

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

Grasping forceps are used for foreign body removal from the patient's body and in most of the cases in the organs in the digestive system.

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 grasping forceps as intended, to describe their use and thus provide a higher degree of safety for the patient.

2. Design

Alton (Shanghai) Instrument Co., Ltd supplies various designs of grasping 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 grasping 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) Instrument Co., Ltd** for inspection by an expert.

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

4. Handling

4.1 Introducing the grasping forceps into the endoscope.

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

4.2 Types

Alton (Shanghai) Medical instruments Co., LTD offers reusable grasping forceps in **15** types Suffix with **GI, GJ, GH, GK, GM103, GM103-H, GM105, GM105-H, GO101, GM102-R, GO102, GL0, GL1, GL2, and GL3**.

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

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

No.	Model Name	Model spec.	Size
1	Reusable Grasping Forceps (Rat Tooth type)	AF-1807GI	Φ1.8*700mm
		AF-1810GI	Φ1.8*1000mm
		AF-1815GI	Φ1.8*1500mm
		AF-2415GI	Φ2.4*1500mm
		AF-2417GI	Φ2.4*1700mm
		AF-2421GI	Φ2.4*2100mm
		AF-2423GI	Φ2.4*2300mm
2	Reusable Grasping Forceps (Rat Tooth with Alligator Jaws type)	AF-1807GJ	Φ1.8*700mm
		AF-1810GJ	Φ1.8*1000mm
		AF-1815GJ	Φ1.8*1500mm
		AF-2415GJ	Φ2.4*1500mm
		AF-2417GJ	Φ2.4*1700mm
		AF-2421GJ	Φ2.4*2100mm
		AF-2423GJ	Φ2.4*2300mm
3	Reusable Grasping Forceps	AF-1807GH	Φ1.8*700mm

	(Alligator type)	AF-1810GH	Φ1.8*1000mm
		AF-1815GH	Φ1.8*1500mm
		AF-2415GH	Φ2.4*1500mm
		AF-2417GH	Φ2.4*1700mm
		AF-2421GH	Φ2.4*2100mm
		AF-2423GH	Φ2.4*2300mm
4	Reusable Grasping Forceps (Pelican type)	AF-1807GK	Φ1.8*700mm
		AF-1810GK	Φ1.8*1000mm
		AF-1815GK	Φ1.8*1500mm
		AF-2415GK	Φ2.4*1500mm
		AF-2417GK	Φ2.4*1700mm
		AF-2421GK	Φ2.4*2100mm
		AF-2423GK	Φ2.4*2300mm
5	Reusable Grasping Forceps (3-Prong type)	AF-1807GM103	Φ1.8*700mm
		AF-1810GM103	Φ1.8*1000mm
		AF-1815GM103	Φ1.8*1500mm
		AF-2415GM103	Φ2.4*1500mm
		AF-2417GM103	Φ2.4*1700mm
		AF-2421GM103	Φ2.4*2100mm
		AF-2423GM103	Φ2.4*2300mm
6	Reusable Grasping Forceps (3-Prong Hook type)	AF-1810GM103-H	Φ1.8*1000mm
		AF-1815GM103-H	Φ1.8*1500mm
		AF-1825GM103-H	Φ1.8*2500mm
		AF-2415GM103-H	Φ2.4*1500mm
		AF-2417GM103-H	Φ2.4*1700mm
		AF-2421GM103-H	Φ2.4*2100mm
		AF-2423GM103-H	Φ2.4*2300mm
7	Reusable Grasping Forceps (5-Prong type)	AF-1807GM105	Φ1.8*700mm
		AF-1810GM105	Φ1.8*1000mm
		AF-1815GM105	Φ1.8*1500mm
		AF-2415GM105	Φ2.4*1500mm
		AF-2417GM105	Φ2.4*1700mm
		AF-2421GM105	Φ2.4*2100mm
		AF-2423GM105	Φ2.4*2300mm
8	Reusable Grasping Forceps (5-Prong Hook type)	AF-1807GM105-H	Φ1.8*700mm
		AF-1810GM105-H	Φ1.8*1000mm
		AF-1815GM105-H	Φ1.8*1500mm
		AF-2415GM105-H	Φ2.4*1500mm
		AF-2417GM105-H	Φ2.4*1700mm
		AF-2421GM105-H	Φ2.4*2100mm
		AF-2423GM105-H	Φ2.4*2300mm
9	Reusable Grasping Forceps (Scissors type)	AF-2415GO101	Φ2.4*1500mm
		AF-2417GO101	Φ2.4*1700mm

		AF-2421GO101	Φ2.4*2100mm
		AF-2423GO101	Φ2.4*2300mm
10	Reusable Grasping Forceps (Rubber Tips type)	AF-1810GM102-R	Φ1.8*1000mm
		AF-1815GM102-R	Φ1.8*1500mm
		AF-2415GM102-R	Φ2.4*1500mm
		AF-2417GM102-R	Φ2.4*1700mm
		AF-2421GM102-R	Φ2.4*2100mm
		AF-2423GM102-R	Φ2.4*2300mm
11	Reusable Grasping Forceps (Half-Scissors type)	AF-2415GO102	Φ2.4*1500mm
		AF-2417GO102	Φ2.4*1700mm
		AF-2421GO102	Φ2.4*2100mm
		AF-2423GO102	Φ2.4*2300mm
12	Reusable Fold Angular Basket (Stainless steel)	AF-1807GL0	Φ1.8*700mm
		AF-1810GL0	Φ1.8*1000mm
		AF-1816GL0	Φ1.8*1600mm
		AF-1825GL0	Φ1.8*2500mm
		AF-2415GL0	Φ2.4*1500mm
		AF-2417GL0	Φ2.4*1700mm
		AF-2421GL0	Φ2.4*2100mm
		AF-2423GL0	Φ2.4*2300mm
13	Reusable Basket without Tip (Nitinol)	AF-1807GL1	Φ1.8*700mm
		AF-1810GL1	Φ1.8*1000mm
		AF-1816GL1	Φ1.8*1600mm
		AF-1825GL1	Φ1.8*2500mm
		AF-2415GL1	Φ2.4*1500mm
		AF-2417GL1	Φ2.4*1700mm
		AF-2421GL1	Φ2.4*2100mm
		AF-2423GL1	Φ2.4*2300mm
14	Reusable Spirality Basket (Nitinol)	AF-1807GL2	Φ1.8*700mm
		AF-1810GL2	Φ1.8*1000mm
		AF-1816GL2	Φ1.8*1600mm
		AF-1825GL2	Φ1.8*2500mm
		AF-2415GL2	Φ2.4*1500mm
		AF-2417GL2	Φ2.4*1700mm
		AF-2421GL2	Φ2.4*2100mm
		AF-2423GL2	Φ2.4*2300mm
15	Reusable Spirality Basket (Stainless steel)	AF-1807GL3	Φ1.8*700mm
		AF-1810GL3	Φ1.8*1000mm
		AF-1816GL3	Φ1.8*1600mm
		AF-1825GL3	Φ1.8*2500mm
		AF-2415GL3	Φ2.4*1500mm
		AF-2417GL3	Φ2.4*1700mm
		AF-2421GL3	Φ2.4*2100mm

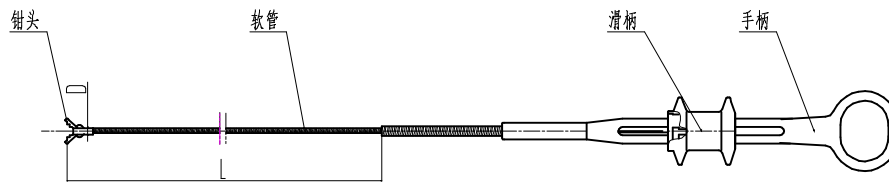
	AF-2423GL3	Φ2.4*2300mm
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Information about the offered dimensions you can get from **Alton (Shanghai) Medical instruments Co., LTD** main catalogue.

4.3 Products structure

The reusable grasping forceps is composed of four components, including the head, tube, Sliding handle and hand holder. The head of the grasping forceps have different head types, including Rat Tooth type, Rat Tooth with Alligator Jaws type, Alligator type, Pelican type, 3-Prong type, 3-Prong Hook type, 3-Prong Hook type, 5-Prong Hook type, Scissors type, Rubber Tips type, Half-Scissors type, Fold Angular Basket type with stainless steel, Basket without Tip type with Nitinol, Spirality Basket type with Nitinol, and Spirality Basket type with Stainless steel, please see figure 1.

Figure1: Components of the reusable grasping forceps



Note: components from the left to right:

1. Head
2. Tube
3. Sliding handle
4. Hand holder

No.	Product components	Material	Materials of body contact (Yes/No)
1	Head	Stainless steel	Yes
2	Head (only for basket model)	Stainless steel, or Nitinol	Yes
3	Tube	Stainless steel, or Stainless steel and PTFE	Yes
4	Bend protection	Stainless steel, or PTFE	No

5	Handle	PSF, or Stainless steel	No
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Conclusion:

Body contact: stainless steel 304, Nitinol, PE and PTFE;

Without body contact: stainless steel, PTFE and PSF.

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. Check the package of grasping forceps should be including: the IFU, product certificate, and the reusable grasping forceps;
- b. Check the single pouch bag if the sealing is damaged or not;
- c. If the sealing of bag is not completed, please don't use it and contact with manufacturer or local distributor to exchange;
- d. Open the package to check all components are useable, if not please contact with manufacturer or local distributor to exchange;
- e. Keep away from moisture;
- f. The reusable instruments are not sterilized by manufacturer, must need complete the sterility before the first use and after every use;
- g. Be storage indoor and keep the device dry;
- h. The device must be used under endoscope, it can't be used independently. If not, it will hurt users also damage other instruments possibly;
- i. 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 grasping forceps head. Such as: the reusable grasping forceps model of AF-2423GI, 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-2423GI	Working channel diameter > or = 2.8mm	<p>24 17/23</p> <p>Working Length (17: 1700mm; 23 and other: ×100mm)</p> <p>External Diameter of forceps head (×0.1mm)</p>

7. Operation

7.1 Insertion into the Endoscope

Grasping forceps must be passed through the endoscope operating channel with its cups closed or with the graspers withdrawn into the tube. Please observe compatibility between Grasping forceps and the endoscope's operating channel diameter.

7.2 Foreign Body Capture and Removal

Once the foreign body is located in the patient's body the following procedure should be done:

7.2.1 Grasping forceps

- a. Insert the Grasping forceps into the endoscope.
- b. Place the forceps in front of the object to be removed and open the cups by pushing the handle spool and capture the object.
- c. Close the cups as much as the object allows and remove object and forceps by withdrawing the endoscope gently. Always keep the cups closed.

8. cleaning and disinfection

The reusable grasping forceps by Alton are not disinfected before leaving factory; all users must complete cleaning and disinfection before first use and after each use, the cleaning and disinfection operation shall be performed according to the local hospital operations manual and parameters from a validated process of cleaning and disinfection.

9. Sterilization (optional)

The reusable grasping forceps by Alton are not sterile before leaving factory, all users

can choose to complete sterilization before first use, and after every use, the sterilization method and conditions as:

- a. Method: by Autoclaving method;
- b. Sterilization conditions: Under the Temperature of 132 °C or the Pressure of 205.8kPa is for 5 minutes.
- c. OR Use a sterilization condition with the parameters of sterilization validation by the users.

10. Validity period

- a. Ten years for storage before opening the single bag;
- b. Can NOT be re-used more than 30 times.

11. Storage

- a. To be storage indoor and keep the environment clean and dry;
- b. The environment Temperature 0°C -40 °C, Relative humidity 30-85%, and air pressure 50.0-106.0KPa.

12. User

By professional and clinical experienced operators.

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.








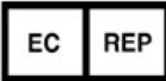



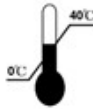

14. Legal Foundation

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	