Thompson Retractor for Medtronic®, Manufactured by Thompson Surgical Instruments, Inc.

Important Instructions for Use of the Thompson Retractor for Medtronic®

Thompson SURGICAL INSTRUMENTS

Thompson Retractor

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ENGLISH – USA ONLY

IMPORTANT INSTRUCTIONS FOR USE OF THE THOMPSON RETRACTOR FOR MEDTRONIC®

PLEASE READ BEFORE USE

Failure to follow these instructions may render device unusable and may void warranty or service agreements.

PERFORMANCE CHARACTERISTICS:

The Thompson Retractor for Medtronic® is a reusable device designed to provide access and exposure for a variety of surgical procedures. The Thompson Retractor for Medtronic® is designed with interchangeable frame components, accessories, and blades to meet a variety of patient anatomies and procedures.

INTENDED USE:

The Thompson Retractor for Medtronic® is intended for use during surgical procedures in order to provide surgical access and exposure.

NON STERILE Thompson Surgical retractor systems and accessories are supplied non-sterile.

This IFU is intended to assist health care personnel in safe use and handling practices, effective reprocessing, and maintenance of all Thompson Surgical Instruments, Inc.'s retractor systems and accessory families. All instruments must be inspected, cleaned, and sterilized prior to each use.

CONTRAINDICATIONS:

None known

WARNINGS AND PRECAUTIONS:

1. Medical professionals should be familiar with all product support literature and videos 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 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. Relax the retractor periodically to ensure proper blood flow in order to reduce the risk of patient injury, including tissue necrosis.
5. Avoid compressing the patient's body with frame components to prevent nerve damage. See user manuals for proper setups and components to meet various patient anatomies.
6. Retractor blades may compress nerves. User must evaluate the need to use free running EMG to monitor events such as retractor nerve compression outside of the visual field to reduce the risk of patient nerve injury.
7. Table mounted frame prevents most retractors from moving relative to patient movement. Use caution when moving patient while retractor is in use to reduce risk of patient injury.
8. Do not move, retract, or adjust blades or frame components when blades are fixed to the spine with pins. Blade pins are not intended for distraction and may break if subjected to undue force. Broken pins could result in patient injury or death.
9. If using pins with blades, ensure pin distal end and thread is always engaged in spine to prevent unexpected sharps which could cause patient or user injury.
10. Products are provided non sterile and must be pre-cleaned, cleaned, visually examined, and sterilized before each use to reduce the risk of patient or user infection or disease transmission.
11. Normal repeated use has little effect on these instruments. Determine end of life by wear and damage due to use. Product should be inspected before each use according to this IFU. Do not use products that show signs of damage such as cracking, deformation, or sharp edges. Do not use product if markings such as Part or Lot Number are not legible. Using damaged instruments could result in sudden loss of exposure or introduction of unexpected sharps which could result in patient or user injury.
12. Thompson Retractor Frames are only for use with other Thompson Retractor Products as provided in kits by Medtronic®. Do not use with incompatible products. Check all Thompson Retractor handles and blades for compatibility. S-Lock (SL) handles and blades can be identified by their gold plunger and nipples, respectively, as well as matching serrations. Swivel-Only (SO) blades have gold nipples, with no serrations, and may only be used with S-Lock handles. Interchangeable handles and blades do not have gold coloring and are smooth with no serrations. Do not attempt to mate SL or SO components with Interchangeable components. If Thompson Retractor products are used with incompatible equipment, or non-compatible handles and blades are used, the retractor may not perform as expected and could contribute to loss of exposure, patient, or user injury.
13. Use of the Thompson Retractor for any purpose other than what is described here and in associated device user manuals, provided by Medtronic®, may cause damage or failure of the device which could result in serious patient injury or death.
14. Ensure frame components, rail clamps, rail adapters, retractor blades, and accessories are securely positioned and locked into place before use to avoid sudden loss of exposure and reduce risk of subsequent patient injury

CLEANING
Adequate reprocessing is contingent upon the thoroughness of cleaning. To ensure acceptable reprocessing, do not delay between the steps below. Before cleaning, disassemble, loosen, or unlock all moving mechanisms or removable parts where possible, without the use of tools. DO NOT allow instruments to dry after use, prior to cleaning. Cleaning and sterilization may be hindered when blood or bloody solutions are allowed to dry on instruments.

Point of Use Cleaning Instructions:

1. Remove all visible soil from instruments using non-shedding wipes.
2. Place instruments in a tray of water or cover with damp towels. Instruments should be cleaned within 30 minutes of use to minimize drying.

Manual Cleaning:
(REQUIRED for all instruments with lumens. Manual cleaning NOT ALLOWED for the Articulating Arms. See automated cleaning below.)
Enzymatic cleaning agents, neutral pH enzymatic cleaners, and soft bristled brushes and soft pipe cleaners are recommended. If available, softened tap water is recommended. De-ionized water should be used for the final rinse step to prevent mineral deposits on surfaces. The following cleaning agents, solutions, or tools should NOT be used: saline solution, alkaline cleaning agents, solutions containing chlorine or aldehydes, formalin, mercury, chlorides, bromides, iodides, or ringers solution, metal brushes or scouring pads. Mineral oil or silicone based lubricants should not be used.

1. Immediately transport the tray containing the covered instruments to a work area dedicated to further reprocessing.
2. Rinse and flush instruments under running tap water for 3 minutes.
3. Scrub instruments with appropriately-sized, soft bristle brushes or pipe cleaners to remove visible soil. Scrub inside any lumens or cavities. Scrub until all visible soil is removed.
4. Using tap water, prepare an enzymatic cleaning solution according to the manufacturer's instructions, dilution recommendations, and temperatures.
5. Place instruments in the enzymatic cleaner, completely submerged, and soak for 45 - 60 minutes.
6. Remove instruments from the enzymatic cleaner and flush under running tap water. Flush lumens or cavities in the water stream. Rinse for 3 minutes.
7. Using tap water, prepare a second enzymatic cleaning solution according to step 4.
8. Place the parts in the enzymatic cleaner, completely submerged, and sonicate for 45 - 60 minutes.
9. Remove the parts from the sonicator and rinse using running tap water. Flush lumens or cavities in the water stream. Rinse for 3 minutes.
10. Repeat rinsing as in step 9, this time with de-ionized water for an additional 3 minutes.
11. Dry the parts using clean, absorbent, non-shedding wipes.
12. Inspect instruments, including lumens and cavities, to ensure contamination has been removed. If soil is present, repeat the cleaning process. Do not proceed with reprocessing of a soiled instrument.

Automated Cleaning:
(Articulating Arms REQUIRE automated cleaning and central tightening knob must be tightened during cleaning. Do not completely submerge these instruments. Automated cleaning NOT ALLOWED for instruments with lumens. All other instruments may use manual or automated cleaning.)

1. Rinse instruments with cold tap water for 2 minutes, ensure visible contamination is removed.
2. Scrub instruments with soft brush, as necessary.
3. Load instruments into automated washer/disinfector in fully extended, open positions to maximize surface exposure.
4. Run washer according to Thompson's validated cleaning cycle shown below.
5. Check instruments for visible contamination following automated cycle. If soil is present, repeat the cleaning process. Do not proceed with reprocessing of a soiled instrument.

Automated Cleaning			
PHASE	**TIME (MIN.)**	**TEMP.**	**DETERGENT/ CONCENTRATION**
Pre-Wash	02:00	Cold Tap Water	N/A
Enzyme Wash	01:00	Hot Tap Water	Enzol® by J&J (1 oz/gal)
Wash 1	02:00	66°C (151°F) (set point)	Renu-Klenz™ by Steris (1/4 oz/gal)
Rinse 1	00:15	Hot Tap Water	N/A
PURW Rinse	00:10 (non-recirculation)	66°C (151°F)	N/A
Drying	07:00	115.5°C (240°F)	N/A

INSPECTION, LUBRICATION, AND TESTING

1. Carefully inspect instruments to ensure all visible contamination removed.
2. Lubricate all moving mechanisms on instruments with a steam penetrable, water-soluble product after every cleaning cycle.
3. Reassemble instruments, as necessary, to test instrument function. Test action of movable parts to ensure smooth operation / uninhibited movement.
4. Carefully inspect all instruments. Do not use any instruments that appear damaged or broken (cracked, deformed, nonfunctional, or altered).
5. Ensure that all instrument laser markings are clearly visible.

STERILIZATION

1. Prepare instruments for sterilization by loosening, unlocking, and disassembling all moving mechanisms or removable parts where possible, without the use of tools.
2. Arrange instruments in dedicated instrument trays to ensure sterilization can penetrate all surfaces.
3. Wrap instruments or instrument tray in 2 layers of 1-ply polypropylene wrap, using sequential wrapping techniques.
4. 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 *

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

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

Sterilization					
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

DISPOSAL:
No special requirements. Dispose of surgical instruments according to local legislation

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

SYMBOL LEGEND:

Manufacturer	Warnings / Precautions	Non-Sterile	Keep Dry / Protect from Moisture	CAUTION: Federal law (USA) restricts these products to sale by or on the order of a physician
Part Number	Batch Code	Date Manufactured	For US audiences only	ATTENTION: Consult accompanying documentation

THIS IFU PERTAINS ONLY TO PRODUCTS MARKED "THOMPSON".