

PART 1 – LAPAROSCOPIC ENDOSCOPES

for medical use

IMPORTANT – PLEASE READ CAREFULLY BEFORE USING

Indications for use:

Miltex® endoscopes have specific indications for use and the user should appropriately decide whether the instrument is suitable for the desired application. Miltex cannot provide any warranty for results due to incorrect application.

It is recommended that each device is used in approved endoscopic procedures by physicians experienced in the art of endoscopy. These instructions are recommended for the proper function of the device. This material is not intended as a reference for endoscopic examination or surgery, nor is it intended to replace training, including relevant preceptorship(s).

The autoclavable endoscopes are identified by the word 'AUTOCLAVABLE' on the instrument.

The endoscopes will be sold as non-sterile, reusable instruments.

For the purpose of these care and handling instructions, Miltex® endoscopes are referred to collectively as Scopes, Telescopes, Laparoscopes or Endoscopes.

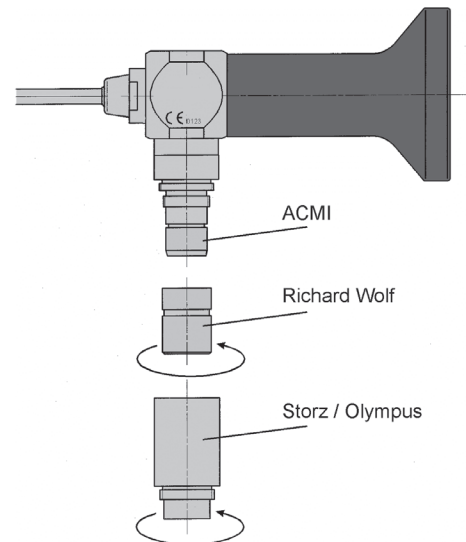
1. EXAMINING THE ENDSCOPE

The endoscope should be examined upon receipt from the supplier as well as before and after each surgery or use. Take particular care to inspect for scratches and dents on the tubing of the distal and/or proximal ends of the instrument which could be indicators of damage to the endoscope. To ensure flawless performance, look through the proximal end of the endoscope into the light while rotating the instrument clockwise. All surfaces should appear flat, shiny and without any distortion. Moisture inside the endoscope and damaged rod lenses will cause a cloudy/hazy image or possibly the complete loss of image.

Before using the endoscope, also check the light connector and distal optic surfaces to verify that they are clean and undamaged. The ACMI, Wolf, and Storz/Olympus light adaptors may need to be removed in order to inspect properly. To ensure sufficient light illumination, connect the fiber optic light source cable to the light connector/post fitting on the endoscope. The light exiting the distal end of the endoscope should be an evenly distributed ball of light without any dark areas.

Fiber Optic Light Post Adaptor Assembly:

The following demonstrates proper mechanical assembly procedures for the endoscopes. Adaptors can be used to fit most fiber optic light cable sources to the endoscope light post. Simply screw the appropriate adaptor on or off the fiber optic light post to prepare the scope for connection to the fiber optic light cable.



Cautions and warnings:

Please be aware that improper use may lead to patient injuries and/or damage to the endoscope. Due to the high energy radiated light emitted from the illumination fiber, the distal end of the endoscope may reach temperatures exceeding 41°C (108°F) within a distance of 8-10mm from the front of the scope.

To avoid burns to the patient, do not leave the tip of the endoscope in direct contact with tissue or combustible materials. Lower the light source output when working in close proximity to the object.

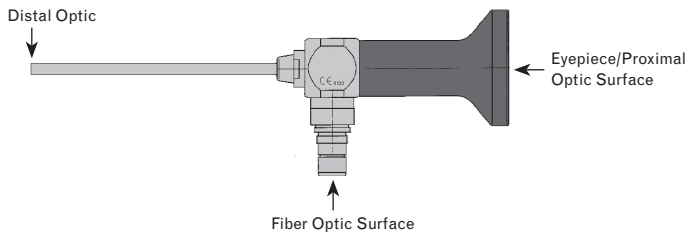
If high-frequency (HF) electrosurgical instruments are used, please take caution to ensure that the working element of such instruments is kept within field of view to prevent accidental burns. A sufficient distance from the tip of the endoscope to other conductive accessories and instruments should be maintained before activating the HF output.

Endoscopes are fragile optomechanical devices that need to be handled with caution. To avoid damage to the endoscope caused by laser burn or exposures, it is necessary to keep the laser delivery system away from all parts of the endoscope.

- *To avoid fogging during surgery, the rear proximal portion of the scope must be entirely free of moisture before it is attached to the camera or coupler.*
- *Extreme heat from steam autoclaving and the high intensity lamp will cause debris on the optical surfaces to possibly discolor, burn and harden if not properly cleaned and removed.*
- *Always hold the endoscope at the housing body and/or eyepiece.*
- *Do not bend the shaft of the scope.*
- *Avoid shaking or dropping the endoscope.*

2. CLEANING:

The endoscope has three optical surfaces that must be cleaned and inspected routinely to ensure both maximum transmission of illumination and a high quality image.



All optics and surfaces of the scope should be cleaned with warm water and a pH-neutral cleaning and disinfecting solution recommended for reprocessing medical endoscopes. Remove the light post fittings and let the endoscope soak inside the pH-neutral solution. Closely follow the manufacturer's instructions for appropriate chemical concentrations and immersion time. Thoroughly rinse the endoscope and fittings to remove the cleaning solution. After the scope and fittings are dry, inspect the instrument for any remaining stains. It is important to closely check the three optical surfaces, as detailed above, to ensure that proper cleaning has been achieved for optimum performance.

Note: Never clean and/or sterilize endoscopes together with other instruments unless they are individually secured within a specialized cleaning container.

Removing stains or deposits on optical surfaces:

Insufficient cleaning or foreign matter in steam during autoclaving process may leave deposits on any of the three optical surfaces of the endoscope. If stains or particles are still present on any of the optical surfaces after cleaning, use an enzymatic solution together with a clean gauze cloth or cotton swab and gently clean the optical surface in circular motions. Rinse the optical surfaces with distilled water to remove any remaining enzymatic solution. If stains or particles persist, repeat the previous steps with a mixture of (1:1) isopropyl alcohol to acetone applied to a fine woven cloth or lens tissue for gentle cleaning. Rinse again with distilled water and carefully dry with a soft woven cloth or lens tissue.

If stains, particles or mineral deposits still persist after following the previously described steps, use the polishing paste (see below cautionary note) which is enclosed with each endoscope. Apply a small amount to a cotton swab and gently clean/polish the optical surface in circular motions. Rinse the optical surfaces with distilled water to remove any remaining polishing paste and carefully dry with a soft woven cloth or lens tissue.

Note: Cleaning with a polishing paste should not be a part of your routine cleaning procedures and should only be applied when the image is cloudy due to deposits on the optical surfaces.

Check each optical surface with reflective light for foreign particles and scratches that could have a negative effect on the image quality.

Warning: Never use Ultrasonic Cleaners which will damage the optical system.

Warning: Prior to autoclaving and due to the extreme steam temperatures, be sure to follow the previous instructions to remove foreign particles and debris so that they do not harden onto the optical surfaces.

3. CHEMICAL DISINFECTION AND STERIS® PROCESS

Miltex® scopes can be immersed and disinfected using processes and chemical solutions clearly approved for use on endoscopes. Always follow individual chemical manufacturer instructions for proper use. The scopes are materially compatible with the Steris® sterilization process. The endoscopes should be rinsed after soaking with sterile water and dried with a sterile cloth.

4. STERILIZATION

Important: Be sure that the scope is cleaned thoroughly before sterilizing. Never clean and sterilize endoscopes together with other instruments unless they are individually secured within a specialized cleaning container. Endoscopes should be sterilized in containers that are specifically designed for the purpose of sterilization. Unless otherwise noted, it is NOT recommended to wrap endoscopes in towels. Towels may leave residue on the optical surfaces of the instrument.

4.1. GAS STERILIZATION

Follow standard hospital procedure for gas sterilization. Place scopes separately from other instruments in a container approved for general use with gas sterilization (such as perforated metal tray).

Note: Verify that there is NO contact between the endoscope and any other metal parts during the sterilization process. This will result in direct heat transfer from the tray to the instrument. Use gauze or loosely woven cloth inserts folded around each item to prevent contact with metal surfaces and to avoid movement during sterilization.

Following 10:90 Etyhlene Oxide / Oxyfume 2002 sterilization cycle as validated:

Preconditioning parameters

Temperature:	55 ± 2°C (131 ± 5°F)
Relative Humidity	≥ 35%
Vacuum:	21 ± 1 In Hg
Pre-Conditioning time	1 hour

4.1. GAS STERILIZATION (cont.)

Sterilization parameters

Ethylene Oxide Carrier:	Oxyfume 2002
Temperature:	55 ± 2°C (131 ± 5°F)
Relative Humidity:	≥ 35%
Pressure (PSIG Start):	19 ± 1 PSIG
Ethylene Oxide concentration:	736 mg/L
Gas Exposure Time (Full cycle):	4 hours
Aeration:	11 hours at 54°C (129°F) minimum

4.2. AUTOCLAVING

Caution: Scopes cannot be steam autoclaved unless “AUTOCLAVABLE” is engraved on the endoscope body. This method would otherwise permanently damage the optical components.

Before each endoscope is autoclaved, make sure that all optical surfaces of the instrument are clean and free from foreign particles (refer to Section 2). Lack of cleanliness before autoclaving can result in severe damage to the endoscope and/or reduced optical performance and shortened service life.

Always follow the standard hospital procedures for sterilization.

Place the clean endoscope in a suitable sterilization tray. A suitable tray should hold the endoscope firmly but gently in place.

Note: Verify that there is NO contact between the endoscope and any other metal parts during the sterilization process. This will result in direct heat transfer from the tray to the instrument. Use gauze or loosely woven cloth inserts folded around each item to prevent contact with metal surfaces and to avoid movement.

Important: NEVER immerse the endoscope into cold water after it has been autoclaved. Rapid temperature changes may damage the optical system and will ultimately void the warranty.

Note: Biological indicators should be used on a regular basis to ensure validated sterilization conditions.

4.2.1. GRAVITY STEAM STERILIZATION

Follow standard hospital procedure for gravity steam sterilization (double wrapped in muslin) at 132°C (270°F) for 10 minutes.

4.2.2. PREVACUUM STERILIZATION

Follow standard hospital procedure for prevacuum steam sterilization (double wrapped in muslin) at 132°C (270°F) for 3 minutes.

After completing the sterilization, the endoscope should be cooled slowly to room temperature in the autoclave.

DO NOT IMMERSE OR RINSE INSTRUMENTS IN COLD WATER OR ANY OTHER LIQUID TO ACCELERATE COOLING.

5. ELECTRICAL SAFETY

Miltex® endoscopes are primarily of metallic construction. The level of electrical isolation is determined by the manufacturer of all equipment used with Miltex® endoscopes and accessories. Experience with predicate devices has shown no safety hazards.

6. STORAGE

a. Miltex® scopes should be stored with the plastic tip protectors covering the distal working end. This will help to protect the delicate portion of the optics.

b. The scope and accessories should be stored either in their shipping box or in a sterilization tray. In either case, proper care should be taken to ensure that the scope is secured from falling or touching other instruments.

Note: Any mechanical manipulation of the eyepiece may result in seal breakage; therefore, do not attempt to remove the eyepiece.

7. SERVICE

Contact the Miltex Repair department at toll free phone number 1-866-854-8300. Miltex does not supply its optical and mechanical parts to any outside company; therefore, only Miltex or its subsidiaries are able to repair Miltex® brand medical endoscopes with original parts and to guarantee the original technical specification and safety of the product.

Additionally, this warranty is void for Miltex® instruments and products serviced by any person or facility other than the Miltex Instrument Repair Services.

8. WARRANTY

Miltex® endoscopes have a 2-year warranty against defects in workmanship and material. Any Miltex endoscopes that prove defective in workmanship or material will either be repaired or replaced at our discretion, without charge. Our liability under this warranty shall be limited to repair or replacement of defective merchandise. This warranty is a limited warranty and is the only warranty made by Miltex. Miltex makes no other warranty, expressed or implied, including any warranty of merchantability and fitness for a particular purpose.

PART 2 - LAPAROSCOPIC SURGICAL HAND INSTRUMENTS for medical use

IMPORTANT – PLEASE READ CAREFULLY BEFORE USING

Indications for use:

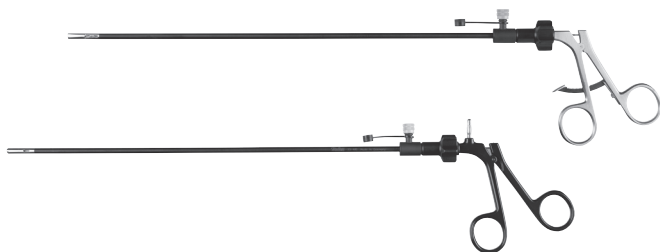
Miltex® laparoscopic surgical hand instruments have specific indications for use and the user should appropriately decide whether the instrument is suitable for the desired application. Miltex cannot provide any warranty for results due to incorrect application.

These instructions are applicable to Miltex® laparoscopic instruments and should be followed to prevent damage to instruments. Damage resulting from instrument misuse and improper care may void the product warranty.

Optimal function of the instruments and longer service life can be achieved when the following instructions are observed:

- Follow instructions for proper cleaning and care of your instruments.
- Handle the instruments with care.
- Avoid contact with other electrosurgical instruments during use. This could result in damage to the protective insulation coating.
- Do not bend or kink instrument sheaths.
- Make sure that insulation of instruments is not damaged via sharp edges or other instruments during use and during cleaning and sterilization.
- Do not drop instruments or hit against hard surfaces.
- Check function of joints and connectors regularly. Use instruments only for the surgical purpose for which they have been designed.
- Avoid excessive force on the instruments.
- Laparoscopic instruments should only be used by trained and authorized personnel.
- Sterilize before use. This instrument is not provided sterile.

Stainless steel and temperature resistant plastic materials are used in the manufacture of laparoscopic surgical instruments. Silicone rings and washers are used as seals on sheaths and other components.



1. CLEANING

Immediately after each use and to prevent residual proteins from drying on instruments, instruments should be fully immersed in appropriate neutral-pH cleaning and disinfecting solution recommended for reprocessing of laparoscopic surgical instruments. Closely follow the cleaning and disinfectant manufacturer instructions for chemical concentration and immersion time recommendations. Plain water washing is not considered adequate. It is recommended that fresh solutions be used every day. Higher concentration and prolonged immersion time may cause corrosion or other damage to the instruments. Always avoid overnight or weekend holding or soaking.

Manual Disinfection and Cleaning:

For *Manual Disinfection and Cleaning*, use a soft nylon brush to gently remove any exterior dirt and debris. Instruments are equipped with a LUER-LOCK connection which should be opened and force flushed using the appropriate equipment and pressure flushing system. A water jet gun should be used on the jaws, joints, handles and the inside of sheaths. After cleaning and disinfection, the instruments should be thoroughly rinsed, both on the exterior and interior sheath, with distilled water. Immediately dry instruments to prevent corrosion. Drying can be performed manually, but a compressed air pistol is recommended for more delicate instruments and is more effective for overall drying.

Thoroughly inspect instruments for effective cleaning (free from any visible dirt and residue). Also inspect the instruments for any damaged, worn, corroded, pitted/porous conditions and ensure proper function. Contact Miltex if damage is observed and if repair is necessary. Apply non-silicone instrument lubricant (such as Miltex REF 3-700 Instrument Spray Lube) to the joints and jaws of the instrument to ensure easy movement. **Caution: Do not oil electrical connections on instruments.**

Machine/Mechanical Disinfection and Cleaning:

For *Machine/Mechanical Disinfection and Cleaning*, follow equipment manufacturer's instructions carefully. Instruments should be stored in carriers or fixed in suitable trays which are intended for cleaning and to prevent movement during instrument processing. Instruments with jaws such as forceps, graspers, scissors, dissectors and needle holders must have the jaws in an open position before cleaning. Instruments equipped with a LUER-LOCK connection should be opened and force flushed using the appropriate equipment and pressure flushing system. Distilled water is recommended to be used as the final rinse to avoid water staining and corrosion on the instrument. Follow equipment manufacturer's drying cycle recommendations. It is recommended that the interior sheath be further manually dried via compressed air pistol to ensure effective internal drying.

Thoroughly inspect instruments for effective cleaning (free from any visible dirt and residue). Also inspect the instruments for any damaged, worn, corroded, pitted/porous conditions and ensure proper function. Contact Miltex if damage is observed and if repair is necessary. Apply non-silicone instrument lubricant (such as Miltex REF 3-700 Instrument Spray Lube) to the joints and jaws of the instrument to ensure easy movement. **Caution: Do not oil electrical connections on instruments.**

Ultrasonic Cleaners:

Ultrasonic Cleaners can also be used for cleaning and removal of contamination and debris. Follow the Ultrasonic Cleaner manufacturer's recommendations for cleaning agents, fill levels, temperature, processing time, etc. Make sure that functional parts do not touch other instruments and all jointed instruments are processed in an open position. We recommend pre-flushing instruments via the equipped LUER-LOCK connection which should be opened and force flushed using the appropriate equipment prior to immersion in the ultrasonic bath. After cleaning and disinfection, the instruments should be thoroughly rinsed, both on the exterior and interior sheath, with distilled water. Immediately dry instruments to prevent corrosion. Drying can be performed manually, but compressed air pistol is recommended for more delicate instruments and is more effective for overall drying.

Thoroughly inspect instruments for effective cleaning (free from any visible dirt and residue). Also inspect the instruments for any damaged, worn, corroded, pitted/porous conditions and ensure proper function. Contact Miltex if damage is observed and if repair is necessary. Apply non-silicone instrument lubricant (such as Miltex REF 3-700 Instrument Spray Lube) to the joints and jaws of the instrument to ensure easy movement. **Caution: Do not oil electrical connections on instruments.**

Warning: Ultrasonic cleaning should never be used for endoscopes and instruments with tungsten carbide inserts.

2. STERILIZATION

Steam sterilization should be carried out by steam under pressure in the complete absence of air in an autoclave set at 134° C as follows:

- Temperature 134°C, Sterilizing time = 5 min.

Instrument jaws and ratchets must be in open position to avoid damage during the sterilization heating and cooling process. Always follow the autoclave manufacturer instructions and recommendations. For autoclaving, place the instruments in a suitable container or sterilization tray. Cutting edges and tips of instruments should always be protected with a soft cloth.

After autoclaving allow all components cool down to room temperature. Sudden changes in temperature may cause damage to the instruments.

3. GAS STERILIZATION

Place the pre-cleaned instrument in a transparent aseptic package. It is recommended to cover tips and cutting edges of instruments to avoid perforation of the packaging. Follow the instruction manual of the manufacturer of the gas sterilization equipment and observe domestic health care regulations. Allow sufficient time for ventilation to remove toxic residues.

4. SERVICE

Contact the Miltex Repair department at toll free phone number 1-866-854-8300. Miltex does not supply its mechanical parts to any outside company, therefore only Miltex or its subsidiaries are able to repair Miltex® brand laparoscopic instruments with original parts and to guarantee the original technical specification and safety of the product.

Additionally, this warranty is void for Miltex® instruments and products serviced by any person or facility other than the Miltex Instrument Repair Services.

5. WARRANTY

Miltex® laparoscopic surgical hand instruments have a 1-year limited warranty against defects in workmanship and material which excludes wear to blades and jaws. Any Miltex laparoscopic instruments that prove defective in workmanship or material will either be repaired or replaced at our discretion, without charge. Our liability under this warranty shall be limited to repair or replacement of defective merchandise. This warranty is a limited warranty and is the only warranty made by Miltex. Miltex makes no other warranty, expressed or implied, including any warranty of merchantability and fitness for a particular purpose.

6. **SYMBOLS** / SÍMBOLOS / SYMBOLES / SYMBOLE AUF DEN ETIKETTEN /
SIMBOLI UTILIZZATI SULLE ETICHETTE / GEBRUIKTE SYMBOLEN OP LABELS



Caution / Precaución / Avertissement / Achtung / Attenzione / Let op



Consult Instructions for Use / Consulte las Instrucciones de uso / Consulter le mode d'emploi /
Gebrauchsanweisung beachten / Consultare le Istruzioni per l'uso / Raadpleeg de Gebruiksaanwijzing



Product complies with requirements of directive 93/42/EEC for medical devices / El producto cumple con los requisitos de la directiva 93/42/EEC para dispositivos médicos / Produit conforme aux exigences de la directive 93/42/CEE relative aux dispositifs médicaux / Das Produkt erfüllt die Anforderungen der Richtlinie 93/42/EWG für medizinische Geräte / Il prodotto è conforme ai requisiti della direttiva 93/42/CEE per i dispositivi medici. / Product is in overeenstemming met de vereisten van richtlijn 93/42/EEC voor medische hulpmiddelen



Batch Code or Lot Number / Código partida o Número de lote / Code Lot / Numéro de lot / Loscode /
Chargennummer / Codice del lotto / Numero di lottor / Chargecode / partijnummer



Catalog Number / Número de catálogo / Numéro de catalogue / Catalog Number / Catalog Number / Catalog
Number



Manufacturer / Fabricante / Fabricant / Hersteller / Produttore / Fabrikant



Authorized Representative in the European Community / Representante autorizado en la Comunidad Europea / Représentant autorisé dans la Communauté Européenne / Autorisierte Vertretung in der Europäischen Union / Rappresentante autorizzato per la Comunità Europea / Geautoriseerd vertegenwoordiger in de Europese Gemeenschap



Latex-free / No contiene látex / Sans latex / latexfrei / Privo di lattice / Latexvrij



Rx Only: Caution: Federal (US) law restricts this device to sale by or on the order of a physician. / Sólo por prescripción médica: Precaución: La ley federal (EE.UU.) restringe la venta de este dispositivo a médicos o por prescripción médica. / Uniquement sur ordonnance : Attention : Selon la loi fédérale des États-Unis, ce dispositif ne peut être vendu que par un médecin ou sur ordonnance médicale. / Nur Rx: Achtung: Das US-Bundesgesetz beschränkt dieses Gerät auf den Verkauf durch oder auf Anweisung von einem Arzt. / Solo Rx: Attenzione: la legge federale degli Stati Uniti limita la possibilità di commercializzare questo dispositivo ai soli medici o dietro presentazione di ricetta medica. / Rx only: Let op: De federale wet in de VS beperkt de verkoop van dit instrument tot door of op voorschrift van een arts.



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