Thompson Retractor Illumination Products Instructions For Use (IFU)

IMPORTANT INFORMATION FOR USE OF THOMPSON RETRACTOR ILLUMINATION PRODUCTS (LITE WAND, RETRACTOR LITE, LITE CLIP, AND LITE WAND INSTRUMENT CASE) **ONLY**

This IFU is intended to assist health care personnel in safe handling practices, effective reprocessing, and maintenance of Thompson Surgical Instruments, Inc.'s illumination products.

Lites will survive a maximum of 50 cycles of steam autoclave sterilization.* All Thompson Retractor products and accessories are not manufactured with natural rubber latex.

Thompson SURGICAL INSTRUMENTS

Thompson Retractor

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IMPORTANT INSTRUCTIONS FOR USE OF THOMPSON LITE WAND, RETRACTOR LITE, AND ACCESSORY LITE CLIP *

PLEASE READ BEFORE 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.

The Thompson Retractor Lite / Lite Wand 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.

INDICATIONS FOR USE:

The Thompson Lite Wand / Retractor Lite is a fiberoptic light intended to be used as part of the reusable surgical retraction system as an additional feature. It is designed to be used in conjunction with a retractor system which it can attach to through the use of a Cam Joint and/or **single use** Lite Clip. The Lite is designed to provide visible illumination of the surgical field or the patient and must be used with 300W and lower Xenon and LED light sources meeting IEC 60601 or equivalent national standards only. The Lite is designed to be used by surgeons and other medical care practitioners in a surgical setting.

NON STERILE Thompson Surgical products are supplied non-sterile.

ALL INSTRUMENTS MUST BE INSPECTED, CLEANED, AND STERILIZED PRIOR TO EACH USE.

SCOPE:

This IFU provides information for the cleaning and sterilization of illumination products 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.

MRI COMPATIBILITY STATEMENT:

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

WARNINGS, PRECAUTIONS, RESIDUAL RISKS, AND UNDESIRABLE EFFECTS:

Medical professionals, including processing 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 damage, burns, electrical shocks, can occur if Retractor Lite is not used according to this IFU and product support literature. References to "patient injury" in this IFU shall encompass the preceding definition.

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 and Retractor Lite / Lite Wand in patients with known sensitivities to certain materials or preexisting conditions. Patient could have allergic or infectious consequences if known sensitivities are not considered.

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.

1. Do not use illumination products if damaged.
2. Do not operate Lite while hot. Operating Lite while hot could lead to user or patient injury. Allow Lite to cool to avoid breakage.
3. Do not allow Lite to contact any sharp edges or pointed objects. Extensive fiber breakage could occur.
4. Do not leave end-fitting face unprotected; scratches can degrade performance.
5. Do not abuse, kink, pull, or stretch Lite. Damage to enclosed glass optical fibers will result in light transmittal losses.
6. Do not attempt to slide Lite Clip off distal end of Lite. Instead, push Lite Clip off the side of the Lite with fingers.
7. Do not lever off of Lite or Lite Clip when attached to retractor blade with other instrumentation to avoid damage to the Lite or Lite Clip and potential subsequent patient injury.
8. Do not soak Lite in Cidex. Employ only the sterilization measures stipulated in this IFU.
9. Do not drape or cover any end of fiber optic cable with any flammable material or item.
10. Product contains silicone.
11. Do not use Lite Clip on lateral lipped blades or blades thicker than 2mm. May cause Lite Clip to weaken or break.

PROCESSING / REPROCESSING INSTRUCTIONS

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

Illumination products must be manually cleaned prior to Sterilization. Use caution when handling Lites after use. The proximal end could be hot; allow instrument to cool to avoid breakage. 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.

Manual Cleaning:

1. With the distal end pointing at a downward angle, use a soft bristled brush to gently scrub the instrument under warm running tap water, for a minimum of one minute.
2. Rinse and actuate the Lite to ensure all areas are accessed by the running water.
3. Using tap water, prepare an enzymatic cleaning solution according to the manufacturer's instructions, dilution recommendations, and temperatures.
4. Dip the soft bristled brush into the detergent and use it to gently scrub the Retractor Lite until all visible soil is removed.
5. Rinse the instrument under warm, gently running tap water, distal end pointing down.
6. Repeat Steps 1 – 5.
7. Dry the Lite using a clean, soft, lint-free cloth. Visually inspect the cloth to ensure no visible soil remains.**

** If visible or residual soil is found, entire Manual Cleaning process must be repeated

DO NOT immerse or rinse in cold water or other fluid, to avoid glass fiber breakage. Extensive breakage will result in light transmitting losses.

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.
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.

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 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.

Steam Autoclave Sterilization (Wrapped)				
Sterilizer Type	**Preconditioning Pulses**	**Temperature**	**Full Cycle Time**	**Dry Time**
Prevacuum	3	132ºC (270ºF)	3 Minutes 4 Minutes	30 Minutes

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.

LIMITATIONS ON REPROCESSING:

Lite will survive a maximum of 50 cycles of steam autoclave sterilization.
*Accessory Lite Clip is a single use product and will survive a maximum of 1 cycle of steam autoclave sterilization.

CONTRAINDICATIONS:

None known.

DISPOSAL:

All products must be disposed of correctly and in accordance with local and national regulations and medical guidelines.

PROPER CARE AND MAINTENANCE:
Illumination products should be utilized without alteration to their original design or fabrication. Treat the glass surfaces at each end of the Lite as you would any fine optical device. The apertures (bundle sizes) of the Lite must be matched to obtain maximum efficiency in light transmission. The Lite Wand and Retractor Lite must be used with 300W and lower Xenon and LED light sources meeting IEC 60601 or equivalent national standards only. **Replace Lite when fiber bundle light transmission output decreases by approximately 30%.**

PRODUCT WARRANTY:
Thompson Surgical Instruments, Inc. warrants all Lites free from defects in material or workmanship under normal operating use for 60 days from the date of delivery. Fibers are not warranted against breakage. Please be cautious when handling and avoid stepping on or kicking the fiber optic cable to prevent damage. Suitability for use of the Retractor Lite for any surgical procedure shall be determined by the user. Thompson Surgical shall not be liable for incidental or consequential damages of any kind. Warranty is void if the Lite is used with light sources over 300W. 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.

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

			
Manufacturer	Country of Manufacture	Date of Manufacture	Do Not Use if Package Damaged
3082	6049	2497	2606

			
Batch Code	Catalogue Number	Do Not Reuse	Non-Sterile
2492	2493	1051	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
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Medical Device	Unique Device Identifier	Not manufactured with natural rubber latex	Application Identifier for Global Trade Item Number (GTIN) per GSI Specification	Application Identifier for Lot Number per GSI Specification