

Rigid Endoscope User Manual

ENDOSCOPE – RIGID WITHOUT WORKING CHANNEL - USER INFORMATION

IEC-InnoView GMBH Endoscopes are precision instruments. Please treat each Endoscope with great care, so it will provide you with many years of service. This leaflet contains important information. Please read the following text thoroughly.

1. Indications for use

Provide illumination and visualization in:

- Diagnostic procedures and in conjunction with instruments operative arthroscopic procedures

- Rotator cuff procedure
- Repair or resection of torn cartilage (meniscus) from knee or shoulder
- Reconstruction of anterior cruciate ligament in knee
- Removal of inflamed lining (synovium) in knee, shoulder, elbow, wrist, ankle
- Release of carpal tunnel
- Repair of torn ligaments
- Removal of loose bone or cartilage in knee, shoulder, elbow, ankle, wrist

- Endoscopic examination and treatment of the nasal cavities and nasal pharynx etc.

IEC-InnoView GMBH Rigid Laparoscopes

Provide illumination and visualization in:

- Diagnostic procedures and in conjunction with instruments operative laparoscopic procedures.

- Unexplained pelvic pain (acute, chronic)
- Infertility work-up
- Tubal sterilization
- Diagnosis and/or treatment of ectopic pregnancy

- Evaluation, diagnosis and/or treatment of pelvic tumors, incl. myomata (less than 16 weeks gestational size)
- Retrieval of foreign bodies
- Determination of the presence and extent of pelvic endometriosis
- Determination of the presence and extent of pelvic inflammatory disease (if not in acute stage)
- Access to abdomen for surgical procedures such as LAVH
- Visualization, diagnosis and/or treatment of perforate abdominal (pelvic organs) etc.

IEC-InnoView GMBH Rigid Cystoscopes

Provide illumination and visualization in:

- Diagnostic procedures and in conjunction with instruments operative urological procedures.

- View interior of male bladder
- Diagnosing disorders of the urinary tract
- Removal of stones that have formed in the urinary tract
- Removal of cancers
- Treat prostate enlargements
- etc.

IEC-InnoView GMBH Rigid Hysteroscopes

Provide illumination and visualization in :

- Diagnostic Hysteroscopy

- Abnormal Uterine Bleeding
- Infertility & Pregnancy Wastage
- Intrauterine foreign Body
- Amenorrhea
- Pelvic Pain
- etc.

- Operative Hysteroscopy

- Directed Biopsy

- Removal of Submucous Fibroids and large Polyps
- Submucous Myomectomy
- Transection of Intrauterine Adhesion
- Transection of Intrauterine Septa
- Endometrial Ablation
- etc.

NOTE: IT IS RECOMMENDED THAT EACH DEVICE IS USED IN APPROVED ENDOSCOPIC PROCEDURES BY PHYSICIANS EXPERIENCED IN THE ART OF ENDOSCOPY.



2. Cautions and Warnings

- Improper use can lead to severe patient injuries and/or damage to the Endoscope. Due to the high energy from the illumination fiber, the distal end of the Endoscope may reach temperatures above 41°C (106°F) within a distance of 10 mm.
- To avoid burns to the patient tissue, do not leave the tip of the Endoscope in direct contact. To prevent potential safety threats to the patient caused by a defective Endoscope, always have at least one additional Endoscope (sterile) ready to be used for the current procedure.
- If High Frequency (HF) electro surgical instruments are used, keep the working element always within the field of view to prevent accidental burns. Always ensure a sufficient distance from the tip of the Endoscope with conductive accessories before activating the HF output. Only medical electrical equipment which complies with IEC 601-1 is allowed to be used with the Endoscope.
- Endoscopes are fragile optomechanical devices which need to be handled with caution. To avoid damages caused from Laser burns it is necessary to keep the Laser delivery fiber away from all parts of the Endoscope.

NOTE

- Always hold the Endoscope at the housing body and/or eyepiece
- Do not bend the tubing
- Avoid shaking or dropping
- Store and sterilize separate
- Use protective polymer tubes (IEC-InnoView GMBH accessories 70-0018-00) for storage and shipping

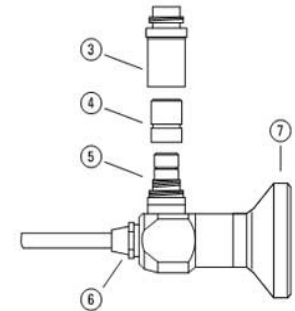
3. Operating and Maintenance Instructions

How to assemble the accessories

The Endoscope has to be checked before and after every use, whether the service performance is ok and the Endoscope has no damages. Furthermore check the light connector to make sure it is clean. Remove the Storz®, Wolf® light adapter to assure proper cleaning if necessary (see cleaning instructions).

See our diagram for the correct choice of light adapters, which screw onto the light connector.

3 Storz®/Olympus® fitting
4 Wolf®/ Dyonics® fitting
5 ACMI®/Stryker® connector
6 Storz®-sheath lock
7 Eyepiece



4. Checking the Optics

- Check the Endoscope immediately after you receive it, as well as before and after each surgery. Scratches and dents on

tubing and/or distal- and proximal end can be signs of damage to the Endoscope.

- To ensure flawless performance, look through the Endoscope (proximal end) into the light while you rotate it clockwise.
- All surfaces should appear flat, shiny and without distortion. Moisture inside the Endoscope as well as damaged rod lenses cause a cloudy/hazy image or complete loss of the image.
- To ensure sufficient light coverage, connect the light fiber cable/light source to the light connector/adaptor of the Endoscope.
- The light exiting the distal end has to be an evenly distributed ball of light without any dark areas.

2. Repeat step one, but now use Isopropyl alcohol instead and rinse again with distilled water.
3. Repeat step one, but now use Acetone instead and rinse with distilled water.
4. Check each surface with reflective light for foreign particles and scratches, which could have a negative effect to the image quality.

How to remove mineral deposits

Use the **IEC-InnoView GMBH** water based Mineral Fluid (Article # 10-0199-00) together with a Q-Tip to remove deposits from optical surfaces. Soak the end of the Q-Tip with the Mineral Fluid, squeeze it slightly onto the optical surface and continue circular motions to remove the deposit. Afterwards rinse the surface with tap water and use a very soft brush to remove the Mineral fluid.

NOTE

This is **NOT** part of your routine cleaning. Use the water based Mineral Fluid only if the image is cloudy due to deposits on the optical surfaces.

NEVER use **Ultrasonic Cleaners**, because it will damage the optical system. The extreme steam temperatures caused during autoclaving will harden foreign particles on the optical surface which may lead to a decrease in image quality or a complete loss of the image.

Sterilization

IEC-InnoView GMBH Endoscopes must be sterilized in Sterilization-Containers, which are specifically designed for the purpose of sterilization. Each Endoscope is individually secured inside the container. It is not recommended to wrap Endoscopes in towels (if the image quality is not sufficient). Towels may leave residue on the optical surfaces.

6. NON-autoclavable Endoscopes

Endoscopes **NOT** marked “**autoclave**” are not allowed to be used in temperatures above 60°C (140°F). It can cause damage to the optical components and will ultimately lead to the expiration of your warranty. Please use chemical solutions which are designed specifically to sterilize instruments and devices (always adhere to the manufacturers instructions).

1. Chemical Sterilization and Steris™ Process. This process currently not allowed by the FDA. For information

<http://www.endoscopy.md/clientuploads/pdf/STERIS%20System%201%20%202-22-10%20Letter.pdf>

InnoView GMBH Endoscopes can be placed in a disinfectant solution and must then be sterilized according to the manufacturers recommended sterilization process. **InnoView GMBH** Endoscopes comply with the Steris™ procedure.

7. Autoclavable Endoscopes

- Only Endoscopes which are marked “autoclave” can be autoclaved !
- Before each Endoscope can be autoclaved, make sure that all optical surfaces are without any foreign particles and the Endoscopes are thoroughly cleaned. Lack of cleanliness before autoclaving can result in severe damage to the Endoscope.
- Carefully secure the Endoscope inside the Sterilizing-Container and make sure it does not touch any other metal objects (instruments/container...)
- Recommended steam sterilizing cycle: 134°C (273°F) over a period of 5-8 minutes.
- Please keep the Sterilizing-Container closed until it has cooled to room temperature. **NEVER** immerse the Endoscope into cold water after it has been autoclaved. Rapid temperature change may damage the optical system and will ultimately void the warranty.

IMPORTANT

NEVER immerse the Endoscope into **cold water** after it has been autoclaved. Rapid temperature change will damage the optical system and will ultimately void the warranty.

Please, use biological indicators on a regular basis to ensure compliant sterilization conditions.

8. Storing

Always use the **InnoView GMBH** polymer tube protector (if provided with the specific Endoscope) for storing as well as the original shipping box (including foam inserts). Always make sure that Endoscopes are stored separately and secured from falling or touching other instruments.

9. Repair Exchange Program

IEC-InnoView GMBH offers a brand new Endoscope to it's dealers which will provide a drastic price reduction in exchange of the old, damaged Endoscope to the hospital.

10. Conformity

InnoView GMBH Endoscopes are CE approved P CE 0124 and have FDA approval P 510 (K)

11. Warranty

InnoView GMBH Endoscopes come with a 2 year minimum warranty. Fluid invasion **WITHOUT** mechanical damage. **NO** warranty on shaver-cut Endoscopy distal tip, broken Rod Lenses and tubing due to mishandling, HF-burnt distal tip etc.

Repairs and modifications performed by unauthorized professionals will lead to the expiration of the warranty.



I N N O V I E W

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5. Cleaning Instructions

NOTE

Never clean and sterilize Endoscopes together with other instruments unless they are individually secured in one container.

IEC-InnoView GMBH Endoscopes must be cleaned with a PH-neutral cleaning solution which is recommended by the manufacturer for reprocessing of medical Endoscopes. Remove the light adapter and let the Endoscope soak inside the PH-neutral solution according to the manufacturers specifications. Ensure the thorough rinsing of the Endoscope and adapters to remove the cleaning solution. After the Endoscope and the adapter are dry, assemble both.

Each Endoscope has three optical surfaces which constantly need to be checked and cleaned for optimum performance:

- Distal End
- Proximal Window
- Fiber Optic Light Connector

Recommended Cleaning Procedure

1. Use an Enzymatic Solution together with a gauze cloth to clean each of the above mentioned surfaces. Afterwards rinse the Endoscope thoroughly with distilled water.