Diversatek™
Healthcare

# Lasso™
# Polypectomy Snare

***Instructions for use.***
***Read carefully prior to use.***

**Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.**


## Diversatek Healthcare

**Corporate Headquarters**
102 E. Keefe Ave.
Milwaukee, WI 53212 USA
**P** 800.558.6408 | 414.265.7620

sales@diversatekhc.com

## DiversatekHealthcare.com



**063-0057 Rev. B, 2019/02, ECO 1974**

**Diversatek Healthcare Lasso™ Polypectomy Snare**
*Instructions for Use.*
*Read carefully prior to use.*

**INTENDED USE**

The polypectomy snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

| Part Number | Description |
|---|---|
| 1180-01 | Oval, 10 mm, rotatable, 230 cm |
| 1180-02 | Oval, 15 mm, rotatable, 230 cm |
| 1180-03 | Oval, 25 mm, rotatable, 230 cm |
| 1180-04 | Oval, 32 mm, rotatable, 230 cm |
| 1180-10 | Hex, 15 mm, rotatable, 230 cm |
| 1180-11 | Hex, 10 mm, 15 mm, 25 mm, rotatable, 230 cm |

**CONTRAINDICATIONS**

The device's contraindications include those specific to endoscopic polypectomy:

1. Those specific to endoscopic procedures to obtain visualization of the polypectomy site.
2. Polyps and adenomas larger than 2 cm in diameter.
3. Multiple adenomatous polyps concentrated to a single area in large numbers.
4. Family neoplasia.
5. Endoscopic morphology has obvious progression suitable for surgical treatment.
6. Uncorrected clotting disorders.

**WARNINGS AND PRECAUTIONS**

1. It is strictly prohibited to use this device on patients with metallic implants such as pacemakers. The high frequency signal can induce heart fibrillation, damage the pacemaker, or produce electric shocks, resulting in serious injury and even death.
2. Do not allow the snare sheath to come into contact with other active equipment such as electrocardiogram monitors, endoscopic light sources and processors, and electrosurgical units. This may cause electromagnetic interference which could harm the patient.
3. If the proper setting of the generator is not known, one should set the unit at a power setting lower than the recommended range and cautiously increase the power until the desired effect is reached.
4. Do not bend the sheath with a radius smaller than 10 mm. Permanent deformation of the electrode lead and device failure may result.
5. Ensure that the device sheath is not distorted during preparation and testing of this device. A distorted sheath may damage equipment.
6. The polypectomy snare is used with a high-frequency coagulator system. The degree of protection against electric shock is determined by the operating frequency rather than the voltage of the coagulator.
7. If the product package is open or damaged when received, do not use this device.
8. Verify the minimum endoscopic channel size required for the use of the device from the product label.
9. Do not use this device for any purpose other than the stated intended use.
10. Verify the expiration date on the package label prior to using the product. If the expiration date has lapsed, do not use.
11. This device should only be used by a trained medical professional.
12. This device should be operated in a clean, well ventilated environment free of corrosive gases with a temperature of 10 ~ 30 °C, relative humidity: 30 ~ 80%, and atmospheric pressure range of 86~106 kPa.
13. It is suggested that the operator and the assistant wear protective gloves to prevent accidental burns. Universal precautions should be used in all cases. While operating the device avoid contact with the patient.
14. It is highly recommended that the user consult the current medical literature on recommended monopolar settings and techniques.
15. No modification of this equipment is allowed.
16. Fluids or flammable agents that may pool under the patient or in body depressions or cavities should be mopped prior to electrosurgery.

**INSTRUCTIONS FOR USE**

1. Upon removing the device from the package, uncoil the device and visually inspect for kinks, bends, breaks, fraying, or other damage. 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 noted, do not use the active cord.
3. Fully retract and extend the snare to confirm smooth operation of the device.
4. With the electrosurgical unit off, prepare the equipment. Securely connect the active cord to the device handle and electrosurgical unit. The active cord fittings should fit snugly into both the device handle and the electrosurgical unit. Following the instructions from the electrosurgical unit manufacturer, position the patient return electrode and connect it to the electrosurgical unit.
5. 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.
6. Advance the device, in small increments, until it is endoscopically viewed exiting the endoscope.
7. Following the electrosurgical unit manufacturer's instructions for settings, verify the desired settings and activate the electrosurgical unit.

**Note:** In order to ensure that the insulating properties of the device are not compromised, do not exceed the maximum rated peak voltage of 800 V. Polypectomy should not be attempted unless proficiency in technique has been developed by the clinician.

8. Proceed with polypectomy.
9. Upon completion of the polypectomy, turn the electrosurgical unit off. Retract the snare into the sheath and remove the device from the endoscope.
10. Retrieve the polyp and prepare the specimen per institutional guidelines.
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. If intending to apply cold snare technique to polyps < 10 mm, connection to the electrosurgical unit is not required. Extend the snare loop into position around the target polyp and pull the handle to resect.

**POTENTIAL COMPLICATIONS**

Potential complications associated with gastrointestinal endoscopy include, but are not limited to: Perforation, fulguration, and immediate or delayed hemorrhage. Main symptoms were abdominal pain, fever and short intestinal cramps. Direct observation is required. Improper snare orientation or position can cause patient injury.



**DESCRIPTION OF SYMBOLS USED ON LABELS**

| | |
|---|---|
|  | Manufactured for |
|  | Use-by date<br>(YYYY-MM-DD) |
| LOT | Lot number |
| REF | Part number |
| STERILE EO | Sterilized using ethylene oxide |
|  | Temperature limit |
|  | Humidity limitation |


Atmospheric pressure limitation


Keep dry


Do not use if package is damaged


Keep away from sunlight


Do not re-use


Consult instructions for use

Not made with natural rubber latex


Refer to instruction manual