V. Mueller[®] Reusable Laparoscopic Instruments

Catalog Code

LA6229	LA6461	LA6461-45	LA6462	LA6466	LA6471	LA6472
LA6476	LA6504	LA6534	LA6538	LA6543	LA6558	LA6590
LA8101	LA8102	LA8103	LA8103-45	LA8104	LA8104-45	LA8105
LA8105-45	LA8105P	LA8106	LA8106-45	LA8107	LA8108	LA8108-45
LA8108P	LA8201	LA8201P	LA8202	LA8203	LA8203-45	LA8204
LA8204-45	LA8204P	LA8205	LA8206	LA8207	LA8208	LA8209
LA8209P	LA8210	LA8211	LA8211-45	LA8212	LA8213	LA8213-45
LA8214	LA8214-45	LA8214P	LA8215	LA8215-45	LA8215P	LA8216
LA8217	LA8217-45	LA8217P	LA8218	LA8219	LA8220	LA8220P
LA8221	LA8221-45	LA8222	LA8223	LA8223-45	LA8223P	LA8224
LA8224-45	LA8225	LA8226	LA8227	LA8228	LA8228-45	LA8229
LA8230	LA8231	LA8232	LA8233	LA8233-45	LA8234	LA8234-45
LA8234P	LA8235	LA8236	LA8237	LA8238	LA8238P	LA8239
LA8239-45	LA8239P	LA8240	LA8241	LA8241-45	LA8242	LA8242-45
LA8243	LA8244	LA8244-45	LA8245	LA8245-45	LA8246	LA8246-45
LA8247	LA8247-45	LA8250	LA8250-45	LA8252	LA8252-45	LA8254
LA8254-45	LA8270	LA8271	LA8272	LA8273	LA8274	LA8275
LA8276	LA8277	LA8278	LA8279	LA8280	LA8281	LA8282
LA8284	LA8300	LA8301	LA8302	LA8302P	LA8303	LA8304
LA8305	LA8306	LA8307	LA8307-45	LA8410	LA8411	LA8412
LA8415	LA8416	LA8500	LA8500-45	LA8501	LA8502	LA8503
LA8503-45	LA8504	LA8504-45	LA8505	LA8505-45	LA8506	LA8506-45
LA8507	LA8507-45	LA8508	LA8508-45	LA8509	LA8509-45	LA8510
LA8510-45	LA8511	LA8511-45	LA8512	LA8513	LA8513-45	LA8514
LA8514-45	LA8515	LA8515-45	LA8517	LA8517-45	LA8518	LA8518-45
LA8519	LA8520	LA8520-45	LA8521	LA8521-45	LA8522	LA8522-45
LA8523	LA8523-45	LA8524	LA8524-45	LA8525	LA8525-45	LA8526
LA8526-45	LA8600	LA8601	LA8602	LA8603	LA8604	LA8605
LA8606	LA8607	LA8610	LA8611	LA8612	LA8615	LA8616
LA8617	LA8627	LA8628	LA8629	LA8630	LA8705	LA8706
LA8707	LA8708	LA8710	LA8805-0	LA8805-30	LA8810-0	LA8810-30
LA8810-45						

Indications for Use

The instrument is 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. It is inserted via a trocar sleeve and is used to prepare, coagulate and cut tissue.

How Supplied

Devices are packaged as non-sterile. Cleaning and sterilization of devices must occur prior to use.

Limits on Reprocessing

For all monopolar electrodes, the useful life of this product is \leq 50 cycles and \leq 2 years.

Warning

Attention: Risk of damage- the instrument is a precision device. Careful handling is important for the accurate functioning of this product. Improper external handling (e.g. bending, banging, dropping, etc.) may cause product malfunction.

Devices shall be used in accordance with these Instructions for Use. Read all sections of this insert prior to use. Improper use of these devices may cause a serious injury. Electrosurgical instruments can pose a significant shock, burn or explosive hazard if used improperly, incorrectly or carelessly.

Improper care and maintenance of the device may render the device non-sterile prior to patient use and may cause serious injury to the health care provider or the patient.

Check for proper grounding of instrument and patient prior to use.

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. A review of current literature on the particular procedure is suggested prior to surgery.

A thorough understanding of the principles and techniques of electrosurgery is necessary to avoid shock and burn hazard to the patient, operator and operating room personnel.

The instrument tip when energized by an electrosurgical 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. Improper connections of accessories may result in inadvertent accessory activation or other potentially hazardous conditions.

Increase generator setting slowly if more current is desired.

Do not energize the instrument unless it is visible through the laparoscope.

When using electrosurgery 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 electrosurgery instrument so as not to burn the patient and surgical drapes.

Do not rest the instrument on the patient.

Prior to each use inspect the laparoscopic instrument for defects. If damage is evident, do not use the instrument; return to V. Mueller for repair/replacement.

To prevent the possibility of electrical shocks or burns, do not use devices with breaks in the insulation.

Cautions

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.

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 the presence of flammable liquids or anaesthetics.

Refer to the labeling and user manual for the electrosurgical generator for additional information on contraindications on electrosurgical or laparoscopic use.

Caution: Federal (USA) law restricts this product to sale by or on the order of a physician.

Instructions for Use of Grasper/Dissector/Scissors/Needle Holder/Retractors

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

Instructions for Use of Electrosurgical Capable Instruments

- 1. Refer to generator manufacturers' instructions prior to use.
- 2. Apply grounding pad to patient and properly connect to generator.
- 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 setting 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.
- Transport devices via the institutions established transport procedure. Instruments should be kept moist by adding water, or a towel moistened with water, to the transport container.
- 3. Prepare enzymatic cleaner.
- 4. Disengage the flushing port cap (on Instruments equipped with a flushing port cap).

Note: Delicate instruments should be handled with care, avoiding the use of steel wool, wire brushes and highly abrasive detergents. Only a soft bristle brush should be used.

- The device should be rinsed in deionized water and brushed to remove all visible soil. Special attention must be paid to slots, stops, ends, hollow tubes and other highly inaccessible areas.
- 6. Using a 20 cc syringe, draw 15 ml of enzymatic cleaner. Attach syringe to luer fitting and flush out the laparoscopic device. Repeat for a total of 3 times.
- Using a second 20 cc syringe, flush the laparoscopic device 3 times with 15 ml of deionized water, as in step 6.
- All parts should be inspected for burrs, nicks, misalignment or bent components. Insulation material, cables and connectors should be inspected for cuts, voids, cracks, tears, abrasions, nicks, gouges, scratches and any exposed metal or breaks in the insulation.
- 9. Dry all components including inside channels and highly inaccessible areas thoroughly using a towel or an air pistol to ensure removal of residual moisture which could cause corrosion.
- 10. Since the resposable 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 buildup 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.

Sterilization

Steam sterilization is recommended for these instruments. 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: This instrument tip, handle, and flushing port (where applicable), should be kept in the open position when sterilized.

Autoclave temperatures should not exceed 280°F (138°C) as handles, insulation or other non-metallic parts may be damaged.

Warranty

These CareFusion, V. Mueller distributed instruments offer a one (1) year warranty against failure in normal use and lifetime warranty against manufacturer and material defects. This warranty does not cover routine re-sharpening and refurbishing, or damage caused by overstress, mechanical shock, improper processing or failure to care for the instrument as described in the instructions for use. Alteration or modification of any of these devices will result in immediate loss of warranty.

Repair Service

Regardless of age, if any V. Mueller device requires service, return the device to an authorized repair service center. For repairs outside the U.S., please contact your local distributor.

Note: All devices being returned for maintenance, repair, etc. must be cleaned and sterilized per these instructions prior to shipment.

Contact Information

CareFusion 75 North Fairway Drive, Vernon Hills, IL 60061 U.S.A. 800-323-9088

www.carefusion.com

For domestic inquiries email: GMB-VMueller-Cust-Support@carefusion.com For international inquiries email: GMB-SIT-International-Team@carefusion.com

Other Resources

To learn more about sterilization practices and what is required of manufacturers and end users, visit www.aami.org, www.aorn.org or www.iso.org.

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