CAELARIS

FYNESSE Hot Snare

Instructions for Use

Rx ONLY

STERILE EO

CAELARIS

Please read all instructions before using this device.

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FYNESSE Hot Snare

【Device Name】FYNESSE Hot Snare

【Intended Use】

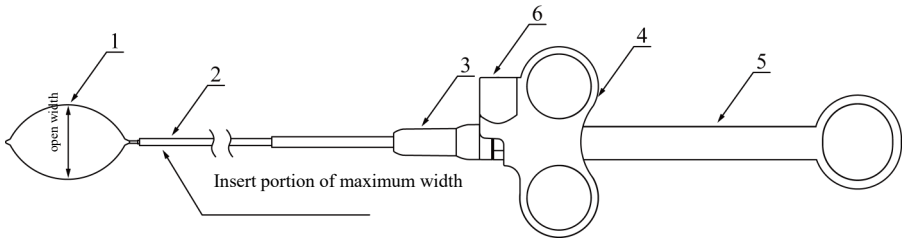
The Polypectomy Snare is used endoscopically in the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.

【Key Components】

Sliding handle, Handle, Connect part, Connect plug, Sheath tube, Electrode.

【Intended patient population】Adult

【Diagram】



1.Electrode 2.Sheath tube 3.Connect part 4.Sliding handle 5.Handle 6.Connector plug

Figure 1

【Model and Dimension】

Electrode shape	Models		Insert portion of maximum width (mm)	Open width of electrode (mm)	Working length(mm)	Snare indication
Oval/ Shield/ Diamond/ Hexagon	Rotary handle	HS&HSH Series	Φ2.4	10/15	2300	Hot/cold
			Φ2.4	25/32	2300	Hot
Round		HS15RR HS25RR	Φ2.4	15/25	2300	Hot

【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 detect that may hinder its performance, do not use it.
2.Inspect the active cord, which must be free of kinks, bends, breaks, exposure for accurate energizing. If there is any abnormality, do not use it.
3.Fully retract and extend the Snare to ensure the operation of the device smoothly.
4.Turn off the electrosurgical unit, and perform the device. Tightly Match the Connector plug and the electrosurgical unit by an appropriate active cord. In accordance with the IFU of electrosurgical unit, placing the negative electrode on the patient and connecting it to the electrosurgical unit.
Or, for the polyps not more than 9mm, if it is intended to be used as a cold snare, don't need to connect with the electrosurgical unit.
5.When the polyps is under the endoscopic view, retracting the snare into the sheath then inserting the sheath into the endoscopic working channel.
Caution: To ensure the patient's safety, the power to the electrosurgical unit should be off until the snare is properly positioned around the polyps.
6.Gently push the device until it can be seen under the endoscopic view.

7.Following the IFU of electrosurgical unit, verifying the desired settings and activating the electrosurgical unit.

Notes： In order to ensure that the insulating properties of the device, do not exceed the maximum rated peak voltage of 800 Vp. Polypectomy must be used by a trained clinician.

Or, for the polyps not more than 9mm, if it is intended to be used as a cold snare, don't need to connect with the electrosurgical unit, just operate the handle to extend the snare loop out to trap the target polyp, and pull the slider to resect.

8.Proceed with polypectomy (hot or cold).

9.Upon completion of the polypectomy, turn off the electrosurgical unit. Retract the snare into the sheath and remove the device from the endoscope.

10.Retrieve the polyps and prepare the specimen according to institutional guidelines.

11.Upon completion of the procedure, disconnect the active cord from the device handle and dispose of the device according to institutional guidelines for biohazardous medical waste.

12.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 Polypectomy Snare with Olympus Corporation's endoscopes.

13.It is recommended using the Polypectomy Snare with ERBE Corporation's electrosurgical unit (Model: VIO 300D).

14. For endoscopic surgery, use the CAELARIS' VYSE Hemoclip,The released Hemoclip can be removed by using the Polypectomy Snare to take the part of the collet to tighten the groove on the upper end of the tube. Place the removed Hemoclip close to the distal end of the endoscope and exit the digestive tract together with the endoscope. Please refer to the following steps:

14.1 Entangling the polypectomy snare to the groove of the clip's bottom (as shown in Figure 1).

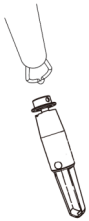


Figure 1

14.2 Gently shrink the snare, and tighten the snare until the closed clip is re-opened, then remove it from the lesion tissue (as shown in Figure 2)

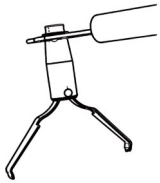


Figure 2

14.3 Treat the removed clip in the same way as the removed foreign body.

【Contraindications】

Contraindications for these devices are those specific to endoscopic polypectomy and tissue resection:

1. Associated with endoscopic operation.
2. Sessile polyps larger than 2cm.
3. Multiple adenomatous polyp and, confined to a single concentrated distribution, larger number.
4. Familial adenomatous polyposis(FAP).
5. Endoscopic morphology has obvious progression, and is suitable for surgical treatment.

The following conditions must be strictly evaluated by the physician:

1. Patients with blood coagulation dysfunction.
2. Patients with hepatic and renal dysfunction.
3. Other conditions need to be evaluated.

【Potential Complication】

Most common potential complications:

1. Immediate or delayed hemorrhages.
2. Immediate or delayed perforation.
3. Post-polypectomy coagulation syndrome (the development of abdominal pain, fever, leukocytosis, and peritoneal inflammation in the absence of bowel perforation after polypectomy with electrocoagulation).

Other possible potential complications include, but not limited to: bloody stool, fulguration, deep mural injury, hyponatremia and transmural burns (characterized by abdominal pain, fever, and transient ileus).

【Warning】

1. It is strictly prohibited to use this device implementation procedures for the patient who implant pacemakers and metal implants. High frequency signal during the usage will cause the heart fibrillation, damage pacemaker or produce electric shocks, resulting in patients with serious injury and even death.
2. Do not use the device together with other equipments, such as high frequency coagulator cable winding device, electrocardiogram, endoscopic system, which may lead to abnormal function of other equipments, and cause a negative effect on the patients.
3. The output power of high frequency generator is the lower the better, do not require higher frequency current, to ensure the effect of the surgical
4.To prevent permanent deformation of the electrode, pls 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.
5.When preparing and testing the electric snare, do not twist the outer sheath to prevent damage to the instrument.
6.Matching the connector plug with the electrosurgical unit, then its anti shock degree was determined by electrosurgical unit.
7.According to the requirements of IEC60529:2013 on the degree of protection into liquid classification for IPX0.
8. According to the definition of item 4 of IEC/CISPR 11:2010, this product is expected for the hospital operating room, using high frequency heating principle to realize electric cutting and electric coagulation. The electromagnetic characteristic classification is group 2 and class A.
9. Direct observation, in addition to the loop is correct orientation, Snare loop positioning undeserved can cause patient injury.
10. EMC: This instrument complies with the standard IEC 60601-1-2 and IEC 60601-2-2.
10.1 Polypectomy Snare is used in conjunction with electrosurgical unit , and the accessories, transducers and cables used should be specified or provided by the manufacturer. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this system could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
10.2 The environment for which the system is suitable: hospital operating room.
10.3 Use of this system adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this system and the other equipment should be observed to verify that they are operating normally.
10.4 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this system could result.
10.5 The EMISSIONS characteristics of this instrument make it suitable for use in hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this instrument might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
10.6 Essential Performance of the ME SYSTEM which consists of electrosurgical unit and Polypectomy Snare : For standby mode and modes that maximize emissions, the actual output power should not exceed ±20% of the output setting.

Manufacturer's instructions and guidance –Electromagnetic Emission	
This instrument is suitable for operation under the electromagnetic Emission environment specified below. The user must ensure that the instrument is operated in the specified environment.	
Emission Test	**Compliance**
Radiated Emission CISPR11	Group 2
Radiated Emission CISPR11	Class A

Manufacturer's instructions and guidance –Electromagnetic Immunity		
This instrument is suitable for operation under the electromagnetic Emission environment specified below. The user must ensure that the instrument is operated in the specified environment.		
Phenomenon	**Basic EMC standard or test**	**IMMUNITY TEST LEVELS**
		Professional healthcare facility environment
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM Fields [a]	IEC 61000-4-3	3 V/m [f] 80 MHz – 2,7 GHz [b] 80 % AM at 1 kHz [c]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 1 below.
Conducted disturbances induced by RF fields [h] [i] [j]	IEC 61000-4-6	3 V [k] 0,15 MHz – 80 MHz 6 V [k] in ISM bands between 0,15 MHz and 80 MHz [l] 80 % AM at 1 kHz [m]
RATED power frequency magnetic fields [d] [e]	IEC 61000-4-8	30 A/m [g] 50 Hz or 60 Hz

a) The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.
b) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.
c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.
e) During the test, the ME EQUIPMENT or ME SYSTEM may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1).
f) Before modulation is applied.
g) This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.
h) Calibration for current injection clamps shall be performed in a 150 Ω system.
i) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
j) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.
k) r.m.s., before modulation is applied.
l) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
m) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

Table 1-Test specifications for ENCLOSURE PORTIMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 –390	TETRA 400	Pulse Modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse Modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b] 18 Hz	2	0,3	28
870						
930						
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b] 217 Hz	2	0,3	28
1845						
1970						
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

11.The polypectomy snare can only be used specifically with CAELARIS' VYSE Removable series Hemoclips (cleared in K211787) and cannot be used with other hemoclips.

【Precaution】

1. If the product package is open or damaged when received, do not use this device.
2. Verify the minimal endoscopic channel size for the use of the device from the product label.
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 device. If the expiration date is lapsed, do not use.
5. This product must be used by a trained physician.
6. Do not cut more than 5 polyps with a single device.

【Operating environment】 endoscopic surgery, clean, well ventilated, temperature of 10 ~ 30 ℃, relative humidity: 30 ~ 80%, atmospheric pressure limitation of 86~106kPa.

【Packaging】One device per pouch, outside with carton and box.

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

【Expiration for Sterilization】Three years after sterilization.

【Sterilization Method】EO sterilization.

【Storage】

After packaging, the device shall be stored in an environment of relative humidity below 80%, temperature of -10℃~+ 40℃, atmospheric pressure limitation of 86~106kPa, 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
	Caution		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		Type BF Applied Part	UDI	Unique Device Identifier
	Single sterile barrier system with protective packaging outside				



Manufactured For:
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Made in China

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