes	30 Minutes

Total weight of wrapped instruments or tray may not exceed 11.4kg (25 pounds). Weight gain, post-sterilization must not exceed 3% of 11.4kg (25 pounds).

STORAGE AND USE

 **STORAGE:** Store sterile, packaged instruments in a limited access area that is well-ventilated, protected from contaminants, and dry.

USE: Carefully examine sterile instrument packaging prior to use, ensuring package integrity is maintained.

WARRANTY, REPAIR AND SERVICE:

The Silicone Sleeve is warranted to be free from defects in materials and workmanship upon arrival. For customer service and return authorization, please call: 1-231-922-0177.

SYMBOL LEGEND:

 Manufacturer	 EC Rep	 CE Mark	 Warnings / Precautions	 Biological Risks	 DO NOT Reuse	 Non-Sterile	 DO NOT Re-sterilize	 Keep Dry / Protect from Moisture	 DO NOT USE if Package Damaged / Compromised
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