2.1 Dimensions: 11 1/2" x 11" Two side printed
2.2 Material: White stock
2.3 Color of Ink: BLACK
3.0 SUPPLIER IDENTIFICATION REQUIREMENTS: Identify each carton or bundle in a shipment with CareFusion stock number, CareFusion F.O. number, manufacturer's name, and quantity.

V. Mueller® Reusable Laparoscopic Instruments

Catalog Code

D eclaration: Reusable Laparoscopic Instruments

Laparoscopic procedures should be performed only by physicians having adequate training and familiarity with laparoscopic techniques. Refer to current medical literature relative to techniques, 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 tissues. 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.

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 dressings.

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 coagulation cables and generators. They are intended only for monopolar coagulation 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 carbonization, 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 anesthetics.

Refer to the labeling and user manual for the electrosurgical generator for additional information on contraindications to 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.
3. 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.
3. Attach monopolar electrosurgical active pad 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.
2. Transport devices via the institution’s 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.
5. 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.
7. Using a second 20 cc syringe, flush the laparoscopic device 3 times with 15 ml of deionized water, as in step 6.
8. All parts 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 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 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 (121°C) + 45 minutes
• 10 minutes @ 275°F (135°C) + 30 minutes

Pneumatic Sterilization Cycle
Exposure Time @ Temperature + Drying Time
• 4 minutes @ 270°F (121°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 over-stress, 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.
800-323-0988
www.carefusion.com
For domestic inquiries email: GMB-VMEUller-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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36-3123F

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