V. Mueller®
Take-Apart Laparoscopic Instruments 256. XXXXXX

Catalog Numbers: All products covered by these instructions for use are listed in the appendix.

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

Indications For Use
Hand held laparoscopic devices, used with a monopolar electrosurgical current, are intended to be used to grasp/dissect, cut, and cauterize adventitial tissue planes between various ducts and arteries during laparoscopic surgery.

Hand held laparoscopic devices, used without a monopolar electrosurgical current, are intended to be used as a manipulator to lift, move, clamp, extract and for grasping, cutting and/or dissecting, placing or retracting structures or adventitial tissue.

These devices are designed to be used through an abdominal portal, the opening maintained by an introducer or cannula which allows for insertion or removal of the device without damage to surrounding soft tissue.

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

Contraindications
Do not use these devices on patients with pacemakers.

Warnings
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 serious injury. In addition, improper care and maintenance of the devices may render the devices non-sterile prior to patient use and may cause serious injury to patient or health care provider.

To reduce capacitive coupling, the device should only be activated when in the activated state.

Capacitive coupling could cause burns and increases risk of shock to the patient.

When using electrosurgical 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 electrosurgical device so as not to burn the patient and/or surgical drapes.

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

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

Start with the lowest possible setting on the electrosurgical unit and gradually increase the power to achieve proper cutting and coagulation.

The energized device tip 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.

Avoid contact with uninsulated devices and do not use them in the presence of combustible/explosive gases or liquids.

Large vertical movements inside the trocar sleeve should not be carried out in the activated state.

Cautions
Devices should be handled and operated by healthcare professionals completely familiar with their use, assembly, and disassembly. Use devices for their intended surgical purposes only. Use of a device for other than that for which it is intended will usually result in a damaged or broken device.

Examples:
1. Use of a grasper to hold or guide another device.
2. Use of a delicate dissector as a grasper.
3. Use of extremely delicate scissors to cut suture.
4. Use of a 5 mm grasper or dissector instead of a 10 mm claw extractor for removal of the device through the cannula.
5. Use of a delicate dissector to remove clips.

Prior to use, all insulated devices should be inspected to ensure proper insulation. Any interruptions in the coating may compromise the safety of the device. To prevent the possibility of electrical shocks or burns, devices with breaks in the insulation should be returned to an authorized repair service center for repair or replacement.

Only the cleaning and sterilization processes which are defined within these instructions for use have been validated.

Do not use devices if they do not satisfactorily perform their intended function or have physical damage.

Avoid mechanical shock or overstressing the devices which will cause damage. Make sure distal effectors are completely closed prior to insertion or removal through cannulas.

Use the appropriate sized cannula for the device being used. For example, use a 5 mm device with a cannula with an inner diameter of at least 5.5 mm.

The maximum recurring peak voltage for devices applicable to these instructions for use is 2kV.

Ring handled devices are designed to be held with one finger and the thumb in the ring handles. Do not hold handle in a whole hand pistol grip which applies excessive force and may damage the device.

Always use caution when inserting or removing instruments through cannulas. Lateral pressure on the instrument during removal can damage the working tip, shaft of the instrument and/or insulation. Be sure the tips are closed and the instrument is pulled straight out until completely clear of the cannula to avoid catching the valve assemblies in the cannula or dislodging the cannula.

Follow manufacturer’s instructions for use for HF Generators. Devices were designed to the bipolar output of HF Generators with a maximum of 100 watts and a maximum output voltage of 600 V.

Remove protective cover from the monopolar connector on handle prior to use.

HF cable used must be completely compatible with the adapter plug.

Monopolar laparoscopic devices are not compatible with bipolar cautery cables and generators. They are intended only for monopolar cautery usage.

All devices must be cleaned and sterilized before use.
Pre-processing Instructions
Initiate cleaning of device within 2 hours of use. All devices must be preprocessed in the completely open and disassembled (i.e. taken-apart) configuration. Note that applicable device disassembly should not require any mechanical tooling (i.e. screwdriver, pliers, etc) unless otherwise indicated.

Manual Cleaning
1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Prepare the enzymatic / neutral pH detergent solution, utilizing tap water with a temperature range of 27°C to 44°C (81°F to 111°F), per manufacturer’s instructions.
3. Place device in the open/relaxed position with flush port open, and completely immerse in the detergent solution and allow device to soak for a minimum of 5 minutes. Actuate all movable parts during the initiation of the soak time.
4. Using a soft bristled brush, remove all visible soil from the device. Actuate device while brushing, paying particular attention to hinges, crevices and other difficult to clean areas. Note: It is recommended that the detergent / solution is changed when it becomes grossly contaminated (bloody and/or turbid).
5. For lum en devices, use a soft bristled brush with a brush diameter and length that is equivalent to lum en diameter and length. Scrub the lum en (i.e. angulated/nonangulated positions) until no visible soil is detected in the lum en rinsing step below.
6. For lum en devices, place the device into the open/relaxed position with the distal tip pointed down. Flush the device with a minimum of 50 ml of detergent solution, utilizing a temperature range of 27°C to 44°C (81°F to 111°F), by using the flushing port located on the handle/shaft. Repeat the flush process a minimum of 2 times (i.e. total of 3 times), ensuring all fluid exiting the lum en is clear of soil.
7. For lum en devices, if visible soil is detected during the final lum en flush, re-perform brushing and flushing of the lum en.
8. Rinse the device by completely immersing in tap water with a temperature range of 27°C to 44°C (81°F to 111°F), by using the flushing port located on the handle/shaft. Repeat the flush process a minimum of 2 times (i.e. total of 3 times).
9. For lum en devices, following the rinsing step, place the device into the open/relaxed position with the distal tip pointed down. Flush the device with a minimum of 50 ml of tap water, utilizing a temperature range of 27°C to 44°C (81°F to 111°F), by using the flushing port located on the handle/shaft. Repeat the flush process a minimum of 2 times (i.e. total of 3 times).
10. Dry the device with a clean, lint-free towel.
11. For lum en devices, manipulate the device to allow rinse water to drain from the lum en.
12. Visually examine each device for cleanliness.
13. If visible soil remains, repeat cleaning procedure.

Automatic Cleaning
In addition to manual cleaning, you may use an ultrasonic machine to aid in the manual cleaning. If you wish to use automatic cleaning for these devices, you must follow the washer manufacturer’s recommendations specific to these types of devices. Most washer manufacturers have specific washing equipment for these types of devices.

Inspection/Maintenance
It is important that every surgical device is inspected after cleaning and prior to use for damage, sharp edges, raw surfaces, ruptures, cracks, or malfunctions. 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 tears in the insulation. All surgical devices should always be handled with great care in transportation, cleaning, maintenance, sterilization, and storage. This is especially valid for cuts, fine points and other sensitive areas. Surgical devices corrode and their functionality is influenced when they come into contact with corrosive substances. Do not place devices in acidic or strong detergents. Replace brittle and cracked sealing caps. If any of these conditions appear, do not use the device.

Pre-sterilization Cleaning
For lum en devices, if visible soil is detected during the final lum en inspection/maintenance. In addition to manual cleaning, you may use an ultrasonic machine to aid in automatic cleaning.

Notes:
- It is recommended that the detergent / solution is changed when it becomes grossly contaminated (bloody and/or turbid).
- For lum en devices, use a soft bristled brush with a brush diameter and length that is equivalent to lum en diameter and length. Scrub the lum en (i.e. angulated/nonangulated positions) until no visible soil is detected in the lum en rinsing step below.
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- For lum en devices, if visible soil is detected during the final lum en flush, re-perform brushing and flushing of the lum en.
- Rinse the device by completely immersing in tap water with a temperature range of 27°C to 44°C (81°F to 111°F), by using the flushing port located on the handle/shaft. Repeat the flush process a minimum of 2 times (i.e. total of 3 times).
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- Dry the device with a clean, lint-free towel.
- For lum en devices, manipulate the device to allow rinse water to drain from the lum en.
- Visually examine each device for cleanliness.
- If visible soil remains, repeat cleaning procedure.

Service and repairs should only be carried out by an authorized repair center identified within this instruction for use.

Repair Service
Return devices for maintenance and repair to:
National Repair Center
2675 South Milford Rd.
Suite B
Highland, MI 48357
For return shipment instructions, please call 1-800-323-9088.

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

Packaging
When sterilizing by autoclave, the device should be wrapped in a lint-free surgical towel or qualified autoclave package such as sterilization wrap. Sterilization wrap material must be cleaned for the applicable sterilization modality by your country’s regulatory body.

Sterilization
Sterilization of devices may be accomplished by steam autoclave. 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 device. Please consult with the sterilizer manufacturer or your facility policy for specific guidelines and instructions. The following parameters are for the devices covered by these instructions.

Prevacuum Steam Sterilization Parameters:
- Minimum Preconditioning Pulses: 3
- Minimum Temperature: 132°C (270°F)
- Minimum Exposure Time: 3 minutes
- Minimum Dry Time: 30 minutes
- Sterilization Configuration: Individually Wrapped (2 layer 1-ply or 1 layer 2-ply)

Note: This device tip, handle, and flushing port (if applicable), should be kept in the open position when sterilized. The use of “flash” sterilization is not recommended, as it will shorten the life of laparoscopic devices.

Storage
After sterilization, devices should remain in sterilization packaging and be stored in a clean, dry environment.
Assembly Instructions Applicable to Products in Table 1

1. Push the insert into the handle's outer shaft such that the insert fully seats into the outer shaft slots. Some rotation of the tip may be necessary to align the tip notches and the outer shaft slots.

2. While holding the outer shaft with the tip pointing away from you, rotate the insert clockwise 45° until loosened. Slide the insert from the outer shaft to the handle by turning the red colored screw connector counter clockw ise. The jaw tips must be closed to ensure proper fit into handle.

3. Open the handle completely and insert the shaft assembly into the outer shaft. This cannot be assembled further if the tip is not seated correctly. If the insert spins more than 45°, insure that the notches are fully inserted into the outer shaft slots.

4. Check the device for smooth operation prior to use.

Disassembly
1. Open the handle completely. With the tip of the instrument pointing away from you, loosen the outer shaft by turning the red colored screw connector counter clockw ise. The jaw tips must be closed to ensure proper fit into handle.

2. While holding the outer shaft with the tip pointing away from you, rotate the insert clockwise 45° until loosened. Slide the insert from the outer shaft.

3. Clean and sterilize immediately.

Note: If device has been received in a pre-assembled configuration, user must disassemble and follow appropriate cleaning, sterilization, and functional check procedures prior to use.

End of Assembly and Disassembly Instructions for Products in Table 1

Warranty
V. Mueller offers a ninety (90) day warranty against failure in normal use. This warranty does not cover routine re-shaping and refurbishing, or repair of damaged caused by misuse, or failure to care for the device as described in the instructions for use. It does not cover devices after they have been repaired, refurbished, or sharpened by anyone other than an authorized service center.

Any adverse event must be reported to the appropriate V. Mueller authorized representative.

IEC Classification: BF Applied Parts

Contact Information
For general inquiries or return shipment instructions, please contact:

CareFusion
V. Mueller Instrumentation
75 North Fairway Drive
Vernon Hills, IL 60061 USA
1-800-323-9088
www.CareFusion.com/V. Mueller
For international inquiries email: GMB-Mueller-Cust-Support@carefusion.com
For information 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

Appendix
All product codes covered by this instruction for use are listed in the following table.

Table 1

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