Advanced Bronchoscopy

Expect™ Pulmonary EBUS-TBNA Needle

Ultraflex™ Tracheobronchial Stent System

CRE™ Pulmonary Balloon Dilatation Catheter

Alair™ Bronchial Thermoplasty Catheter
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.

<table>
<thead>
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<th>Diagnostic Devices</th>
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<td>1 eXcelon™</td>
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<td>6 CRE™</td>
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</tr>
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<td>7 Zero Tip™</td>
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<td>Single-Use Airway Retrieval Basket</td>
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<table>
<thead>
<tr>
<th>Tracheobronchial Stents</th>
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<tr>
<td>8 Ultraflex™</td>
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<tr>
<td>Single-Use Tracheobronchial Stent System</td>
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<table>
<thead>
<tr>
<th>Bronchial Thermoplasty</th>
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<tbody>
<tr>
<td>10 The Alair™ System</td>
</tr>
<tr>
<td>Bronchial Thermoplasty</td>
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</table>
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

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**eXcelon**
Single-Use Transbronchial Aspiration Needle

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**eXcelon Single-Use Transbronchial Aspiration Needle**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>Product Description*</th>
<th>Needle Gauge</th>
<th>Needle Length (mm)</th>
<th>Catheter Length (cm)</th>
<th>Sheath O.D. (mm)</th>
<th>Units</th>
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</table>

*Needle packaged with 20cc Syringe.

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

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

<table>
<thead>
<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>Needle Size</th>
<th>Minimum Working Channel (mm)</th>
<th>Sheath Outer Diameter (mm)</th>
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<td>1.4</td>
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<td>08714729893189</td>
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</table>

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.
Cellebrity™ Single-Use Cytology Brush

The Cellebrity 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

<table>
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<tr>
<th>Cellebrity Single-Use Cytology Brushes</th>
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<tbody>
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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 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

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**Radial Jaw 4 Pulmonary Biopsy Forceps**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>Product Description</th>
<th>Jaw OD (mm)</th>
<th>Working Length (cm)</th>
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<td>Single Use Biopsy Forceps - Pulmonary Standard Capacity</td>
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<td>08714729792871</td>
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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 CRE Pulmonary Balloon Dilatation Catheter 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” 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

### CRE Pulmonary Balloon Dilators

<table>
<thead>
<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>Diameter (mm) at 3 ATM</th>
<th>Diameter (mm) at Intermediate Pressure</th>
<th>Diameter (mm) at Maximum</th>
<th>Balloon Length (cm)</th>
<th>Catheter Length (cm)</th>
<th>Units</th>
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<tbody>
<tr>
<td>M0055030</td>
<td>08714729456186</td>
<td>12</td>
<td>13.5 @ 4.5 atm</td>
<td>15 @ 8 atm</td>
<td>5.5</td>
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<td>Each</td>
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<tr>
<td>M0055031</td>
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<td>18 @ 7 atm</td>
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<td>Each</td>
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<tr>
<td>M0055032</td>
<td>08714729456209</td>
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<td>19 @ 4.5 atm</td>
<td>20 @ 6 atm</td>
<td>5.5</td>
<td>110</td>
<td>Each</td>
</tr>
<tr>
<td>M0055033</td>
<td>08714729456216</td>
<td>8</td>
<td>9 @ 5.5 atm</td>
<td>10 @ 9 atm</td>
<td>3.0</td>
<td>110</td>
<td>Each</td>
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<tr>
<td>M0055034</td>
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<td>15 @ 8 atm</td>
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<td>110</td>
<td>Each</td>
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**Inflation/Deflation Devices and Accessories**

**Alliance II Inflation System**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>Description</th>
<th>Units</th>
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<tr>
<td>M0055062</td>
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<td>Inflation Handle</td>
<td>Each</td>
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<tr>
<td>M0055066</td>
<td>08714729283332</td>
<td>Single-Use Syringe/Gauge Assembly</td>
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**CRE SteriFlate Disposable Inflation Device**

<table>
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<th>Order Number</th>
<th>GTIN</th>
<th>Description</th>
<th>Units</th>
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<tr>
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<td>CRE SteriFlate Disposable Inflation Device</td>
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**Jagwire Single-Use Pulmonary Guidewire**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>O.D. (in)</th>
<th>Length (cm)</th>
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<td>.035</td>
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</table>
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**
- Nitincl 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

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Zero Tip™
Single-Use Airway Retrieval Basket

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

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### Zero Tip Single-Use Airway Retrieval Basket

<table>
<thead>
<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>Product Description</th>
<th>O.D. (mm)</th>
<th>Sheath Length (cm)</th>
<th>Working Opening (mm)</th>
<th>Basket Sheath Material</th>
<th>Units</th>
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Therapeutic Devices
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 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 Partially Covered Stent System

<table>
<thead>
<tr>
<th>Covered Distal Release GTIN</th>
<th>Covered Distal Release (Fr)</th>
<th>Expanded Stent OD* (mm)</th>
<th>Expanded Stent Length (mm)</th>
<th>Covered Compressed Stent OD (Fr)</th>
<th>Cover Length (mm)</th>
<th>Tip Max OD (mm)</th>
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### Amplatz Super Stiff Guidewire

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<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>Description</th>
<th>OD (mm)</th>
<th>Length (mm)</th>
<th>Tip Style</th>
<th>Packaging</th>
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<tbody>
<tr>
<td>M00550090</td>
<td>087147293013929</td>
<td>Amplatz Super Stiff Guidewire</td>
<td>.038</td>
<td>260</td>
<td>Straight</td>
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</tbody>
</table>
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

Uncovered Distal Release
Proximal Release GTIN
8
20
15
4.1 Each
M00576410 08714729837770
M00576420 08714729837787
M00576430 08714729837794
M00576440 08714729837800
M00576450 08714729837817
M00576460 08714729837824
M00576470 08714729837831
M00576480 08714729837848
M00576490 08714729837855
M00576330 08714729837778
M00576340 08714729837772
M00576350 08714729837732
M00576360 08714729837749
M00576370 08714729837756
M00576380 08714729837763

Uncovered Compressed Stent OD (Fr)
14
18
20
20
20
20
20
20
14
16
16
16
18
18
20
20

Tip Max OD (mm) Units
4.1
4.1
4.1
4.1
4.1
4.1
4.1
4.1
Each
Each
Each
Each
Each
Each
Each
Each
Each
Each
Each
Each
Each
Each
Each
Each

Ultraflex™
Single-Use Tracheobronchial Stent System

Ultraflex Tracheobronchial Uncovered Stent System

Uncovered Distal Release GTIN
- - M00576410 08714729837770
- - M00576420 08714729837787
- - M00576430 08714729837794
08714729837688
- - M00576440 08714729837800
- - M00576450 08714729837817
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- - M00576460 08714729837824
- - M00576470 08714729837831
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- - M00576480 08714729837848
- - M00576490 08714729837855
08714729837718
- - M00576330 08714729837778
08714729837725
- - M00576340 08714729837732
- - M00576350 08714729837749
08714729837756
- - M00576360 08714729837763
- - M00576370 08714729837770
- - M00576380 08714729837776

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

Ultraflex Tracheobronchial Stent Delivery System

Post Stent

Ultraflex Tracheobronchial Uncovered Stent System

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
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.
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 ≥ 3mm in diameter and distal to main stem bronchi

➤ Requires ≥ 2.0mm working channel diameter bronchoscope

**Alair RF Controller**
RF energy electrode array

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**Alair Bronchial Thermoplasty Catheter and Radiofrequency Controller**

<table>
<thead>
<tr>
<th>Alair Bronchial Thermoplasty Catheter</th>
<th>Alair RF Controller</th>
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<tbody>
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<td>08714729796895</td>
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*Note: Initial stocking order requires a minimum order of 6 catheters (covering the complete treatment of 2 patients)