Thompson Retractor

IMPORTANT INFORMATION FOR USE OF THOMPSON RETRACTOR SYSTEMS AND INSTRUMENT CASES

(NOT including illumination products, silicone sleeve, or discontinued Adjustable Height Rail Clamp. Please note, this does include the new Infinite Height Rail Clamp.):

This IFU is intended to assist health care personnel in safe handling practices, effective reprocessing, and maintenance of all Thompson Surgical Instruments, Inc.'s retractor systems and accessory families.

Thompson SURGICAL INSTRUMENTS

Thompson Surgical Instruments, Inc.
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Traverse City, Michigan 49684
phone: (800) 227-7543 (IN USA)
(231) 922-0177 (OUTSIDE USA)
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121415
dc trifu1215

SHIPPING ADDRESS:

RMA#:_____
Thompson Surgical Instruments, Inc.
10321 East Cherry Bend Road
Traverse City, Michigan 49684
phone: (231) 922-0177
Indicate (RMA #) on return shipments

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
THE NETHERLANDS

CE 0297

ENGLISH

IMPORTANT INFORMATION FOR USE OF THOMPSON RETRACTOR SYSTEMS AND INSTRUMENT CASES

PLEASE READ BEFORE USE

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

DESCRIPTION:

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

SCOPE:

This IFU provides recommended information for the cleaning and sterilization of reusable surgical retractor systems and accessories* that are manufactured and/or distributed by Thompson Surgical Instruments, Inc. **Always reference our website, www.thompsonsurgical.com, for the most current revision of this IFU.**

**Accessories refer to our retractor system components such as adapters, wrenches, instrument cases, etc. This does NOT refer to our illumination products, silicone sleeve, or Adjustable Height Rail Clamp.*

INTENDED USE:

The Thompson Retractor 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

LIMITATIONS ON REPROCESSING:

Repeat processing, according to the instructions in this IFU, has minimal effect on instrument life. End of usable life for metal surgical instruments is normally determined by wear and damage due to intended surgical use. Any limitations to reprocessing cycles will be noted in this IFU.

WARNINGS AND PRECAUTIONS:

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

CJD (Creutzfeldt-Jakob Disease): Discard or destroy instruments in contact or exposed to patients with CJD, or those suspected of CJD.
(Thompson Surgical does not advocate nor provide any validated instructions to eliminate risk of cross-contamination.)

1. Medical professionals should be familiar with all product support literature and videos to perform procedures with this device before use.
2. Many variables such as patient anatomy, pathology, and surgical techniques may influence the procedure's outcome. Patient and procedure selection is the responsibility of the medical professional.
3. Do not over-retract. Only use as much retraction as necessary to provide adequate exposure and access.
4. Relax the retractor periodically to ensure proper blood flow.
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. Table mounted frame prevents most retractors from moving relative to patient movement. Use caution when moving patient while retractor is in use.
7. Do not move, retract, or adjust blades or frame components when blades are fixed to the spine with pins.
8. If using pins with blades, ensure pin distal end and thread is always engaged in spine to prevent unexpected sharps.
9. Products are provided non sterile and must be cleaned and sterilized before each use.
10. Normal repeated use has little effect on these instruments. Determine end of life by wear and damage due to use.
11. 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.
12. Check stability of OR table rails or rail adapters/accessories before table mounting the Thompson Retractor. Only table mount to secure, non-movable rails and do not use if movement is evident.
13. Thompson Retractor products are only for use with other Thompson Retractor products unless otherwise specified by the manufacturer, such as through the offering of competitor adapter handles and other products.
14. Use of the Thompson Retractor 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.
15. US Federal Law restricts this device to sale to or on the order of a physician.

DO'S AND DON'TS

DO'S
Use only soft, nylon brushes
Use neutral (7) or low pH chemicals
Use water-soluble instrument lube before each sterilization
Pre-clean instruments before sterilizing
Dry instruments prior to storing
Protect instruments when storing
Inspect instruments for damage
Use distilled water when soaking instruments

DON'TS
Use metal or abrasive brushes / pads
Use high pH (>9) chemicals
Use silicone lube or mineral oil
Sterilize without first pre-cleaning
Store instruments wet or semi-dry
Store instruments unprotected / piled
Use damaged / suspect instruments
Use saline when soaking instruments

SYMBOL LEGEND:

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

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PROCESSING / REPROCESSING INSTRUCTIONS FOR THOMPSON RETRACTOR SYSTEMS AND INSTRUMENT CASES

(NOT including illumination products, silicone sleeve, or discontinued Adjustable Height Rail Clamp. Please note, this does include the new Infinite Height Rail Clamp.):

HOSPITAL MUST ENSURE OPERATIONS ARE PERFORMED USING THE APPROPRIATE EQUIPMENT, MATERIALS, AND TRAINED PERSONNEL. ANY DEVIATIONS FROM THIS IFU SHOULD BE EVALUATED FOR EFFECTIVENESS TO AVOID POTENTIAL ADVERSE CONSEQUENCES.

CLEANING

Adequate reprocessing is contingent upon the thoroughness of cleaning. To ensure acceptable reprocessing, do not delay between the steps below. Clean instruments as soon as reasonably practical, or within at least 30 minutes following use. Keep instruments moist and covered / wrapped until transported to Point of Use. DO NOT allow saline, blood, or other organic debris to dry on instruments.

Point of Use / Pre-Cleaning Instructions:

1. Disassemble, loosen, or unlock instruments where possible.
2. Rinse/flush instruments under cool or lukewarm running water.
3. Remove excess soil while rinsing, using non-abrasive brush/cloth.

NOTE: Do not completely submerge Articulating Arm central black knob during cleaning. Ensure knob is tightened during cleaning but open during sterilization. Manual Cleaning is NOT ALLOWED for Articulating Arm.

Manual Cleaning:

1. Soak instruments in prepared enzymatic solution for 20 minutes.
2. Gently scrub all surfaces, including crevices and hard-to-reach areas, with soft, nylon brush.
3. Remove / rinse instruments under water for 3 minutes–thoroughly and aggressively flush difficult to reach areas.
4. Submerge instruments in prepared detergent of ultrasonic unit for 10 minutes at 45-50 kHz.
5. Rinse instruments in purified / distilled water for 3 minutes, or until no visible contamination remains.
6. Repeat above sonication and rinse steps.
7. Dry instruments using clean, lint-free cloth and/or compressed air to remove moisture from crevices and hard to reach areas.
8. Repeat if necessary.

Cleaning Agents Used in Validation:
(prepared according to Manufacturer's recommendations)
· Enzol® by Johnson & Johnson (1 oz/gal, using lukewarm tap water)
· ValSure® Neutral Detergent by Steris (1/4 oz/gal, using lukewarm tap water in ultrasonic unit)

Final Rinse Used in Validation
Reverse Osmosis / Deionized water (RO/DI)

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.

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

STERILIZATION

1. Prepare instruments for sterilization by loosening, unlocking, and disassembling all moving mechanisms or removable parts where possible.
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.*

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

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).

INSPECTION, LUBRICATION, AND TESTING

1. Carefully inspect instruments to ensure all visible contamination removed. Reassemble instruments, as necessary, to test instrument function.
2. Lubricate all moving mechanisms on instruments with a steam penetrable, water-soluble product after every cleaning cycle. (Such as Surgislip® by Ruhof.)
3. Test action of movable parts to ensure smooth operation / uninhibited movement.

· Do not use any instruments that appear damaged or broken (cracked, deformed, nonfunctional, or altered).
· Lubricate articulated instruments after every cleaning cycle.

STORAGE AND USE

If package integrity is compromised or suspect, repeat Processing / Reprocessing Instructions.

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.

EQUIPMENT RETURNS: HOSPITAL RESPONSIBILITIES

ALL loaner and trial equipment returns must be fully reprocessed before shipping to Thompson Surgical Instruments, Inc. (10321 East Cherry Bend Road, Traverse City, MI 49684). Hospital must indicate cleaning / sterilization of instruments on return packaging. RMA must be referenced on outside of package.

Prevent damage of returned equipment:
· ALWAYS place parts in designated holders / spaces when using organized instrument cases.
· NEVER ship Elite II Rail Clamps / Infinite Height Rail Clamps / Power Rail Clamps inside instrument cases; MUST package separately.

PRODUCT WARRANTY

Thompson Surgical Instruments, Inc. warrants all instruments free from defects in material or workmanship for 10 years*. Warranty void if product failure resulted from normal wear and tear from instrument use, accident, abuse, misapplication, negligence, or if the product has been damaged, altered, or repaired outside of Thompson Surgical's facility. Warranty void if purchased from a non-authorized supplier/ distributor.

* Malleable blades carry a 2 year guarantee against defects in both material and workmanship. Blade finishes do not carry a warranty.
(Illumination Products: Xenon products carry a 60 day guarantee; LED products carry a 1 year guarantee.)

UPGRADE PROGRAM

Please contact your Account Manager at 1-800-227-7543, or visit our website www.thompsonsurgical.com for details.

REFURBISHMENT PROGRAM

Please contact your Account Manager at 1-800-227-7543, or visit our website www.thompsonsurgical.com for details.