CAPITAL
medical resources

Rigid Autoclavable Endoscopes

Instructions for Use

PRIOR TO USE: All instruments are carefully inspected before shipment. Because damage may occur in transit, please inspect the instrument thoroughly upon receipt and prior to use. Do not use if the scope is damaged in any way.

CAUTION: All scopes are reusable, and packaged non-sterile. They must be cleaned and sterilized prior to use.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

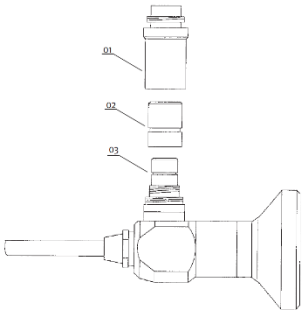
INDICATIONS FOR USE: For use by, or as directed by, a surgeon in endoscopic surgery. Scopes should be handled and operated by personnel completely familiar with their use.

ASSEMBLY:

Light Cable Connection. Select appropriate light cable connection by screwing on adaptor to light post connection.

1. Storz® / Aesculap® / Olympus® Adaptor
2. Wolf® Adaptor
3. ACMI® Connection (no adaptor)

See diagram (next)



HANDLING: Always handle the scope with extreme care to prevent damage to the internal and external lenses of the scopes. Always grasp by the eyepiece or body, not the scope shaft. Do not allow other instruments to come in contact with the scope or be placed on top of the scope. Gently insert and remove the scope from any cannulas or sterilization trays being careful not to stress the insertion tube.

DANGER OF BURNS OR FIRE!

- During use, the distal end and the light cable connection can become very hot. Avoid direct contact with tissue and flammable materials. If possible do not select the maximum illumination setting on the light source, but only the brightest level that is required.
- When operating the device with RF electrodes, ensure that the active electrode is always within the field of view and there is no contact with the endoscope or other metal components of the instruments.
- In the case of laser surgery, do not use reflective objects in the working area and do not direct the laser beam toward the endoscope.

RECOMMENDED CLEANING PROCEDURE: As with any cleaning procedure, personnel should follow accepted guidelines for hand washing, personal protective attire, etc. as those recommended by AAMI Standard and Recommended Practices.

Removable parts such as light guide connectors and adaptors should be removed and cleaned and sterilized separately (See Image at left for reference). Any stopcocks should be put in the "open" position.

STEP 1: Maintain Moisture: Immediately after use, place the scopes in a tray/container and cover with a towel moistened with sterile distilled water or use enzymatic foam to keep the scopes moist.

STEP 2: Enzymatic Soak: Immerse scopes in an approved enzymatic solution per manufacturer's instructions making sure to carefully follow recommendations for solution concentration and soak times.

STEP 3: Rinse: Rinse thoroughly with tap water.

STEP 4: Clean Scopes: Using a small, soft-bristled cleaning brush, clean the optical portions of the scope while immersed in cleaning solution. Clean the shaft by wiping with a soft cloth. Clean the distal window, eyepiece window and fiber end of the light post with a cotton tip applicator or soft cloth moistened with 70% isopropyl alcohol. **DO NOT use coarse abrasives or metal brushes in the cleaning process.**

STEP 5: Rinse: Immerse and rinse in demineralized water and wipe with a clean, lint-free cloth.

STEP 6: Visual & Functional Inspection: Visually inspect the scope.

- **Visually Inspect Lens Surfaces**: Using magnification, inspect the distal and eyepiece windows for any disinfectant residue, fingerprints, scratches, chips or missing glass.
- **Visually Inspect the Image:** Look through the scope at close up surface. The image should be sharp, bright and unclouded. If defects in the image are present (haziness, partial image, spots, etc., re-clean the distal and eyepiece lenses with alcohol and

recheck.) If problems still persist do not use as scope may be unsafe for patient use.

- **Visually Inspect for External Damage:** Check for any external damage such as dents, sharp edges or bent scope).
- **Inspect light transmission:** Visually inspect light fibers by looking at the light post fibers and distal fibers while holding the opposite end up to a light. Excessive broken fibers (black dots) or burnt or yellow fibers may indicate repair is needed.

STEP 7: Dry: Scopes must be thoroughly dried prior to sterilization using a soft cloth or compressed air.

CAUTION: DO NOT PLACE IN ULTRASONIC CLEANER OR WASHER-STERILIZER!

CAUTION: DO NOT USE DAMAGED ENDOSCOPES. RISK OF PATIENT INJURY!

NON-AUTOCLAVABLE SCOPE STERILIZATION:

After cleaning the scope (following the above 7-step cleaning process) the scope is ready for sterilization.

ETO PARAMETERS:
Gas: 6% Ethylene Oxide, 94% Carbon Dioxide
Chamber Pressure: 25p psi (1.7 bar)
Temperature: 131 Degree F (55 Degree C)
Exposure Time: 60 Minutes
Packaging: Standard sterilization bags made of paper laminate
Aeration Time: 24 hours room temperature

AUTOCLAVABLE SCOPE STERILIZATION:

After cleaning the scope (following the above 7-step cleaning process) the scope is ready for sterilization.

AUTOCLAVE PARAMETERS:

- Pre-vacuum cycle.
- Packaging: Wrapped or containerize scopes
- Temperature: Max 273°F (134°C) plus tolerance according to DIN EN ISO17665
- Exposure Time: At least 3-5 Minutes at 132°- 134°C
- Cooling: After sterilization the scope must be allowed to cool at room temperature. DO NOT attempt to accelerate the cooling process as lens and seal damage can result.

Only scopes marked "Autoclave" or "Autoclavable" can be processed in this method.

STERRAD® & STERIS®

Consult the sterilizer manufacturer to ensure the items are suitable for sterilization and closely follow their instructions for reprocessing each device.

Basic stability of the materials used in the manufacturing are compatible with these low-temp methods. However it is NOT recommended to switch back and forth between sterilization methods as stress on the metals and adhesives may result.

The Steris® System (Steris, Mentor, Ohio) uses peracetic acid in a proprietary liquid processor to sterilize items in less than 30 minutes at 50-55°C. This method is a just-in-time process and sterility cannot be maintained for long term storage.

Sterrad® (Advanced Sterilization Processes of Irvine, Calif.) uses plasma and/or vapor phase are another sterilization modality for endoscopic instruments. It is FDA-approved for use in the United States. Check with the company for restrictions on lumen sizes which have been approved.

Use of these methods of sterilization may cause cosmetic changes to the devices that may not necessarily impact the functionality of the equipment.

REPAIRS AND MAINTENANCE:

Should your instrument require repair or maintenance, contact Capital Medical Resources at 614-657-7780 or info@capitalmedicalresources.com for Return Authorization and address. Please ensure that all instruments for repair are thoroughly cleaned and sterilized prior to sending in for repair.

STORAGE:

Following sterilization, store the endoscopes in a sterilizing container or single/double sterile packaging unit until they are reused. The storage location must be dust-free, of low microbiological contamination, dry, dark and free from temperature fluctuations.

DISCLOSURE:

Capital Medical Resources, its subsidiaries and Manufacturer exclude all warranties, except Capital Medical Resources' applicable standard warranty whether expressed or implied, including but not limited to, any implied warranties or merchantability or fitness for a particular purpose. Neither Capital Medical Resources nor manufacturer shall be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from use of this product. Neither Capital Medical Resources nor Manufacturer assume nor authorize any person to assume for them any other or additional liability or responsibility in connection with these products. We accept no liability in the case of improper handling, incorrect or inadequate preparation or unauthorized use or repairs.