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受控状态:

受控

一次性使用活检钳 英文版使用说明书 (A/0 版)

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文件修订记录

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Disposable Biopsy Forceps

User Manual

Important Information to Customers

Security ID and Definitions

The safety information included in this instruction help users identify potential hazards and avoid them. Two IDs are used herein to highlight potential hazards: warnings and notes.











Safety information about the use of the device is provided herein. Please read through and understand all instructions before use. In case of failing to follow the warning and note information related to the device in a correct way, there may be a personal injury, device function failure and warranty failure.
















Warning	Indicates a potentially hazardous situation that may cause serious device damage or personal casualty if not avoided.
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Note	Indicates tips on operation or recommendation on maintenance; mistakes may be caused if they are not followed.
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Symbol Description

The following is a list of the symbols used on the device and meanings:

Symbol	Definition of Symbols
	Sterilized using Ethylene Oxide
	Catalogue Number
	Batch code
	Date of Manufacture
	Manufacturer
	Do not re-use
	Fragile, handle with care
	This way up
	Keep dry
	Keep away from sunlight

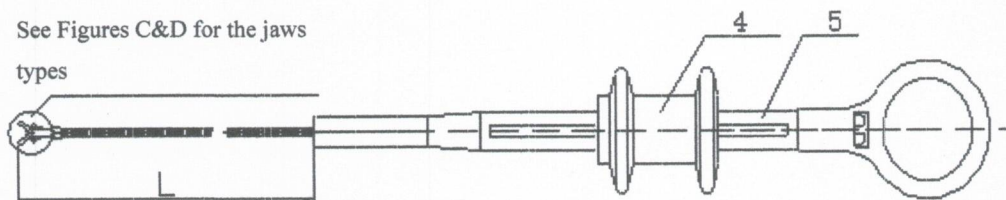
	Stacking limit
	Do not use if the packing is damaged
	Use-by date
	Caution
	Temperature Limit
	Humidity Limitation
	Do not re-sterilize
	Single sterile barrier system
	Consult instructions for use
	Medical Device
	Unique device Identifier
	European union approval
	Caution: Federal law prohibits dispensing without prescription
	Authorized representative in the European Community
	Manufacturer's serial number to identify a specific medical device

Note

Be familiar with and understand the meaning of these symbols before operating the device.

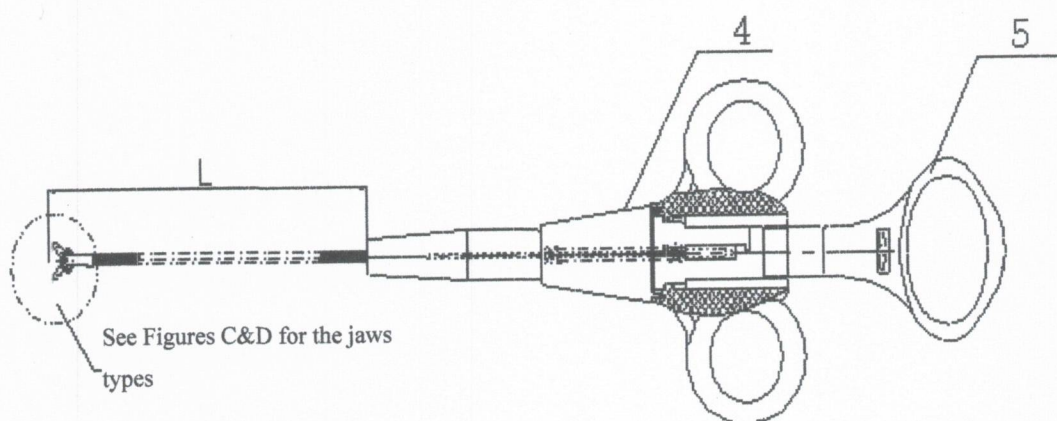
Product Introduction

Biopsy Forceps are composed of forceps head, stay cable, slip ring, outer sheath and handle. The structural styles and basic dimensions of the biopsy forceps are shown in Figures A-D and Table 1.



1. Forceps head; 2. Stay cable; 3. Outer sheath; 4. Slip ring; 5. Handle

Figure A Diagram of Product Structure of Disposable Biopsy Forceps (Roller Type)



1. Forceps head; 2. Stay cable; 3. Outer sheath; 4. Slip ring; 5. Handle
Figure B Diagram of Product Structure of Disposable Biopsy Forceps (Finger Lock Type)

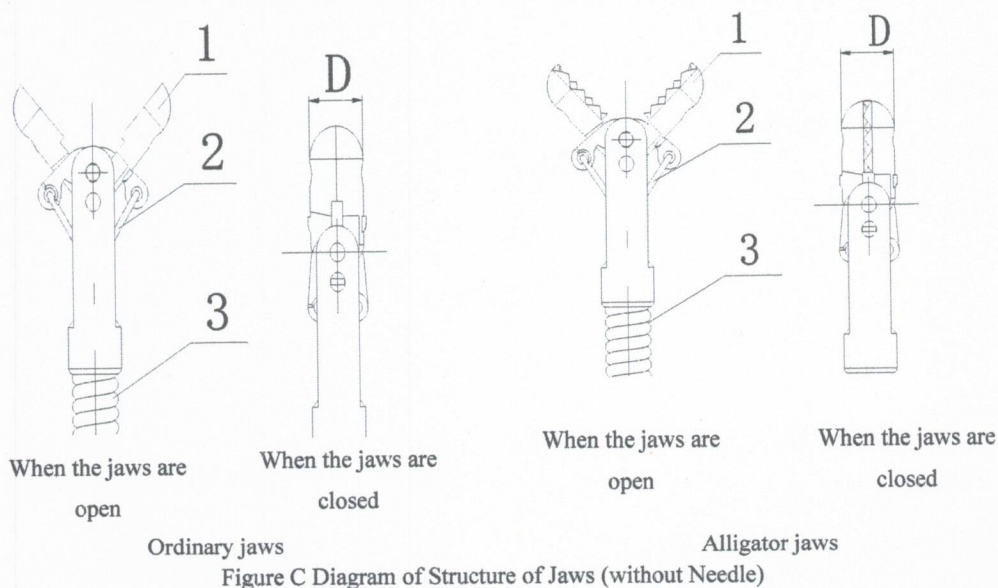


Figure C Diagram of Structure of Jaws (without Needle)

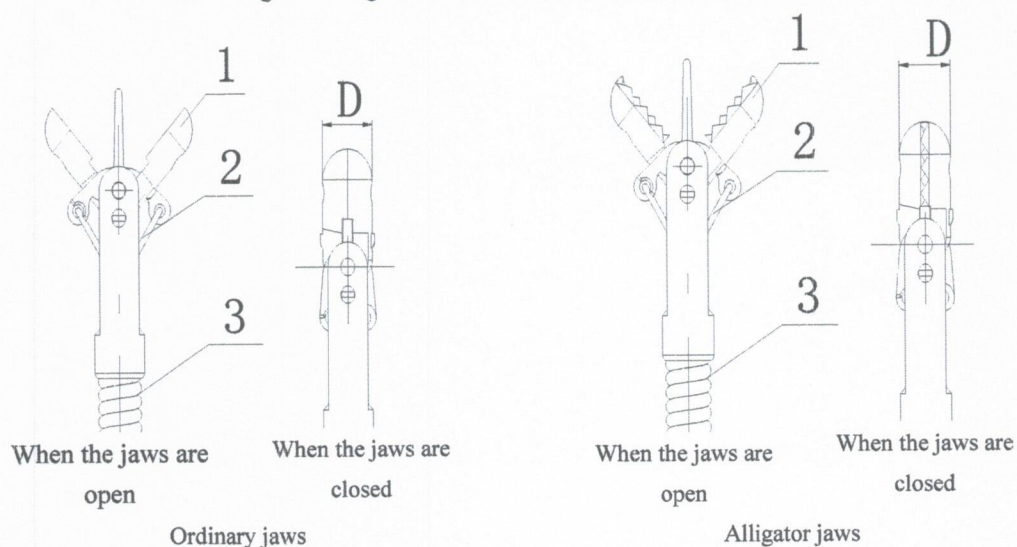


Figure D Diagram of Structure of Jaws (with Needle)

Product model

Table 1. Basic Dimensions of Disposable Biopsy Forceps Unit: mm

Model	Features	Closing diameter of jaws (D)		Effective length (L)		Total length (l)	Scope of Application (minimum diameter of endoscopic forceps channel)
		Dimensions	Allowance	Dimensions	Allowance		
TCYH-T1A-O-D-L TCYH1-T1A-O-D-L	Ordinary jaws, without needle, sheath not covered with plastic	φ1.8	0~—0.2	700, 1050, 1100, 1200, 1600, 1800, 2300, 2600	±50	Effective length L+(155±3)	φ2
		φ2.3		1200, 1600, 1800, 2000, 2300, 2600			φ2.8
TCYH-T1A-P-D-L TCYH1-T1A-P-D-L	Ordinary jaws, without needle, sheath covered with plastic	φ1.8		700, 1050, 1100, 1200, 1600, 1800, 2300, 2600			φ2
		φ2.3		1200, 1600, 1800, 2000, 2300, 2600			φ2.8
TCYH-T1B-O-D-L TCYH1-T1B-O-D-L	Ordinary jaws, with needle, sheath not covered with plastic	φ1.8		700, 1050, 1100, 1200, 1600, 1800, 2300, 2600			φ2
		φ2.3		1200, 1600, 1800, 2000, 2300, 2600			φ2.8
TCYH-T1B-P-D-L TCYH1-T1B-P-D-L	Ordinary jaws, with needle, sheath covered with plastic	φ1.8		700, 1050, 1100, 1200, 1600, 1800, 2300, 2600			φ2
		φ2.3		1200, 1600, 1800, 2000, 2300, 2600			φ2.8
TCYH-T2A-O-D-L TCYH1-T2A-O-D-L	Alligator jaws, without needle, sheath not covered with plastic	φ1.8		700, 1050, 1100, 1200, 1600, 1800, 2300, 2600			φ2
		φ2.3		1200, 1600, 1800, 2000, 2300, 2600			φ2.8
TCYH-T2A-P-D-L TCYH1-T2A-P-D-L	Alligator jaws, without needle, sheath covered with plastic	φ1.8		700, 1050, 1100, 1200, 1600, 1800, 2300, 2600			φ2
		φ2.3		1200, 1600, 1800, 2000, 2300, 2600			φ2.8
TCYH-T2B-O-D-L TCYH1-T2B-O-D-L	Alligator jaws, with needle, sheath not covered with plastic	φ1.8		700, 1050, 1100, 1200, 1600, 1800, 2300, 2600			φ2
		φ2.3		1200, 1600, 1800, 2000, 2300, 2600			φ2.8
TCYH-T2B-P-D-L TCYH1-T2B-P-D-L	Alligator jaws, with needle, sheath covered with plastic	φ1.8		700, 1050, 1100, 1200, 1600, 1800, 2300, 2600			φ2
		φ2.3		1200, 1600, 1800, 2000, 2300, 2600			φ2.8

Scope of Application

It is applicable for clinically taking the biological tissue samples of the digestive tract and respiratory tract under endoscope.

Usage

1. When the product is used, the sterilization operating specification shall be strictly followed.
2. According to the shape, location and hardness of the lesion, choose the biopsy forceps with/without needle. For most tissue, choose the biopsy forceps without needle. However, when it is difficult to grasp the tissue with the biopsy forceps without needle, with proneness to falling off, it is necessary to consider biopsy forceps with needle, because the needle tip has a positioning

function.

3. Under the observation of the endoscope, the biopsy forceps enter the sampling site through the endoscope forceps channel. Push the handle slip ring (open the jaws), make it close to the tissue to be sampled, pull the handle slip ring (close the jaws), then pull the outer tube and take out the biopsy forceps. (Roller type slip ring)
4. Under the observation of the endoscope, the biopsy forceps enter the sampling site through the endoscope forceps channel. Since the finger lock jaws are normally closed, during use, first push the handle slip ring (open the jaws), make it close to the tissue to be sampled, and loosen the slip ring to make the slip ring reset automatically (or apply a little pressure to push the slip ring). At this time, the jaws will automatically reset and close. And then pull the outer tube back and take out the biopsy forceps. (Finger lock type slip ring)

Contraindication

Contraindicated in people who cannot tolerate endoscopy such as patients with severe cardiopulmonary disease.

Warnings and Notes

1. When the product is used, the sterilization operating specification shall be strictly followed.
2. The outer sheath diameter of the biopsy forceps is Ø1.8mm, Ø2.3mm, and the minimum diameter of the endoscopic forceps channel that can pass through is Ø2.0mm and Ø2.8mm respectively. It is recommended for endoscopes with the forceps channel of Ø3.2mm.
3. The biopsy forceps are disposable and can be used after opening the sterile package. Once the package is found to be damaged, it must not be used.
4. The biopsy forceps are sterilized by ethylene oxide. Please check the indicator on the sterile packing box of the product before use. "Red" indicates that the product has not been sterilized by ethylene oxide and cannot be used; "blue" indicates that the product has been sterilized by ethylene oxide for direct clinical use. The forceps are delivered in a sterile sealed package. The validity period is two years from the date of sterilization. Products beyond the validity period are strictly prohibited to use.
5. Only experienced physicians familiar with endoscopic techniques can perform endoscopic surgery. Before surgery, physicians should consult relevant books and literature to understand the techniques, complications, and risks of endoscopy.
6. This user manual is only a general introduction to the use of the biopsy forceps, and is not for surgical guidance. The surgeon must refer to the relevant medical literature and related surgical atlas during the operation.

Warning

1. The product is for use by physicians who have received professional knowledge and technical training and (or) under the guidance of personnel with relevant experience.
2. After use of the product, the device shall be discarded in accordance with recognized hospital guidelines

Storage and Transportation

1. Storage: The products are stored in a room with a relative humidity of not more than 90%, good ventilation and no corrosive gas.
2. Transportation: The packaged products can be transported by ordinary tools, and shall be handled with care to avoid direct sunlight, severe collision, rain and forceful extrusion.

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