

Instruction for Use

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Dear customer:

Thank you for using our products. Please read the manual carefully before you use our products so that you can use and maintain the products accurately.

1. Intended Use

The reusable biopsy forceps can get biopsy tissue from alimentary canal mucous membrane to provide the pathologic basis for diagnosis.

The patient populations: for adults only.

The instruments can only be used with an endoscope.

These instruments are not meant for any other purpose!

Do not work with damaged instruments!

This instruction is intended to assist the user in using the biopsy forceps as intended, to describe their use and thus provide a higher degree of safety for the patient.

2. Design

Alton (Shanghai) Medical Instruments Co., Ltd. supplies various designs of biopsy forceps for various applications. Information on the range of sizes available may be obtained directly from us.

3. Before usage

The user should study these instructions carefully before using the biopsy forceps. The functional principles and handling must be completely understood.

In addition, the user must inspect the instrument for defects and damage, after removing it from the pack. If damage or defects are detected in this inspection, the instrument must not be used on the patient and must immediately be returned to **Alton (Shanghai) Medical Instruments Co., Ltd.** for inspection by an expert.

Please note that you do not need to exert much force on the handle, in order to carry out the biopsy. The amount of strength to be used is the equivalent of a gentle handshake.

NOTE: The reusable biopsy forceps is not supplied sterile by Alton before leaving factory in delivery. The biopsy forceps must be inspected for damage before use. Only undamaged biopsy forceps must be used! The instrument must be sterilized before the first use and after every use.

4. Handling

4.1 Introducing the biopsy forceps into the endoscope.

Biopsy forceps must only be introduced into the operating channel of the endoscope with **forceps jaws closed**. For this, appropriate diameters of biopsy forceps and operating channels must be considered (see “Table 1”).

4.2 Types

Alton (Shanghai) Medical instruments Co., Ltd. offers reusable biopsy forceps in **6 types Suffix with BS, BV, BT, BW, BU and BWU**.

(See the “Table 1” model list of reusable biopsy forceps attached)

Table 1: The models of reusable biopsy forceps in the list

No.	Model Name	Model spec.	Size
1	Reusable Biopsy Forceps (Standard type)	AF-1810BS	Φ1.8*1000mm
		AF-1815BS	Φ1.8*1500mm
		AF-1825BS	Φ1.8*2500mm
		AF-2415BS	Φ2.4*1500mm
		AF-2417BS	Φ2.4*1700mm
		AF-2421BS	Φ2.4*2100mm
		AF-2423BS	Φ2.4*2300mm
2	Reusable Biopsy Forceps (Alligator, Single Moving Cup type)	AF-1810BV	Φ1.8*1000mm
		AF-1815BV	Φ1.8*1500mm
		AF-1825BV	Φ1.8*2500mm
		AF-2415BV	Φ2.4*1500mm
		AF-2417BV	Φ2.4*1700mm

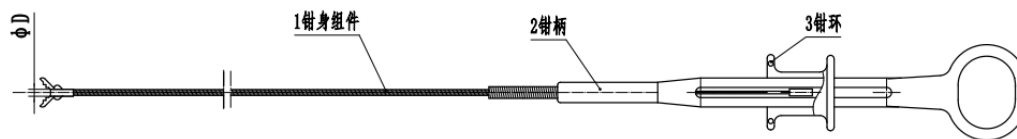
		AF-2421BV	Φ2.4*2100mm
		AF-2423BV	Φ2.4*2300mm
3	Reusable Biopsy Forceps (Oval Fenestrated Cups type)	AF-1810BT	Φ1.8*1000mm
		AF-1815BT	Φ1.8*1500mm
		AF-1825BT	Φ1.8*2500mm
		AF-2415BT	Φ2.4*1500mm
		AF-2417BT	Φ2.4*1700mm
		AF-2421BT	Φ2.4*2100mm
		AF-2423BT	Φ2.4*2300mm
4	Reusable Biopsy Forceps (Oval Fenestrated Cups with Needle type)	AF-1810BW	Φ1.8*1000mm
		AF-1815BW	Φ1.8*1500mm
		AF-1825BW	Φ1.8*2500mm
		AF-2415BW	Φ2.4*1500mm
		AF-2417BW	Φ2.4*1700mm
		AF-2421BW	Φ2.4*2100mm
		AF-2423BW	Φ2.4*2300mm
5	Reusable Biopsy Forceps (Alligator Jaws type)	AF-1810BU	Φ1.8*1000mm
		AF-1815BU	Φ1.8*1500mm
		AF-1825BU	Φ1.8*2500mm
		AF-2415BU	Φ2.4*1500mm
		AF-2417BU	Φ2.4*1700mm
		AF-2421BU	Φ2.4*2100mm
		AF-2423BU	Φ2.4*2300mm
6	Reusable Biopsy Forceps (Alligator Jaws with Needle type)	AF-1810BWU	Φ1.8*1000mm
		AF-1815BWU	Φ1.8*1500mm
		AF-1825BWU	Φ1.8*2500mm
		AF-2415BWU	Φ2.4*1500mm
		AF-2417BWU	Φ2.4*1700mm
		AF-2421BWU	Φ2.4*2100mm
		AF-2423BWU	Φ2.4*2300mm

Information about the offered dimensions you can get from **Alton (Shanghai) Medical Instruments Co., Ltd.** main catalogue.

4.3 Products structure

The reusable biopsy forceps is composed of head, tube and handle. The head of the biopsy forceps have different head types, including Standard type, Alligator with Single Moving Cup type, Oval Fenestrated Cups type, Oval Fenestrated Cups with Needle type, Alligator Jaws type and Alligator Jaws with Needle type, please see figure 1.

Figure1: Components of the reusable biopsy forceps



Note:

- 1- The components of forceps body;
- 2- The Bend-protection;
- 3- The clamp ring.

The material list of Reusable Biopsy Forceps

No.	Product components	Material	Materials of body contact (Yes/No)
1	Head	Stainless steel	Yes
2	Tube	Stainless steel	Yes
3	Bend protection	Stainless steel	No
4	Handle	PSF, or Stainless steel	No

5. Contraindication

- a. Required by professional operators to use this device;
- b. Do not use this device to treat patients in any of situations if may be at risk for their life's;
- c. To avoid any of unsafe situations for patients while using this device as far as possible.

6. Cautions

- a. Keep away from moisture;
- b. Must be sterilized after every use;
- c. Be storage indoor and keep it dry;
- d. All users of the forceps must have got clinical experienced medical staff, who are professional operator.
- e. The reusable biopsy forceps is not sterilized before ex-factory by Alton for delivery. The shelf life of the reusable biopsy forceps is for 3 years or being sterilized by 30 times at most, so users must be sterilized before use. Also, after using, users should make sterilization as well and keep the device dry to storage in door, detailed method referring by the IFU of ALT-IFU-14;

f. The device must be used under endoscope, it can't be used independently. If not, it will hurt users also damage other instruments possibly;

g. All users must realize the type, function and working channel diameter of the forceps. The diameter of working channel must be greater than the outer diameter of the reusable biopsy forceps head. Such as: the reusable biopsy forceps model of AF-2423BS, the outer diameter of the whole tube is for 2.4mm, and it suits to use the endoscope which the working channel is for 2.8mm or bigger than 2.8mm, with lengthen 2300mm.

Refer to the product specification and recommendatory endoscope are according to example as in "the Table 2" as followed.

Table 2 the specification and intended scope sheet

Model	Scope range	Note
AF-D2416BS	Working channel diameter > or= 2.8mm	<p>24 16/23</p> <p>Working Length (16: 1650mm; 23 and other: ×100mm)</p> <p>External Diameter of clip head (×0.1mm)</p>
AF-2423BS		

7. Operation

- Position the biopsy forceps just in front of the place from which the sample is to be taken from the patient;
- Push the plastic spool gently forward to open the jaws of the forceps;
- Introduce the forceps into the tissue, pull the plastic spool back (causing the forceps jaws to close) and carefully remove the tissue sample;
- Hold the forceps jaws in the closed position and slowly withdraw the entire instrument from the endoscope;
- The tissue sample thus obtained may now be prepared for further examination processes.

8. Cleaning, Drying and Disinfection

The temperature condition is recommended below 30 °C to be used for cleaning

and disinfection of reusable products

8.1 Preparation before cleaning

To prepare all related items including water tub, soft brush, gauze, multi-enzyme cleaning solution, dry duster and others if necessary.

8.2 Cleaning

Step 1 Washing: Wash the products with drinking water not higher than 45 °C for 30 seconds;

Step 2 Rinsing: Put products into the ultrasonic cleaning machine of 40HZ power; and then add multi-enzyme washing liquid of 0.5% by the ultrasonic cleaning for 2 minutes; after that, use the drinking water by ultrasonic rinsing for 3 times, each time for 5 minutes.

Step3 Final Rinsing: Put products into the purified water with conductivity \leq 15us/cm (25 °C) to rinse for 30 seconds in final step.

8.3 Drying

Drying products at 50 \pm 5 °C for 120 mins.

8.4 Disinfecting

8.4.1 Using the purified water of conductivity \leq 5.1us/cm (25 °C) to diluted glutaraldehyde solution;

8.4.2 Dilute 2.5% glutaraldehyde disinfectant to pour into the container, add the sodium bicarbonate to adjust pH (pH 7.5 \leq 8.0 after adjustment), then put 0.5% sodium nitrite to avoid being rusty;

8.4.3 Take products and cover with the Glutaraldehyde disinfection liquid completely to seal the container for 45 mins;

8.4.4 Then, use the purified water with conductivity \leq 15us/cm (25 °C) to wash for 30 seconds;

8.4.5 Final, drying all products at 50 \pm 5 °C for 120 mins.

8.5 Packing

8.5.1 Five mins later when products finished disinfecting process to be wrapped in squares and both positive and negative sides cover more than 3 layers by triangular medical degreasing gauze;

8.5.2 Place the sterilized products flat in the sterilizing basket, pay attention to handle and put them lightly, and place and load the sterilized products layer by layer in the sterilizing pot during the products verification to put every product on each

layer.

9. Sterilization

● Sterilization

The reusable instruments by Alton are not sterile before leaving factory in delivery, all users must complete sterilization before use, and also need finish sterilization after every use, the sterilization method and conditions introduced as:

- a). It is a not sterile device for delivery;
- b). It must be sterilized before first use;
- c). Method: by Autoclaving method;
- d). Sterilization conditions: Under the Temperature of 132 °C and the Pressure of 202.7kPa are for 5 minutes.

10. Use validity period

- a) Ten years for storage before opening the single bag;
- b) Can be sterilized at most for 30 times.

11. Storage

- a. Drop some lubricant (company dedicated) on the joints of the devices after dry and sterilization, then storage after dried;
- b. Avoid direct sunlight and rain;
- c. To be storage indoor, where with the Temperature 0 °C -40 °C, Relative humidity 30-85%, and air pressure 50.0-106.0KPa.

12. User

The users of instruments of the **Alton (Shanghai) Medical instruments Co., Ltd.** must be specialists in their fields. An appropriate and specific training for preparation, care and maintenance of the flexible instruments is required.

13. Repairing and Complaints

All instruments are not allowed:

- a. To be changed if the sterilization validity date exceed than the date printed on labels;
- b. To be repaired if for single use device














14. Legal Foundation

The Law of the European Union is applied.

15. Product Support

In case of questions or difficulties concerning our instruments please contact the local distributors or the **Alton (Shanghai) Medical instruments Co., Ltd.** directly during regular working hours.

16. Symbols List

NO.	Description	Symbols on labels
1	CATALOGUE NUMBER	
2	MANUFACTURER	
3	DATE OF MANUFACTURE	
4	USE BY	
5	BATCH CODE	
6	STERILIZED USING STEAM	
7	NON-STERILE (sold in non-sterile conditions)	
8	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	
9	Notified body number	
10	KEEP DRY	
11	KEEP AWAY FROM SUNLIGHT	
12	TEMPERATURE LIMITATION	
13	DO NOT USE IF PACKAGE IS DAMAGED	
14	CONSULT INSTRUCTIONS FOR USE	