

Zero Tip™

Airway Retrieval Basket

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Caution/Rx Only:

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Warnings:

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Some objects may be too large to be removed endoscopically with a retrieval basket. To avoid object impaction, fluoroscopy or x-ray should be used to determine the size of the object; do not use the Zero Tip Airway Retrieval Basket if the object is too large to be removed endoscopically or held in the basket.

This device must not come in contact with any electrified instrument.

Intended Use / Indications for Use:

The Zero Tip Airway Retrieval Basket is intended to be used to endoscopically remove foreign bodies in the airway.

Contraindications:

- This procedure should not be attempted in any patient whose general medical condition and degree of respiratory failure would not allow that patient to tolerate bronchoscopy (rigid or fiberoptic) and/or the manipulation required to perform the procedure.
- Uncooperative patient.

Precautions/Cautions:

- Before using, inspect the blister pouch for any breach of the package to ensure a sterile product and inspect product for any damage. If seal has been broken or product is damaged DO NOT USE. Immediately return package and product to Boston Scientific.
- Kinks in the sheath will hinder the mechanical operation of the basket.
- If anesthesia is induced, it is recommended that positive pressure ventilation be avoided as this may drive the foreign body further toward the periphery.

Refer to the device directions for use for complete instructions on device use.

Adverse Events:

Adverse events which may result from the use of a basket in a bronchoscopic procedure include, but are not limited to:

- Pneumothorax
- Pneumomediastinum
- Laryngospasm
- Entrapment
- Evulsion
- Hemorrhage
- Inability to disengage from irretrievable object
- Subglottic edema
- Laryngeal edema
- Basket inversion
- Obstruction of ventilation
- Displacement of foreign body to a more unfavorable or peripheral location
- Fracture of an organic foreign body
- Loss of a large foreign body in the subglottic area during withdrawal, resulting in airway obstruction