V. Mueller®
Take-Apart Laparoscopic Instruments

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 position to deliver energy to the target tissue.

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 un-insulated 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 forceps to remove excised tissue through 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 cannula. 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 cannula to avoid catching the valve assemblies in cannulas 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.

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Pre-processing Instructions

Initiate cleaning of device within 2 hours of use. All devices must be processed in the completely open and disassembled (ie. taken-apart) configuration. Note that applicable device disassembly should not require any mechanical tooling (ie. 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 lumen devices, use a soft bristled brush with a brush diameter and length that is equivalent to lumen diameter and length. Scrub the lumen (i.e. angulated/nonangulated positions) until no visible soil is detected in the lumen rinsing step below.
6. For lumen 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 lumen is clear of soil.
7. For lumen devices, if visible soil is detected during the final lumen flush, re-perform brushing and flushing of the lumen.
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), for a minimum of 30 seconds to remove any residual detergent or debris.
9. For lumen 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 lumen devices, manipulate the device to allow rinse water to drain from the lumen.
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 malfunctioning. 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.

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.

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

Before each use, insulated devices should be examined separately again for any damage to the insulation, and in case of damage, they should be exchanged. HF cable used must be completely compatible with the adapter plug.

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 cleared 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.

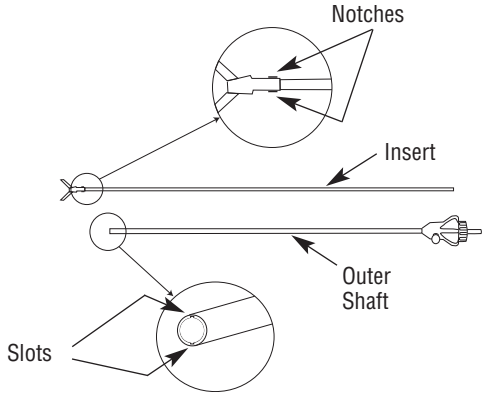
Storage

After sterilization, devices should remain in sterilization packaging and be stored in a clean, dry environment.

Assembly Instructions Applicable to Products in Table 1

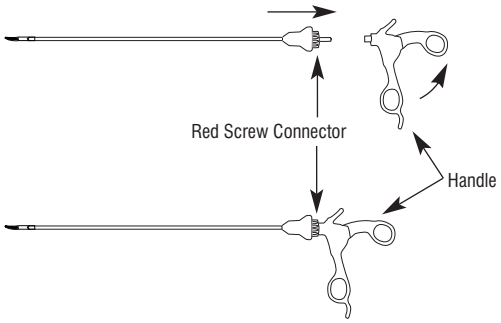
1. Push the insert into the handle's outer shaft such that the insert fully seats into the outer shaft. Some rotation of the tip may be necessary to align the tip notches and the outer shaft slots.

2. While holding the outer shaft, rotate the insert, with jaws closed, counter clockwise 45° until tight.



NOTICE: The device 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.

3. Open the handle completely and insert the shaft assembly into the handle. Tighten the outer shaft to the handle by turning the red colored screw connector. The jaw tips must be closed to ensure proper fit into handle.



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

Disassembly

1. Open the handle completely. Loosen the outer shaft by turning the red colored screw connector. Slide outer shaft away from handle.
2. While holding the outer shaft, rotate the insert clockwise 45° until loosened. Slide the insert from the outer shaft.
3. Clean and sterilize immediately.

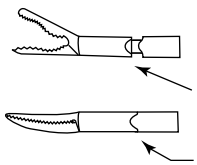
Note: If device has been received in a pre-assembled configuration, user must disassemble and follow appropriate cleaning, sterilization, and functional check procedures prior to use.

End of Assembly and Disassembly instructions for products in Table 1

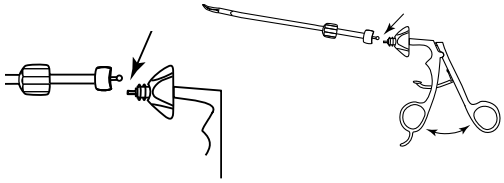
Assembly Instructions Applicable to Products in Table 2

1. Slide the insert into the shaft.

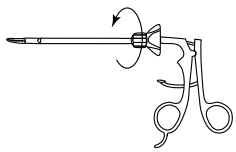
2. Notice the tongue and groove configuration. The insert should snap firmly into the shaft.



3. With the insert jaw closed and the handle open (just like you would open a pair of scissors), place the "ball" of the insert into the cutout of the handle; then squeeze the handle shut, and keep it shut. The jaw tips must be closed to ensure proper fit into handle.

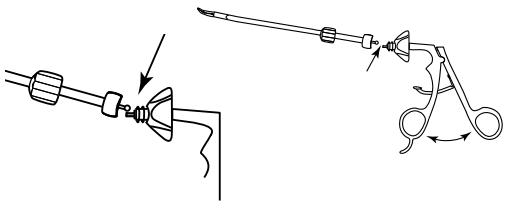


4. Turn the nut counterclockwise onto the handle. Now the device is ready to use.

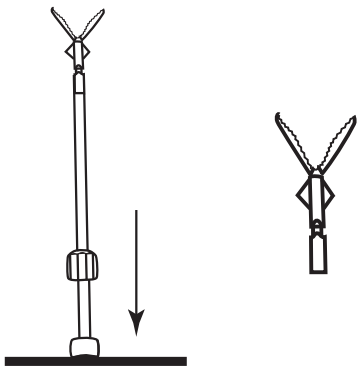


Disassembly

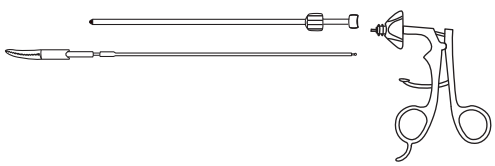
1. Unscrew the nut on the handle clockwise.
2. Open the handle (just like you would open a pair of scissors) and lift the "ball" of the insert out of the cutout area.



3. Firmly grasping the shaft with both hands, press the little "ball" on a hard surface until the insert detaches from the shaft.



4. Pull the insert out of the shaft. Now you will have 3 separate pieces: a handle, a shaft with a nut, and an insert.



End of Assembly and Disassembly instructions for products in Table 2

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 type of misuse or abuse of the device and repair or modification by an unauthorized repair representative will render the warranty void. CareFusion assumes no liabilities if the device is misused, abused, or repaired or modified by an unauthorized party.

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

IEC Classification: BF Applied Parts

Contact Information

For general inquires or return shipment instructions, please contact:

CareFusion
V. Mueller Instrumentation
1500 Waukegan Rd
McGaw Park, IL 60085
1-800-323-9088
www. CareFusion.com/V. Mueller
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

Appendix

All product codes covered by these instructions are listed in the following tables.

Table 1

256.00010U	256.15020B	256.31020B	256.66310U	256.81420B
256.00020B	256.15410U	256.31410U	256.66320B	256.83010U
256.00310U	256.15420B	256.31420B	256.70010U	256.83020B
256.00320B	256.16030U	256.33010U	256.70020B	256.83410U
256.01010U	256.18010U	256.33020B	256.70310U	256.83420B
256.01020B	256.18020B	256.33410U	256.70320B	256.84010U
256.01410U	256.18410U	256.33420B	256.71010U	256.84020B
256.01420B	256.18420B	256.34010U	256.71020B	256.84410U
256.02010U	256.19010U	256.34020B	256.71310U	256.84420B
256.02020B	256.19020B	256.34410U	256.71320B	256.85010U
256.02410U	256.19410U	256.34420B	256.72010U	256.85020B
256.03010U	256.19420B	256.35010U	256.72020B	256.85410U
256.03020B	256.21010U	256.35020B	256.72310U	256.85420B
256.03410U	256.21030B	256.35410U	256.72320B	256.86010U
256.03420B	256.21410U	256.35420B	256.73010U	256.86020B
256.05010U	256.21420B	256.36010U	256.73020B	256.86310U
256.05020B	256.23010U	256.36020B	256.73310U	256.86320B
256.05410U	256.23020B	256.36410U	256.73320B	256.88010U
256.05420B	256.23030U	256.36420B	256.75010U	256.88020B
256.06010U	256.23410U	256.37030U	256.75020B	256.88410U
256.06020B	256.23420B	256.37330U	256.75410U	256.88420B
256.06310U	256.23430U	256.60010U	256.75420B	256.90010U
256.06320B	256.24010U	256.60020B	256.76010U	256.90020B
256.07330U	256.24020B	256.60310U	256.76310U	256.90310U
256.08030U	256.24410U	256.60320B	256.78010U	256.90320B
256.10030U	256.24420B	256.61010U	256.78020B	256.9900RU
256.12010U	256.28010U	256.61020B	256.78310U	256.99010U
256.12020B	256.28020B	256.61310U	256.78320B	256.99020B
256.12410U	256.28410U	256.61320B	256.79010U	256.99030U
256.12420B	256.28420B	256.62010U	256.79020B	256.99100U
256.13010U	256.29010U	256.62020B	256.79410U	256.99300U
256.13020B	256.29020B	256.62310U	256.79420B	256.99400U
256.13410U	256.29410U	256.62320B	256.81010U	256.99800U
256.13420B	256.29420B	256.66010U	256.81020B	
256.15010U	256.31010U	256.66020B	256.81410U	

Table 2

F256.00010	F256.13010	F256.25010	F256.61010	F256.83010
F256.00020	F256.13110	F256.28010	F256.61020	F256.84010
F256.00110	F256.13410	F256.29010	F256.61310	F256.86010
F256.01010	F256.13810	F256.31020	F256.62020	F256.86020
F256.01020	F256.14410	F256.31810	F256.65010	F256.86210
F256.01210	F256.14810	F256.34010	F256.66010	F256.88110
F256.01410	F256.15010	F256.34020	F256.70020	F256.90210
F256.02020	F256.16030	F256.34420	F256.70210	F256.90410
F256.05010	F256.17010	F256.44010	F256.71010	F256.99004
F256.05110	F256.18010	F256.44011	F256.71020	F256.99005
F256.06010	F256.20020	F256.44020	F256.75010	F256.99010
F256.06020	F256.21010	F256.44710	F256.75410	F256.99020
F256.07030	F256.21020	F256.46010	F256.77010	F256.99030
F256.08030	F256.21410	F256.46020	F256.77810	F256.99100
F256.10030	F256.23010	F256.46610	F256.78010	F256.99200
F256.10230	F256.23020	F256.46710	F256.78310	F256.99300
F256.10330	F256.23030	F256.47610	F256.79020	F256.99400
F256.11010	F256.23410	F256.47710	F256.81010	F256.99600
F256.12010	F256.24020	F256.48010	F256.81410	F256.99700
F256.12020	F256.24810	F256.48610	F256.82030	F256.99800

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