

Instructions for Use

【Product Name】 Foreign Body Retrievers

【Intended Use】 Foreign Body Retrievers are used in the retrieval of foreign bodies from the gastrointestinal tract.

【Product Description】 The Foreign Body Retrievers consist of 3 parts: the grasping head(1), catheter (2)(flexible twisted wire/ plastic outer sheathe) and handle(3) as shown in Figure 1.

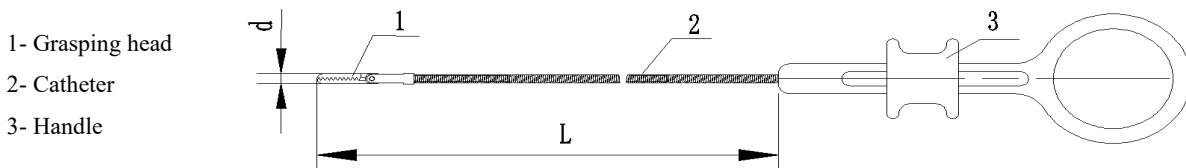
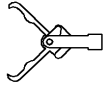
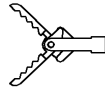

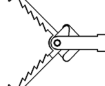
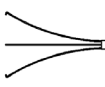

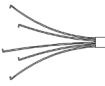
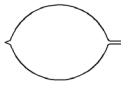

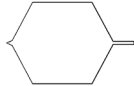
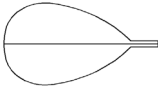
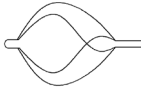
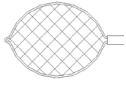


Figure 1 Foreign Body Retrievers

【Specification】

Table 1 Foreign Body Retrievers

Type	Model number	Grasping head shape	Picture
Tooth shape	A1	Rat tooth	
	A2	Alligator	
	A3	Rat tooth alligator	
	A4	Pelican	
Claw shape	B1	3-pod type	
	B2	4-pod type	
	B3	5-pod type	
Snare shape	C1	oval	
	C2	crescent	

	C3	hexagonal	
Basket shape	D1	Loop	
	D2	Spiral	
	D3	Mesh	



Users can choose different specifications based on procedural requirements.

【Inspection–Prior to Use】

1. Inspect the catheter for kinks, fraying, cracks damage or deformities.
2. Ensure the surface of the handle is smooth and clean, with no visible scratches or blemishes.
3. Check that the grasping head can open and close easily.
4. Uncoil the catheter completely and check for kinks or cracks.
5. Close (retract) and open (deploy) the handle several times and observe that the device functions properly.
6. Check that the connections between head, catheter, and handle are sturdy.

【Pre-Use Instructions】

1. Check the packing carefully for damage and moisture.
2. Do not use if device is damaged or has any visible deformities.

【Clinical Use】

A1: Used to grasp and remove the foreign bodies with complex shapes , such as the recycle of irregular objects or stents.

A2: Used to remove that objects such as coins.

A3: Used to recover drainage tubes or small foreign bodies.

A4: Used to grasp and remove a wide range of special foreign bodies, such as rubber and textile.

B1, B2, B3: Used in the removal of polyps or diseased tissue.

C1: Used in the removal of foreign bodies from the colon.

C2: Used in the removal of foreign bodies from the colon.

C3: Used to grasp and remove food bolus and other slippery foreign bodies.

D1, D2: Used to grasp and remove gallstones in the bile duct, or the foreign bodies in the upper and lower digestive tract.

D3: Used to retrieve polyps and other foreign bodies.

【Instructions for Use】

1. While monitoring endoscopically, slowly insert foreign body retriever into the instrument channel until the distal end of the catheter is endoscopically visualized.
2. When the foreign body retriever reaches the foreign body, open the grasping head to capture the foreign body and slowly retract the retriever.

Warning:

- (1) The foreign body retriever should only be inserted if the lumen is clear and free of any blockage or it may cause instrument damage, hemorrhage, or perforation of internal organs.
- (2) Do not insert the foreign body retriever if the endoscope is extremely articulated as this could cause the device to exit the endoscope with too much speed or force resulting in perforation of internal organs, hemorrhage, or injury to the mucous membrane.
- (3) Do not push or pull the foreign body retriever suddenly. This may cause perforation of internal organs, hemorrhage, or injury to the mucous membrane.
- 3. After use, handle and dispose of this device in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

【Notes】

- 1. This device should only be operated by physicians or other medical staff under the supervision of a physician. Endoscopic procedures should only be performed by personnel with adequate training and knowledge of endoscopic techniques and polyp retrieval. Prior to use, personnel should understand the potential complications, hazards, and risks related to patient safety.
- 2. Do not use this device for any medical purposes other than its intended use.
- 3. The use of this device is strictly prohibited if the packaging has been damaged.
- 4. Reuse this device is forbidden. This is a single-use device and must be properly disposed of after one use.
- 5. Do not use product after expiration.

【Contraindications】 Do not use it if :

- 1. The patient’s health is too poor for the procedure.
- 2. The patient is susceptible to hemorrhage or has any blood disorder.
- 3. The foreign object could become loosened, dislodged, or aspirated into the trachea.
- 4. The patient is experiencing any condition that the physician judges to be unsafe.

【Packaging】 Each product is packaged in paper/plastic bag.

【Sterilized method】 Ethylene oxide sterilization.

【Sterilization valid】 Two years after the date of sterilization.

【Storage Requirements】 Store in a well-ventilated room with no higher than 80% relative humidity.

【Label Symbol】



"Consult instructions for use"



"Caution"



"Do not reuse"



"Date of manufacture"



"Lot number"



"Do not use if package is damaged"



"Authorized Representative in the European Union"



"Sterilized using ethylene oxide"



"Use-by date"



"Manufacturer"



"Catalogue number"



: Changzhou Health Microport Medical Device Co., Ltd.

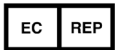
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