4. Verify the expiration date on the package label prior to using the produce. If the expiration date has lapsed, do not use.
5. By after endoscopic surgery professional training of medical personnel to use operating according to operation specification.

**Operating environment** endoscopic surgery, clean, well ventilated, temperature of 10 ~ 30 °C, relative humidity: 30 ~ 80%, atmospheric pressure limitation of 86~106kPa.

**Packaging** One device per pouch, outside with carton and box.

**Manufacturing Date** It can be found on the package labels.

**Shelf life** Three years

**Labeling Instructions**

- Do not reuse
- Consult instruction for use
- Sterilized using Ethylene Oxide
- Keep away from sunlight
- Do not use if package is damaged
- Keep dry
- Use by date
- Batch code
- Date of manufacture
- Catalogue number
- Fragile handle with care
- Stacking no more than 6 layers
- Up
- Manufacturer
- Type BF Applied Part
- Humidity limitation
- Atmospheric pressure limitation
- Temperature limitation
- EU Certification by TUV-SUD
- To sale by or on the order of a physician.

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**Sterilization Method** EO sterilization.

**Storage Mode**
After packaging, the device shall be stored in an environment of relative humidity below 80%, temperature of -10°C ~ 40°C, atmospheric pressure limitation of 86~106kPa, and noncorrosive gases and well-ventilated room.

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**Polypectomy Snare**

**Instruction for use**

Manufactured for: KEY SURGICAL
8101 WALLACE ROAD / EDEN PRAIRIE, MN 55344 / USA
(US) PH: 800.541.7995 KEYSURGICAL.COM
(UK) TEL: +44(0)1628 810626 KEYSURGICAL.CO.UK
(EU): TEL: +49 4363 905900 INTERLOCKMED.COM

File No.: AG9.507AQ.0000.SM1.Z
Version: Z
Issued date: 2019.11.28
Polypectomy Snare

**Device Name**  Polypectomy Snare

**Intended use**
Polypectomy Snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

**Key Components**
- Handle
- Connector plug
- Fixed/Rotary part
- Sheath
- Electrode

**Diagram**

![Diagram](image)


**Model and Dimension**

<table>
<thead>
<tr>
<th>Model Specifications</th>
<th>Insert portion of maximum width (mm)</th>
<th>Open width of electrode (mm)</th>
<th>Working length (mm)</th>
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</thead>
<tbody>
<tr>
<td>Normal handle</td>
<td>5071/5072/5073/5074/5079</td>
<td>2.4</td>
<td>10/15/25/32</td>
</tr>
<tr>
<td>Rotate handle</td>
<td>5075/5076/5077/5078/5079</td>
<td>2.4</td>
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**Instruction for use**

1. Upon removing the device from the package, uncoil the device and visually inspect with particular attention to kinks, bends, breaks or fraying. If an abnormality is detected that would prohibit proper working condition, do not use.
2. Inspect the active cord. The cord must be free of kinks, bends, breaks and exposed wires to allow for accurate transfer of current. If an abnormality is detected that would prohibit proper working condition, do not use.
3. Do not use this device for any purpose other than the stated intended use.
4. Verify the minimal endoscopic channel size for the use of the device.
5. Proceed with polypectomy.
6. Upon completion of the polypectomy, turn the electrosurgical unit off. Retract the snare into the sheath and remove the device from the endoscope.
7. Following the electrosurgical unit manufacturer’s instructions for settings, verify the desired settings and activate the electrosurgical unit.
8. Do not use this device in conditions that would prohibit proper working condition, do not use.
9. When the polyp is in endoscopic view, introduce the sheath and retracted snare into the endoscope accessory channel. Caution: To ensure patient safety, the power to the electrosurgical unit should remain off until the snare is properly positioned around the polyp.
10. Advance the device, in small increments, until it is endoscopically viewed exiting the endoscope.
11. Upon completion of the procedure, disconnect the active cord from the device handle and dispose of this device per institutional guidelines for biohazardous medical waste.
12. The polyp and prepare the specimen per institutional guidelines.
13. Preparation and testing operation on the device, do not cause the sheath pipe distortion of the operation, prevent the damage of equipment.
14. Do not make the device with other equipment, such as high frequency coagulator cable winding device, electrodugram, endoscopic system, is likely to lead to abnormal function of other devices, which have a negative effect on the patients.
15. The output power of high frequency generator is lower, the better, not too demanding high frequency current, is limited to just assuring effect of the procedures.
16. The product with high frequency generator connected after its application part, its anti shock degree was determined by high frequency current will make the heart fibrillation, damaged pacemaker or producing electric shocks, resulting in patients with serious injury and even death.
17. According to the specified in the IEC60529:2013 on the degree of protection into liquid classification for IPX0.
18. According to the definition of item 4 of IEC/CISPR 11:2010, this product is expected for the hospital operating room, use of high frequency heating principle to realize electric cutting and electric coagulation, the electromagnetic characteristic classification for group 1 and class A.

**Model Specifications**

- Normal handle: 5071/5072/5073/5074/5079
- Rotate handle: 5075/5076/5077/5078/5079

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**Potential Complications**

Potential complications associated with gastrointestinal endoscopy include, but are not limited to: Perforation, fulguration, hemorrhage or late hair style immediately. Main symptoms were abdominal pain, fever and short intestinal cramps of burn through wall. Direct observation, in addition to the loop is correct orientation. Snare loop positioning undeserved can cause patient injury.

**Warning**

1. It is strictly prohibited to use this device implementation procedures for the patient that implant pacemakers and metal implants. When using the high frequency signal will make the heart fibrillation, damaged pacemaker or producing electric shocks, resulting in patients with serious injury and even death.
2. Do not make the device with other equipment, such as high frequency coagulator cable winding device, electrodugram, endoscopic system, is likely to lead to abnormal function of other devices, which have a negative effect on the patients.

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**Precaution**

1. If the product package is open or damaged when received, do not use this devise.
2. Verify the minimal endoscopic channel size for the use of the device from the product label.
3. Do not use this device for any purpose other than the stated intended use.