

# Ultraflex™ Tracheobronchial Stent System

*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 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.

The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

Visually inspect the system for any sign of damage. DO NOT USE if the system has any visible signs of damage. Failure to observe this precaution may result in patient injury.

The device is supplied sterile and intended for single use only. The packaging and device should be inspected prior to use. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Do not attempt to reload a deployed or partially deployed stent.

The stent is not intended to be removed once it is properly positioned. However, if it becomes necessary to remove the stent immediately post-deployment, the stent may be removed using forceps with teeth or a retrieval snare.

Placement of the Ultraflex Tracheobronchial Stent System is contraindicated in patients with strictures that cannot be dilated to at least 4 mm or cannot pass a bronchoscope.

The stent is not intended to be removed once it is properly positioned. However, if it becomes necessary to remove the stent immediately post-deployment, the stent may be removed using forceps with teeth or a retrieval snare.

## MRI Safety Information:

Non-clinical testing has demonstrated that the Ultraflex Tracheobronchial Stent is MR Conditional. A patient with an Ultraflex Tracheobronchial Stent can be safely scanned under the following conditions:

- Static magnetic field of 1.5 tesla and 3.0 tesla only
- Maximum spatial gradient magnetic field of 2,500 gauss/cm (25 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Ultraflex Tracheobronchial Stent is expected to produce a maximum temperature rise of 4.0 °C after 15 minutes of continuous scanning.

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In non-clinical testing, the image artifact caused by the device extends approximately 12 mm from the Ultraflex Tracheobronchial Stent when imaged with a gradient echo pulse sequence in a 3 tesla MRI system. The artifact does obscure the device lumen. Boston Scientific recommends that the patient register the MR conditions disclosed in this Directions for Use with the MedicAlert Foundation

(www.medicalert.org) or equivalent organization.

## Contents

One (1) Ultraflex Tracheobronchial Stent System

## Intended Use / Indications for Use:

The Ultraflex Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

## Contraindications:

The Ultraflex™ Tracheobronchial Stent System is contraindicated for:

- Concurrent fistula of the tracheobronchial tree, unless a covered stent is being used.
- Tracheobronchial obstruction with a luminal diameter which cannot be dilated to and maintained at least 4 mm, or preventing passage of either a rigid or flexible bronchoscope
- Patients for whom bronchoscopic procedures are contraindicated
- Any use other than those specifically outlined under Indications for Use

## Precautions:

The Ultraflex Tracheobronchial Stent System should be used with caution and only after careful consideration in patients with:

- Compromised immune system
- Elevated bleeding times or coagulopathies
- Prior pneumonectomy
- Concurrent acute inflammation in the lumen, as this may potentiate granuloma formation and fibrosis
- A tumor stricture adjacent to a major vessel, as this may potentiate fistula formation
- Placement of an improperly sized stent can lead to a higher incidence of granulation tissue formation
- Placement of any type of stent in the subglottic trachea is associated with a higher rate of granuloma formation and should be avoided
- The Ultraflex Tracheobronchial Stent is made of Nitinol, an alloy of nickel and titanium, which may cause an allergic reaction in individuals with nickel sensitivity

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- Laser ablation to treat excessive granulation tissue post stent placement may result in loss of stent integrity and/or cause airway fire
- If possible, avoid choosing of a stent which would cross bronchial side branches when placed

## Adverse Events:

Complications have been reported in the literature for tracheobronchial stent placement with both conventional plastic stents and available expandable metal stents. These include, but are not limited to the following:

### Procedural Complications

- Stent misplacement
- Bleeding
- Tracheobronchial perforation and pneumothorax
- Pain
- Aspiration
- Oxygen desaturation related to sedation or procedural instrumentation infection
- Infection
- Pneumoperitoneum

### Post-Stent Placement Complications

- Halitosis
- Stent migration
- Tracheitis
- Hemoptysis
- Dysphagia
- Stent occlusion due to mucous accumulation
- Stent occlusion due to tumor ingrowth
- Stent occlusion due to tumor overgrowth of stent ends
- Stent occlusion due to granulomatous tissue ingrowth
- Restenosis due to granulomatous tissue formation at stent ends
- Recurrent obstructive dyspnea related to stent occlusion or migration
- Tracheobronchial wall ulceration and/or perforation and/or hemorrhage
- Infection and septic shock
- Aphonia
- Death
- Stent Fracture
- Obstructive atelectasis (even with a well-positioned stent)
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