

Pulmonary Endoscopy

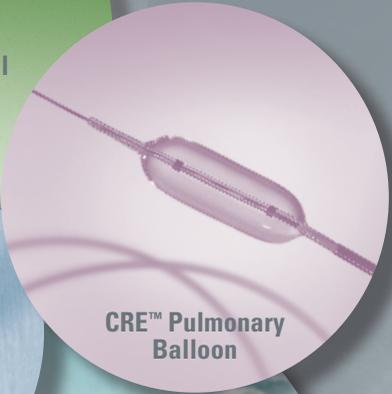
Boston
Scientific



**Alair[®] Bronchial
Thermoplasty
Catheter**



**Radial Jaw[®] 4
Pulmonary Forceps**



**CRE[™] Pulmonary
Balloon**



**Ultraflex[™]
Tracheobronchial
Stent System**



Endoscopy

Diagnostic Devices

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Single-Use Biopsy Forceps

2 Cellebriety®

Single-Use Cytology Brushes

3 eXcelon®

Single-Use Transbronchial
Aspiration Needle

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Bronchial Thermoplasty

Pulmonary Endoscopy

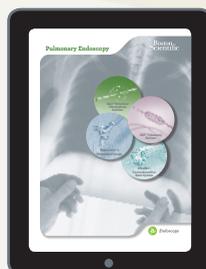
Boston Scientific is committed to **helping advance the diagnosis and treatment of pulmonary diseases** by focusing on the development of less invasive devices and procedures.

In the past, we have demonstrated this dedication by bringing to market the first metal stent technology to help manage airway obstruction. Our stent technologies have since been used to benefit thousands of patients.

In addition to our innovation in airway stent technologies, Boston Scientific offers a range of diagnostic and therapeutic devices including biopsy forceps, transbronchial aspiration needles, cytology brushes, dilation balloons, and retrieval baskets.

We would also like to introduce Bronchial Thermoplasty, a new device-based treatment of severe persistent asthma in patients 18 years and older.

Our mission is to remain the globally recognized leader in the management of pulmonary disease. We are fully dedicated to developing devices and procedures to improve the quality of life for patients.



This brochure is also available for download to your iPad® Device.

Radial Jaw® 4

Single-Use Pulmonary Biopsy Forceps

The Radial Jaw 4 Pulmonary Biopsy Forceps are intended to collect tissue endoscopically for histologic examination.

New Surgical Stainless Steel Jaw with Improved Micromesh teeth

Designed to Provide:

- Tissue specimens for excellent sample handling and preparation
- Clean, precise bite for accurate histological diagnosis

New Streamlined Catheter

Designed to Provide:

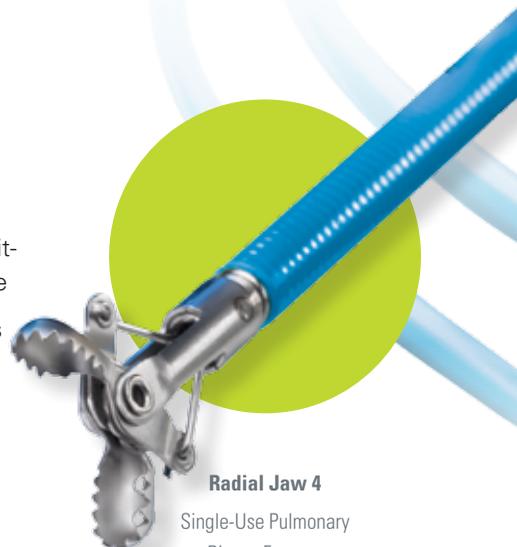
- Enhanced passability through tortuous anatomy
- The right balance of columnar strength and flexibility for excellent pushability and control during scope passage

Single-Use

- Eliminates the risk of transmitting patient-to-patient disease
- Provides first time sharpness

New Distal End Tube

- Improved visibility
- Prevents inadvertent lodging of the cap in the scope working channel



Radial Jaw 4
Single-Use Pulmonary
Biopsy Forceps

Radial Jaw 4 Pulmonary

Single-Use Biopsy Forceps

Radial Jaw 4 Single-Use Pulmonary Biopsy Forceps

Order Number	Product Description	Differentiator	Jaw OD (mm)	Working Length (cm)	Minimum Working Channel (mm)	Units
M00515181	Single Use Biopsy Forceps	Pulmonary Standard Capacity	1.8	100	2.0	Box 5
M00515182	Single Use Biopsy Forceps	Pulmonary Standard Capacity	1.8	100	2.0	Box 20
M00515191	Single Use Biopsy Forceps	Pulmonary Standard Capacity w/ Needle	1.8	100	2.0	Box 5
M00515192	Single Use Biopsy Forceps	Pulmonary Standard Capacity w/ Needle	1.8	100	2.0	Box 20
M00515201	Single Use Biopsy Forceps	Pulmonary Large Capacity	2.2	100	2.8	Box 5
M00515202	Single Use Biopsy Forceps	Pulmonary Large Capacity	2.2	100	2.8	Box 20

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

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Celebrity®

Single-Use Cytology Brush

The Celebrity Cytology Brush is indicated for acquiring tissue samples used for the diagnosis of suspected pathology in the airway tree.

PTFE Sheath

- Designed to help reduce friction, facilitating passage through the scope

Stainless Steel Wire Shaft

- Intended to provide strength to help resist kinking or bending during advancement

Bullet-Shaped Tip

- Designed to help reduce tissue trauma

Ergonomic Handle

- Ergonomic handle with automatic stop
- Facilitates single-hand brush advancement and withdrawal
- Helps reduce the risk of overwithdrawal and subsequent kinking of proximal shaft



Celebrity

Single-Use Cytology Brushes

Celebrity Single-Use Cytology Brushes

Order Number	Product Description	Required Working Channel (mm)	Bristle O.D. (mm)	Sheath Length (cm)	Units
M00516001	Cytology Brushes	2.0	1.0	140	Box 10
M00516011	Cytology Brushes	2.0	1.5	140	Box 10
M00516071	Cytology Brushes	2.0	1.9	100	Box 10
M00516151	Cytology Brushes	2.0	1.9	150	Box 10

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The eXcelon Transbronchial Aspiration Needle is indicated for use in aspiration in carinal, paratracheal, and hilar lesions of the bronchial tree where biopsy forceps cannot obtain a submucosal sample.

Procedural Safety Features

- ▶ Button Lock system is designed to reduce risk of accidental needle deployment during catheter advancement, potentially avoiding costly scope damage
- ▶ Fused hub and needle configuration is designed to help prevent needle detachment
- ▶ Clear catheter designed for visualization if blood is drawn during aspiration

High Performance Design

- ▶ "X-Catheter" is engineered to promote responsiveness and kink resistance for smooth needle penetration
- ▶ Distal coil is designed to promote tip flexibility while maintaining rigidity at the proximal end
- ▶ Needle internal volume is designed to provide increased space for specimen collection

Procedural Convenience Features

- ▶ Syringe locking feature is designed to reduce aspirating effort during the procedure and facilitate "single-handed" actuation
- ▶ Ergonomic handle design
- ▶ No need to disconnect syringe to break vacuum



The needle is locked in the extended position when button lock is depressed, moved completely forward and released next to the symbol shown above.



The needle is locked in the retracted position when button lock is depressed, moved completely back and released next to the symbol shown above.



X-Catheter Design

eXcelon

Single-Use Transbronchial Aspiration Needle

eXcelon Single-Use Transbronchial Aspiration Needle

**Needle packaged with 20cc Syringe.*

Order Number	Product Description*	Needle Gauge	Needle Length (mm)	Catheter Length (cm)	Sheath O.D. (mm)	Units
M00564101	Transbronchial Aspiration Needle	19	15	130	1.8	Box 5
M00564111	Transbronchial Aspiration Needle	20	15	130	1.8	Box 5
M00564121	Transbronchial Aspiration Needle	21	15	130	1.8	Box 5

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

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The CRE Pulmonary Balloon Dilator is intended to be used to endoscopically dilate strictures of the airway tree.

Three-in-One Technology

- Designed for successive, gradual dilation of strictures
- Helps eliminate the need for multiple balloons to employ multi-size dilation therapy

First Balloon Indicated for the Airway

- Indicated for airway stricture management

High Degree of Radial Vector Force

- Promotes low stricture compliance with little or no balloon waisting

0.035" Guidewire Compatible

- Designed for use with 0.035" Jagwire® Pulmonary Guidewires

Rectilinear Shoulder Design

- Engineered to help promote endoscopic visualization
- Designed to provide greater usable balloon surface area during dilation

Radiopaque Markers

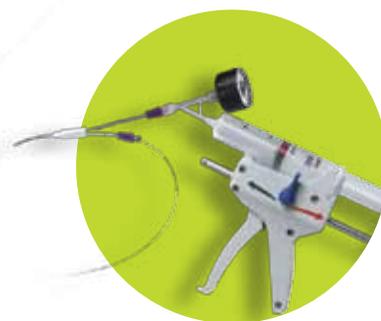
- Designed to facilitate fluoroscopic guidance of balloon positioning within a stricture

Inflation and Deflation

- Compatible with the Alliance™ II Inflation System
- Designed for rapid inflation and deflation when used with the Alliance II Inflation System



CRE Pulmonary Balloon Dilator



Alliance™ II Inflation System

CRE

Single-Use Pulmonary Balloon Dilator

CRE Pulmonary Balloon Dilators

Order Number	Diameter at 3 ATM	Diameter (mm) at Intermediate Pressure	Diameter (mm) at Maximum	Balloon Length (cm)	Catheter Length (cm)	Units
M00550300	12	13.5 @ 4.5 atm	15 @ 8 atm	5.5	75	Each
M00550310	15	16.5 @ 4.5 atm	18 @ 7 atm	5.5	75	Each
M00550320	18	19 @ 4.5 atm	20 @ 6 atm	5.5	75	Each
M00550330	8	9 @ 5.5 atm	10 @ 9 atm	3.0	75	Each
M00550340	10	11 @ 5 atm	12 @ 8 atm	3.0	75	Each
M00550350	12	13.5 @ 4.5 atm	15 @ 8 atm	3.0	75	Each

Alliance II Inflation System

Order Number	Product Description	Units
M00550620	Inflation Handle	Each
M00550601	Single-Use Syringe/Gauge Assembly	Box 5

Jagwire Single-Use Pulmonary Guidewire

Order Number	Product Description	O.D. (in)	Length (cm)	Units
M00515171	Jagwire Single-Use Pulmonary Guidewire	.035	180	Box 2

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

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Zero Tip™

Airway Retrieval Basket

Zero Tip Airway Retrieval Basket is indicated to be used to endoscopically remove foreign bodies in the airway.

Access

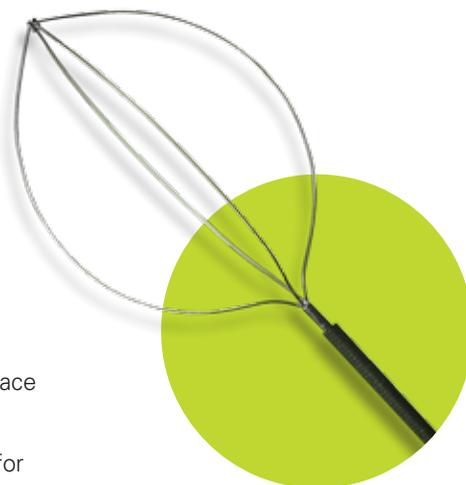
- Designed for access to the upper lobes where rigid bronchoscopy may be insufficient

Low-Profile Tip Design

- Flattened distal surface designed to reduce tissue-to-tip interface for smooth manipulation
- Knotted basket tip designed to help prevent wire movement for more reliable foreign body capture
- Low-profile basket configuration facilitates proximity to foreign body, enhancing retrieval

Advanced Construction

- Nitinol wire construction designed to offer a kink-resistant, flexible wire for scope deflection
- Low-friction sheath designed for smooth scope passage
- Multi-layer sheath is designed to enhance pushability, while maintaining flexibility for enhanced scope deflection



Zero Tip
Airway Retrieval Basket



Nitinol wire
construction for enhanced
scope deflection.



Engineered for foreign
body retrieval, even in the
upper lobes.

Zero Tip

Airway Retrieval Basket

Zero Tip Airway Retrieval Basket

Order Number	Product Description	O.D. (mm)	Sheath Length (cm)	Working Opening (mm)	Basket Sheath Material	Units
M00513200	Zero Tip Airway Retrieval Basket	0.8	120	12	Polyimide / PTFE	Each
M00513210	Zero Tip Airway Retrieval Basket	1.0	120	16	Polyimide / PTFE	Each

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

Single-Use Stent System

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

The Ultraflex Tracheobronchial Stent System is Designed to Address the Following Clinical Needs:

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 while diffusing acute compression forces

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

Polyurethane Covering

- On the covered version, covering helps resist tumor growth



Ultraflex
Tracheobronchial
Covered Stent System



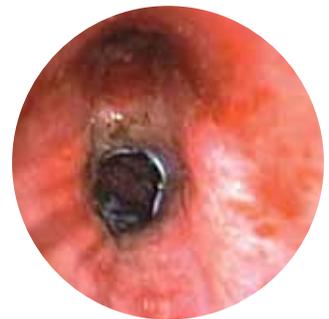
Ultraflex
Tracheobronchial
Uncovered Stent System



PET Scan



LLL Tumor



Post Stent



Ultraflex
Tracheobronchial Stent
Delivery System

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

Ultraflex™ Tracheobronchial

Single-Use Stent System

Ultraflex Tracheobronchial Single-Use Stent System

ORDERING CODES			DIMENSIONS						
Covered Distal Release	Uncovered Distal Release	Uncovered Proximal Release	Expanded Stent OD (mm)	Expanded Stent Length (mm)	Cover Length (If Applicable) (mm)	Compressed Stent OD (Fr)	Tip Max OD (mm)	Units	
-	-	M00564640	8	20	-	15	4.1	Each	
M00564740	-	M00564650	8	40	25	15	4.1	Each	
-	-	M00564660	10	20	-	16	4.1	Each	
M00564750	M00564500	-	10	30	15	16	4.1	Each	
M00564760	-	M00564670	10	40	25	16	4.1	Each	
-	-	M00564680	12	20	-	17	4.1	Each	
M00564770	M00564510	-	12	30	15	17	4.1	Each	
M00564780	-	M00564690	12	40	25	17	4.1	Each	
-	-	M00564700	14	20	-	18	4.1	Each	
M00564790	M00564520	-	14	30	15	18	4.1	Each	
M00564800	-	M00564710	14	40	25	18	4.1	Each	
M00564810	-	M00564720	14	60	45	18	4.1	Each	
M00564820	-	-	14	80	65	18	4.1	Each	
M00564830	M00564530	-	16	40	25	19	5.3	Each	
M00564840	M00564540	-	16	60	45	19	5.3	Each	
M00564850	-	-	16	80	65	19	5.3	Each	
M00564860	M00564560	-	18	40	25	22	5.3	Each	
M00564870	M00564570	-	18	60	45	22	5.3	Each	
M00564880	-	-	18	80	65	22	5.3	Each	
M00564890	M00564590	-	20	40	25	22	5.3	Each	
M00564900	M00564600	-	20	60	45	22	5.3	Each	
M00564910	-	-	20	80	65	22	5.3	Each	

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

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Polyflex®

Self-Expanding Silicone Airway Stent

The Polyflex Self-Expanding Silicone Airway Stent is fully covered and has been designed to reduce in-growth and /or endothelialization of the stent.

Indications

- Compression or strictures due to tumors (trachea and main bronchus)
- Stenosis of the central airway (such as trachea and main bronchus)
- Tracheoesophageal fistula
- Airway complications such as anastomosis and stenosis

Placement Technique

- The Polyflex Airway Stent requires rigid bronchoscopy

Gentle, Radial Force

- Designed to adapt to airway anatomy
- Helps maintain patency

Full-length Silicone Coating

- Helps prevent tumor in-growth
- Designed to seal tracheoesophageal and bronchoesophageal fistulae

Engineered to Elongate when Stretched Lengthwise

- Facilitates stent change or removal

Broad Range of Widths and Lengths

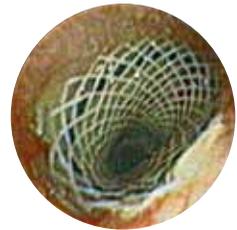
- Facilitates placement in a range of strictures

Radiopaque Delivery System

- Helps facilitate precise positioning and controlled use



Polyflex
Self-Expanding Silicone Airway Stent



Polyflex Airway Stent in benign tracheal stenosis – shows adaptation to irregularities of the tracheal lumen

Note: Polyflex Airway is contraindicated for operable benign tracheal stenosis



Self-expanding stent made of silicone with polyester mesh

Polyester mesh structure on outer stent surface

Designed to help reduce migration

Thin wall diameter

Engineered for airway patency

Radiopaque markers

Help promote visibility during placement and post-operative follow-up

Silicone edge reinforcement

Designed to help reduce tissue granulation formation

Smooth inner surface

Designed to resist secretory incrustation

Polyflex®

Self-Expanding Silicone Airway Stent

Polyflex Self-Expanding Silicone Airway Stent

Order Number	Stent ID (mm)	Stent Length (mm)	Delivery System Diameter (mm)	Units	Order Number	Stent ID (mm)	Stent Length (mm)	Delivery System Diameter (mm)	Units
M00570000	8	20	7	Each	M00570170	16	50	10	Each
M00570010	8	30	7	Each	M00570180	16	60	10	Each
M00570020	10	20	8	Each	M00570190	16	70	10	Each
M00570030	10	30	8	Each	M00570200	18	30	11	Each
M00570040	10	40	8	Each	M00570210	18	40	11	Each
M00570050	10	50	8	Each	M00570220	18	50	11	Each
M00570060	12	20	9	Each	M00570230	18	60	11	Each
M00570070	12	30	9	Each	M00570240	18	70	11	Each
M00570080	12	40	9	Each	M00570250	18	80	11	Each
M00570090	12	50	9	Each	M00570260	20	40	12	Each
M00570100	14	20	9	Each	M00570270	20	50	12	Each
M00570110	14	30	9	Each	M00570280	20	60	12	Each
M00570120	14	40	9	Each	M00570290	20	70	12	Each
M00570130	14	50	9	Each	M00570300	20	80	12	Each
M00570140	14	60	9	Each	M00570310	22	50	13	Each
M00570150	16	30	10	Each	M00570320	22	60	13	Each
M00570160	16	40	10	Each	M00570330	22	80	13	Each

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

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Dynamic™ (Y) Stent

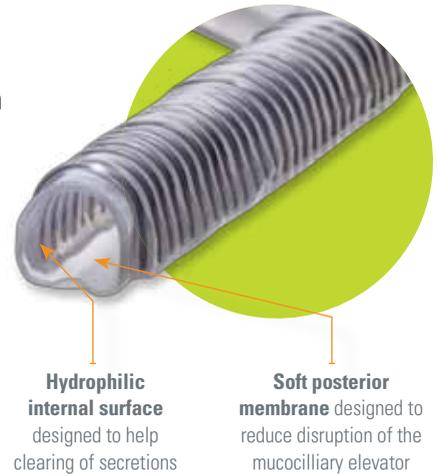
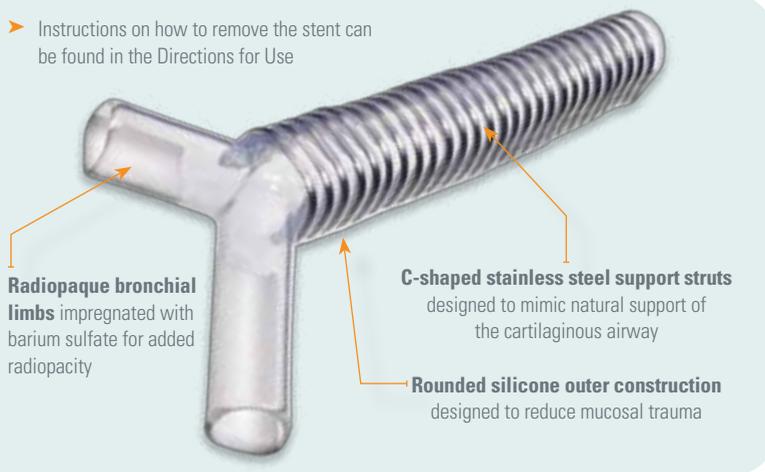
Bifurcated Tracheobronchial Stent

The Dynamic (Y) Stent is a tracheobronchial stent designed specifically for the airway anatomy. The stent, which consists of a single piece construction bifurcated tube, is designed to simultaneously secure the trachea, left mainstem and right mainstem bronchus.

The Dynamic (Y) Stent is intended to maintain patent airways in tracheal stenosis and seal tracheoesophageal fistulas. In addition the stent is applicable to the following conditions, including:

- Tracheomalacia
- Stenosis secondary to lung transplantation

- Instructions on how to remove the stent can be found in the Directions for Use



Post-operative chest radiograph confirming proper stent position

Dynamic (Y)

Bifurcated Tracheobronchial Stent

Dynamic (Y) Bifurcated Tracheobronchial Stent

Order Number	Tracheal Width (l) (mm)	Bronchial Width (l) (mm)	Tracheal Length (mm)	Bronchial Lengths (R / L) (mm)	Units
M00570670	11	8	110	25 / 40	Each
M00570680	13	10	110	25 / 40	Each
M00570690	15	12	110	25 / 40	Each

INDICATIONS: Airway complications such as anastomosis and stenosis following lung transplantation; Tracheo-malacia; Tracheoesophageal fistula

CONTRAINDICATIONS: None in life threatening emergencies; Laryngeal obstruction; Bilateral paralysis of recurrent laryngeal nerve; Patent tracheal stoma; Need for artificial ventilation

WARNING: Do not use on patients with: Operable stenosis; Mature, open tracheostoma; Patients who need artificial respiration because of indications other than stenosis; Compression of airway by vascular anomalies (e.g. aortic aneurysm)

APPLICATION: The stent is designed for use by a physician trained in stent insertion of tracheobronchial stents under laryngoscopic, or rigid bronchoscopy.

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The Alair® System



Bronchial Thermoplasty (BT) is a new procedure indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists.

What is BT?

- BT is a bronchoscopy based procedure that uses radiofrequency (RF) energy (or heat) to reduce the amount of excess airway smooth muscle (ASM) present in the airways and limit its ability to contract and narrow the airway. A complete BT treatment is performed in three outpatient procedure visits, each scheduled approximately three weeks apart.

The Alair System Alair Catheter

A single-use device designed to be delivered through the working channel of a standard bronchoscope.

- Expandable electrode array with four 5mm electrodes that deliver RF energy to airways ≥ 3 mm in diameter and distal to main stem bronchi
- Requires ≥ 2.0 mm working channel diameter bronchoscope



Alair Catheter

RF energy electrode array



Alair RF Controller

Alair

Bronchial Thermoplasty Catheter and Radiofrequency Controller

Alair Bronchial Thermoplasty Catheter

Order Number	Model Number	Description	Units
M005ATS25010	Alair ATS 2-5	Alair Bronchial Thermoplasty Catheter	1 each*

*Note: Initial stocking order requires a minimum order of 6 catheters (covering the complete treatment of 2 patients)

Alair Radiofrequency Controller

Order Number	Model Number	Description	Units
M005ATS20000	Alair ATS 200	Alair Bronchial Thermoplasty Controller	1 each

Brief Statement of Relevant Indications for Use, Contraindications, Warnings, and Adverse Events: The Alair® Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists. The Alair® System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. Previously treated airways of the lung should not be retreated with the Alair® System. Patients should be stable and suitable to undergo bronchoscopy. The most common side effect of BT is an expected transient increase in the frequency and worsening of respiratory-related symptoms.

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

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Boston Scientific

Defining tomorrow, today.™

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ENDO-XXXXX-AA XM September 2012

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