AVALIGN
German Specialty Instruments Division

Indications for Use

Avalign 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 anesthetics.

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.

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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

NOTE: BUTTON ELECTRODES, SPATULA ELECTRODES, HOOK ELECTRODES AND NEEDLE ELECTRODES CANNOT BE DISASSEMBLED FOR CLEANING.

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.

Tools and Accessories:

Water	Cold Tap Water (<20°C/ 68°F) Warm Water (38°-49°C/ 100°-120°F) Hot Tap Water (> 40°C/ 104°F) Deionized (DI) or Reverse Osmosis (RO) Water (ambient)
Cleaning Agents	Neutral Enzymatic Detergent pH 6.0-8.0 i.e. MetriZyme, EndoZime, Enzol

Accessories	Assorted Sizes of Brushes and/or Pipe Cleaners with Nylon Bristles Sterile Syringes or equivalent Absorbent, Low Line Disposable Cloths or equivalent Soaking Pans
Equipment	Medical Compressed Air Ultrasonic Cleaner (Sonicator) Automated Washer

Point of Use and Containment:

1. Follow health care facility point of use practices. Keep devices moist after use to prevent soil from drying and removed excess soil and debris from all surfaces, crevices, sliding mechanisms, hinged joints, and all other hard-to-clean design features
2. Follow universal precautions and contain devices in closed or covered containers for transport to central supply.
3. All devices must be cleaned in the completely open and disassembled (i.e. taken apart) configuration.

Manual Cleaning:

4. Prepare neutral pH enzymatic detergent per vendor's directions. Enzol® enzymatic detergent is recommended at a preparation of 1 oz./gallon using lukewarm water.
5. Fully immerse device in the prepared detergent per labeling instructions. Allow device to soak for a minimum of 5 minutes.
6. Actuate all movable parts during the soak time to allow complete penetration of detergent to hard to reach areas.
7. Scrub the device, using a soft bristled brush (may also include a syringe and pipe cleaner), paying particular attention to movable parts, crevices, and other hard to reach areas until all visible soil has been removed.
   a. For lumen devices, flush internal lumens with detergent using an appropriately sized syringe at least 7 times with a minimum of 15mL of detergent. If available, use flush ports for flushing.
8. Rinse the device with warm water.
9. Place the device into a bath of warm water and allow device to soak for a minimum of 3 minutes. Actuate all moveable parts during the entire soak time.
10. Prepare neutral pH enzymatic detergent in the sonicator (as per vendor directions) and sonicate the instruments for a minimum of 10 minutes. Note: Enzyme solution shall be changed when it becomes grossly contaminated (bloody and/or turbid).
11. Rinse all surfaces and crevices in running reverse osmosis or deionized (RO/DI) water for a minimum of 3 minutes to remove any residual detergent or debris.
    a. For lumen devices, flush internal lumens a minimum of 3 times with RO/DI water (minimum of 15 mL) using an appropriately sized syringe. If available, use flush ports for flushing.
12. Dry the instrument with a clean, soft cloth. Filtered, compressed air may be used to aid drying.
13. Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure.

Automated Cleaning:

Note: All devices must be manually pre-cleaned prior to any automated cleaning process, follow steps 1-9. Steps 10-13 are optional but advised.

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Decontamination / Cleaning / Sterilization (continued)

14. Clean devices within a washer/disinfector utilizing the equipment and detergent manufacturers' instructions per the below minimum parameters.

Phase	Time (minutes)	Temperature	Detergent Type & Concentration
Pre-wash 1	02:00	Cold Tap Water	N/A
Enzyme Wash	02:00	Hot Tap Water	Enzyme Detergent
Rinse 1	01:00	Hot Tap Water	N/A
Purified Water Rinse	00:10	146-150°F/ 63-66°C	N/A
Drying	15:00	194°F/ 90°C	N/A

15. Dry excess moisture using an absorbent cloth. Dry any internal areas with filtered, compressed air.
16. Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure.

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.