

# 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 polyp traps are used for collecting and separating polyps.

It is only for single use.

## 2. Design

**Alton (Shanghai) Medical Instruments Co., Ltd.** supplies polyp traps in one standard size applicable for most endoscopes.

## 3. Before use

The user should study these instructions carefully before using polyp traps.

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 endoscope and must immediately be returned to **Alton (Shanghai) Medical Instruments Co., Ltd.** for inspection by an expert.

**The polyp traps are supplied non-sterile by Alton in delivery. The polyp trap must be inspected for damage before use. Only undamaged device must be used! The instrument must only be used once.**

#### 4. Types

**Alton (Shanghai) Medical Instruments Co., Ltd.** offers in **2 types Suffix with AF-DPT and AF-DPT-S.**

**(See the “Table 1” model list of Polyp Trap attached)**

**Table 1: The models of Polyp Trap in the list**

| No. | Model Name  | Model spec. |
|-----|---|-------------|
| 1   | Polyp trap<br>(Disposable model, with separated four collected space) | AF-DPT      |
| 2   | Polyp trap<br>(Disposable model, with full collected space)           | AF-DPT-S    |

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

#### 5. Products description

##### 5.1 Products Structure

The Polyp Trap is consists of cover, body, and pipe. Refer to the Figure 1.



Figure 1 the picture of Polyp trap

##### 5.2 Products material

The Polyp trap is made of PE (Polyethylene), PS (Polystyrene), and PP (Polypropylene) please see Table 2.

Table 2 The material list of Polyp trap

| No. | Product components | Material      | Materials of body contact (Yes/No) |
|-----|--------------------|---------------|------------------------------------|
| 1   | The Cover          | Polyethylene  | No                                 |
| 2   | The Body           | Polystyrene   | No                                 |
| 3   | The Pipe           | Polypropylene | No                                 |

## 6. Cautions

- a. Required by professional operators to use this device;
- b. The polyp traps are not sterilized by manufacturer;
- c. The polyp traps are only for single use, and must be destroyed after use;
- d. Keep away from moisture;
- e. Polyp Traps are only usable in conjunction with an endoscope;
- f. These instruments are not intended for other applications.

## 7. Operation

### 7.1 Check before use

- a. If the package is included of the IFU, the certificate of the product, and the product;
- b. If the package sealing is completed;
- c. Open the single pouch, if the polyp traps are damaged. If any damaged, please don't use it and contact to Alton or local distributor to exchange immediately.

### 7.2 Operation

- a. Please pay attention to the compatibility between the Polyp Trap and the endoscope;
- b. Firmly connect the first graded tube to the suction tube (vacuum tube);
- c. Now firmly connect the second tube to the endoscope (supply connection);
- d. Turn the lid of the Trap to place the marking arrow on position "O" to avoid the Polyp sucked;
- e. Now Polyps can be sucked / collected. Therefore turn the lid carefully and place the marking arrow on position 1, 2, 3, 4 . Please collect only one Polyp per chamber;
- f. After each collection turn the lid until the marking arrow is back on position "O";
- g. When finished and all Polyps are collected, remove the tube connected to the suction pump from the Polyp Trap. Then disconnect the other tube from the Polyp Trap. Now you can remove the polyps from the chambers and transfer them for analysis to the laboratory;

## **8. Sterilization**

- a. The Polyp Trap are not sterilized by Alton in delivery;
- b. No need to be sterilized before use;
- c. Only for single use if disposable models.

## **9. Validity period**

Ten years for storage before opening the single bag.

## **10. Storage**

- a. Do not place objects on the Polyp Trap or its packaging;
- b. Do not store the Polyp Trap near aggressive chemical products;
- c. Do not expose the Polyp Trap to direct or indirect sunlight or other ultra-violet rays;
- d. Storage temperature: 0-40 ° C;
- e. Storage humidity: 30-85%;

## **11. User**

The user of this products must be specialized in the field of endoscopy. He/She should have special training in handling and reprocessing of products for flexible endoscopy.

## **12. Repairing and Complaints**

All instruments are not allowed:

- a. In the interest of the health of our employees only disinfected or sterilized instruments will be taken back. These must be labelled as such, otherwise handling is not possible;
- b. To be repaired if for single use device.



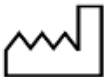




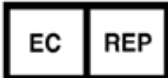



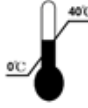


## **13. Legal Foundation**

The Law of the European Union is applied.

## **14. Product Support**

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

## 15. Symbols List

| NO. | Description  | Symbols on labels  |
|-----|--|--|
| 1   | CATALOGUE NUMBER                                       |    |
| 2   | MANUFACTURER   |    |
| 3   | DATE OF MANUFACTURE                                    |    |
| 4   | USE BY   |    |
| 5   | BATCH CODE   |    |
| 6   | NON-STERILE<br>(sold in non-sterile conditions)        |    |
| 7   | DO NOT REUSE   |   |
| 8   | AUTHORISED REPRESENTATIVE IN THE<br>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                           |  |