CAELARIS

EXTRACTA Biopsy Forceps
Instructions for Use

Rx ONLY

STERILE EO

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Please read all instructions before using this device.

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EXTRACTA Biopsy Forceps

【**Device Name**】EXTRACTA Biopsy Forceps

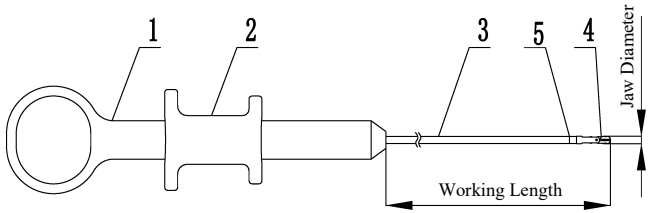
【**Intended Use**】

This device is used to enter human gastrointestinal tract (stomach or duodenum) via flexible endoscope to obtain tissue sa mple in order to understand disease pathology.

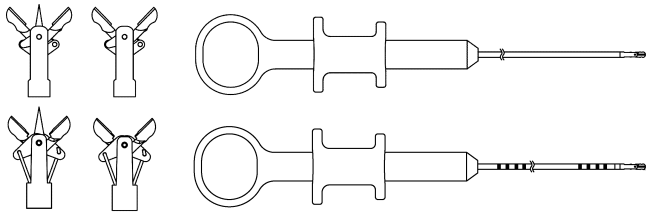
【**Key Components**】 Stainless steel and ABS

【**Intended patient population**】Adult

【**Diagram**】



1.Handle part 2.Sliding Handle 3.Spring Hose 4.Forceps Head Part 5.Spring end



【**Model and Dimension**】

Model / Specification	Jaw Diameter (mm)	Working Length (mm)	Minimum diameter of suitable working channel	Plastic Coated or not	Swinging or not	Rotatable or not	Jaw Description
FJ Series /FLG Series /FPDNS Series	1.8/2.3/ 2.8	1600/2300	⌀2.0/⌀2.8/⌀ 3.2	Yes	No	Yes	Smooth Edge / Smooth Edge With Spike/Precision Serrated /Precision Serrated With Spike
FSD Series	2.3	2300	⌀2.8	Yes	Yes	No	

【**Features**】

1.A flexible tube with smooth appearance is used to avoid damage to the endoscope channel, and under the guidance of the endoscope, it is easy to enter the human gastrointestinal tract to obtain tissue samples.
2.The forceps are assembled for more flexible open-close and a safe construction.
3.Arc design is adapted in each transition component of forceps. The damage to the endoscope channel and human body is small.
4.The product is sterile product and easy to use.

【**Directions for Use**】

1.Observing the biopsy object through endoscope and choosing suitable biopsy forceps for endoscopy test and grasping object.
2.Pulling the slider to close the jaws and inserting the forceps along the biopsy channel of the endoscope.
3.Slowly advancing the biopsy forceps until the distal end of the forceps appear within the endoscopic field of view.
4.Pushing the forceps to the target biopsy site, opening the cups and pushing closely to the tissue. If the angle of the forceps head is found to be inappropriate, the hose and the forceps head can be driven by rotating the handle to rotate the biopsy forceps as a whole and adjust to the appropriate angle.
Note:

1) The forceps cup of model FSD Series can be swinging. Pushing one of the opening cups forward against the side wall of the tissue, the opening cup can be swinging for gripping.
2) The forceps cup of model FJ Series, FLG Series and FPDNS Series Series can be rotating. The forceps cup can rotate a long with handle.
5.Pulling the slider to close the forceps for grasping the tissue.
6.Caution: If the forceps fail to be closed, remove both the endoscope and biopsy forceps from the body's natural cavity, then manually close the cup and withdraw the biopsy forceps from the endoscope
7.Pull back the slider to keep cups closed and gently withdraw forceps from endoscope.
8.Preparing the specimens for testing in accordance with national and regional institutional guidelines.

【Precaution】

1.Do not use if the package is damaged.
2.Expired products are prohibited.
3.Read the IFU carefully prior to use.
4.Prior to use, examine the device for any damage or malfunction such as drops, bent components or inability to open and close the jaws. If the problem exists, please do not use.
5.During use, gently push the forceps through the endoscope channel. If resistance is encountered during advancing, do not apply force in case of damaging the endoscope.
6.This device is intended for single-use only. Do not re-use, reprocess, or re-sterilize single-use products. After use, dispose of it according to local and institutional guidelines.
7.This product must be used by a trained physician.

【Warning】

1.Do not force the distal end of the insertion portion against body cavity tissue, which might cause patient injury, such as perforation, bleeding, or mucous membrane damage.
2.Do not insert the instrument into the endoscope while the cups are open. Otherwise, patient injury, such as perforation, bleeding, or mucosal membrane damage could occur. It could also damage the endoscope and/or instrument.
3.The biopsy may cause bleeding. The risk of bleeding increases if you take a large sample or press excessively on the tissue distal to the instrument. Biopsy only in the smallest area necessary.
4.Make sure that the cups closed evenly and are properly aligned when the slider is pulled.

【Contraindication】

The contraindication related to the operation of endoscopy with biopsy forceps includes (but not limited) disorder of blood coagulation.

【Potential Complications】

Most common potential complications:

1.Bleeding.
2. Pain.
3.Hypoxia.
4.Fever.
5.Superficial mucosal tear.

The following complications are specific to biopsy in the upper airways and tracheobronchial tree:

6.Pneumothorax.
7.Hemoptysis.
8.Pneumonia.

Other possible potential complications include, but not limited to: infection, perforation death and lung lacerations (specific to biopsy in the upper airways and tracheobronchial tree).

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

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



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Made in China

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