
Single-Use Biopsy Forceps



INSTRUCTIONS FOR USE

STERILE	EO
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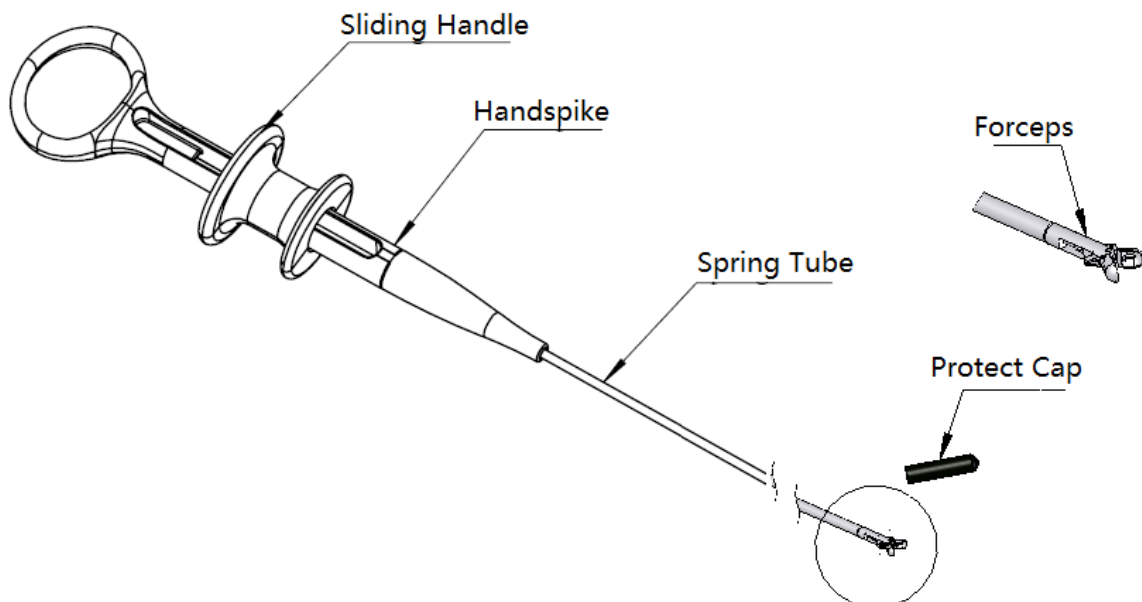


Rx ONLY**CAUTION:** This device should be sold by or on the order of a physician**WARNING:**

1. Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your ANREI MEDICAL representative.
2. For single use only. DO NOT REUSE, REPROCESS OR RESTERILIZE. Reuse, reprocessing or resterilization 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 resterilization may also create a risk of contamination of the device and /or cause patient infection or cross-infection, including, but not limited to , the transmission of infections disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
3. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

【Device Name】 Single-Use Biopsy Forceps**【Intended Use】** This device is used to enter human gastrointestinal tract (stomach or duodenum) via endoscope to obtain tissue sample in order to understand disease pathology.**【Structure】**

The structure is shown in figure 1.



Jaw Diameter X can be used in ϕ 2.8, ϕ 3.2 working channel.

【Functional Characteristics】

1. Using smooth coil to avoid any possible damage to the endoscope channel; under the guidance of endoscope it can easily enter human body to obtain tissue samples.
2. The device uses multi-link or steel wire hook structure to make it easier and more flexible to grasp tissue samples.
3. The device is sterile and easy to operate.
4. The cups use medical grade stainless steel material. They have great hardness and the blade is sharp which prevents patient from having trauma.

【Direction for Use】

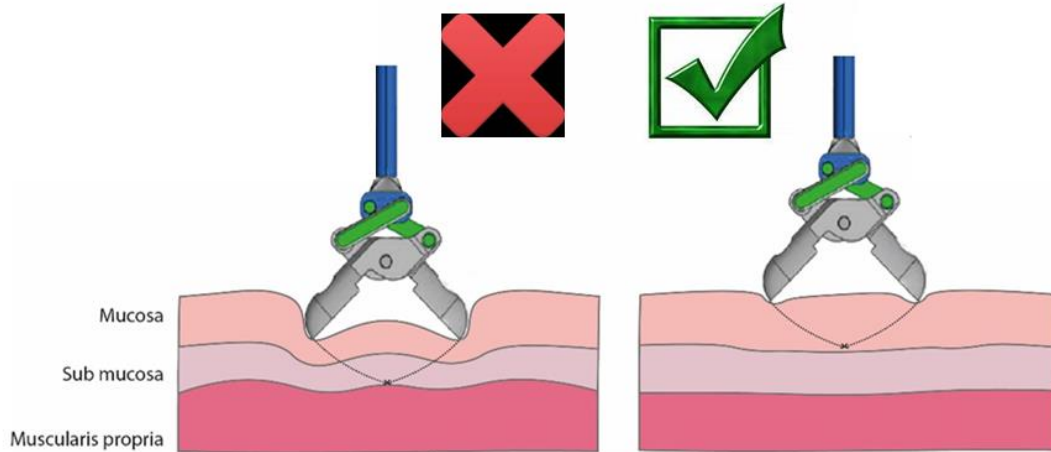
They are first inserted into the accessory channel of endoscope and into the stomach or duodenum. The jaws of the forceps are targeted to lesion. Then the handle is moved forward to open the jaws, the jaws positioned to the tissue sample, the spool pulled to close the jaws, and the device withdrawn to retrieve the tissue sample.

【Potential Side Effects】

They can be bleeding, broken tissue, and infection. Be aware the possible existence of side effects even the device is used correctly. Thus, the device is used only for patients during specific operations.

【Caution】

1. Do not use if the package is open or damaged.
2. Do not use if it is expired.
3. The device is a single use sterile product. Destroy after use. Do not reuse.
4. The device can only be operated by the trained clinician.
5. Model A, B, C, D, J, K, M, N biopsy forceps can offer the larger cutting force for tissue collection by using. In order to decrease adverse event, for example: excessive bleeding and perforation. The operators need to follow these steps as follows:
When the forceps are in open position on the mucosa before collection, limit the pushing force of the forceps on the mucosa. A gentle push will help to control the biopsy depth in the wall.



Although the operators follow the above steps, these possibilities of excessive bleeding and perforation cannot be absolutely excluded.

【Packaging】

Pouch: 1 set per pouch

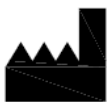
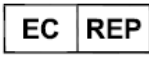






Box: 10 pouches per box






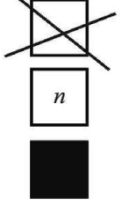





Carton: 10 boxes per carton

【Date of Manufacture】

Please refer to the label on pouch.

【Symbol Instruction】

	Manufacturer		Authorized representative in the EC
	Date of manufacture		Use-by date
	Batch code		Catalogue number
	Sterilized using ethylene oxide		Do not use if package is damaged

	Fragile, handle with care		Keep away from sunlight
	Protect from heat and radioactive sources		Keep dry
	This way up		Stacking limit by number
	Temperature limit		Do not re-use
	EC notified body identification number		Caution
	Consult instructions for use		

【Sterilization】 Sterilized using ethylene oxide

【Storage】 After packaging, the device shall be stored in an environment that has relative humidity of less than 80%, temperature of 10°C - 40°C, and no corrosive gases and is well-ventilated.

【Shelf Life】 3 years after sterilization.

【Manufacturer】 Anrei Medical (HZ) Co., Ltd.

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【Zip Code】 310018

【Telephone Number】 400-8096118

【Fax Number】 86-571-87603502

【Website】 www.anrei.com.cn

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