



Millennium Surgical Corp Reusable Laparoscopic Instruments

**MILLENNIUM
SURGICAL**
SURGICALINSTRUMENTS.COM

UNMATCHED SERVICE · UNLIMITED INSTRUMENTS

822 Montgomery Ave #205
Narberth, PA 19072
(800) 600-0428

IFU-2017.01.05

Intended Use

The Laparoscopic Grasper/Dissector with monopolar electro-surgical foot switch connector is intended to be used to grasp/dissect and cauterize adventitial tissue planes between various ducts and arteries during laparoscopic surgery.

The Laparoscopic Scissors with monopolar electro-surgical foot switch connector are intended to be used to cut and cauterize adventitial tissue between various ducts and arteries during laparoscopic surgery.

The Endoscopic Non-Electrosurgical 5mm and 10mm Fan Retractors, Laparoscopic Needle Holders and 10mm instruments without monopolar electro-surgical foot switch connector are intended to be used in endoscopic surgeries as manipulators to lift, move, clamp, extract and place or retract structures or adventitial tissue.

Caution

These instruments are not compatible with bipolar cautery cables and generators. They are intended only for monopolar cautery usage. Activating this device when not in contact with target tissue or when not in position to deliver energy to target tissues for fulguration may cause capacitive coupling. Capacitive coupling could cause burns and increases risk of shock to patient. Federal (USA) law restricts this product to sale by or on the order of a physician.

Warning & Precautions

1. Check for proper grounding of instrument and patient prior to use.
2. Laparoscopic procedures should be performed only by physicians having adequate training and familiarity with laparoscopic techniques. Refer to current medical literature relative to technique, complications and hazards prior to performing any laparoscopic procedure.
3. A thorough understanding of the principles and techniques of electro-surgery is necessary to avoid shock and burn hazard to the patient, operator, and operating room personnel.
4. The instrument tip when energized by an electro-surgical generator has the potential to burn, cut and coagulate tissue. Care should be taken when using this device as contact with surrounding tissue in the field can produce excessive tissue burn. Verify compatibility of instrumentation and ensure that electrical isolation or grounding is not compromised and that the patient is properly grounded at all times. Use lowest dial setting to achieve desired surgical effect. Check ground and connectors before increasing generator setting. Increase generator setting slowly if more current is desired.
5. Do not energize the instrument unless it is visible through the laparoscope.
6. When using electro-surgery generators be sure to follow the manufacturer's recommendations for patient and staff safety. The patient should be grounded by use of a grounding pad, which is properly connected to the electrical generator. Care should be taken when handling the electro-surgery instrument so as not to burn the patient and surgical drapes. A review of current literature on the particular procedure is suggested prior to surgery.
7. Prior to each use, inspect the laparoscopic instrument for defects. If damage is evident, do not use the instrument; please return to Millennium Surgical Corporation for repair/replacement.



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Instructions for Use of Graspers, Dissectors, Scissors, Needle Holders, and Retractors

1. Prior to use, clean and sterilize instrument as per instructions.
2. Inspect instrument for any signs of defects.
3. Under laparoscopic visualization, insert instrument through appropriate cannula, advancing until desired depth is obtained.
4. Acutate handle to grasp, cut, move, etc.

Instructions for Use of Electrosurgical Capable Instruments

Refer to generator manufacturer instructions prior to use.

1. Apply grounding pad to patient and properly connect to generator.
2. Attach monopolar electrosurgical active cord to electrosurgical connection on the instrument's handle and adjust the power, using lowest dial setting to achieve the desired surgical effect. Check ground and connectors before increasing generator setting. Increase generator slowly if more current is desired.

Care and Handling

Immediately after each surgical procedure, clean all instruments thoroughly as follows:

1. Remove gross soil from instruments with a disposable sponge moistened with water.
2. Transport the instruments to the decontamination area by means of a closed containment system. Instruments should be kept moist by adding water, or a towel moistened with water, to the transport container.
3. Prepare enzymatic cleaner according to the prescribed direction (1 part cleaner per 9 parts deionized water 10% w/w).
4. Disengage the flushing port cap (when applicable). Note: Delicate instruments should be handled with care, avoiding the use of steel wool, wire brushes and highly abrasive detergents.
5. The device should be rinsed in deionized water and brushed to remove all visible soil.
6. Using a 20cc syringe, draw 15 ml of enzymatic cleaner. Attach syringe to lure fitting and flush out the laparoscopic device. Repeat for a total of three times.
7. Using a second 20cc syringe, flush the laparoscopic device 3 times with 15 ml of deionized water, as in step 6.
8. All parts should be inspected for burrs, nicks, misalignment or bent components. Insulation material should be free of nicks, gouges, scratches and any exposed metal or breaks in the insulation.
9. Dry all components thoroughly using a towel or an air pistol to ensure removal of residual moisture which could cause erosion.
10. Since the reusable instruments require reassembly prior to use, they should be lubricated with non-silicone, antimicrobial, water-soluble solution for 30-40 seconds. Do not rinse or towel-dry after lubrication. Do not use mineral oil, petroleum jelly or silicone sprays which can inhibit sterilization and cause build-up in the crevices of the instruments. Sterilization should follow lubrication.
11. Return items to designated storage container. All ring-handled instruments should be placed on pins or racks. Instruments with flushing port caps should have the cap left in the open position. Proceed with Sterilization.



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Sterilization

Sterilization of instruments may be accomplished by steam or a chemical sterilant. Time and temperature parameters required may vary according to type of sterilizer, cycle design and packaging material. Each institution is responsible for determining the efficacy of the sterilization schedule used to sterilize this laparoscopic instrument. Please consult with the maker of your sterilizer or your facility's policy for specific guidelines and instructions. The following is provided for informational purposes:

Open flush port cap prior to sterilization.

When sterilizing by autoclave, the device should be wrapped in a lint-free surgical towel or qualified autoclave package and sterilized using the following cycles:

Gravity Sterilization Cycle

Exposure Time @ Temperature + Drying Time

30 minutes @ 250 F (121 C) + 45 minutes

15 minutes @ 270 F (132 C) + 45 minutes

10 minutes @ 275 F (135 C) + 30 minutes

Prevacuum Sterilization Cycle

Exposure Time @ Temperature + Drying Time

4 minutes @ 270 F (132 C) + 30 minutes

3 minutes @ 275 F (135 C) + 16 minutes

Note: The instrument tip, handle, and flushing port (where applicable), should be kept in the open position when sterilized.

The STERIS PROCESS employs a per acetic acid in a strong concentration at a low temperature to provide a sterile instrument in approximately 20 minutes. The STERIS PROCESS is compatible with Millennium's instrumentation. When using the system, care should be taken to ensure that instruments are properly placed in the container. Instruments must be aligned with finger grips oriented towards the top of the processor and the lumen parallel to the length of the processor. It is also recommended that the flushing port cap be removed from the port prior to system activation. This arrangement is necessary to allow free flow of the sterilant to all areas of the instrument.

1 Year Warranty

Millennium Surgical Corporation offers a one (1) year warranty against failure in normal use. This warranty does not cover routine re-sharpening and refurbishing, or repair of damage caused by misuse, or failure to care for the instrument as described in the instructions for use. It does not cover instruments after they have been repaired, refurbished, or sharpened by anyone other than a Millennium Surgical Corporation authorized repair representative.

Service

Contact: Millennium Surgical Corporation, 822 Montgomery Ave, #205, Narberth, PA 19072

To order, please contact us at 1-800-600-0428.

Warning: If this device is/was used in a patient with or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!