INSTRUCTIONS FOR USE

Non-Sterile / Multiple Use

*Caution: Please read all instructions prior to use*

ISO 9001: 1994
AMTAC Cert No. 163
Intended Use:
The ACCU-Surg® Bipolar Laparoscopic Electrodes are intended to be used with the ACCU-Surg® Suction / Irrigation Cannula. They are surgical tools for cutting and coagulation used for GYN and General Surgery for such procedures as coagulation of endometrium, laparoscopic myomectomy, laparoscopic leiomyoma coagulation (myolysis), bleeding control of pelvic vessels and laparoscopic cholecystectomy. Pathology and/or surgeons choice will determine the tip style used.

Caution:
1. The ACCU-Surg® Bipolar Laparoscopic Electrodes are delicate instruments and should be handled accordingly. Do not drop or otherwise handle in a rough manner. The instruments are designed for limited reuse.
2. Do not irrigate or aspirate fluids when the electrodes are activated.
3. The electrodes should be activated only when in contact with the tissue.
4. Clean the electrode tip as necessary during surgery to maximize conductance of current to tissues.

Instructions For Use:
1. Insert the electrode into the proximal end of the Suction / Irrigation Cannula and screw firmly in place. Attach the power cord to the proximal end of the electrode. The connector should completely cover the metal post.
2. Retract the electrode inside the outer cannula prior to insertion into the trocar sleeve. To retract, pull the electrode shaft back through the rubber sealing cap.
3. Extend the electrode tip beyond the distal end of the cannula for cutting and coagulation. To extend, guide the electrode shaft down through the rubber sealing cap until the tip is visible.
4. The electrodes are manipulated by hand for rotation, fixation and axial movements.
5. Important - Before aspirating fluids retract the electrode inside the outer cannula.

NOTE: Recommended use of the electrodes only in combination with Electro Surgical Units which are EN 60601-2-2 / IEC 601-2-2 Certified.
Cleaning and Sterilization:

1. Remove the electrode from the Suction / Irrigation Cannula and thoroughly wash with soap and water. Ultrasonic cleaning is recommended.

2. Carefully clean the tip of the electrodes to avoid damaging the insulation between the electrode poles.

3. The black connector and rubber sealing cap are to be removed from the electrode shaft for cleaning.

4. The electrodes can safely be ETO or steam sterilized. Notice: In order to attain a 10^6 sterility level, the manufacture’s written instructions for operating the sterilizer should be followed. Sterilizers vary in design and performance characteristics, so cycle parameters should always be verified against the sterilizer manufacturer’s written instructions for the specific sterilizer and load configuration being used. The most common sterilization temperatures are --

<table>
<thead>
<tr>
<th>Type of Sterilizer</th>
<th>Temperature Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity Displacement</td>
<td>250-254° F (121-123° C)</td>
</tr>
<tr>
<td>Pre-Vacuum</td>
<td>270-275° F (132-135° C)</td>
</tr>
<tr>
<td></td>
<td>285-291° F (141-144° C)</td>
</tr>
<tr>
<td>Flush</td>
<td>250-254° F (121-123° C)</td>
</tr>
<tr>
<td>Pressure</td>
<td>270-275° F (132-135° C)</td>
</tr>
<tr>
<td>Pulse</td>
<td>285-291° F (141-144° C)</td>
</tr>
</tbody>
</table>

Reorder Number:

9360  Bipolar Electrode with L-Hook Tip
9361  Bipolar Electrode with Needle Tip
9362  Bipolar Electrode with Ball Tip

9440F Dual Trumpet Valve Handle
9440F027  5mm x 33cm Outer Cannula

Authorized Representative per Medical Device Directive
Hallmark International Management Consultants
Systems House, Westgate, Tadcaster,
North Yorkshire LS24 9AA, UK

REV:040999