Exacto® コールド スネア

Exacto® cold snare

再注文番号HZ-711115

Reorder No. HZ-711115

取扱説明書
INSTRUCTIONS FOR USE

US Endoscopy
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A subsidiary of STERIS Corporation

00731875 Rev. C

This product is not made with natural rubber latex.

Intended Use:
The Exacto® cold snare is intended to be used without diathermic energy for the endoscopic resection of polyp tissue in the gastrointestinal tract.

Description	Product Number	Sheath Diameter	Sheath Length	Wire Diameter	Approximate Snare Size (mm) Width and Length
Exacto® cold snare	HZ-711115	2.4 mm	230 cm	0.30mm .012 inches	9 X 19

Warnings and Precautions:

- Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques.
- Consult the medical literature relative to techniques, contraindications, complications and hazards prior to any endoscopic procedure.
- A thorough understanding of the technical principles, clinical applications, and risks associated with cold snaring (non-electrical) polypectomy and tissue resection is necessary before using this product.
- These devices are compatible with an endoscope channel of 2.8 mm or larger.
- Do not attempt to reuse, reprocess, refurbish, remanufacture, or resterilize this device. STERIS Endoscopy did not design this device nor is it intended to be reused, reprocessed, refurbished, remanufactured, or resterilized. Performing such activities on this disposable medical device presents a safety risk to patients (i.e. compromised device integrity, cross-contamination, infection).
- Disengage the snare from the polyp if there is a risk of complication.
- Care should be exercised when grasping tissue to avoid inadvertently grasping tissue or organs not intended for retrieval.
- If resistance to insertion is encountered, reduce the angulation (or lower the forceps elevator if applicable) until the instrument passes smoothly.
- Short strokes, 1”-1.5” (2.5cm – 3.8cm) in length, are recommended throughout device passage to avoid sheath kinking.
- The following conditions may not allow the device to function properly or cause patient injury:
  1) Attempting to advance the handle to the open position with too much speed or force,
  2) Attempting to pass or open the device in an extremely articulated endoscope,
  3) Attempting to actuate the device in an extremely coiled position and/or,
  4) Attempting to actuate the device when the handle is at an acute angle in relation to the sheath.

Contraindications:

- Contraindications include, but are not limited to, those specific to any endoscopic procedure.

Prior to Use:

1. Prior to clinical use, inspect and familiarize yourself with the device. If there is evidence of damage**, do not use this product and contact your local Product Specialist.**
2. Ensure that the device is compatible with an endoscope channel of 2.8mm or larger before insertion.
3. Remove the device from the package and uncoil the entire device and drape in a “U” shaped configuration, holding the proximal end in one hand and the distal sheath in the opposite hand.
4. Move the finger rings back and forth to confirm that the snare loop opens and closes smoothly prior to inserting into the endoscope.
5. Ensure the snare loop is fully retracted into the catheter prior to insertion into the endoscope.

   - Note: The Exacto® cold snare is *not* intended to be used with diathermic energy and, therefore, has no diathermic handle connection.

Directions for use:

1. Insert the device into the biopsy port of the endoscope using short strokes, approximately 1”-1.5” (2.5cm – 3.8cm) in length throughout device passage to avoid sheath kinking.
2. When the polyp has been endoscopically visualized, extend the distal tip of the catheter into the endoscopic field of view.
3. Gently deploy the snare loop to a fully open position.
4. Place the snare around the polyp tissue being resected using proper endoscopic technique.
5. After the polyp(s) has been satisfactorily resected, the snare should be retracted back into the catheter.
6. The polyp tissue should be collected and the specimen(s) prepared according to standard technique for histologic evaluation.

Product Disposal:

After use, this product may be a potential biohazard which presents a risk of cross-contamination. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Issued Date: September 2019

Warning:
An issued or revision date for these instructions is included for the user's information. In the event that two years have elapsed between this date and product use, the user should contact STERIS to determine if additional information is available.

Serious incidents that have occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred.

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Made in the U.S.A.

ラベルおよび取扱説明書にあるマークの説明
Explanation of symbols used on Labels and Instructions for Use

SDO (if applicable)	Symbol and Reference Number	Title of Symbol	Meaning of Symbol
ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling, and information to be supplied	**5.1.1** 	**Manufacturer** **メーカー**	**Indicates the medical device manufacturer** **医療機器の製造業者を示します**
	5.1.3 	**Date of Manufacture** **製造日**	**Indicates the date when the medical device was manufactured** **医療機器が製造された日付を示します**
	5.1.4 	**Use By** **使用期限**	**Indicates the date after which the medical device is not to be used.** **医療機器が使用されなくなる日付を示します**
	5.1.5 	**Batch Code** **バッチ コード**	**Indicates the manufacturer's batch code** **メーカーのバッチ コードを示します**
	5.1.6 	**Catalog Number** **カタログ番号**	**Indicates the manufacturer's catalogue number** **メーカーのカタログ番号を示します**
	5.2.3 	**Sterilized by Ethylene Oxide** **酸化エチレンで滅菌済み**	**Indicates a medical device that has been sterilized using ethylene oxide** **酸化エチレンを使用して滅菌された医療機器であることを示します**
	5.2.6 	**Do Not Re-Sterilize** **再滅菌禁止**	**Indicates a medical device that is not to be resterilized** **再殺菌されない医療機器であることを示します**
	5.2.8 	**Do not use if package is damaged** **包装が破損している場合は使用禁止**	**Do not use if the product sterile barrier system or its packaging is compromised.** **製品の無菌バリア システムまたはその包装が破損している場合は使用しないでください。**
	5.3.4 	**Keep dry** **湿気厳禁**	**Indicates a medical device that needs to be protected from moisture** **湿気から保護する必要がある医療機器であることを示します**
	5.3.1 	**Biological Risks** **生物学的リスク**	**Indicates that there are potential biological risks** **潜在的な生物学的リスクがあることを示します**

	5.4.2 	**Do not reuse** **再利用の禁止**	**Indicates a medical device that is intended for a single procedure** **単一の手順を対象とした医療機器でることを示します**
	5.4.3 	**Consult instructions for use** **使用説明書の参照**	**Indicates the need for the user to consult instructions for use** **使用説明書を参照する必要があることを示します**
	5.4.4 	**Caution** **注意**	**Consult instructions for use for cautionary information** **注意事項については、使用説明書を参照してください**
21 CFR 801.109 (b) (1)	N/A  Rx Only (U.S.A)	**Caution: Federal law (U.S.A.) restricts this device to sale or on the order of a physician.** **注意：連邦法（米国）により、本機器の販売先は医師の指示を受ける者のみに制限されています。**	
N/A	**N/A** 	**Unique Device Identifier** **固有の機器 ID**	**Indicates the unique device identifier** **固有の機器 ID を示します**
N/A	**N/A** 	**Medical Device** **医療機器**	**Indicates the product is a medical device** **本製品は医療機器であることを示します**
N/A	**N/A** 	**Contents** **内容物**	**Number of devices/kits within packaging** **包装内の機器/キットの数**
N/A	**N/A**	**Length** **長さ**	**Indicates length measurement** **長さ測定値を示します**
N/A	**N/A** 	**O.D.** **外径**	**Indicates outer diameter** **外径を示します**