CAELARIS

Please read all instructions before using this device.

SLYCER Cold Snare

Instruction for use

Rx ONLY

STERILE EO

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SLYCER Cold Snare

【Device Name】SLYCER Cold Snare

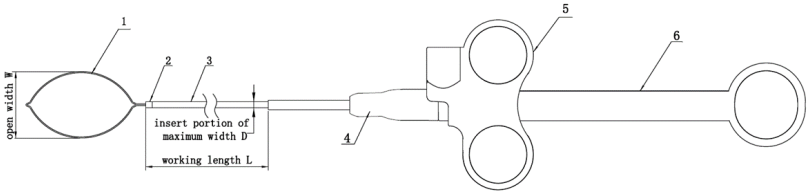
【Intended Use】

The device is used for endoscopic remove foreign bodies, especially for the small polyps. It is used without energy. The device is supplied sterile and intended for single use only.

【Intended patient population】

Adult

【Key Components】Handle, Connect part, Metal cap (Applicable to specifications of model CS10RM& CS15RM), Sheath tube, Sliding handle, Loop.



【Diagram】

1. Loop 2. Metal cap (Applicable to specifications of model CS10RM& CS15RM) 3. Sheath tube
4. Connect part 5. Sliding handle 6. Handle

【Model and Dimension】

Loop shape	Models		Insert portion of maximum width (mm)	Open width of loop (mm)	Working length (mm)
Oval/ Round	Rotary handle	CS Series	Φ2.4	10/15	2300
Shield			Φ2.4	10/15	2300

【Direction for Use】

1.Taking out the device from the pouch and uncoiling it. Carefully inspect whether there are kinks, bents or breaks on the surface. If an abnormality is detecting that may hinder its performance, do not use it.
2.Fully retract and extend the snare to ensure the operation of the device smoothly.
3.When the polyps is under the endoscopic view, retracting the snare into the sheath then inserting the sheath into the endoscopic working channel.
4.Gently push the device until it can be seen under the endoscopic view.
Caution: When the polyps is smaller than 5mm, and the patient has no blood coagulation dysfunction.
5. Try to use the snare trap the target foreign body or polyps, then slowly tighten the snare.
6. Upon completion of the trap, retract the snare into the sheath and remove the device from the endoscope.
7. Retrieve the polyps and prepare the specimen according to the institutional guidelines.
8. Upon completion of the procedure, dispose of this device according to the institutional guidelines for bio-hazardous medical waste.

【Contraindications】

1.Those specific to the primary endoscopic procedure to be performed in gaining access to the polypectomy site.
2.Include, but not limited to: Coagulopathy and insufficiently prepped bowel.

【Potential Complications】

Most common potential complications:
1. Immediate or delayed hemorrhages.
2. Immediate or delayed perforation.
3. Abdominal pain.
Other possible potential complications include, but not limited to: hyponatremia and hematochezia.

【Notes】

1.To prevent permanent deformation of the electrode, please do not attempt to bend the outer sheath with a small diameter (less than 20mm), which may cause difficulty in operation or even failure of the instrument.
2. To ensure the snare goes through the endoscope channel smoothly: Specification: φ2.4 series of snare requires the

endoscope channel larger than 2.8mm. It is recommended using the Cold Snare with Olympus Corporation's endoscopes.
3. The device is not made with natural rubber latex.

【Precaution】

1. If the product package is open or damaged when received, do not use this device.
2. 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.
3. Disengage the snare from the polyps if there is risk of complication.
4. Be careful when grasping the tissue to avoid grasping tissue or organs that are not suitable for retrieval inadvertently.
5. Verify the minimal endoscopic channel size from the product label.
6. Do not use this device for any purpose other than the stated intended use.
7. Verify the expiration date on the package label prior to using the produce. If the expiration date is lapsed, do not use.

【Operating environment】 Ambient temperature:10~40℃, Relative humidity:30~85%.

【Packaging】 One device per pouch, with box.

【Manufacturing Date】 It can be found on the package labels.

【Sterilization Method】 EO sterilization.

【Expiration for Sterilization】 Three years after sterilization.

【Storage】

After packaging, the device shall be stored in an environment of relative humidity below 80%, temperature of -10℃ - 40℃, and noncorrosive gases and well-ventilated room.

【Labeling Instructions】

	Do not re-use		Consult instructions for use or consult electronic instructions for use		To sale by or on the order of a physician
	Use-by date		Batch code		Catalogue number
	Date of manufacture		Sterilized using ethylene oxide		Medical Device
	Fragile，handle with care		Stacking no more than 6 layers		Keep away from sunlight
	Up		Manufacturer		Do not resterilize
	Single sterile barrier system		Keep dry		Do not use if package is damaged and consult instructions for use
	Atmospheric pressure limitation		Temperature limit		Humidity limitation
	Single sterile barrier system with protective packaging outside		Unique Device Identifier		Caution



Manufactured For:

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Made in China

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