INSTRUCTIONS FOR USE DISPOSABLE COBRA™ Snares
Rotatable Retrieval Device

DEVICE DESCRIPTION

- The COBRA™ Snare consists of a snare at the distal end a and a retrieval net at the proximal end of the snare. The device is extended and retracted from the outer sheath using a three-ring handle. The device is available with an hexagonal or oval tip.
- The device used in conjunction with an electrosurgical unit for endoscopic polypectomy and can be used without electrosurgical unit as a cold COBRA™

WARNING

- Endoscopy should only be performed by a physician who has adequate experience and training.
- Please read these instructions carefully, failure to follow these instructions may lead to serious medical consequences.
- This device is for single use only. Do not reuse, reprocess or re-sterilize. Reuse, re-processing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection including, but not limited to, transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury illness or death of patient.
- Used product and packing should be disposed of in accordance with hospital, administrative and/or local government policy.

INTENDED USE

- The COBRA™ Snare is intended to be used by licensed physicians only (excluding non-physician specialists) with adequate training and experience in the removal and collecting of polyps, from the gastrointestinal tract under endoscopic visualization

INDICATIONS

This device is indicated for removal and collecting of polyps in the gastrointestinal (GI) tract under endoscopic visualization. COBRA™ Snare may be used in Hot or Cold mode.

When selecting the COBR™ Snare for use, the physician shall asses the suitability of the device for the patient age and anatomy. In general, a 2.5mm diameter snare is designed for adults

ENVIRONMENT OF USE

The intended environment of use is at a physician's office or hospital operating room

CONTRAINDICATIONS

- General medical condition that would not allow tolerance to endoscopy and/or other manipulation required.
- Patients demonstrating resistance.
- The device may not be used for applications other than for which it is intended.
- The device must not be passed through an incompatible endoscope (colonoscopy, gastroscopy and bronchoscopy)
- The device must not be re-sterilized and reused.
- The device is not intended to be implanted

PRECAUTIONS

- The device is ETO ste. Do not use this device if there is any evidence of damage trileo the sterile package.
- Do not use this device for any purpose other than the stated intended use.
- Verify the expiration date on the package label of sterile devices prior to using the product. If the expiration date has lapsed, do not use or re-sterilize the device.

WARNINGS

- 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.
- This device is not intended to be used in the presence of flammable liquid, in an oxygen enriched atmosphere or in the presence of explosive gases.
- Any electrosurgical device constitutes a potential electrical hazard to the patient and/or the operator.
- No modification of this device is allowed.
- Fluid or flammable agents that may poll under the patient or in body depressions or cavities should be mopped prior to electro surgery.

INSTRUCTIONS FOR USE

1. Insert the device into the biopsy port of the endoscope. Short strokes, 1”-1.5” (2.5 cm-3.8cm) in length, are recommended throughout device passage to avoid sheath kinking.
2. Position patient return electrode and connect to electrosurgical unit following instructions from the electrosurgical unit manufacturer.
3. Attach the respective endoscope active cord to the COBRA™ snare’s diathermic handle connection just prior to excision of polyps or tissue.
4. Consult the electrosurgical generator manufacturer’s instructions for use for proper settings and use of the electrical surgical generator.
5. When the polyp has been endoscopically visualized, extend the distal tip of the catheter into the endoscopic field of view.
6. Gently deploy the snare loop to a fully open position.
7. Place the snare around the polyp tissue being resected using proper endoscopic technique
8. Rotation of the handle to the tip of snares is one to one. Rotate the instrument before you connect the power cord and position it over the polyp.
9. Resect the polyp using proper surgical technique. The electrosurgical generator should be set to the proper setting that will allow resection with controlled hemostasis.
10. After the polyp(s) has been satisfactorily resected, the polyp will stay inside of the net.
11. Retract the scope with the COBRA™ Snare holding the polyp.
12. Once the polyp(s) has been satisfactorily resected, the polyp fragment(s) should be removed and the specimen(s) prepared according to standard technique for histologic evaluation.

REPORTING

Customer in the EU shall report any serious incident associated with the device to their National Competent Authority, distributor, and Horizon International Corporation.

Any serious incident that has occurred in relation to the device must be notified to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

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This product is protected by one or more of the following United States Patents:9,101,342; 8,858,567.

COBRA™ is a Trademark of Horizons International Corp.

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Symbol	Description	Symbol	Description
CR	Contry of manufacture		Translation
	Date of manufacture		Do not use if package is damaged
	Use by date		Do not re-use
LOT	Batch Code		Consult instructions for use
REF	Catalogue number		Important cautionary information
STERILE EO	Sterilized using ethylene oxide		Do not re-sterilize
℞ ONLY	Caution Federal (USA) law restricts this device to sale by or on the order of a physician	LATEX	Latex Free
	Keep Away from Sunlight		Keep Dry
	Type BF applied part	MD	Medical Device
	Importer	EC REP	Authorized Representative
UDI	Unique device identifier		Refer to instruction manual/ booklet
	Sterile Barrier		