

# EndoTExtractor

FOREIGN BODY RETRIEVAL DEVICE



STERILE EO



R<sub>x</sub> only

FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

EN - INSTRUCTIONS FOR USE



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Think Within.



**Intended Use**

The EndoTEExtractor is intended to be used in the endoscopic retrieval of foreign body, food bolus, and excised tissue such as polyps.

**Contraindications**

None known within the scope of the intended use.

**Warnings and Precautions**

Do not use if package is opened or damaged.

Visually inspect before use. Do not use if any abnormality is found or if the device is not operating properly.

This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure, infection, and/or transmission of disease.

Patient clinical conditions and type of foreign bodies may result in using various retrieval techniques. The technique used is at the discretion of the physician.

Do not kink tubing when loading into endoscope.

Avoid blindly passing the device past the foreign body.

Avoid inadvertently grasping tissues or organs not intended for retrieval.

Retrieval of sharp objects may tear the retrieval component. Device failure during extraction may result in mucosal injury or the need for additional intervention. Exercise clinical judgment and use caution during manipulation.

Do not deploy handle quickly, in an acute position or when the endoscope is in an extremely articulated or coiled position.

Do not apply excessive force to the handle when grasping a foreign body. Excessive force may cause the prongs to buckle, resulting in compromised device performance or failed retrieval.

If the control loop becomes entangled, manipulate the handle as needed to carefully disengage the loop before proceeding.

Maintain moderate pressure when passing the trachea to avoid losing the foreign body.

Use caution when removing the foreign body after retrieval. Not doing so may result in damage to the device.

**Instructions**

1. Verify the endoscope accessory channel size is compatible with the device.
2. Peel the pouch open, remove the device from pouch. Visually inspect the device for kinks, loose, or broken parts.
3. Form the device into a "U" shape and deploy and retract to verify proper actuation.
4. Retract the device into the outer sheath before inserting the device into the working channel of the endoscope. If resistance is met when the bending tip of the endoscope is angulated, release the bending angle slightly until the

instrument passes smoothly. Do not force the device into an angulated endoscope as this could damage the endoscope.

5. Deploy, position, and retract the device to retrieve the foreign body.
6. After the foreign body is collected, retract the device and endoscope while maintaining moderate pressure when passing the trachea to avoid losing the foreign body.

### **Notes**

Use of this device restricted to a trained healthcare professional.

In the event of a malfunction, discontinue use and save for return and contact your local representative.

Serious incidents that have occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred.

### **Disposal**

Dispose of the device after use in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

### **Storage**

Store sterile instruments at room temperature.

Do not expose to disinfectants, solvents, radiation, UV light or any other substance or environment that could compromise the sterility of the unit.



Do not place any objects on the device or packaging.

**Symbols**

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A symbol glossary can be found at [endotherapeutics.com/symbol-glossary](http://endotherapeutics.com/symbol-glossary)

EN - Symbols

	EN - Quantity of devices in pouch
	EN - Quantity of devices in box

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