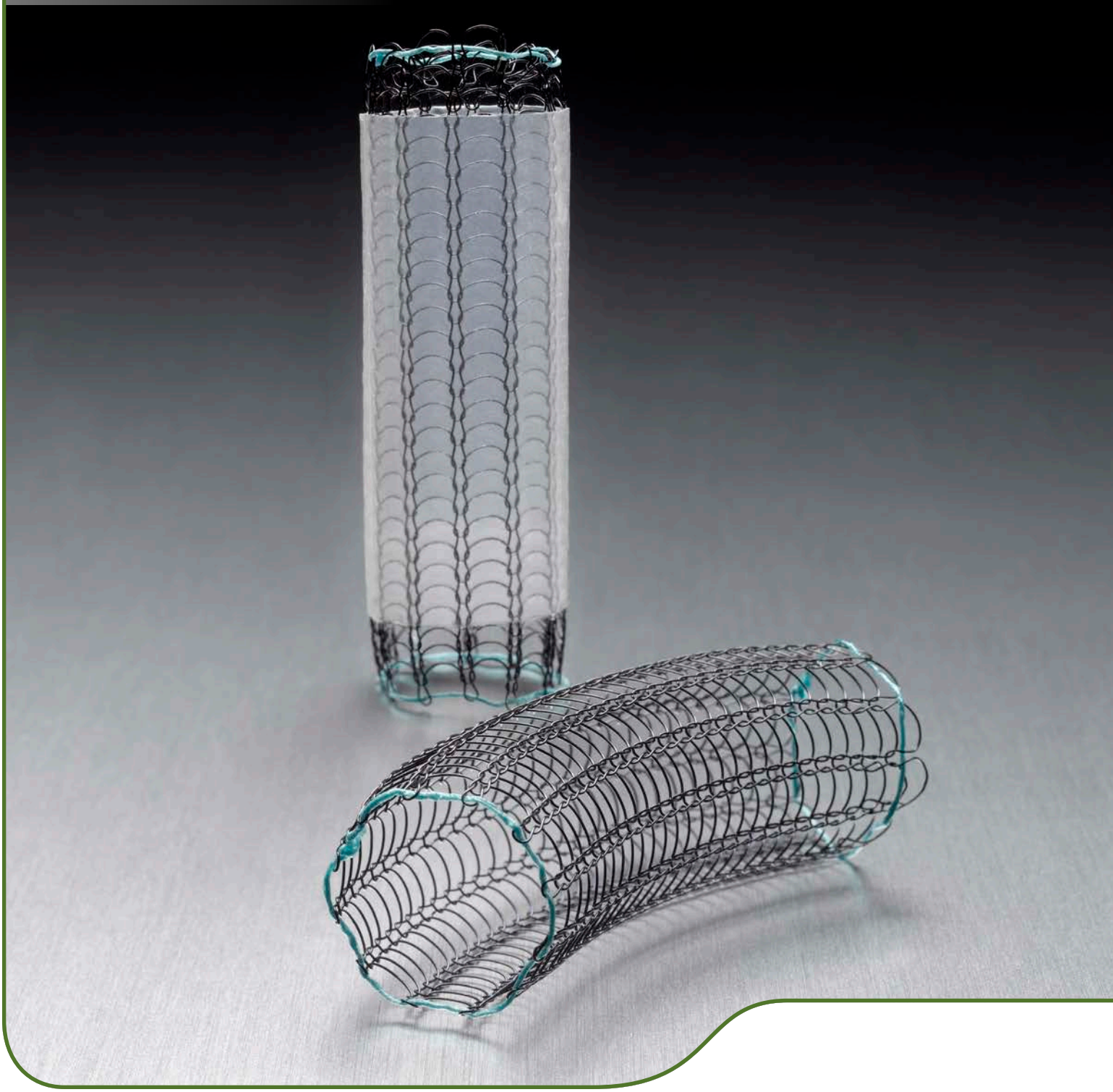
Ultraflex™

Boston Scientific

Single-Use Tracheobronchial
Stent System



Ultraflex™

Single-Use Tracheobronchial Stent System

The Ultraflex Tracheobronchial Stent System is provided sterile in both covered and uncovered versions and is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Accommodate Varying Airway Anatomy without Kinking

Knitted Nitinol Design
Stent geometry is designed to adapt to anatomical contours and exert constant, gentle radial pressure to maintain patency

Wide Range of Sizes
Variety of lengths and diameters in both covered and uncovered designs is intended to allow for complete bridging of stricture

Clear Secretions

Flexible Open Loop Design
Epithelization of uncovered stent may promote mucociliary clearance

Resist Migration

Uncovered Ends
Epithelization of ends may limit migration

Resist Tumor Ingrowth

Silicone Covering
On the covered version, covering helps resist tumor growth

Delivery System

Low Profile
The compressed stent and delivery system have between a 5-7mm outer diameter. The system is designed to facilitate advancement across tumors and may be placed via flexible or rigid bronchoscopy

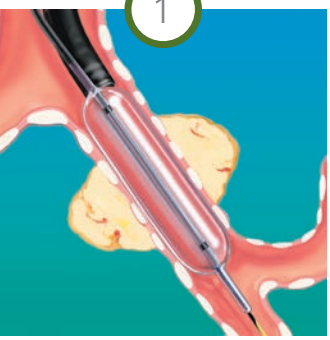
Flexibility
The flexible delivery catheter is designed to enhance the ease of navigation through the airway

Radiopaque Markers
Radiopaque markers on the delivery catheter are designed to target the deployed position of the stent

Distal or Proximal Release
Different release systems are designed to allow the physician greater control over stent deployment

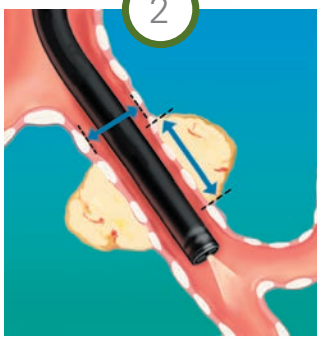
NOTE: Recommended guidewire, 0.035"
Jagwire Guidewire (Order # M00515171)

Overview of Procedural Steps*



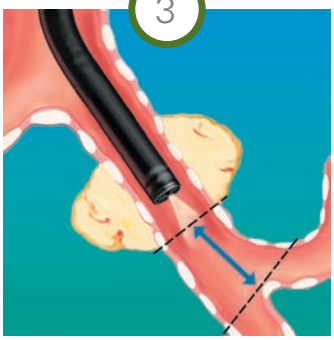
Location of Stricture and Pre-Dilation

- If necessary, airway is pre-dilated to 75% of normal size



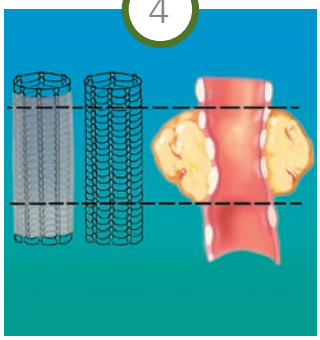
Determination of Stricture Length and Diameter

- Via Bronchoscopic examination
- Via Fluoroscopic examination
- Via CT Imaging



Stricture Examination

- Bronchial Branches are identified
- Stricture Margins are identified (radiopaque markers may be used)
- Intraluminal tumor or granulation tissue is removed if necessary



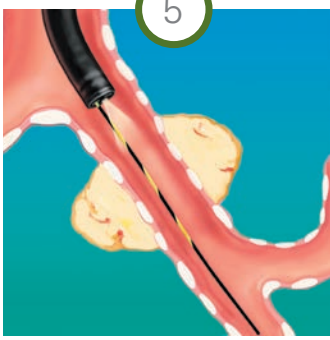
Selection of Stent Size

Length

- Stricture must be completely bridged
- Normal mucosa should be overlapped by 1-2 cm

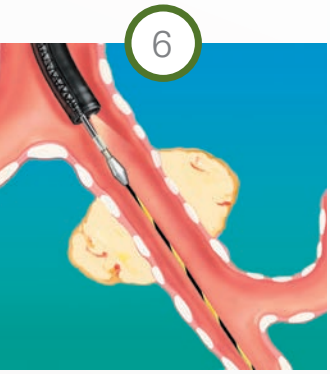
Diameter

- Should be equal to normal proximal lumen

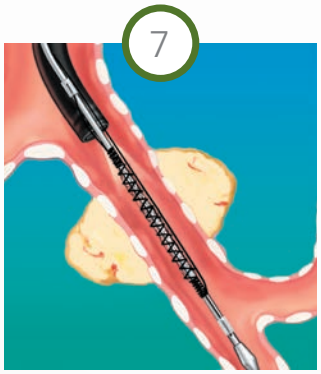


Guidewire Insertion

- 0.035" Jagwire™ Guidewire is placed
- Bronchoscope is removed

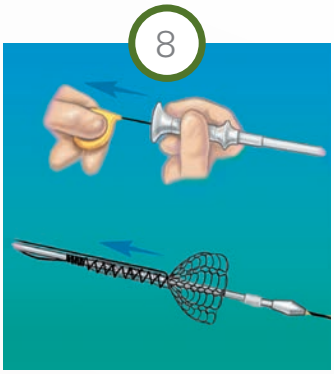


Delivery Catheter is Inserted Over Guidewire



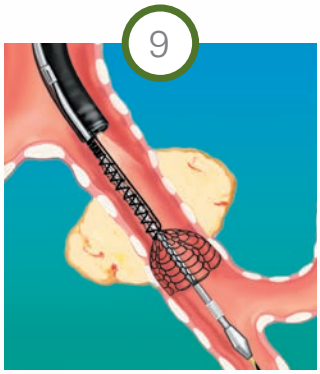
Advancement of Stent to Stricture

- Bronchoscope is re-placed into the airway
- Under bronchoscopic visualization, catheter is advanced over the guidewire
- Using fluoroscopic guidance and radiopaque markers, stent is centered across stricture



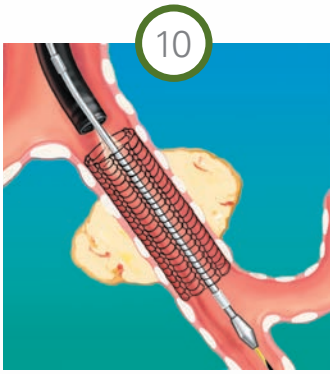
Deployment of Stent

- Holding catheter steady, ring is gently pulled with finger to deploy stent



Adjustment of Stent Position – OPTIONAL

- Catheter is pulled toward the operator to reposition†
- Deployment is then continued



Complete Deployment Confirmation and System Removal

Deployment Confirmed

- Via Bronchoscopic examination
- Via Fluoroscopic examination

Delivery System Removed

- Delivery system is removed carefully by rotating catheter
- Bronchoscope is removed.

** This overview is provided for illustrative purposes only and is intended only as a brief summary of how placement procedures for the Ultraflex Tracheobronchial Stent System are generally performed. It is not a substitute for exercise of proper medical judgment by a physician in the care of specific patients, or for the Instructions for Use included with the device.*

† For distal and proximal release systems, the inner catheter and stent can be pulled towards the operator and away from the operator, respectively. Repositioning may be limited by scope position or tortuous anatomy, among other factors.

Ultraflex™

Single-Use Tracheobronchial Stent System

Ultraflex Single-Use Uncovered and Covered Tracheobronchial Stent System (Each)

UNCOVERED				COVERED							
Uncovered Distal Release	Uncovered Distal Release GTIN	Uncovered Proximal Release	Uncovered Proximal Release GTIN	Covered Distal Release	Covered Distal Release GTIN	Expanded Stent OD (mm)	Expanded Stent Length (mm)	Uncovered Compressed Stent OD (Fr)	Covered Compressed Stent OD (Fr)	Cover Length (if applicable) (mm)	Tip Max OD (mm)
-	-	M00576410	8714729837770	-	-	8	20	15	-	-	4.0
-	-	M00576420	8714729837787	M00576520	8714729842323	8	40	15	16	25	4.0
-	-	M00576430	8714729837794	-	-	10	20	15	-	-	4.0
M00576300	8714729837688	-	-	M00576530	8714729842330	10	30	15	18	15	4.0
-	-	M00576440	8714729837800	M00576540	8714729842347	10	40	15	18	25	4.0
-	-	M00576450	8714729837817	-	-	12	20	17	-	-	4.0
M00576310	8714729837695	-	-	M00576550	8714729842354	12	30	17	20	15	4.0
-	-	M00576460	8714729837824	M00576560	8714729842361	12	40	17	20	25	4.0
-	-	M00576470	8714729837831	-	-	14	20	18	-	-	4.0
M00576320	8714729837701	-	-	M00576570	8714729842378	14	30	18	24	15	4.0
-	-	M00576480	8714729837848	M00576580	8714729842385	14	40	18	24	25	4.0
-	-	M00576490	8714729837855	M00576590	8714729842392	14	60	18	24	45	4.0
-	-	-	-	M00576600	8714729842408	14	80	-	24	65	4.0
M00576330	8714729837718	-	-	M00576610	8714729842415	16	40	20	25	25	5.1
M00576340	8714729837725	-	-	M00576620	8714729842422	16	60	20	25	45	5.1
-	-	-	-	M00576630	8714729842439	16	80	-	25	65	5.1
M00576350	8714729837732	-	-	M00576640	8714729842446	18	40	20	27	25	5.1
M00576360	8714729837749	-	-	M00576650	8714729842453	18	60	20	27	45	5.1
-	-	-	-	M00576660	8714729842460	18	80	-	27	65	5.1
M00576370	8714729837756	-	-	M00576670	8714729842477	20	40	20	27	25	5.1
M00576380	8714729837763	-	-	M00576680	8714729842484	20	60	20	27	45	5.1
-	-	-	-	M00576690	8714729842491	20	80	-	27	65	5.1

Pulmonary Jagwire™ Guidewire (Box 2)

Order Number	GTIN	O.D. (in)	Total Length (cm)
M00515171	08714729455813	0.035	180

CRE™ Pulmonary Balloon Dilators (Each)

Order Number	GTIN	Diameter @3 ATM	Diameter (mm) @ Intermediate ATM	Diameter (mm) @ Max. Inflation ATM	Balloon Length (cm)	Catheter Length (cm)
M00550300	08714729456186	12	13.5 @ 4.5	15 @ 8	5.5	75
M00550310	08714729456193	15	16.5 @ 4.5	18 @ 7	5.5	75
M00550320	08714729456209	18	19 @ 4.5	20 @ 6	5.5	75
M00550330	08714729456216	8	9 @ 5.5	10 @ 9	3.0	75
M00550340	08714729456223	10	11 @ 5	12 @ 8	3.0	75
M00550350	08714729456230	12	13.5 @ 4.5	15 @ 8	3.0	75

Specifications for all Ultraflex Tracheobronchial Stent Systems: Catheter Length - 95cm.

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

All trademarks are the property of their respective owners.

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.

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

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Ordering Information
1.888.272.1001

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