

Disposable Cytology Brush

IFU

(Please read this manual carefully before usage)

File No.: ALT-IFU-05

Version: C/2

Revision	Date	Description	Author	Approval
C/0	Jun.2005	Created	Yujun CHEN	Changhui HE
C/1	Jan. 2017	Update	Vivian LI	Haoxiang HE
C/2	4 th Aug.2021	Update	Vivian LI	Jianwen LU

Instruction for Use

Europe authorized representative

Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

Tel: +49-40-2513175

Fax: +49-40-255726

Dimdi No.: DE/0000040627

E-mail: shholding@hotmail.com



Alton (Shanghai) Medical Instruments Co., Ltd

Address: No. 24 Building, JinShao Rd. 1688, Baoshan District, 200949 Shanghai,
PEOPLE'S REPUBLIC OF CHINA

Tel: +86 21 5677 8511

Fax: +86 21 6630 7823



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 AF-series flexible disposable cytology brush consists of brush head, tube, bend protection and handle. The head of disposable cytology brushes have different head types because of different client's requirements, including straight type and oval type.

Disposable cytology brush can take cells from tissue surface and then make smear for cytological examination to help clinicians distinguish.

The instruments can only be used under an endoscope.

These instruments are not meant for any other purpose!

Do not operate with damaged instruments!

This handbook should only be an aid to help the user to use disposable cytology brush correctly in order to guarantee safe procedures and avoid unnecessary risks for the patients.

2. Types

Alton (Shanghai) Medical Instruments Co., LTD offers disposable cytology brushes in three different types included as:

- Straight Type,
- Oval Type, and
- ERCP type, with Double Lumen

(See the “Table 1” model list of disposable cytology brush attached with different lengths under demand of endoscopes by operators)

Table 1: The model list of disposable cytology brush

No	Product Name	Model Name	Size
1	Disposable Cytology Brush (Straight Type)	AF-D1810WB	Φ1.8×1000mm
		AF-D1812WB	Φ1.8×1200mm
		AF-D1816WB	Φ1.8×1600mm
		AF-D2416WB	Φ2.4×1600mm
		AF-D2421WB	Φ2.4×2100mm
		AF-D2423WB	Φ2.4×2300mm
		AF-D2425WB	Φ2.4×2500mm
2	Disposable Cytology Brush (Oval Type)	AF-D1810WB-C	Φ1.8×1000mm
		AF-D1812WB-C	Φ1.8×1200mm
		AF-D1816WB-C	Φ1.8×1600mm
		AF-D2416WB-C	Φ2.4×1600mm
		AF-D2421WB-C	Φ2.4×2100mm
		AF-D2423WB-C	Φ2.4×2300mm
		AF-D2425WB-C	Φ2.4×2500mm
3	Disposable Cytology Brushes (ERCP type, Double Lumen)	AF-D2421WB2	Φ2.4×2100mm

Please refer to the drawing example as followed:



Note:

1. the head: to select different head types for use
2. the tube: for different usage need to select different length
3. the handle: for all disposable cytology brushes

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

3. Key material

Key material of disposable cytology brush (see template 1)

Template 1 key material of disposable cytology brush

No.	Product components	Material	Materials of body contact (Yes/No)
1	Head	Stainless steel with Nylon	Yes
2	Tube	Inner: stainless steel	No
		Out: PTFE	Yes
3	Bend protection	PTFE	No
4	Handle	ABS	No

4. Advices before First Application

Please read carefully and follow all safety operating instructions and warnings information before first application of the device.

A previous knowledge regarding handling and operation is required and essential.

Unpack the instrument carefully and examine the devices for any possibility of damage.

In case of any damage or missing items contact your distributor immediately.

The disposable cytology brushes are supplied sterile. They must be inspected for damage before use. Only undamaged disposable electrical snare can be used!
The instrument must only be used once.

5. Cautions

- a. Keep away from moisture.
- b. Refer to package label for minimum channel size required for this device.
- c. The sterilization or the tolerance of the products may not be enough, patients may have risks of being infected or being harm by the re-using or re-processing products, please use it only once.
- d. After use, dispose of products and packaging in accordance with hospital, administrative and/or local government policies.

- e. If the single bag or the surface of the device damaged, the device doesn't can be used.

6. 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.

7. Operation

7.1 Insertion into the Endoscope

The brush has to be retracted completely into the Teflon tube to be introduced into the operating channel. Please observe the compatibility between the Cytology Brush's tube and the endoscopes operating channel diameter(see catalogue).

7.2 Do not bend the Cytology Brushes

- a. Take the brush completely out of the tube by pushing the handle.
- b. Place the brush in front of the tissue area to be analyzed.
- c. Slide the brush completely back into the tube by pulling the handle.

8. Sterilization

Disposable cytology brushes are delivered sterilized by ETO gas. The disposable instruments must only be used once. The disposable cytology brushes have to be destroyed by the hospital after first use.

8. The period of validity for sterilization is for three years.

10. Storage

- 1) Products cannot be stored under heavy pressure in order to avoid distortion.
- 2) The storage 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.

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.

11. 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.

12. Repairing and Complaints

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

13. Legal Foundation

The Law of the European Union is applied.








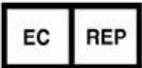





14. Product Support

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

Version: C/2

Date: 2021.8.4

15. Symbols

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	