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# Thompson Silicone Sleeve

Important Instructions for Use (IFU) of Thompson Silicone Sleeves

Thompson SURGICAL INSTRUMENTS

Thompson Retractor

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## IMPORTANT INSTRUCTIONS FOR USE OF THOMPSON SILICONE SLEEVES

## PLEASE READ BEFORE USE

This IFU is intended to assist medical professionals in safe use and handling practices, effective reprocessing, and maintenance of Thompson Surgical Instruments, Inc.'s Silicone Sleeve accessory. All Silicone Sleeves must be inspected and sterilized prior to use. For Important Instructions for use of the Thompson Retractor, please see the Thompson Retractor IFU (TRIFU).

The use of these guidelines does not remove or limit the user's ultimate responsibility for sterility of any Thompson Surgical Instruments device used at their facility. In countries where reprocessing requirements are more stringent than those provided herein, it is the duty of the processor to comply with said ordinances.

⚠ **The Thompson Retractor and accessories are not intended to treat or monitor any disease conditions. Failure to follow these instructions may cause harm to the patient, may render device unusable, and void warranty or service agreements.**

**DEVICE DESCRIPTION:**
The Silicone Sleeve is a single-use device made of medical grade translucent silicone elastomer designed to surround blades and aid in soft tissue retraction.

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


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

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

**CONTRAINDICATIONS:**
None known.

⚠ **WARNINGS, PRECAUTIONS, RESIDUAL RISKS, AND UNDESIRABLE SIDE EFFECTS:**

1. Medical professionals, including reprocessing technicians, should be familiar with all product support literature and videos, including assembly, use, and disassembly, to perform procedures with this device before use. Patient injury, including but not limited to, tissue, nerve, or vascular damage, can occur if retractor is not used according to this IFU and product support literature. References to "patient injury" in this IFU shall encompass the preceding definition.
2. Many variables such as patient anatomy, pathology, and surgical techniques may influence the procedure's outcome. Patient, product, and procedure selection is the sole responsibility of the medical professional. Carefully consider the use of the retractor system with sleeve in patients with known sensitivities to certain materials or preexisting conditions. Patient could have allergic or infectious consequences if known sensitivities are not considered.
3. Do not over-retract. Only use as much retraction as necessary to provide adequate exposure and access in order to reduce the risk of damage to the product and patient injury.
4. Products are provided non sterile and must be visually examined and sterilized before use to reduce the risk of patient or user infection or disease transmission.
5. Product should be inspected before each use according to this IFU. Do not use products that show signs of damage such as, but not limited to, cracking or deformation. Do not use product if Part or Lot Number are not legible (in both Plain Text and 2d Data Matrix). Using damaged Silicone Sleeves could result in sudden loss of exposure or introduction of unexpected sharps which could result in patient or user injury.
6. Do not puncture/cut Silicone Sleeve in vivo or when fully retracted around an open blade. Puncturing/cutting Silicone Sleeve in vivo or when fully retracted around an open blade could result in sudden loss of exposure or introduction of unexpected sharps which could result in patient or user injury.
7. Thompson Silicone Sleeves are only for use with Thompson Retractor products. Do not use with incompatible products. If Thompson Silicone Sleeves are used with incompatible equipment, the retractor and sleeve may not perform as expected and could contribute to loss of exposure, patient, or user injury.
8. 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.

**STERILIZATION**

To ensure the Silicone Sleeve keeps a cylindrical shape, do not crush during sterilization.

1. Arrange in instrument trays to ensure sterilization can penetrate all surfaces.
2. Wrap instruments or instrument tray in 2 layers of 1-ply polypropylene wrap, using sequential wrapping techniques. (ISO 11607-1:2019)
3. Place wrapped instruments in sterilizer, following validated parameters as indicated below.

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

| Sterilization | | | | | |
|---|---|---|---|---|---|
| **PRODUCT** | **METHOD** | **CYCLE** | **CYCLE TEMP** | **EXPOSURE TIME** | **MIN. DRY TIME** |
| Thompson Retractor | Steam | Prevacuum | 132°C (270°F) | 4 Minutes | 30 Minutes *** |

**** Dry time was validated utilizing a 15 minute open door phase and 30 minute cool down phase. Refer to sterilizer manufacturer's recommendations to determine if longer dry time is required. NOTE: Sterilization validation demonstrated a sterility assurance level of $\leq 10^{-6}$*

**The processing instructions provided herein are in accordance with EN ISO 17664 and EN ISO 17665 and have been validated as being capable of preparing Thompson Surgical Instruments for reuse.**

**STORAGE:**

The Silicone Sleeve can remain in storage for up to 5 years as described in the expiration date on the Silicone Sleeve label. Store sterile, packaged instruments in a limited access area that is well-ventilated, protected from contaminants, and dry.

**DISPOSAL:**

After use, this product may be a potential biohazard. Handle and dispose of in accordance with local and national regulations and medical guidelines.

**PRODUCT COMPLAINTS:**

Any medical professional who experiences dissatisfaction in the product quality, reliability, safety, effectiveness, and/or performance should notify Thompson Surgical Instruments, Inc.

If any Thompson product ever "malfunctions" and may have contributed to patient injury or death, Thompson should be notified immediately.

When filing a complaint, please provide part number and description, lot number, your name, phone number, email, facility name and address, and the nature of the complaint.

For Service and Warranty information, please visit: https://thompsonsurgical.com/service-warranty/ or speak to your Thompson Account Representative for further information.

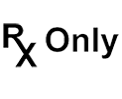
**MRI COMPATIBILITY STATEMENT:**

This device has not been evaluated for safety, efficacy, and/or compatibility in the MR environment. The safety of the Thompson Retractor in the MR environment is not known and has not been tested for magnetic field interactions, heating, induced electrical fields, and artifacts.

**SYMBOL LEGEND:**

|  |  |  |  |  |  |  |
|---|---|---|---|---|---|---|
| Manufacturer | Country of Manufacure | Date of Manufacure | Importer | Batch Code | Catalogue Number | Use by Date |
| 3082 | 6049 | 2497 | 3725 | 2492 | 2493 | 2607 |

|  |  |  |  |  |  |
|---|---|---|---|---|---|
| Do Not Reuse | Non-Sterile | Do Not Resterilize | Caution | Consult Instructions for Use | Translation |
| 1050 | 2609 | 2608 | 0434A | 1641 | 3728 |

|  |  |  |  |  |  |
|---|---|---|---|---|---|
| Medical Device | Unique Device Identifier | Not manufactured with natural rubber latex | Authorized representative in the European Union | CE Marking | CAUTION: Federal law (USA) restricts these products to sale by or on the order of a physician |

**SYMBOL LEGEND (continued):**

| | | | |
|---|---|---|---|
| (01) | (10) | CH REP | UK REP |
| Application Identifier for Global Trade Item Number (GTIN) per GSI Specification | Application Identifier for Lot Number per GSI Specification | Authorized representative in Switzerland | Authorized representative in the United Kingdom |

For complete symbol definition, enter corresponding 4-digit code at https://www.iso.org/obp/ui/

**A summary of safety and clinical performance (SSCP) is available at www.thompsonsurgical.com or on the Eudamed Database (when available).**

**THIS IFU PERTAINS ONLY TO PRODUCTS MARKED "THOMPSON".**