

Advanced Bronchoscopy

**Boston
Scientific**
Advancing science for life™

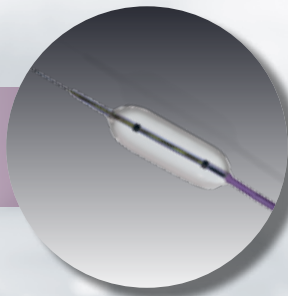


Expect™ Pulmonary
EBUS-TBNA Needle

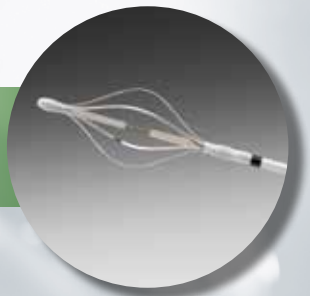


Ultraflex™
Tracheobronchial
Stent System

CRE™ Pulmonary
Balloon Dilatation
Catheter



Alair™ Bronchial
Thermoplasty Catheter



Diagnostic Devices

- 1 **eXcelon™**
Single-Use Transbronchial
Aspiration Needle
- 2 **Expect™ Pulmonary**
Endobronchial Ultrasound
Transbronchial Aspiration Needle
- 4 **Cellebrity™**
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Single-Use Biopsy Forceps

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Tracheobronchial
Stent System

Bronchial Thermoplasty

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Bronchial Thermoplasty

Pulmonary Endoscopy

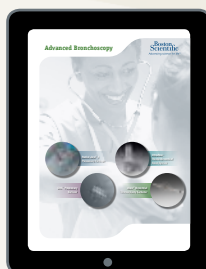
Boston Scientific is committed to **helping advance the diagnosis and treatment of pulmonary diseases** by focusing on the development of less invasive devices and procedures.

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 are also pleased to offer Bronchial Thermoplasty, the only 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.

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

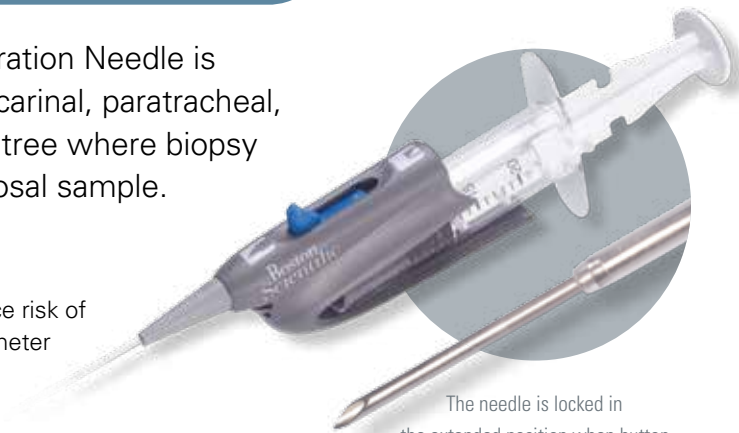
- Button Lock system is designed to reduce risk of accidental needle deployment during catheter advancement, potentially avoiding costly scope damage
- Fused distal coil and needle configuration is designed to help prevent needle detachment
- Clear catheter designed for visualization if blood is drawn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

High Performance Design

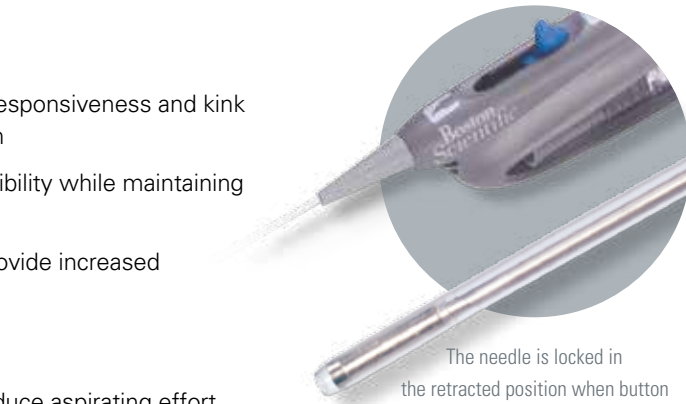
- “X-Catheter” is engineered to promote responsiveness and kink resistance for smooth needle penetration
- Distal coil is designed to promote tip flexibility while maintaining rigidity at the proximal end
- Needle internal volume is designed to provide increased space for specimen collection

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	GTIN	Product Description*	Needle Gauge	Needle Length (mm)	Catheter Length (cm)	Sheath O.D. (mm)	Units
M00564101	08714729456452	Transbronchial Aspiration Needle	19	15	130	1.8	Box 5
M00564111	08714729456469	Transbronchial Aspiration Needle	20	15	130	1.8	Box 5
M00564121	08714729456476	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.
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Expect™ Pulmonary

Endobronchial Ultrasound Transbronchial Aspiration Needle

The Expect Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle is designed to be used with endobronchial ultrasound endoscopes for ultrasound guided fine needle aspiration of the submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract.

Reliability

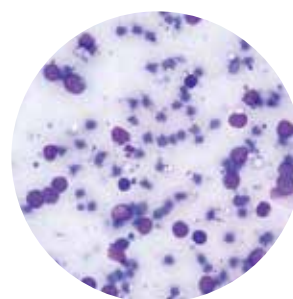
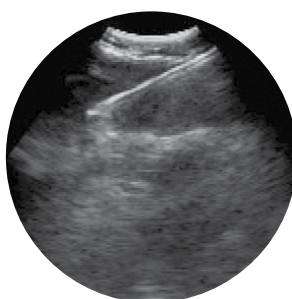
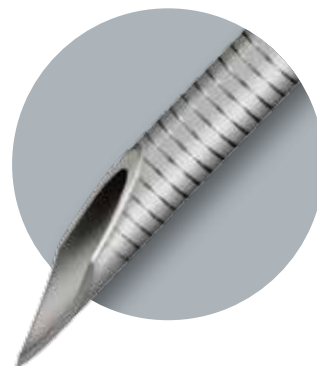
- Sharp needle tip grind is designed for precise penetration into the target area. Testing shows no deterioration in sample quality throughout a procedure.¹

Durability

- Cobalt chromium needle provides benefits over some stainless steel alloys including greater needle hardness and excellent tensile properties to deliver²:
 - Superior needle penetration²
 - Improved pushability and kink resistance²
 - Increased resistance to needle damage or deformation after multiple passes²
 - Thin wall of needle maximizing inner diameter for improved sample collection

Highly Visible Echogenic Pattern

- Extends onto needle tip to help provide precise guidance within the target site
- Helps to maintain needle tip visibility at all times during a procedure



Designed for reliable
tissue sample collection

¹Data on file.

²Catheter and Specialty Needle Alloys, an abstract from Materials & Processes for Medical Devices Conference & Exposition, Minneapolis, MN, August 10-12, 2009.
Ultrasound and pathology images courtesy of Dr. Septimiu Murgu

Features

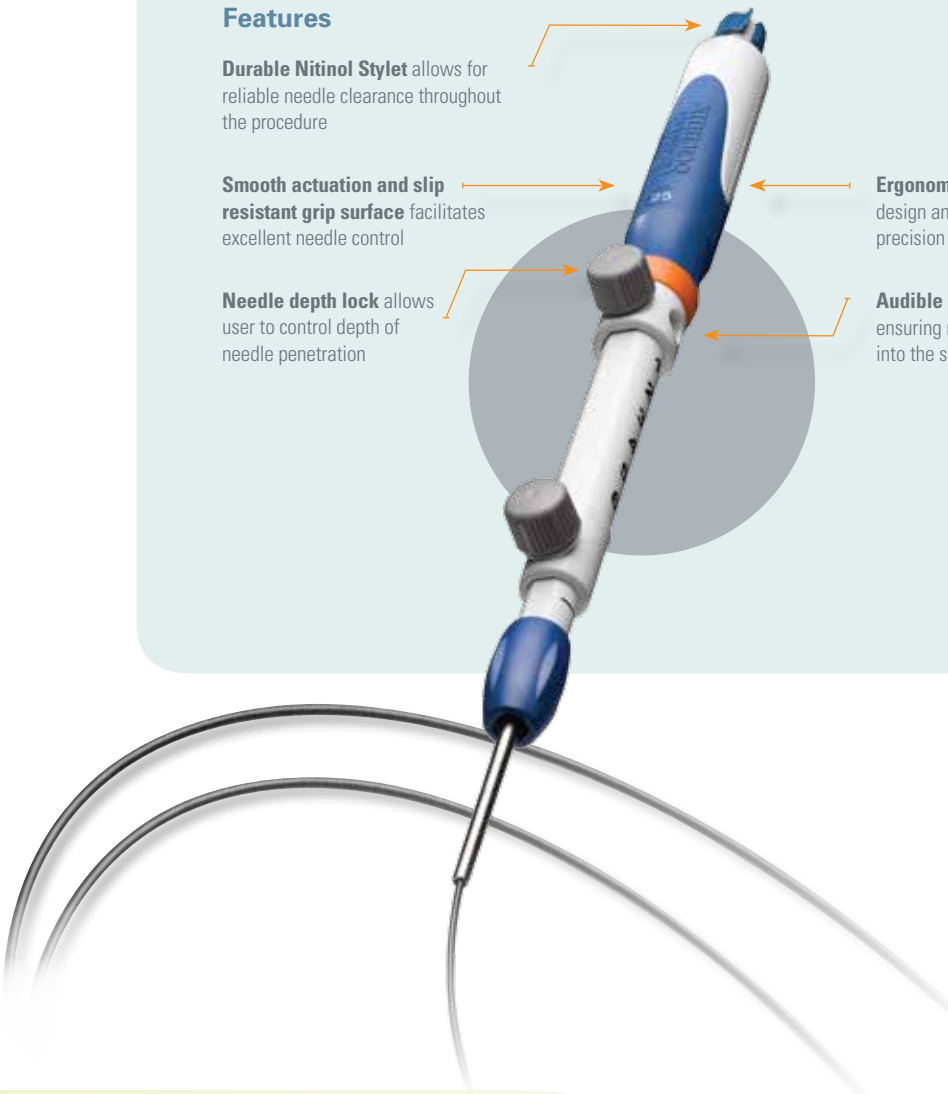
Durable Nitinol Stylet allows for reliable needle clearance throughout the procedure

Smooth actuation and slip resistant grip surface facilitates excellent needle control

Needle depth lock allows user to control depth of needle penetration

Ergonomic rotating handle design and tactile feel to provide precision and control

Audible and tactile feedback ensuring needle is fully retracted into the sheath procedure



Expect™ Pulmonary

Endobronchial Ultrasound Transbronchial Aspiration Needle

Olympus Scope Compatible

Order Number	GTIN	Needle Size	Minimum Working Channel (mm)	Sheath Outer Diameter (mm)	Units
M005 58220	08714729861409	Expect Pulmonary 22Ga – Olympus Scope Compatible	2.0	1.6	Each
M005 58250	08714729861416	Expect Pulmonary 25Ga – Olympus Scope Compatible	2.0	1.4	Each
M005 58731	08714729893189	Expect Pulmonary Needle Adaptor – Olympus Scope Compatible	N/A	N/A	Box 10

Indications, Contraindications, Warnings and Instructions for Use 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.

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

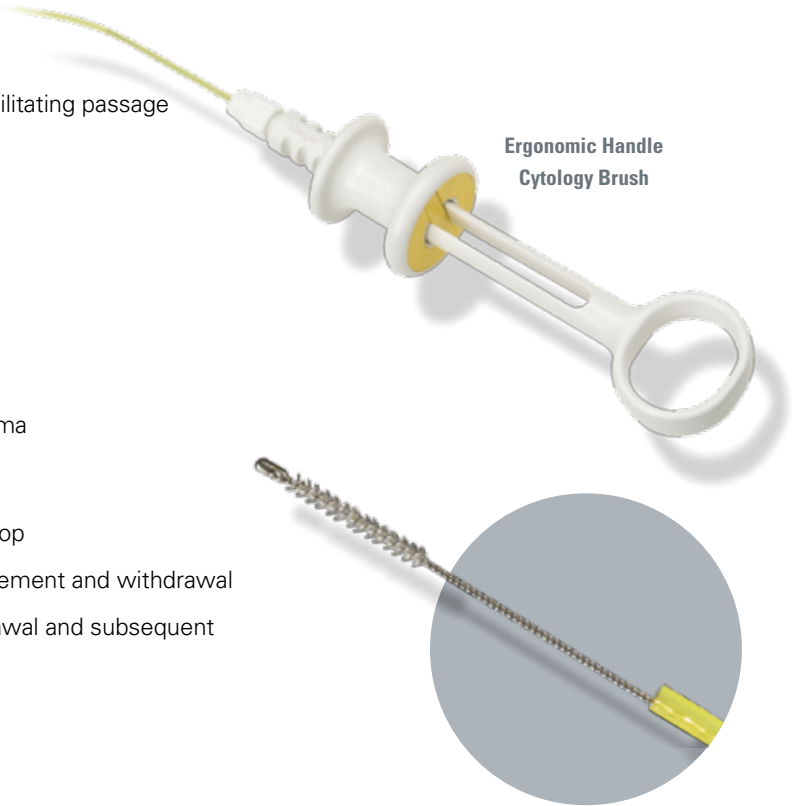
- Intended to provide strength to help resist kinking or bending during advancement

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



Ergonomic Handle
Cytology Brush

Cytology Brush

Celebrity
Single-Use Cytology Brushes

Celebrity Single-Use Cytology Brushes						
Order Number	GTIN	Product Description	Required Working Channel (mm)	Bristle O.D. (mm)	Sheath Length (cm)	Units
M00516001	08714729138983	Cytology Brushes	2.0	1.0	140	Box 10
M00516011	08714729138990	Cytology Brushes	2.0	1.5	140	Box 10
M00516071	08714729139089	Cytology Brushes	2.0	1.9	100	Box 10
M00516151	08714729014003	Cytology Brushes	2.0	1.9	150	Box 10

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.
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Radial Jaw™ 4

Single-Use Pulmonary Biopsy Forceps

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

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

Streamlined Catheter

Designed to Provide:

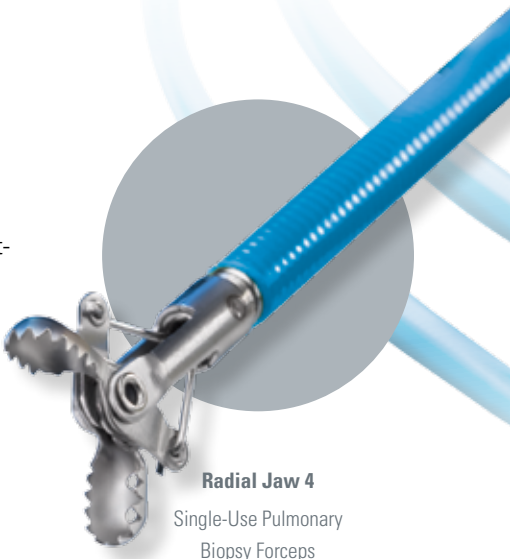
- Enhanced passability through tortuous anatomy
- The right balance of columnar strength and flexibility for excellent pushability and control during scope passage

Single-Use

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

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	GTIN	Product Description	Differentiator	Jaw OD (mm)	Working Length (cm)	Minimum Working Channel (mm)	Units
M00515181	08714729792864	Single Use Biopsy Forceps	Pulmonary Standard Capacity	1.8	100	2.0	Box 5
M00515182	08714729799337	Single Use Biopsy Forceps	Pulmonary Standard Capacity	1.8	100	2.0	Box 20
M00515191	08714729792871	Single Use Biopsy Forceps	Pulmonary Standard Capacity w/ Needle	1.8	100	2.0	Box 5
M00515192	08714729818083	Single Use Biopsy Forceps	Pulmonary Standard Capacity w/ Needle	1.8	100	2.0	Box 20
M00515201	08714729793281	Single Use Biopsy Forceps	Pulmonary Large Capacity	2.2	100	2.8	Box 5
M00515202	08714729818076	Single Use Biopsy Forceps	Pulmonary Large Capacity	2.2	100	2.8	Box 20

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



CRE Pulmonary
Balloon Dilatation Catheter

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" guidewires, such as Jagwire™ Pulmonary Guidewires

Rectilinear Shoulder Design

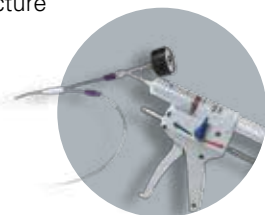
- Engineered to help promote endoscopic visualization
- Designed to provide greater usable balloon surface area during dilation

Radiopaque Markers

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

Inflation and Deflation

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



Alliance™ II
Inflation System

CRE

Single-Use Pulmonary Balloon Dilator

CRE Pulmonary Balloon Dilators

Order Number	GTIN	Diameter at 3 ATM	Diameter (mm) at Intermediate Pressure	Diameter (mm) at Maximum	Balloon Length (cm)	Catheter Length (cm)	Units
M00550300	08714729456186	12	13.5 @ 4.5 atm	15 @ 8 atm	5.5	110	Each
M00550310	08714729456193	15	16.5 @ 4.5 atm	18 @ 7 atm	5.5	110	Each
M00550320	08714729456209	18	19 @ 4.5 atm	20 @ 6 atm	5.5	110	Each
M00550330	08714729456216	8	9 @ 5.5 atm	10 @ 9 atm	3.0	110	Each
M00550340	08714729456223	10	11 @ 5 atm	12 @ 8 atm	3.0	110	Each
M00550350	08714729456230	12	13.5 @ 4.5 atm	15 @ 8 atm	3.0	110	Each

Inflation/Deflation Devices and Accessories

Alliance II Inflation System

Order Number	GTIN	Product Description	Units
M00550620	08714729283881	Inflation Handle	Each
M00550601	08714729129332	Single-Use Syringe/ Gauge Assembly	Box 5

CRE SteriFlate Disposable Inflation Device

Order Number	GTIN	Description	Units
M00550630	00856877002506	CRE SteriFlate Disposable Inflation Device	Each

Jagwire Single-Use Pulmonary Guidewire

Order Number	GTIN	O.D. (in)	Length (cm)	Units
M00515171	08714729455813	.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™

Single-Use Airway Retrieval Basket

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

Access

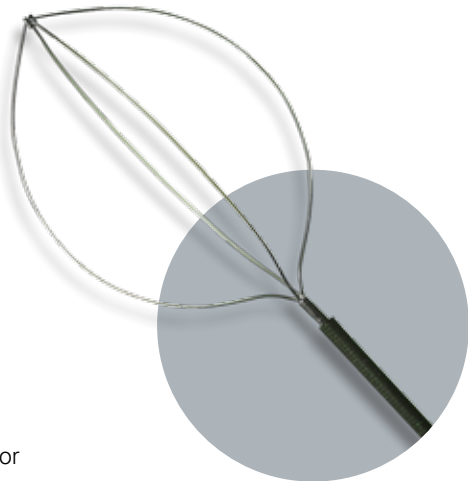
- Designed for access to the upper lobes where rigid bronchoscopy may be insufficient

Low-Profile Tip Design

- Flattened distal surface of the basket 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 wire 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

Single-Use Airway Retrieval Basket

Zero Tip Single-Use Airway Retrieval Basket

Order Number	GTIN	Product Description	O.D. (mm)	Sheath Length (cm)	Working Opening (mm)	Basket Sheath Material	Units
M00513200	08714729414995	Zero Tip Airway Retrieval Basket	0.8	120	12	Polyimide / PTFE	Each
M00513210	08714729415008	Zero Tip Airway Retrieval Basket	1.0	120	16	Polyimide / PTFE	Each

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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.

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

Clear Secretions

Flexible Open Loop Design

- Epithelization of uncovered stent may promote mucociliary clearance

Resist Migration

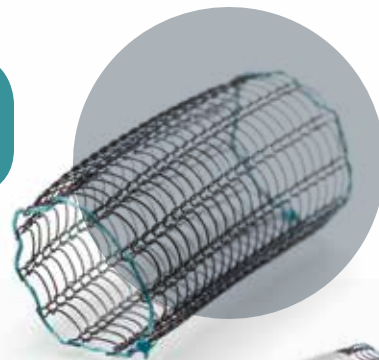
Uncovered Ends

- Epithelization of ends may limit migration

Resist Tumor Ingrowth

Silicone Covering

- Covering helps resist tumor growth



Ultraflex

Tracheobronchial

Uncovered and Covered Stent System

Ultraflex

Single-Use Tracheobronchial Stent System

Ultraflex Tracheobronchial Partially Covered Stent System

Covered Distal Release	Covered Distal Release GTIN	Expanded Stent OD* (mm)	Expanded Stent Length (mm)	Covered Compressed Stent OD (Fr)	Cover Length (mm)	Tip Max OD (mm)	Units
M00576520	08714729842323	8	40	16	25	4.1	Each
M00576530	08714729842330	10	30	18	15	4.1	Each
M00576540	08714729842347	10	40	18	25	4.1	Each
M00576550	08714729842354	12	30	20	15	4.1	Each
M00576560	08714729842361	12	40	20	25	4.1	Each
M00576570	08714729842378	14	30	24	15	4.1	Each
M00576580	08714729842385	14	40	24	25	4.1	Each
M00576590	08714729842392	14	60	24	45	4.1	Each
M00576600	08714729842408	14	80	24	65	4.1	Each
M00576610	08714729842415	16	40	25	25	5.3	Each
M00576620	08714729842422	16	60	25	45	5.3	Each
M00576630	08714729842439	16	80	25	65	5.3	Each
M00576640	08714729842446	18	40	27	25	5.3	Each
M00576650	08714729842453	18	60	27	45	5.3	Each
M00576660	08714729842460	18	80	27	65	5.3	Each
M00576670	08714729842477	20	40	27	25	5.3	Each
M00576680	08714729842484	20	60	27	45	5.3	Each
M00576690	08714729842491	20	80	27	65	5.3	Each

Amplatz Super Stiff™ Guidewire

Order Number	GTIN	Description	OD (in)	Length (mm)	Tip Style	Packaging
M00550090	08714729301929	Amplatz Super Stiff Guidewire	.038	260	Straight	Each



Delivery System

Low Profile

- The compressed stent and delivery system have between a 5-9mm 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



Post Stent*

Ultraflex™

Single-Use Tracheobronchial Stent System

Ultraflex Tracheobronchial Uncovered Stent System

Uncovered Distal Release	Uncovered Distal Release GTIN	Proximal Release	Proximal Release GTIN	Expanded Stent OD** (mm)	Expanded Stent Length (mm)	Uncovered Compressed Stent OD (Fr)	Tip Max OD (mm)	Units
-	-	M00576410	08714729837770	8	20	15	4.1	Each
-	-	M00576420	08714729837787	8	40	15	4.1	Each
-	-	M00576430	08714729837794	10	20	15	4.1	Each
M00576300	08714729837688	-	-	10	30	15	4.1	Each
-	-	M00576440	08714729837800	10	40	15	4.1	Each
-	-	M00576450	08714729837817	12	20	17	4.1	Each
M00576310	08714729837695	-	-	12	30	17	4.1	Each
-	-	M00576460	08714729837824	12	40	17	4.1	Each
-	-	M00576470	08714729837831	14	20	18	4.1	Each
M00576320	08714729837701	-	-	14	30	18	4.1	Each
-	-	M00576480	08714729837848	14	40	18	4.1	Each
-	-	M00576490	08714729837855	14	60	18	4.1	Each
M00576330	08714729837718	-	-	16	40	20	5.3	Each
M00576340	08714729837725	-	-	16	60	20	5.3	Each
M00576350	08714729837732	-	-	18	40	20	5.3	Each
M00576360	08714729837749	-	-	18	60	20	5.3	Each
M00576370	08714729837756	-	-	20	40	20	5.3	Each
M00576380	08714729837763	-	-	20	60	20	5.3	Each

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.

*Image courtesy of Dr. David R. Riker

**Data on file at Boston Scientific

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The Alair™ System

**Bronchial
Thermoplasty**
DELIVERED BY THE ALAIR® SYSTEM

Bronchial Thermoplasty (BT) is a 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?

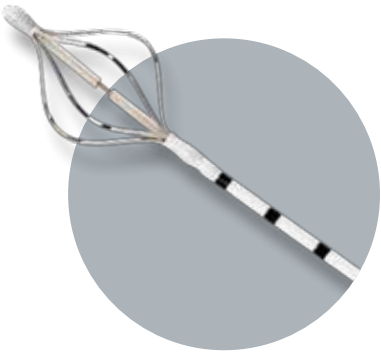
- BT is a bronchoscopy based procedure that uses radiofrequency (RF) energy (or heat) to reduce the amount of excess airway smooth muscle (ASM) present in the airways and limit its ability to contract and narrow the airway. A complete BT treatment is performed in three outpatient procedure visits, each 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 $\geq 3\text{mm}$ in diameter and distal to main stem bronchi
- Requires $\geq 2.0\text{mm}$ 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	GTIN	Model Number	Description	Units
M005ATS25010	08714729802792	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	GTIN	Model Number	Description	Units
M005ATS20000	08714729796695	Alair ATS 200	Alair Radiofrequency 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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www.BronchSuite.com

Ordering Information
1.888.272.1001

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