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## MiSeal™ Reposable Thermal Ligating Shears

### Instructions For Use

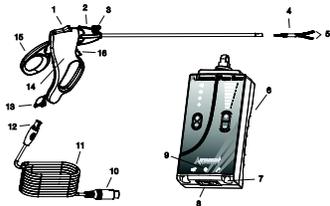
Only for use with Microline Surgical Universal Power Supply (UPS) (REF 200-006R). Please see Instructions for Use packaged with the MiSeal Kit and the UPS.

### Device Description

The Microline Surgical MiSeal Reposable Thermal Ligating Shears are designed to provide thermal ligation and division in various surgical procedures. The MiSeal Reposable Thermal Ligating Shears consist of a reusable handpiece with a disposable tip. The device has heating elements at the distal tip which are activated by a finger switch located on the handpiece of the device. The MiSeal Reposable Thermal Ligating Shears are designed to allow the surgeon control of the heating element power of the device in order to accommodate for individual patient anatomy. An instrument cord connects the handpiece to the Universal Power Supply (UPS).

### Intended Use

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting natural or synthetic, nonmetallic sutures during surgery. The MiSeal Kit contains a disposable tip and an instrument cord, which are single patient use. The MiSeal Handpiece can be used multiple times when the cleaning and sterilization procedures detailed in this Instructions For Use are followed.

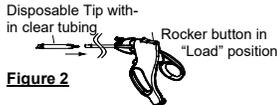


**Figure 1**

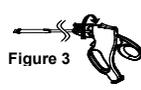
- |                                    |                                |
|------------------------------------|--------------------------------|
| 1. Rocker Button                   | 9. Power On LED Indicator      |
| 2. Rotator                         | 10. UPS Connector              |
| 3. Luer Cap                        | 11. Disposable Instrument Cord |
| 4. Disposable Tip                  | 12. Handpiece Connector        |
| 5. Jaws with Heating Elements      | 13. Receptacle Cap             |
| 6. Universal Power Supply (UPS)    | 14. Reusable Handpiece         |
| 7. Instrument Connector Receptacle | 15. Thumb Trigger              |
| 8. On/Off Switch                   | 16. Finger Switch              |

### Handpiece / Tip Assembly:

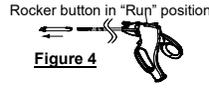
1. Remove the MiSeal Disposable Tip from the outer packaging. Keep the tip within the clear tubing as this will help the tip's jaws remain closed during tip installation.
2. Push the rocker button on the rear of the handpiece to the "load" position to engage the shaft locking mechanism (See Figure 2). A red graphic indicator will now be visible on the side of the rocker button.



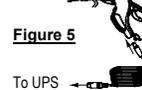
**Figure 2**



**Figure 3**



**Figure 4**



**Figure 5**

3. With the tip's jaws in their closed position, insert the tip into shaft. If the jaws are not completely closed when screwed onto the handpiece, they may not completely close to cut or grasp.
4. Holding the metallic tube of the tip within the clear tubing, turn the rotator clockwise until the tip is screwed tight and clicks into place (See Figure 3). Ensure that the rear hub of tip is in full contact with the shaft of the handpiece such that no gap exists between the rear hub of the tip and the end of the shaft.
5. Remove the clear tubing.
6. Push the rocker button on the handpiece forward to the "run" position to disengage the shaft locking mechanism (See Figure 4). A green graphic indicator will now be visible on the side of the rocker button.
7. Test the device by moving the thumb trigger to verify proper jaw opening and closing.
8. The device is ready to connect to the UPS for pre-check.

### Connection to Power Source (See Figure 5)

1. Remove the MiSeal Disposable Instrument Cord from the packaging.
2. Unplug the receptacle cap from the handpiece.
3. Uncoil the instrument cord; align the key portion of the handpiece connector with the key portion of the connector receptacle on the MiSeal Handpiece. Insert the handpiece connector firmly into the connector receptacle of the MiSeal Handpiece.
4. Pass the UPS connector end of the MiSeal Instrument Cord off the sterile field.
5. Align the key portion of the UPS connector with the key portion of the instrument connector receptacle on the UPS. Insert the UPS connector firmly into the instrument connector receptacle (non-sterile) of the UPS.
6. Turn on the UPS power switch.

**Notes:**

- A light adjacent to the instrument connector receptacle of the UPS will illuminate to verify proper connection. If the light is not illuminated after turning "ON" the UPS, unplug the UPS connector, realign the key portion and reinsert the connector into the instrument receptacle.
- The heating elements' power can be adjusted in the "Variable" mode if desired. (See the UPS Instructions for Use)
- The heating elements span the length of the jaws. Tissue grasped outside this region will not be subject to sealing and division.

### Pre-Check

The MiSeal Reposable Thermal Ligating Shears have two power options accessible from the finger switch of the handpiece; a variable mode (power output manually set at the UPS) and a high mode. Do not touch the device tip while performing the pre-check as this may cause injury. The following sequence will verify electrical function:

1. Press the buttons on the UPS to adjust the power output setting to #1 to reduce the heat output to minimum power (See the UPS Instructions for Use).
2. Soak a sterile 4 inch x 4 inch gauze pad in saline.
3. Place the gauze pad between the jaws of the device and close the jaws using the thumb trigger (See Figure 6). Do not depress the finger switch.
4. There should be no steam generated from the gauze pad nor tones emitted from the UPS.

### Variable Power Check

5. Depress the finger switch partially. This allows the user to adjust the heat output (via the UPS). A hissing sound from the gauze pad and a pulsing tone indicate the device is active in the "Variable" mode of the UPS. If a constant tone is emitted and steam generated, the finger switch was depressed too far. Release the finger switch and try again. This mode is utilized when vessels are being sealed.

### High Power Check

6. Continue to depress the finger switch until it is fully depressed. This engages the high power option in the device activating the heat output to maximum power. Generation of steam with a hissing sound from the gauze pad and a continuous higher pitched tone indicate the device is active in the "High" mode of the UPS. This mode is utilized in avascular tissue or where sealing of vessels is not a primary concern.

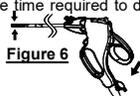
### Troubleshooting

- If there is no audible tone, check the electrical connections to the UPS and ensure the power switch is in the "ON" position. An indicator light located at the instrument connector receptacle of the UPS should be illuminated, in addition to the green power indicator light on the UPS.
- If steam is generated during variable power check, verify a #1 UPS setting.
- If there is an absence of steam during high power check, add more saline to the gauze pad.
- If there is hissing sound and/or steam generation without an audible tone, DO NOT use the device or UPS and contact Microline Surgical Customer Service.

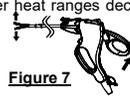
### Using the Device

**Note:** Individual patient anatomy and physician technique can influence the performance of the device. The following steps are recommendations only.

1. Grasp desired tissue between the jaws of the MiSeal Reposable Thermal Ligating Shears and gently squeeze the thumb trigger and handpiece to close the jaws (See Figure 6). Depress the finger switch to achieve the desired power output. Do not squeeze the handpiece with excessive force. Hemostasis is best achieved with moderate pressure. Generally, lower heat ranges increase the sealing capabilities and the time required to divide tissue. Higher heat ranges decrease the time to divide and may compromise seal integrity.



**Figure 6**



**Figure 7**

**Note:** Depressing the finger switch and squeezing the thumb trigger activates the heating elements. This is not recommended when there is no tissue between the jaws of the MiSeal Reposable Thermal Ligating Shears.

2. After the desired sealing and division of tissue is accomplished, release the finger switch and open the jaws (See Figure 7). This deactivates the heating elements.

3. After removing the device, examine tissue for hemostasis. If hemostasis is not present, use appropriate techniques to achieve hemostasis.

4. If desired, progress to a new region of tissue to be sealed and divided.

**Note:** It may be desirable to occasionally clean the tip of the device during the surgical procedure. A saline-moistened surgical gauze or sponge may be applied gently to the jaws in a linear motion along the heating elements to remove buildup of coagulated blood and tissue debris. After cleaning the tip, it may also be desirable to open and close the jaws several times by squeezing and releasing the thumb trigger to ensure optimal performance.

5. At the end of the surgical procedure, disconnect and discard the MiSeal Tip and Instrument Cord. To remove the instrument cord, hold the handpiece connector and pull away from the handpiece. To remove the tip, hold the rotator and turn the tip counter-clockwise until detachment is achieved.

#### Precautions and Warnings

• The MiSeal Tip and Instrument Cord are not designed for reuse or reprocessing for reuse. Reuse of single-use devices creates a potential risk of patient or user infections, injury, illness or death.

• Do not use if the handpiece, tip or instrument cord is damaged.

• Do not use a scalpel or other sharp metal instrument to clean the tip's jaws as the heating elements may be damaged.

• Refrain from unnecessary activation of the heating elements while there is no tissue grasped between the jaws of the MiSeal Reposable Thermal Ligating Shears as this activity may result in premature degradation of the device.

• Do not touch the device tip while performing the pre-check as this may cause injury.

• Do not touch an electrosurgical (Bovie) electrode to any part of the MiSeal Reposable Thermal Ligating Shears.

• The device is not intended for continuous use. A recommended duty cycle is approximately five (5) to ten (10) seconds on, ten (10) seconds off.

• Only use the MiSeal Reposable Thermal Ligating Shears with the Microline Surgical Universal Power Supply (REF 200-006R). Use of any other power supply may damage the device and could prevent proper function during use.

• Activating the device with excessive force or traction may result in an incomplete seal. If hemostasis is not present, use appropriate techniques to achieve hemostasis.

• Procedures using instruments for sealing and dividing of tissue during surgery should be performed only by persons having adequate training and familiarity with these surgical techniques. Consult the medical literature relative to techniques, complications and hazards prior to performance of any procedure. Surgeons using this device should be familiar with the specific anatomy of the region in which they intend to perform the procedure.

• There are no unusual risks associated with the proper disposal of this equipment. Follow any local regulations regarding proper disposal of used disposable components.

• Store in a cool, dry place.

#### Warnings

• Do not use in the presence of flammable materials (e.g. alcohol, flammable anesthetics).

• Always disconnect the tip and instrument cord from the handpiece before discarding; the UPS and MiSeal Handpiece are reusable.

#### Contraindications

The MiSeal Reposable Thermal Ligating Shears are not to be used as a fallopian tube sterilization device.

#### Compliance with Standards

When used with the UPS (REF 200-006R), the device complies with IEC60601-1 requirements for type CF applied part and meets electromagnetic compatibility requirements of IEC60601-1-2.

#### Cleaning - MiSeal Handpiece Only

The tip and instrument cord are to be detached from handpiece and discarded prior to cleaning and sterilization of the handpiece.

1. Prepare an enzymatic solution containing 60 mL of ENZOL<sup>®</sup> Enzymatic Detergent per 4 L of water at 38° C.

2. Remove the luer cap from the flushing port on the shaft.

3. Wipe down the connector receptacle cap with the prepared enzymatic solution, rinse with deionized water and insert into the cable connector receptacle at the bottom of the handpiece.

4. Rinse the device with warm tap water (36° C) for a minimum of one (1) minute.

5. Pre-soak the device in the prepared enzymatic solution for ten (10) minutes.

6. In the prepared enzymatic solution, ensure all moveable assemblies including the triggers and rotator are actuated.

7. Connect a 60 mL luer type syringe filled with the prepared enzymatic solution to the flushing port where the luer cap was removed.

8. Using the syringe, flush the inside of the shaft three (3) times with the enzymatic solution.

9. Remove the syringe and repeat flushing with warm tap water. Flush until clear water exits.

10. Brush the device under warm water to avoid airborne contaminants. Ensure all moveable assemblies including the triggers and rotator are actuated under water.

11. Make sure that all visible bioburden has been removed.

12. Remove the receptacle cap and rinse the entire device with deionized water for one (1) minute. After the rinse, flush inside of the shaft three (3) times with deionized water for a final rinse.

13. Inspect the device for functionality and package appropriately for sterilization.

#### Sterilization - MiSeal Handpiece Only:

1. Prior to sterilization, the device must be thoroughly cleaned.

2. Wrap the device.

3. Sterilize the device following the protocol provided by the sterilizer manufacturer.

The following validated steam sterilization cycles are recommended as minimum guidelines:

Gravity Cycle: 4 minutes @ 270°F (132°C) and 20 minutes of drying time.

Pre-Vacuum Cycle: 4 minutes @ 270°F (132°C) and 20 minutes of drying time.

#### Return Policy:

Returns must be made within 30 days of shipment and must be in original, unopened packaging. Disposable products must be returned in complete, unopened boxes. Returned product is subject to a 25% restocking fee based on the original purchase price. Prior to returning any device for repair, contact Microline Surgical Customer Service to obtain an RGA. Unauthorized returns will not be accepted. All returns must be shipped freight pre-paid. This device will be returned unrepared to the sender if the following conditions are not met:

- Proper cleaning and sterilization after last procedure or a declaration of decontamination.

- The device must be assigned an RGA number.

- The RGA number must be clearly visible on the outside of the box it is shipped in.

**Handpiece validation:** The handpiece has been validated for fifty cleaning/sterilization cycles.

#### Warranty Information for MiSeal Disposable Kit:

All Microline Surgical tips and accessories are unconditionally guaranteed against defects in material and workmanship. Microline Surgical will, at its option and without charge, either repair or replace any tip or accessory which Microline Surgical determines to be defective in material or workmanship when used for its intended surgical purposes.

#### Warranty Information for MiSeal Handpiece:

Microline Surgical warrants that its devices are free from any defects in both material and workmanship. Microline Surgical shall not be held liable for any incidental or consequential damage of any kind. Reusable handpieces are covered by a one year limited warranty, valid only to the original purchaser of the device. Irrelevant of the nature of the repair, Microline Surgical will return to the customer a "like new" device completely refurbished and upgraded to Microline Surgical factory specifications.

- Gross abuse or neglect of a Microline Surgical device will void this warranty.

- Work performed on a device by anyone other than an authorized service center will void this warranty and will subject the device to a premium repair charge.

#### Symbol Definition



Means: Latex Free



Medical Device Safety Service GmbH  
Schiffgraben 41  
D-30175 Hannover  
Germany

Rx Only



Manufactured under one or more of US patents: 7,033,351; 7,011,656; 6,908,463; 6,860,880; 6,695,837; 6,626,901. Patents Pending.

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