Overview

Product

Ultraflex™ Tracheobronchial Stent System – IFU # 51223446

Caution/Rx Only:

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

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.

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 lumenal 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

Adverse Events:

The potential complications associated with tracheobronchial stent placement may include:

- Allergic reaction
- Aphonia
- Aspiration
- Bleeding/Hemorrhage
- Burn

- Bronchospasm
- Death
- Dysphagia
- Dyspnea
- Fistula formation
- Halitosis
- Hemoptysis
- Inadequate stent expansion
- Infection and sepsis
- Inflammation
- Obstructive atelectasis (even with a well-positioned stent)
- Pain/Discomfort
- Perforation
- Pneumoperitoneum
- Pneumothorax
- Respiratory distress
- Respiratory failure
- Restenosis
- Sedation or anesthesia complications
- Stent fracture
- Stent migration
- Stent misplacement
- Stent occlusion due to mucous, tissue ingrowth/overgrowth
- Tissue damage
- Tissue ingrowth OR overgrowth
- Tracheitis
- Ulceration and fistula formation

Warnings:

This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

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.

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.
- Laser ablation to treat excessive granulation tissue post stent placement may result in loss of stent integrity and/or cause airway fire.
- Placement of any type of stent in the subglottic trachea is associated with a higher rate of granuloma formation and should be avoided.

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

Physicians should use judgement based on experience in dilating airway strictures. Perforation, bleeding and/or migration could result from dilation of a tumor.

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 in order to avoid patient injuries such as perforation, hemorrhage and/or obstruction.

If possible, avoid choosing of a stent which would cross bronchial side branches when placed in order to avoid respiratory complications.

Do not attempt to reload a deployed or partially deployed stent in order to avoid damage to the stent/delivery system and/or patient injury.

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.

Precautions:

Read the entire Procedural Instructions for the specific stent system being employed.
Note: It may take 24-72 hours for the stent to fully expand

MRI Safety Information:

MRI Safety Information A person with the Ultraflex Stent(s) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury	
Device Name	Ultraflex Stent
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Cylindrical Whole-body Coil Cylindrical Head Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration/ Temperature Rise	Under scan conditions defined above, Ultraflex Stent is expected to have a temperature rise of less than 4 °C and can be used for 60 minutes of continuous RF
MR Image Artifact	Image artifact caused by device may extend approximately 13 mm from the perimeter and 7 mm from the end of the stent with a spin and gradient echo pulse sequence