

# Disposable Biopsy Forceps

## IFU

(Please read this manual carefully before usage)

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## 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

To get biopsy tissue from alimentary canal mucous membrane to provide the pathologic basis for diagnosis.

- **Biopsy forceps must only be used with an endoscope!**
- **These instruments are not designed for other applications!**
- **Damaged instruments must not be used!**
- **Please check the needle in the head of the biopsy forceps. The needle must be stand straight!**

These instructions are 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 Instrument 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 Instrument 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.**

**Disposable biopsy forceps are supplied sterile. The biopsy forceps must be inspected for damage before use. Only undamaged biopsy forceps must be used! The instrument must only be used once.**

### 4. Cautions

- 1) Only trained and/or experienced clinician can use this product.
- 2) Disposable biopsy forceps produced from Alton (Shanghai) Medical Instruments Co., Ltd. was sterilized before delivery so that Disposable biopsy forceps can be applied directly.
- 3) The product must be used with endoscope, and it cannot be used alone. It cannot be changed arbitrarily, mended or used for other ways. Otherwise, patients and users will be injured and the other medical devices may be damaged.

### 5. Contraindication

Disposable biopsy forceps cannot be used in the patients who have following characteristics:

- Severe dysfunction of cruor
- Systemic hemorrhage disease
- Severe hypertension and diabetes
- Serious heart and lung disease(s) who cannot endure endoscopic medical inspection
- Neurological diseases
- Patients who don't want to do endoscopic medical inspection
- Acute inflammation in upper digestive tract and/or ulcer
- Narrow in upper digestive tract so that it is not accessible for endoscope

- Patients who are allergic for this product or the harden agent
- Patients who are not suitable for the product according to diagnosis

## 6. Handling

6.1 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 the “Table 1” model list of disposable biopsy forceps attached).

6.2 The patient populations: for adults only. All models are in 8 types suffix with BT, BTC, BW, BWC, BU, BUC, BZ and BZC.

**Table 1: The model list of disposable biopsy forceps**

No.	Product Name	Model Name	Size
1	Disposable Biopsy Forceps (Oval Cups)	AF-D1007BT	Φ1.0*700mm
		AF-D1009BT	Φ1.0*900mm
		AF-D1012BT	Φ1.0*1200mm
		AF-D1015BT	Φ1.0*1500mm
		AF-D1810BT	Φ1.8*1000mm
		AF-D1812BT	Φ1.8*1200mm
		AF-D1815BT	Φ1.8*1500mm
		AF-D1816BT	Φ1.8*1600mm
		AF-D1818BT	Φ1.8*1800mm
		AF-D1823BT	Φ1.8*2300mm
		AF-D1825BT	Φ1.8*2500mm
		AF-D2416BT	Φ2.4*1600mm
		AF-D2418BT	Φ2.4*1800mm
		AF-D2421BT	Φ2.4*2100mm
		AF-D2423BT	Φ2.4*2300mm
2	Disposable Biopsy Forceps (Oval Cups with Needle)	AF-D1810BW	Φ1.8*1000mm
		AF-D1812BW	Φ1.8*1200mm
		AF-D1816BW	Φ1.8*1600mm
		AF-D1818BW	Φ1.8*1800mm
		AF-D1823BW	Φ1.8*2300mm
		AF-D1825BW	Φ1.8*2500mm
		AF-D2416BW	Φ2.4*1600mm
		AF-D2418BW	Φ2.4*1800mm
		AF-D2421BW	Φ2.4*2100mm
		AF-D2423BW	Φ2.4*2300mm
		AF-D2823BW	Φ2.8*2300mm

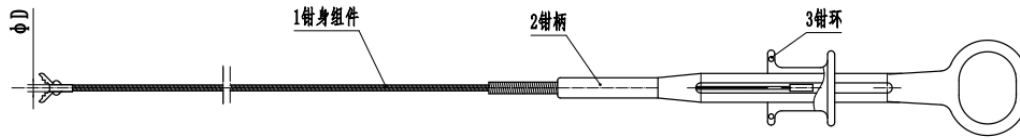
		AF-D3023BW	Φ3.0*2300mm
3	Disposable Biopsy Forceps (Oval Cups Coated)	AF-D1810BTC	Φ1.8*1000mm
		AF-D1812BTC	Φ1.8*1200mm
		AF-D1816BTC	Φ1.8*1600mm
		AF-D1818BTC	Φ1.8*1800mm
		AF-D1823BTC	Φ1.8*2300mm
		AF-D1825BTC	Φ1.8*2500mm
		AF-D2416BTC	Φ2.4*1600mm
		AF-D2418BTC	Φ2.4*1800mm
		AF-D2421BTC	Φ2.4*2100mm
		AF-D2423BTC	Φ2.4*2300mm
		AF-D3023BTC	Φ3.0*2300mm
4	Disposable Biopsy Forceps (Oval Cups with Needle Coated)	AF-D1810BWC	Φ1.8*1000mm
		AF-D1812BWC	Φ1.8*1200mm
		AF-D1816BWC	Φ1.8*1600mm
		AF-D1818BWC	Φ1.8*1800mm
		AF-D1823BWC	Φ1.8*2300mm
		AF-D1825BWC	Φ1.8*2500mm
		AF-D2416BWC	Φ2.4*1600mm
		AF-D2418BWC	Φ2.4*1800mm
		AF-D2421BWC	Φ2.4*2100mm
		AF-D2423BWC	Φ2.4*2300mm
		AF-D2823BWC	Φ2.8*2300mm
AF-D3023BWC	Φ3.0*2300mm		
5	Disposable Biopsy Forceps (Alligator Cups)	AF-D1007BU	Φ1.0*700mm
		AF-D1009BU	Φ1.0*900mm
		AF-D1012BU	Φ1.0*1200mm
		AF-D1015BU	Φ1.0*1500mm
		AF-D1810BU	Φ1.8*1000mm
		AF-D1812BU	Φ1.8*1200mm
		AF-D1816BU	Φ1.8*1600mm
		AF-D1818BU	Φ1.8*1800mm
		AF-D1823BU	Φ1.8*2300mm
		AF-D1825BU	Φ1.8*2500mm
		AF-D2416BU	Φ2.4*1600mm
		AF-D2418BU	Φ2.4*1800mm
		AF-D2421BU	Φ2.4*2100mm
		AF-D2423BU	Φ2.4*2300mm
		AF-D2823BU	Φ2.8*2300mm
AF-D3023BU	Φ3.0*2300mm		
6	Disposable Biopsy Forceps (Alligator Cups with Needle)	AF-D1810BZ	Φ1.8*1000mm
		AF-D1812BZ	Φ1.8*1200mm
		AF-D1816BZ	Φ1.8*1600mm

		AF-D1818BZ	Φ1.8*1800mm
		AF-D1823BZ	Φ1.8*2300mm
		AF-D1825BZ	Φ1.8*2500mm
		AF-D2416BZ	Φ2.4*1600mm
		AF-D2418BZ	Φ2.4*1800mm
		AF-D2421BZ	Φ2.4*2100mm
		AF-D2423BZ	Φ2.4*2300mm
		AF-D2823BZ	Φ2.8*2300mm
		AF-D3023BZ	Φ3.0*2300mm
7	Disposable Biopsy Forceps (Alligator Cups Coated)	AF-D1810BUC	Φ1.8*1000mm
		AF-D1812BUC	Φ1.8*1200mm
		AF-D1816BUC	Φ1.8*1600mm
		AF-D1818BUC	Φ1.8*1800mm
		AF-D1823BUC	Φ1.8*2300mm
		AF-D1825BUC	Φ1.8*2500mm
		AF-D2416BUC	Φ2.4*1600mm
		AF-D2418BUC	Φ2.4*1800mm
		AF-D2421BUC	Φ2.4*2100mm
		AF-D2423BUC	Φ2.4*2300mm
		AF-D2823BUC	Φ2.8*2300mm
		AF-D3023BUC	Φ3.0*2300mm
8	Disposable Biopsy Forceps (Alligator Cups with Needle Coated)	AF-D1810BZC	Φ1.8*1000mm
		AF-D1812BZC	Φ1.8*1200mm
		AF-D1815BZC	Φ1.8*1500mm
		AF-D1816BZC	Φ1.8*1600mm
		AF-D1818BZC	Φ1.8*1800mm
		AF-D1823BZC	Φ1.8*2300mm
		AF-D1825BZC	Φ1.8*2500mm
		AF-D2416BZC	Φ2.4*1600mm
		AF-D2418BZC	Φ2.4*1800mm
		AF-D2421BZC	Φ2.4*2100mm
		AF-D2423BZC	Φ2.4*2300mm
		AF-D2823BZC	Φ2.8*2300mm
AF-D3023BZC	Φ3.0*2300mm		

### 6.3 Products structure

The disposable biopsy forceps is composed of head, tube and handle. The head of disposable biopsy forceps have different head types, including oval cups, oval cups coated, oval cups with needle, oval cups with needle coated, alligator cups, alligator cups coated, alligator cups with needle, alligator cups with needle coated, please see figure 1.

*Figure1: Components of the disposable biopsy forceps*



Note:

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

The material list of Disposable Biopsy Forceps

No.	Product components	Material	Materials of body contact (Yes/No)
1	Head (forceps jaw)	stainless steel	Yes
2	Tube	Inner: stainless steel	No
		Out: stainless steel, or Out: stainless steel + PE coated	Yes
3	Bend protection	PTFE	No
4	Handle	ABS	No

#### 6.4 Before Use

- 1) Check the content in the package: Instruction for use, product qualification and product should be contained in the package.
- 2) Check whether the product package is sealed or not.
- 3) Check whether each component of disposable biopsy forceps is damaged or not when users open the package. If disposable biopsy forceps is damaged, please do not use it.
- 4) Users should contact **Alton (Shanghai) Medical Instruments Co., Ltd.** or the suppliers immediately so that it can be exchanged on time.
- 5) After use, disposable biopsy forceps should be destroyed and disinfected.
- 6) According to the relevant national regulations, aseptic medical devices which have been disinfected and destroyed or not destroyed must be delivered to the organization licensed by law which is engaged in a disposition of medical wastes so that the aseptic devices can be destroyed and disposed centralized.

#### 6.5 Biopsy

- 6.5.1 Position the biopsy forceps just in front of the place from which the sample is to be taken from the patient.

- 6.5.2 Push the plastic spool gently forward to open the jaws of the forceps.
- 6.5.3 Introduce the forceps into the tissue, pull the plastic spool back (causing the forceps jaws to close) and carefully remove the tissue sample.
- 6.5.4 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.

## **7. Cleaning/Sterilization**

The disposable biopsy forceps is delivered sterilized by ETO gas. They must be only for single use. The disposable device has to be destroyed by the hospital after first use.

## **8. The method of repairing and maintenance**

All instruments are not allowed:

- 1) To be changed if the sterilization validity date exceed than the date printed on labels
- 2) To be repaired if for single use device

## **9. The requirements of working environment**

The working environment of disposable biopsy forceps requires temperature is from 0°C to 40°C, the relative humidity is from 30-85%, air pressure: 50.0-106.0KPa.

## **10. Storage and transport conditions**

During storage, the biopsy forceps may not have a minimum diameter of less than 20 cm when wound up.

- 1) Products cannot be stored and delivered under heavy pressure in order to avoid distortion.
- 2) The storage and transport conditions include:
  - a. Temperature range: 0°C -40 °C;
  - b. Humidity range: 30% - 85%;
  - c. Air pressure: 50.0-106.0KPa;
  - d. Stored in clean and dry environment;
  - e. Avoid to be shined directly;
  - f. Deliver by general transport tool, but must avoid by severe shock, vibration, rain and snow splashing.
    - Do not put any objects on the instrument or its package!
    - Do not store the instruments near aggressive chemical products!
    - Do not expose the instruments to direct or indirect sunlight or other ultra-violet



rays!

Complaints will not be taken under consideration if the instruments have been stored improperly.

Incorrect storage of the instruments invalidates any claims.

### **11. Period of validity**

The period of validity for sterilization is three years.

### **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. Dispatches for repair and claims**

In the interest of our employees' health, only sterilised or disinfected instruments will be accepted as returns. They should be labelled as such; otherwise they cannot be handled further.

### **14. Legal Foundation**

The Law of the European Union is applied.












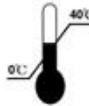

### **15. Product Support**

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

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**Date: 2021.8.4**

## 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 ETHYLENE OXIDE	
7	DO NOT REUSE	
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	