



Product

Zero Tip™ Airway Retrieval Basket

51753276-01A_IFU_Zero Tip Airway Retrieval Basket

Rx Only Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

REUSE WARNING

For single 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.

DEVICE DESCRIPTION

The Zero Tip Airway Retrieval Basket consists of a wire shaft (or cannula) housed in a flexible sheath with a multi-wire 360°, self-expanding basket at the distal end. A handle is attached proximally via a luer lock connector to open and close the basket. The Zero Tip Airway Retrieval Basket is designed to be used through working channel (2.0 mm or larger) of an endoscope, such as a flexible fiberoptic or rigid bronchoscope during the procedure.

Contents

The package includes:

- One (1) Airway retrieval basket
- One (1) Introducer

Operating Principle

The Zero Tip Airway Retrieval Basket accomplishes bronchoscopic removal of foreign bodies from the airway tree through the manipulation of the proximal handle of the device which opens and closes the basket. The basket located on the distal end of the device, features a low-profile, flexible, knotted-tip Nitinol wire design, which helps to grasp, manipulate and/or remove objects obstructing the airway tree.

Materials

- Contains cobalt: CAS No. 7440-48-4; EN No. 231-158-0.
- Defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1% weight by weight.

Note: Current scientific evidence supports that metal alloys containing cobalt used in medical devices, do not cause an increased risk of cancer or adverse reproductive effects.

User Information

Use of this device should be restricted to use by or under the supervision of physicians trained in bronchoscopic procedures. Care should be exercised to prevent perforation or trauma of the linings and associated tissue.

The Zero Tip Airway Retrieval Basket is for single use and has no other user serviceable parts.

- Do not attempt to repair or to alter the device.
- Do not resterilize the device.
- Any use of this device, other than those indicated in these instructions is not recommended.

INTENDED USE/INDICATIONS FOR USE

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

Clinical Benefit Statement

The intended clinical benefit of Zero Tip Airway Retrieval basket is for the removal of 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.

WARNINGS

- Some objects may be too large to be removed endoscopically with a retrieval basket. Do not use the Zero Tip Airway Retrieval Basket if the object is too large to be removed endoscopically or held in the basket to avoid patient injury. To avoid object impaction, fluoroscopy or x-ray should be used to determine the size of the object.
- This device must not come in contact with any electrified instrument, as this may result in patient injury such as electric shock, burn, or tissue damage.

OPERATIONAL INSTRUCTIONS

Warning:

If resistance is encountered during advancement or withdrawal of device, DO NOT EXERT EXCESSIVE FORCE.

Precaution:

- 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.
- Objects may be too large once captured in the basket to withdraw the basket fully into the sheath or the scope. Do not exert excessive force to withdraw basketed object into sheath or into scope. Carefully maintain basket position to hold the object in place. The bronchoscope and foreign body are then removed as a unit.

ADVERSE EVENTS

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

- Airway obstruction
- Allergic reaction
- Bronchospasm
- Displacement of foreign body to a more unfavorable or peripheral location

- Edema (eg.-laryngeal, subglottic, tracheal, etc)
- Entrapment
- Evulsion
- Fracture of an organic foreign body
- Hemorrhage
- Laryngospasm
- Pneumomediastinum
- Pneumothorax
- Respiratory Distress
- Respiratory Failure

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