

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

Bite Blocks are used to prevent the patient from biting down on the endoscope during gastroscopy therapy.

This instruction for use aims to help the user to use the Bite Blocks appropriately and prevent damage to the endoscope.

It is only for single use instrument.

2. Design

Alton (Shanghai) Medical Instruments Co., Ltd. supplies various designs of bite blocks for use. Information on the different of sizes available may be obtained directly from us.

3. Before use

Please read the instructions and warnings thoroughly before the initial use. Previous knowledge of the handling and operation are vital and necessary. Remove

the packaging carefully and inspect the product thoroughly for possible defects and damage. In the case of damaged or missing parts please contact to **Alton (Shanghai) Medical Instruments Co., Ltd.** or local dealer immediately.

The instruments are supplied non-sterile! Inspect the product and packaging for possible defects and damage! Only undamaged products may be used. The product is intended for single use!

4. Types

Alton (Shanghai) Medical Instruments Co., Ltd. offers bite blocks in **6 types Suffix with GBW, GB, GBW-C, GBW-N, GB-N and GBW-O.**

(See the “Table 1” typical model list of Bite Blocks attached)

Table 1: The models of Bite Blocks in the list

No.	Model Name	Model spec.
1	Bite Blocks (Disposable, with Elastic band, for Adult)	AF-GBW
2	Bite Blocks (Disposable, with Elastic band, for Children)	AF-GBW-C
3	Bite Blocks (Disposable, without Elastic band, for Adult)	AF-GB
4	Bite Blocks (Disposable, with Elastic band, for No Teeth)	AF-GBW-N
5	Bite Blocks (Disposable, without Elastic band, for No Teeth)	AF-GB-N
6	Bite Blocks (Disposable, OxyFlow Oxygen Mouthguard)	AF-GBW-O

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

4.1 Products drawing

The structures of Bite blocks have two components included, which are the bite block and band if for with band models. Please see figure 1 and table 2

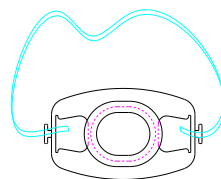


figure 1 the bite block and band

Table 2 The material list of bite blocks

No.	Product components	Material	Materials of body contact (Yes/No)
1	Bite block (disposable models)	ABS	No
2	Band	Rubber latex	No

5. Cautions

- a) Required by professional operators to use this device;
- b) Users must realize the type for selection
- c) The bite blocks are not sterilized by manufacturer
- d) Only for single use, and must be destroyed after use;
- e) Keep away from moisture.

6. Operation

6.1 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 it is damaged or not. If any damaged, please don't use it and contact to Alton or local distributor to exchange immediately.

6.2 Operation

- a. Open the single pouch, and use it according to the IFU by operator;
- b. Select the model to according to different patients to avoid any harms for patients.

7. Sterilization/Cleaning

- a. The bite blocks are not sterilized by Alton in delivery;
- b. No need to be sterilized before use;
- c. Only for single use.

8. Validity period

Ten years for storage before opening the single bag.

9. 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;

- c. Avoid direct sunlight.

10. User

By professional and clinical experienced operators.

11. 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.



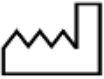




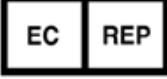





12. Legal Foundation

The Law of the European Union is applied.

13. 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.

14. 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 (sold in non-sterile conditions)	
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	