

For product information, contact:

**Olsen MEDICAL®**

3230 Commerce Center Place

Louisville, Kentucky, 40211

Phone: (502) 772-4280 < > (800) 297-6344

See our products at

<http://www.olsenmedical.com>

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

## **OLSEN MEDICAL® Integrated Irrigation Tubing and Bipolar Cord Set**

### **Description:**

The OLSEN MEDICAL® Integrated Irrigation Tubing and Bipolar Cord Set has a nonpyrogenic fluid pathway and is sterile. The components of the bipolar cord are two plugs and a female twin pin connector and are integrated to an irrigation tubing with a male LUER-LOK™ connector, silicone tubing and fittings, an on/off clamp and an inlet spike with cover. A single use bipolar cord and irrigation tubing are integrated into one set. This integrated set provides the system with a one unit delivery conduit and cable for carrying irrigating solution and electro-surgical energy to the Bipolar Irrigating Forceps for coagulation and irrigation of tissue.

The OLSEN MEDICAL® bipolar irrigating forceps or equivalent bipolar irrigating forceps, may be purchased separately or as part of a set containing the forceps with the integrated irrigation tubing and bipolar cord. Any OLSEN MEDICAL® irrigating or non-irrigating forceps can be used in the cutting mode, and we recommend that insulated irrigating forceps be used with the compatible electro-surgical generator.

### **Handling:**

1. Inspect package for damage before use. Discard if damaged or seal is broken.
2. Inspect device after opening in a sterile field. Discard if damaged.
3. Device use and application to be determined by doctor.

### **Storage:**

Store at +5 °C to +30 °C. Relative Humidity: 30% - 75% non-condensing. This device should be stored in a clean dry and moisture free area in the original shipping carton or in a protective storage case.

### **Sterility:**

Sterility is guaranteed up to the expiration unless package is opened or seal is broken.

### **Sterilization:**

Single Use Only. Dispose after use. Do not resterilize.

### **Indications:**

The OLSEN MEDICAL® Integrated Irrigation

Tubing and Bipolar Cord Set (Catalog No. 40-3xxxR/G) is a single use product sold sterile and is intended for use with a standard bipolar irrigating forceps like the OLSEN MEDICAL® Bipolar Irrigating Forceps and the Codman & Shurtleff, Malis™ CMC® Bipolar Systems to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation. This device is intended for use with the Codman/Malis™ CMC® -II and the CODMAN/MALIS™ CMC® -III Bipolar Cut and Coagulation System (or equivalent) Electrosurgical Generator.

Bipolar forceps specifically designed for irrigating are required for use with this tubing and cord set. Please read the instruction manuals supplied with the irrigation module and the bipolar coagulator or electro-surgical systems before using this product.

### **Caution:**

- This device is an accessory to an Electrosurgical System and is intended for use in general surgical procedures. This device should be used only by individuals who are adequately trained and licensed to use such devices.
- Do not allow the irrigation tubing or bipolar cord to come in contact with sharp objects.
- Do not separate the irrigation tubing from the electrical cord as this may cause the set to malfunction.
- This product is designed for use only with collapsible containers and with bipolar electro-surgical units only.

### **Warning:**

Careless use of any element in electro-surgical systems may cause serious burn, shock, and fire or explosion hazard. The use of the device with safely functioning and compatible handles, cords, electro-surgical generators and accessories is the user's responsibility. Read and understand all precautions and instructions before attempting to use any electro-surgical devices.

### **Surgical Assembly Instructions:**

#### **Important Product Code Information**

The OLSEN MEDICAL® Integrated Irrigation Tubing and Bipolar Cord Set with product codes 40-3000G and Kits with product codes 20-0xxxG are designed to work with gravity style pumps such as the CODMAN/Malis™ CMC® II Irrigation Module. The Tubing/Cord set with product code 40-3001R and Kits with product codes 20-0xxxR are designed to work with rotary style irrigation modules such as the Codman/Malis™ Irrigation Module 1000. The Tubing/Cord sets are not interchangeable and must be used with the correct type of pump.

### **Surgical Assembly Instructions for 40-3000G or 20-0xxxG (to be used with gravity-style pumps):**

1. Power on the irrigation module and the bipolar generator.
2. Remove the OLSEN MEDICAL®

Integrated Irrigation Tubing and Bipolar Cord Set from the peel pouch and slide off the polyethylene band using aseptic technique.

3. Engage the on/off clamp to the off position and remove the cover from the inlet spike. Insert the inlet spike into the stopper of the irrigation container while holding the bag in a vertical position with the stopper in the up position. Avoid twisting of the spike. Hang the container on an I.V. pole at a level above the forceps with the stopper facing down. The height of the irrigation bag determines the level of irrigation flow. Depending on the preference of the user, the bag can be lowered to decrease the irrigation pressure or raised to increase the irrigation flow.
4. The silicone tubing between the two white plastic fittings will be loaded into the irrigation module. Insert the plastic fitting closest to the irrigation solution container into the top keyhole slot of the irrigation module with the silicone tubing hanging down. Place the plastic fitting closest to the instrument into the lower slot on the base of the irrigation module.
5. Retract the occluding arm by pressing and holding the load switch on the irrigation module. Load the irrigation tubing such that it will be occluded by the arm when the load switch is released. Release the load switch.
6. Discard the black protective cap located on the male LUER-LOK® connector. Connect the set's male LUER-LOK® connector to the female irrigation port on the forceps. Prime the irrigation tubing by releasing the on/off clamp and allowing the solution to flow into the tubing. Press and hold the load switch on the irrigation module. Prime the set fully before releasing the load switch eliminating as many bubbles as possible and verifying flow through the tubing and through the male LUER-LOK® connector.
7. Connect the twin pin end of the irrigating bipolar forceps into the female connector on the cord.
8. Insert the two plugs into the bipolar output of the generator.

### **Surgical Assembly Instructions for 40-3001R, and Forceps Kit 20-0xxxR (to be used with rotary-style pumps):**

1. Power on the irrigation module and the bipolar generator.
2. Remove the OLSEN MEDICAL® Integrated Irrigation Tubing and Bipolar Cord Set from the peel pouch and slide off the polyethylene band using aseptic technique.
3. Engage the on/off clamp to the off position and remove the cover from the inlet spike. Insert the inlet spike into the stopper of the irrigation container while holding it in a vertical position with the stopper in the up position. Avoid twisting of the spike. Hang the container on an I.V. pole at a level above the forceps with the

stopper facing down. Please note: The height of the irrigation bag determines the level of irrigation flow. Depending on the preference of the user, the bag can be lowered to decrease the irrigation pressure or raised to increase the irrigation flow.

4. Open the door to the irrigation module and lift the pump hood. Locate the silicone tubing between the two white plastic fittings. Insert the plastic fitting closest to the irrigation bag into the top slot of the irrigation module and pass the silicone tubing around the rollers. Place the plastic fitting closest to the instrument through the opening at the base of the pump.
5. Discard the black protective cap located on the male LUER LOK<sup>®</sup> connector. Connect the set's male LUER-LOK<sup>®</sup> connector to the female irrigation port on the forceps. Prime the irrigation tubing by releasing the on/off clamp and allowing the solution to flow into the tubing. Prime the set fully, eliminating as many bubbles as possible and verifying flow through the tubing and the male LUER-LOK<sup>®</sup> connector. Close the door to the pump hood when the set is fully primed, taking care not to crimp the silicone tubing. Close the door to the irrigation module.
6. Connect the twin pin end of the irrigating bipolar forceps into the female connector on the cord.
7. Insert the two plugs into the bipolar output of the generator.

**WARRANTY:**

All products are warranted to be free from defects in workmanship and materials. Any product that proves defective in workmanship or materials will be repaired or replaced at our discretion free of charge. Repair, modification, or alteration to any product that is performed by anyone not authorized by Olsen Medical<sup>®</sup> will result in the immediate loss of warranty.

MALIS<sup>™</sup> is a trademark of Leonard L. Malis, M.D.  
 CMC<sup>®</sup> is a registered trademark of Codman & Shurtleff, Inc.  
 LUER-LOK<sup>®</sup> is a registered trademark of Becton, Dickinson, and Company<sup>™</sup>  
 SYNERGY<sup>®</sup> is a registered trademark of Codman & Shurtleff, Inc.  
 OLSEN<sup>®</sup> is a registered trademark of Olsen Medical.

**SYMBOLS:**



Catalog or Reference Number



Manufacturers Identification



Use By: (YYYY-MM-DD)



For Single Use Only



Lot Number



Consult accompanying documents



No Latex



Sterile: By Ethylene Oxide