Lariat™ flexible bladder snare

Reorder No. 00913702

INSTRUCTIONS FOR USE
This device is not made with natural rubber latex.

Intended Use:
The Lariat™ flexible bladder snare for tissue transection is intended to be used in the urological tract for tissue transection for Histopathologic examination.

<table>
<thead>
<tr>
<th>Description</th>
<th>Product Number</th>
<th>Sheath Diameter</th>
<th>French Size</th>
<th>Sheath Length</th>
<th>Approximate Snare Size (cm)</th>
<th>Active Cord Style</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexible Bladder Snare</td>
<td>00913702</td>
<td>3.0 mm</td>
<td>9.0 Fr</td>
<td>50 cm</td>
<td>3.0 X 6.0</td>
<td>Olympus</td>
</tr>
</tbody>
</table>

Warnings and Precautions:
- Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques.
- Consult the medical literature relative to techniques, contraindications, complications and hazards prior to any endoscopic procedure.
- Do not use this device if there is any apparent shipping or handling damage.
- This device is compatible with an endoscope channel of 2.8mm or larger.
- This is a MONOPOLAR device. Before using this device, follow recommendations provided by electrosurgical unit manufacturer to ensure patient safety through proper placement and utilization of patient return electrode. Ensure a proper path from patient return electrode to electrosurgical unit is maintained throughout the procedure.
- The Lariat™ flexible bladder snare is intended to be used with all generators that provide monopolar radiofrequency current and with an Olympus type active cord.
- Use only nonconductive irrigation solutions such as sterile water or Glycine.
- Endoscopic snaring with diathermic snares should not be performed without a thorough understanding of the principles of diathermic energy. Consult the electrosurgical generator manufacturer’s instruction booklet for proper settings and use of the generator.
- In order to ensure that the insulating properties of the device are not compromised, do not exceed the maximum rated peak voltage of 2500 V.
- US Urology did not design this device to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of the device to ensure patient and/or user safety.
- **These disposable medical devices are not intended for reuse.** Any institution, practitioner or third party, who reprocesses, refurbishes, remanufactures, resterilizes and/or reuses these disposable medical devices must bear full responsibility for product safety and effectiveness.

Contraindications:
Contraindications include those specific to any endoscopic procedure, as well as those specific to tissue resection and fulguration.

Directions for Use:

1. Following suggested medical techniques, prepare the patient for endoscopy.
2. Inspect active cord. Cord must be free of kinks, bends, breaks and exposed wires to allow for accurate transfer of current. If an abnormality is noted, do not use active cord.
3. Inspect the device for any signs of shipping or handling damage. **CAUTION: Do not use this electrosurgical device if it has been cut, burned or damaged. Damaged insulation may cause unsafe currents in either the patient or the operator.**
4. With electrosurgical unit off, prepare equipment. Securely attach the respective Olympus style active cord to the snare’s diathermic handle connection. Following instructions from electrosurgical manufacturer, position patient return electrode and connect it to electrosurgical unit.
5. Fully retract and extend snare to confirm smooth operation of the device.
6. When the target tumor/polyp has been endoscopically visualized, introduce sheath and retracted snare into endoscope accessory channel. **CAUTION: To ensure patient safety, power to electrosurgical unit should remain off until snare is properly positioned around the targeted tumor/polyp.**
7. Advance device, in small increments, until endoscopically viewed exiting endoscope.
8. Advance snare wire out of sheath and position it around the tumor/polyp to be resected. **WARNING: When applying current, tissue must be isolated from surrounding mucosa. Failure to isolate tissue may cause fulguration of normal mucosa and/or perforation. Contact of snare wire with endoscope during electrosurgery may cause grounding, which could result in injury to patient and/or operator as well as damage to endoscope and/or snare wire.**
9. Following electrosurgical unit manufacturer’s instructions for settings, verify desired settings and activate electrosurgical unit. **CAUTION: When starting a diathermic procedure, it is best to use a low setting. When necessary, increase to a level where desired coagulation or cutting is observed.**
11. Upon completion of tumor resection/polypectomy, turn electrosurgical unit off. Retract snare into sheath and remove device from endoscope.
12. Retrieve and prepare specimen per institutional guidelines.
Product Disposal:
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Issued Date: January 2012

Warning:
An issued or revision date for these instructions is included for the user's information. In the event two years has elapsed between this date and product use, the user should contact US Urology to determine if additional information is available.

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Olympus® is a registered trademark of Olympus Corp.

Made in the U.S.A.
### Explanation of symbols used on Labels and Instructions for Use

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use By</strong></td>
<td>Sterilized by Ethylene Oxide</td>
</tr>
<tr>
<td><strong>Contents</strong></td>
<td>Non-Sterile</td>
</tr>
<tr>
<td><strong>Reference</strong></td>
<td>Single Use Only</td>
</tr>
<tr>
<td><strong>Lot</strong></td>
<td>Do Not Re-Sterilize</td>
</tr>
<tr>
<td><strong>Date of Manufacture</strong></td>
<td>Latex Free</td>
</tr>
<tr>
<td><strong>Length</strong></td>
<td>Read instructions prior to using this product</td>
</tr>
<tr>
<td><strong>Authorized Representative in the European Community</strong></td>
<td>For use with Olympus active cord</td>
</tr>
<tr>
<td><strong>Store at controlled room temperature</strong></td>
<td>For use with Microvasive active cord</td>
</tr>
<tr>
<td><strong>I.D.</strong></td>
<td>O.D.</td>
</tr>
<tr>
<td><strong>Discard within 24 hours after opening package</strong></td>
<td>Product contains Phthalates</td>
</tr>
<tr>
<td><strong>Do not use if packaging or product damage is evident. For sterile products only, contents are sterile if package is unopened and undamaged.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.</strong></td>
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