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

- 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.

- 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

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

IEC-InnoView GMBH Rigid Hysteroscopes

Provide illumination and visualization in:
- Diagnostic Hysteroscopy

- 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.

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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 threads 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.

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.

4. Checking the Optics

- Check the Endoscope immediately after you receive it, as well as before and after each surgery. Scratches and dents on
1. Chemical Sterilization and SterisTM Process. This process currently not allowed by the FDA. For information http://www.endoscopy.md/clientuploads/pdf/STERIS%20System%201%2020%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 SterisTM 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.

8. Storing

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.

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 ( CE 0124 and have FDA approval ( 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.

INNOVIEW

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