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

Important Instructions for Use of the Thompson Retractor for Medtronic®

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IMPORTANT INSTRUCTIONS FOR USE OF THE THOMPSON RETRACTOR FOR MEDTRONIC®
PLEASE READ BEFORE USE

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

The use of these guidelines does not remove or limit the user's ultimate responsibility for cleanliness and 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 is 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 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. The Thompson Retractor is intended for use by well informed physicians in appropriate health care facilities.
NOTE: DO NOT IMPLANT THE INSTRUMENTS

NON STERILE

Thompson Surgical retractor systems and accessories are supplied non-sterile.
Instrument Cases and Trays are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses. Instrument Cases and Trays are not intended on their own to maintain sterility: they are intended to be used in conjunction with a legally marketed and/or appropriate sterilization wrap.

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 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. Pins can break under undue stress and may create sharps which may cause patient injury.
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 (in both Plain Text and 2d Data Matrix). Using damaged instruments could result in sudden loss of exposure or introduction of unexpected sharps which could result in patient or user injury.

WARNINGS, PRECAUTIONS, RESIDUAL RISKS, AND UNDESIRABLE SIDE EFFECTS (continued):

12. Check stability of OR table rails or rail adapters/accessories before table mounting the Thompson Retractor. Only table mount to secure, non-moveable rails and do not use if movement is evident to reduce the risk of sudden loss of exposure and potential complications due to the frame moving such as increased operating time or patient injury.
13. 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. Refer to Thompson literature for visual examples. 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.
14. 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.
15. 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.
16. Metal instruments are conductive and can transmit unwanted electrical current and heat to the patient. Do not allow sources of electrical current or heat to contact the instruments to reduce potential injury to patient. Such contact is considered misuse of the retractor.

Prion Diseases: Discard or destroy instruments in contact or exposed to patients with prion diseases, or those suspected of prion diseases. Thompson Surgical does not advocate nor provide any validated instructions to eliminate risk of cross-contamination or transmission.

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.

Enzymatic cleaning agents are validated for automated and manual cleaning for instruments and accessories.

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 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. Pure 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 (continued):

Automated Enzymatic Cleaning			
PHASE	**TIME (MIN.)**	**TEMP.**	**DETERGENT/ CONCENTRATION**
Pre-Wash	02:00	Cold Tap Water	N/A
Enzyme Wash	01:00	Hot Tap Water	(1 - 2 oz/gal)
Neutral pH Detergent Wash	02:00	66°C (151°F) (set point)	(1/4 - 1 oz/gal)
Rinse 1	00:15	Hot Tap Water	N/A
Purified Water Rinse	00:10 (non-recirculation)	66°C (151°F)	N/A
Drying	07:00	115.5°C (240°F)	N/A

Note: Enzymatic cleaning cycle validated using Enzol® Enzymatic detergent and ValSure® Neutral pH detergent using manufacturer recommended concentrations. Use only low-foaming neutral pH enzymatic cleaning agents for Automated Enzymatic Cleaning and prepare according to manufacturer recommendation. The automated washer/disinfector manufacturer's instructions should be followed.

INSPECTION, MAINTENANCE, AND TESTING

Instruments must be inspected pre- and post- processing and prior to use. Inspection must include a visual and functional inspection of product integrity and mechanisms. Do not use if any form of damage is present. Use of an instrument in spite of visual damage is considered misuse per this IFU.

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. Consult Lubrication Instructions for further information.
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. Do not use instruments in which the laser markings are not visible (in both Plain Text and 2d Data Matrix). Using instruments in spite of visible damage or lack of laser markings is considered misuse.
6. If damaged instruments are identified, contact Thompson Surgical using the Product Complaints process.

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. (ISO 11607-1)
4. 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 ≤10^{-6}*

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

STORAGE:
Store in clean, dry conditions at room temperature.

DISPOSAL:
All products must be disposed of correctly and 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.

Instruments returned to Thompson Surgical Instruments should be reprocessed according to this IFU (cleaned, sterilized) before return.

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 Manufacture	Date of Manufacure	For US audiences only
3082	6049	2497	
			
Batch Code	Catalogue Number	Do Not Reuse	Non-Sterile
2492	2493	1050	2609
			
Caution	Consult Instructions for Use	Keep Dry / Protect from moisture	CAUTION: Federal law (USA) restricts these products to sale by or on the order of a physician
0434A	1641	0626	
				(10)
Medical Device	Unique Device Identifier	Not manufactured with natural rubber latex	CE Marking	Application Identifier for Lot Number per GSI Specification

(01)
Application Identifier for Global Trade Item Number (GTIN) per GSI Specification

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

THIS IFU PERTAINS ONLY TO PRODUCTS MARKED "THOMPSON".