



Indications for Use

Instrumed Laparoscopes and Accessories are intended to be used by qualified physicians to provide access, illumination and visualization of internal structures and for manipulating soft tissue (grasping, cutting, coagulating, dissecting, and suturing) in a wide variety of diagnostic and therapeutic laparoscopic/urologic closed and minimally invasive procedures.

Caution: Federal U.S. laws restrict this device to sale by or on the order of a physician only. Special safety precautions should be observed when using electrosurgical instruments. Electrosurgical instruments can pose a significant shock, burn or explosion hazard if used improperly, incorrectly or carelessly.

Caution: Please refer to the labelling and user manual for the electrosurgical generator for additional information on contraindications on electrosurgical or laparoscopic use.

Cautions & Warnings:

Avoid touching or grounding electrosurgical instruments to non-insulated instruments, scopes, trocar sleeves, etc. All persons using such devices should be knowledgeable in the use and handling of laparoscopic instruments, laparoscopes, coagulation equipment, their accessories and other related equipment.

Test all instruments, accessories and equipment prior to each use. Written standard operating procedures for cleaning, sterilization, storage, inspection and maintenance of the instruments, accessories and equipment are recommended.

To avoid tissue carbonation, the operating voltage of the HF generator must not exceed 650 peak voltage (Vp) for all monopolar electrodes.

Do not use electrosurgical instruments on patients with pacemakers.

Do not use in presence of flammable liquids or anaesthetics.

Electrosurgical generators used with these devices are designed to cause destruction of tissue and are inherently dangerous if operated improperly. Follow all safety precautions and instructions supplied by the manufacturer of the electrosurgical generator.

The electrode tip must always be in full view before activating power. Apply power only when electrode tip is in full contact with the tissue selected for coagulation. Electrode tip must not come in contact with the laparoscope or other metal instruments during use.

Failure to observe these cautions and contraindications may result in injury, malfunction or other unanticipated occurrences or events for the operator, staff and/or the patient.



Contraindications

Contraindications to endoscopic procedures, not necessarily monopolar coagulation include; Not intended for contraceptive coagulation of the fallopian tube but may be used to achieve hemostasis following transection of the tube.

As identified in the Manual of Endoscopy available from the American Association of Gynecologic Laparoscopists: The presence of large pelvic or pelvic-abdominal masses, hypovolemic shock and severe cardiac decompensation. Also, intestinal obstruction and marked bowel distention, increase of possibility of pelvic and abdominal adhesions. A significantly elevated diaphragm contra-indicates the use of insufflation which may be necessary for proper surgical visualization and may increase the chance of inadvertent bowel injury. Pelvic abscess, chronic pulmonary disease, diaphragmatic hernia, obesity, and septic peritonitis may exclude some patients from surgical consideration depending on severity of these conditions.

Decontamination / Cleaning / Sterilization

Initial use of new instruments: Every instrument must be cleaned and sterilized before it is used for the first time. These instruments were developed for sterilization by autoclave.

Limits on Reprocessing

The useful life of monopolar electrodes is ≤ 50 cycles and ≤ 2 years.

Inspection and functional check: It is very important to carefully examine each surgical instrument/scope for breaks, cracks or malfunction before use. It is especially essential to check areas such as blades, points, ends, stops and snaps as well as all movable parts. Do not use damaged instruments. Never attempt to make repairs yourself. Service and repairs should be referred to trained qualified persons only.

Cleaning and Maintenance: Every surgical instrument should be disinfected and thoroughly cleaned after each use. Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean, inspect and test each instrument carefully. Sterilize all instruments before surgery. A good cleaning and maintenance procedure will extend the useful life of the instrument.

Special attention must be paid to slots, stops, ends, hollow tubes and other highly inaccessible areas. Check insulation, cables and connectors for cuts, voids, cracks, tears, abrasions, etc.

Do not use damaged instruments. Cleaning and rinsing must take place immediately after each use for best results. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future sterilization.

Instruments must be completely cleaned and rinsed of all foreign body matter. Use warm water and a commercially available instrument pre-soak or cleaning agent. Enzymatic cleaners must be used to remove protein deposits. Follow the enzymatic cleaner's instructions and rinse thoroughly

* Do not use corrosive cleaning agents (i.e. bleach). Cleaning solutions and rinses at or near a neutral pH (7.0) are best.

* Do not use abrasive cleaners.

* Only a soft bristle brush should be used.



Decontamination / Cleaning / Sterilization (continued)

- * Immerse the entire device in detergent and clean while soaking. Use a minimum of six strokes out with an instrument brush for all inside channels. Rinse with sterile, deionized water. Repeat this procedure.
- * Can be disinfected in the washing machine up to 203°F.
- * Rinse thoroughly with distilled water.
- * Prepare for storage and/or sterilization.

After cleaning and rinsing, dry instruments completely and carefully with compressed air including inside channels and highly inaccessible areas.

Note: After cleaning and before sterilization, treat all instruments with oil which is considered as being physiologically safe, especially their blades, ends, stops, snaps, and all movable parts.

Storage and Sterilization: Instruments must be stored in a clean, dry, moisture free area. The instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect tips with cloth, gauze or tubing if stored in drawers.

Thoroughly clean instruments of all debris, tissue and foreign matter prior to sterilization. Follow the sterilizer manufacturer's instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the instruments being sterilized including the internal surface and tubes channels. Allow instrument to air cool to room temperature before use.

Standard Sterilization Method: Use steam autoclave sterilization only. Standard autoclave cycle. Steam sterilize at 270°F for fifteen (15) minutes. Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. (Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times.) Caution: Autoclave temperatures should not exceed 280°F as handles, insulation or other non-metallic parts may be damaged.

Handling: All surgical instruments must be handled with the greatest care when being transported, cleaned, treated, sterilized and stored. This is especially true for blades, fine points and other sensitive areas. Surgical instruments corrode and their functions are impaired if they come into contact with aggressive materials. The instruments must not be exposed to acids or other aggressive cleaning agents.

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NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING IS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY TO ACHIEVE THE DESIRED RESULT. THIS REQUIRES VALIDATION AND ROUTINE MONITORING OF THE PROCESS. LIKEWISE, ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.