Ultraflex™

Single-Use Tracheobrochial Stent System

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

UNCOVERED		COVERED				
Uncovered Distal Release	**Uncovered Proximal Release**	**Covered Distal Release**	**Expanded Stent OD (mm)**	**Expanded Stent Length (mm)**	**Cover Length (if applicable) (MM)**	**Tip Max OD (mm)**
-	M00564640	-	8	20	-	4.1
-	M00564650	M00564740	8	40	25	4.1
-	M00564660	-	10	20	-	4.1
M00564500	-	M00564750	10	30	15	4.1
-	M00564670	M00564760	10	40	25	4.1
-	M00564680	-	12	20	-	4.1
M00564510	-	M00564770	12	30	15	4.1
-	M00564690	M00564780	12	40	25	4.1
-	M00564700	-	14	20	-	4.1
M00564520	-	M00564790	14	30	15	4.1
-	M00564710	M00564800	14	40	25	4.1
-	M00564720	M00564810	14	60	45	4.1
-	-	M00564820	14	80	65	4.1
M00564530	-	M00564830	16	40	25	5.3
M00564540	-	M00564840	16	60	45	5.3
-	-	M00564850	16	80	65	5.3
M00564560	-	M00564860	18	40	25	5.3
M00564570	-	M00564870	18	60	45	5.3
-	-	M00564880	18	80	65	5.3
M00564590	-	M00564890	20	40	25	5.3
M00564600	-	M00564900	20	60	45	5.3
-	-	M00564910	20	80	65	5.3

Pulmonary Jagwire™ Guidewire (Box 2)

Order Number	O.D. (in)/(mm)	Total Length (cm)
M00515171	0.035/0.89	180

CRE™ Pulmonary Balloon Dilatation Catheter (Each)

Order Number	Diameter @3 ATM	Diameter (mm) @ Intermediate ATM	Diameter (mm) @Max. Inflation ATM	Balloon Length (cm)	Catheter Length (cm)
M00550300	12	13.5 @ 4.5	15 @ 8	5.5	110
M00550310	15	16.5 @ 4.5	18 @ 7	5.5	110
M00550320	18	19 @ 4.5	20 @ 6	5.5	110
M00550330	8	9 @ 5.5	10 @ 9	3.0	110
M00550340	10	11 @ 5	12 @ 8	3.0	110
M00550350	12	13.5 @ 4.5	15 @ 8	3.0	110

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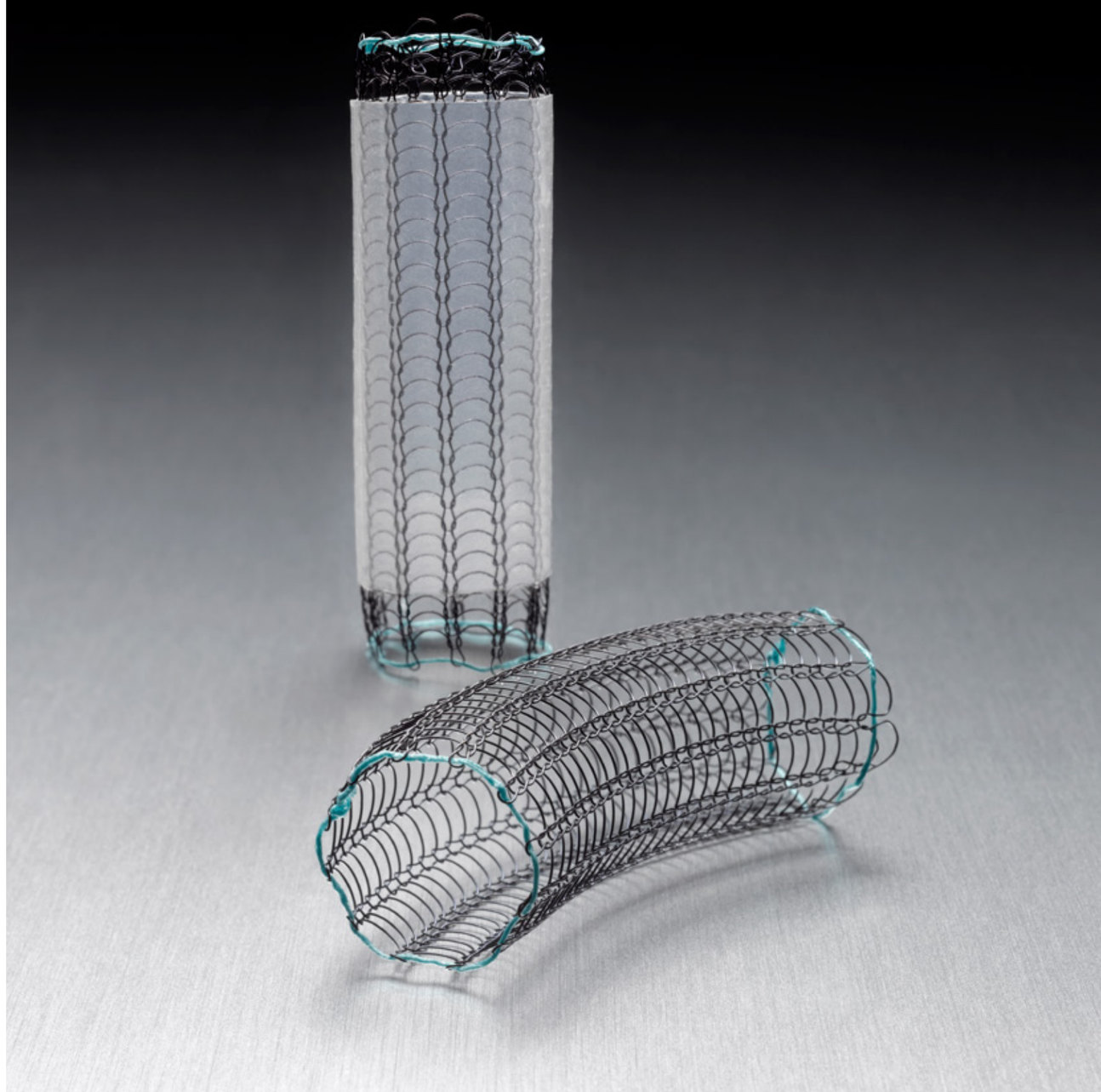


Ultraflex™

Single-Use Tracheobrochial Stent System

The Ultraflex Tracheobronchial Stent System 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
Epithelisation of uncovered stent may promote mucociliary clearance

Resist Migration

Uncovered Ends
Epithelisation of ends may limit migration

Resist Tumor Ingrowth

Polyurethane Covering
On the covered version, covering helps resist tumor ingrowth.

Delivery System

Low Profile
The compressed stent and delivery system have between a 5-9 mm outer diameter. The system is designed to facilitate advancement across tumors and may be placed via flexible or rigid bronchoscopy

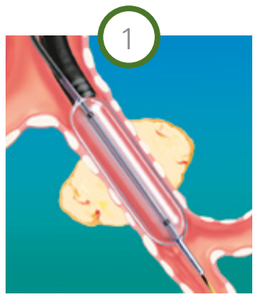
Flexibility
The flexible delivery catheter is designed to enhance the ease of navigation through the airway

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

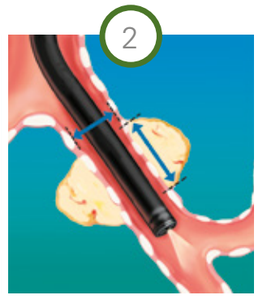
NOTE: Recommended guidewire, 0.035" Jagwire Guidewire (Order # M00515171)

Overview of Procedural Steps*



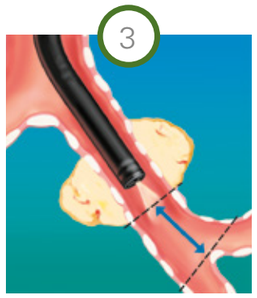
Location of Stricture and Pre-Dilation

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



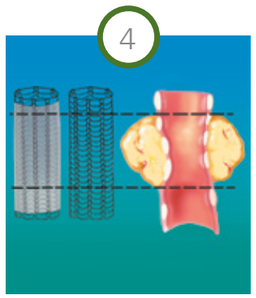
Determination of Stricture Length and Diameter

- 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



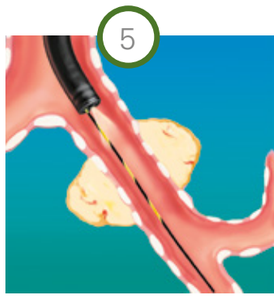
Selection of Stent Size

Length

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

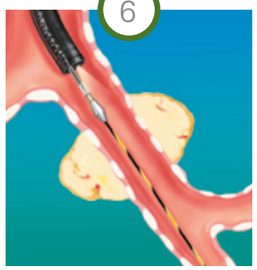
Diameter

- Should be equal to normal proximal lumen

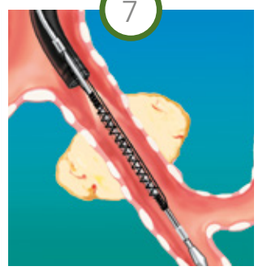


Guidewire Insertion

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

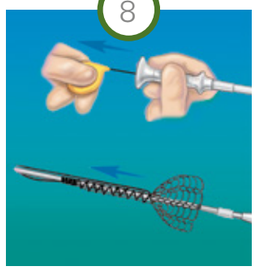


Delivery Catheter is Inserted Over Guidewire



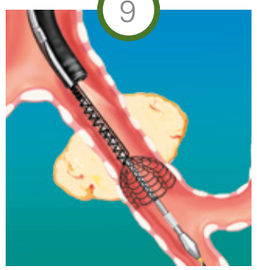
Advancement of Stent to Stricture

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



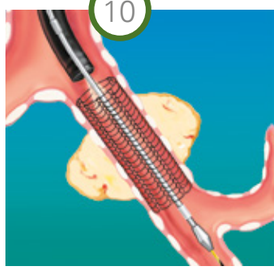
Deployment of Stent

- 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.