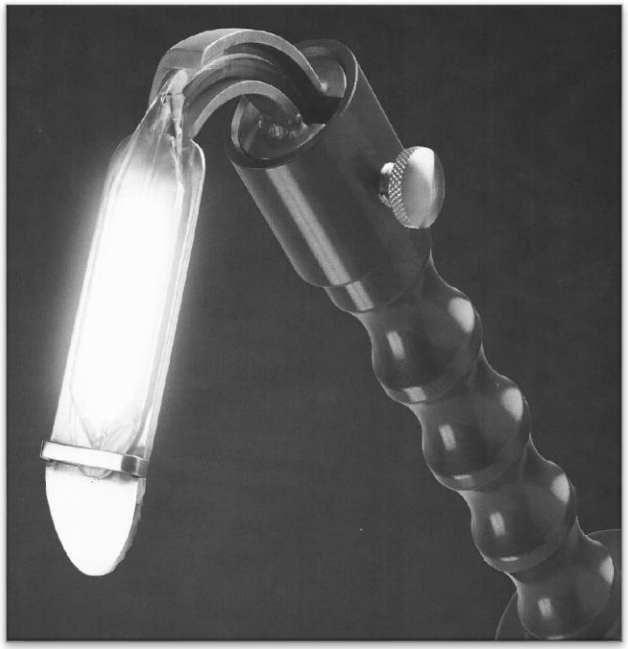
Instructions for Use Manual

TracLux™ Illuminated Retractor System



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Rx ONLY

IM16001 Rev C

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To ensure safety, this manual should be read and understood in its entirety before utilizing the TracLux™ Retractor Lighting System.

SYMBOL EXPLANATION

Non-Sterile Product – Component must be sterilized prior to use

Attention: Read Instruction Manual for Warnings Precautions and Instructions for Use.

Single Use – Do not Reuse

No Latex in Product

Rx ONLY Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

STATEMENT OF USE / PRECAUTION

The TracLux™ Retractor is a surgical hand-held lighted system designed to provide additional lighting to the surgical field. Trained personnel should understand all symbol explanations, instruction for use, assembly and disassembly guidelines including cleaning and sterilization required prior to utilizing the system.

⚠ The Disposable Light carrier is classified as a Non-Sterile, Single Use Product. The Disposable Light Carrier must be sterilized prior to its single use. ⊗ Do not use the light carrier more than one sterilization cycle as this may cause risk contamination to the product and patient injury.

All other components which include the Handle, Lock Nut, Interchangeable Blade and Fiber Optic Cable may be cleaned and sterilized prior to each use.

⚠ Do not use TracLux™ Retractor system if any components are missing or appear to be broken, cracked or warn parts which potentially could result in user or patient injury. Never leave TracLux™ Retractor unattended which potentially could result in user or patient injury.

⚠ Do not utilize any Xenon Light Source rated over 300 Watts or light source that is unfiltered as this could cause heat transmission and possible patient injury. Validate the light source prior to usage.

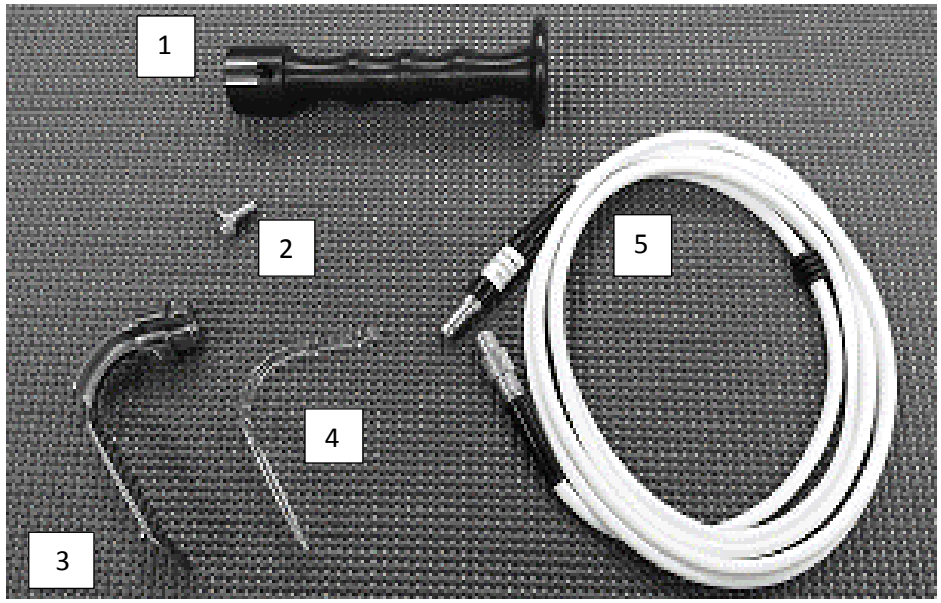
⚠ Allow fiber optic Cable to cool 10 minutes prior to disconnecting from light source otherwise could result in user injury. Never place fiber optic cable on patient or surgical drape which potentially could result in patient injury.

INSTRUCTIONS FOR USE

The TracLux™ Retractor System consists of 5 separate components which are Non-Sterile and must be cleaned and sterilized prior to each use.

⚠ The Light Carrier is Non-Sterile – Single Use only and must be sterilized prior to use and then disposed.

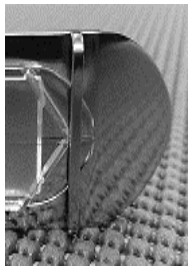
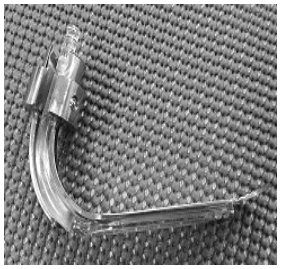
1. Handle
2. Lock Nut
3. Interchangeable Blade
4. Disposable Light Carrier ⊗
5. Fiber optic Cable – Wolf End fitting



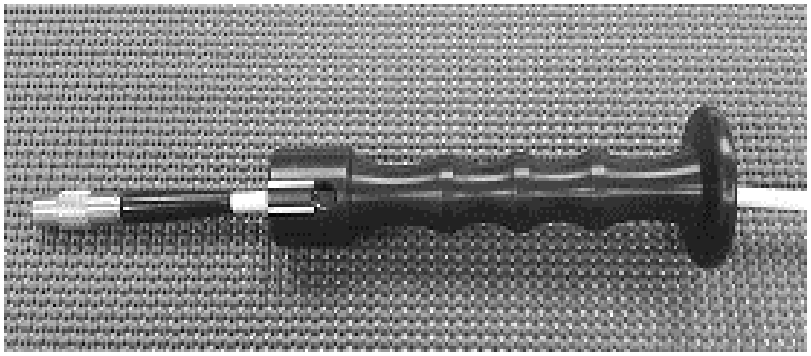
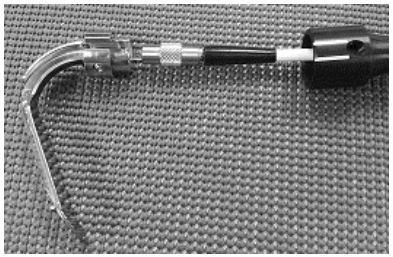
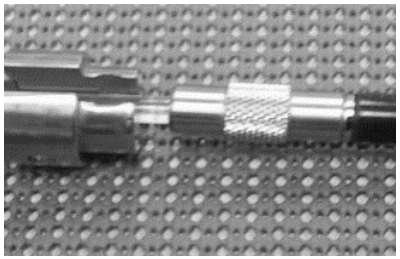
Assembly of all sterilized components are to be done in sterile environment prior to surgical use.

ASSEMBLY GUIDELINES

STEP 1: Insert light carrier into interchangeable blade. Slide the light carrier tip into the lower tab at an angle then insert curved neck into upper channel of blade.

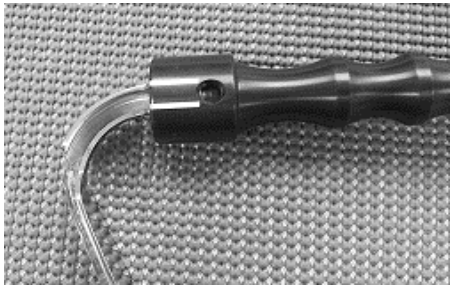




STEP 2: Slide fiber optic cable through handle. Connect cable to light carrier and make sure it is securely connected and in place.

ASSEMBLY GUIDELINES

STEP 3: Align slot in blade with parallel lines on handle and firmly snap together. Tighten locking pin into handle and pull on blade to ensure locking pin is securely engaged with blade and light carrier prior to use.




INTERCHANGING OF BLADES DURING SURGICAL PROCEDURE

Interchanging of blades must be done in a sterile environment by designated trained personnel.

Make sure the light source is not emitting light via the fiber optic cable. Intensity on the light source should be turned to OFF position.

⚠ If there is any heat detected when disconnecting the handle from the blade do not proceed and allow the system to cool prior to interchanging of blades.

Remove locking pin and disconnect blade from handle. Leave light carrier in blade and disconnect cable from light carrier. Attach cable to new light carrier and blade. Align blade into handle and lock in place according to assembly guidelines. Intensity on light source should be turn back to ON position for light transmission.

DISSASSEMBLY GUIDELINES

Allow system to cool for 10 minutes prior to disconnecting cable from light source port. Remove locking pin and disconnect blade. Leave light carrier in blade and disconnect cable. Remove light carrier from blade and dispose. Other components must be cleaned and sterilized prior to next use.

CLEANING GUIDELINES – Handle/Locking Pin/Blade

The reusable retractor components must be cleaned, functionally checked and sterilized prior to each use. Do not use a retractor with broken, cracked or warn parts. ⚠ Misuse or improper handling may result in damage, potentially resulting in user or patient injury.

Manual Processing Instructions for Use with Enzymatic Detergents for General Surgical Instruments.

Pre-Cleaning: Soak the retractor components in water for a minimum time of 5 minutes. Brush under water with a soft brush until all visible residues are removed.

Cleaning: Place reusable retractor components in an ultrasonic bath at 104°F (40°C) with 0.8% solution of enzymatic cleaner. Sonicate for 10 minutes (minimum).

Remove the reusable retractor components and flush with de-ionized water for approximately 15 seconds while using a soft brush until all detergent residue has been removed. Dry using a lint-free sterile cloth.

Note: The preparation of concentration, temperature and application time of the cleaning agent must be according to the instructions for use provided by the detergent manufacturer. Detergents must be approved for use with metal reusable general surgical instruments.

CLEANING GUIDELINES – Fiber Optic Cable

The fiber optic cable may be cleaned using a mild soap or non-oil cleaner. ⚠DO NOT use synthetic detergents or oil-based soaps. The petroleum components of these soaps may be absorbed by the silicone rubber components and may leach out during use and cause a tissue reaction. Avoid scratching glass fibers at ends of cable. Damage to fibers may reduce light transmission.

NOTE: Use a mild cleaning solution with a pH range of 5 to 9.

1. Clean thoroughly using a soft-bristled brush in a lukewarm water-soap solution to remove any possible contamination.
2. Rinse thoroughly in lukewarm water.
3. Rinse thoroughly in distilled water.
4. Allow cable to air dry prior to sterilization.

STERILIZATION GUIDELINES

After cleaning and inspection, place all retractor components in a sterilization container or packaging which will protect the instrument from the environment as well as permit sterilization. After sterilization the retractor components should remain in the sterilization container or packaging for protection from the environment and to maintain sterility.

Retractor must be sterilized in disassembled components. The following steam sterilization cycle may be used for all components, including single use light carrier:

Sterilization Method:	Prev-Vacuum
Instrument Configuration:	Wrapped
Temperature:	270°F (132°C)
Exposure Time (minimum)	4 minutes
Drying Time (minimum)	10 minutes

⚠ Use of cleaning and sterilization methods other than those provided by AcuLux must be validated by the healthcare facility using appropriate laboratory methods. For additional product details or information, please contact AcuLux, Inc.

LIGHTSOURCE GUIDELINES

The TracLux™ Retractor System was designed to be utilized with XenaLight™ XLT II light source which provides brilliant pure white light with no heat issues at the surgical site. ⚠ Light sources such as Halogen, LED are not recommended due to low output and color rendition. 300 Watt Xenon units that are properly filtered and validated to be used with other manufacturer cables may be utilized with the system but must be validated for use by user. ⚠ Do not utilize any Xenon Light Source rated over 300 Watts as this could cause heat transmission and possible patient injury.

CABLE GUIDELINES

The end fitting on the cable is designed to fit into any Wolf Port on light source. Allow cable 10 minutes to cool before disconnecting from light source. Avoid dropping the cable end fitting on hard surface to avoid fracture in the glass end fitting.

WARRANTY

AcuLux, Inc. warrants the TracLux™ Retractor System when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications when subject to normal use and service for a period of one year from date of purchase from AcuLux, Inc. or an authorized agent. Fiber optic Retractor Cables are warranted against damage at the strain relief and end fittings proving to be defective. There is no warranty on the fiber optic cable due to fiber breakage, broken clad rods due to abuse or poor handling or cable end fittings that are burned from other manufacturer's light sources. AcuLux, Inc. will either repair or

replace any components found to be defective or at variance from manufacturer's specification within this time at no cost to the customer. It shall be the purchaser's responsibility to return the product to the authorized distributor, agent, or service representative.

This warranty does not cover the product of breakage or failure due to tampering, misuse, neglect, accidents, improper installation, modification, shipping, or to improper maintenance, service and cleaning procedures. This warranty is also void if the product is not used in accordance with manufacturer's recommendations or if required service by other than AcuLux, Inc. or an authorized agent. Purchase date determines warranty requirements. No other express or implied warranty is given.

NOTATIONS

When life of this product has ended, dispose of it reliably and properly in a dedicated container and not with general waste. AcuLux, Inc. cannot advise users as to general or specific disposal regulations for federal, state/provincial, and/or local municipalities. It is the responsibility of the waste generator to ensure proper classification and disposal of waste products.

The information contained in this manual is subject to change without notice. AcuLux, Inc. makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties or merchantability and fitness for a particular purpose. AcuLux, Inc. shall not be liable for errors contained herein or for incidental consequential damages in connection with the furnishing, performance, or use of this material. For additional service on repair, parts or other inquiries contact:

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