

Ultraflex™ Tracheobronchial Stent System

Covered with Distal Release or Noncovered with Distal/Proximal Release Systems

ULTRAFLEX SINGLE-USE COVERED TRACHEOBRONCHIAL STENT SYSTEM - DISTAL RELEASE

Tracheal Stents

Order Number	Max. Stent O.D. (mm)	Expanded Stent Length (mm)	Tip Max. O.D. (Fr)	Compressed Stent O.D. (Fr)	Covered Length (cm)
M00569480	14	40	13	18	2.5
M00569490	14	60	13	18	4.5
M00569500	14	80	13	18	6.5
M00569510	16	40	22	19	2.5
M00569520	16	60	22	19	4.5
M00569530	16	80	22	19	6.5
M00569540	18	40	22	22	2.5
M00569550	18	60	22	22	4.5
M00569560	18	80	22	22	6.5
M00569570	20	40	22	22	2.5
M00569580	20	60	22	22	4.5
M00569590	20	80	22	22	6.5

Bronchial Stents

Order Number	Max. Stent O.D. (mm)	Expanded Stent Length (mm)	Tip Max. O.D. (Fr)	Compressed Stent O.D. (Fr)	Covered Length (cm)
M00569050	10	30	12	16	1.5
M00569060	12	30	12	17	1.5
M00569040	14	30	12	18	1.5
M00569410	8	40	13	15	2.5
M00569430	10	40	13	16	2.5
M00569450	12	40	13	17	2.5
M00569480	14	40	13	18	2.5
M00569490	14	60	13	18	4.5

ULTRAFLEX SINGLE-USE NONCOVERED TRACHEOBRONCHIAL STENT SYSTEM - PROXIMAL RELEASE

Tracheal Stents

Order Number	Max. Stent O.D. (mm)	Expanded Stent Length (mm)	Tip Max. O.D. (Fr)	Compressed Stent O.D. (Fr)
M00569920	14	40	13	18
M00569930	14	60	13	18
M00569000	14	80	13	18

Bronchial Stents

Order Number	Max. Stent O.D. (mm)	Expanded Stent Length (mm)	Tip Max. O.D. (Fr)	Compressed Stent O.D. (Fr)
M00568920	8	20	13	15
M00568930	8	40	13	15
M00568940	10	20	13	16
M00568950	10	40	13	16
M00568960	12	20	13	17
M00568970	12	40	13	17
M00568980	14	20	13	18
M00569920	14	40	13	18
M00569930	14	60	13	18

ULTRAFLEX SINGLE-USE NONCOVERED TRACHEOBRONCHIAL STENT SYSTEM - DISTAL RELEASE

Tracheal Stents

Order Number	Max. Stent O.D. (mm)	Expanded Stent Length (mm)	Tip Max. O.D. (Fr)	Compressed Stent O.D. (Fr)
M00569230	16	40	22	19
M00569240	16	60	22	19
M00569250	16	80	22	19
M00569260	18	40	22	22
M00569270	18	60	22	22
M00569280	18	80	22	22
M00569290	20	40	22	22
M00569300	20	60	22	22
M00569310	20	80	22	22

Bronchial Stents

Order Number	Max. Stent O.D. (mm)	Expanded Stent Length (mm)	Tip Max. O.D. (Fr)	Compressed Stent O.D. (Fr)
M00569070	10	30	12	16
M00569080	12	30	12	17
M00569090	14	30	12	18

Specifications for all Ultraflex Tracheobronchial Stent Systems:

Proximal 10-14cm Shaft Maximum O.D.: 16Fr

Catheter Length: 95cm

Ultraflex™ Tracheobronchial Stent System

Covered or Noncovered with Distal or Proximal Release

INSTRUCTIONS FOR USE

Refer to the operator's manual for complete instructions for use.

INDICATIONS

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

WARNING: 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.

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 4mm, or preventing passage of either a rigid or flexible bronchoscope; for patients for whom bronchoscopic procedures are contraindicated; and for any use other than those specifically outlined under the Indications for Use.

WARNINGS

For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization 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 or reprocessing 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 government policy.

POTENTIAL COMPLICATIONS

Procedural Complications:

Potential adverse effects may include, but are not limited to, stent misplacement, bleeding, tracheobronchial perforation and pneumothorax, pain, aspiration, oxygen desaturation related to sedation or procedural instrumentation infection, and infection.

Post-stent Placement Complications:

Potential adverse effects may include, but are not limited to: halitosis, stent migration, 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, and obstructive atelectasis (even with a well-positioned stent).

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

CAUTIONS

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

- 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
- Laser ablation to treat excessive granulation tissue post stent placement may result in loss of stent integrity and/or cause airway fire
- This product contains no detectable latex

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Boston Scientific
Tel 508.650.8000
www.bostonscientific.com

Ordering Information
1.800.225.3226

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