Diversatek™
Healthcare

Lasso™
Rotatable Polypectomy Snare (COLD)

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

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INTENDED USE

The Lasso™ Rotatable Polypectomy Snare (COLD) is used for endoscopic removal of foreign bodies, especially for small polyps. It is used without diathermic energy. The device is supplied sterile and intended for single use only.

Part Number	Description
1180-12	Oval, 10 mm, Rotatable, 230 cm, Cold Only
1180-13	Oval, 15 mm, Rotatable, 230 cm, Cold Only
1180-14	Hex, 10 mm, Rotatable, 230 cm, Cold Only
1180-15	Hex, 15 mm, Rotatable, 230 cm, Cold Only

CONTRAINDICATIONS

Contraindications include, but are not limited to, those specific to endoscopic polypectomy.

WARNINGS AND PRECAUTIONS

1. If the product package is open or damaged when received, do not use this device.
2. The snares require an endoscope with a minimum working channel of 2.8mm.
3. Do not use this device for any purpose other than the stated intended use.
4. Verify the expiration date on the package label prior to using the product. If the expiration date is lapsed, do not use.
5. The device should only be used by a trained medical professional.
6. A full understanding of the technical principles, clinical applications, risks associated with cold snaring (non-electrical) polypectomy and tissue resection is necessary before using this product.
7. Disengage the snare from the polyps if there is risk of complication.
8. Be careful when grasping the tissue to avoid grasping tissue or organs that are not suitable for retrieval.

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. Fully retract and extend the snare to confirm smooth operation of the device.
3. When the polyp is in endoscopic view, introduce the sheath and retracted snare into the endoscope accessory channel.
4. Advance the device in small increments until it is endoscopically viewed exiting the endoscope.
5. Extend the snare loop into position around the target polyp and pull the handle to resect.
6. Retrieve the polyp and prepare the specimen per institutional guidelines.
7. Upon completion of the polypectomy, retract the snare into the sheath and remove the device from the endoscope.
8. Upon completion of the procedure, dispose of this device per institutional guidelines for biohazardous medical waste.

POTENTIAL COMPLICATIONS

Potential complications associated with gastrointestinal endoscopy include, but are not limited to: Perforation, hemorrhage, aspiration, fever, infection, hypotension, allergic reaction to medication, respiratory depression or arrest, cardiac arrhythmia, or arrest. 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 (YYYY-MM-DD)
	Lot number
	Part number
	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