Advanced Bronchoscopy

- Alair™ Bronchial Thermoplasty Catheter
- Expect™ Pulmonary EBUS-TBNA Needle
- CRE™ Pulmonary Balloon Dilatation Catheter
- Ultraflex™ Tracheobronchial Stent System
- Ultraflex™ Tracheobronchial Stent System
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

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.

<table>
<thead>
<tr>
<th>eXcelon Single-Use Transbronchial Aspiration Needle</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Order Number</td>
<td>Product Description*</td>
</tr>
<tr>
<td>M00564101</td>
<td>Transbronchial Aspiration Needle 19 15 130 1.8 Box 5</td>
</tr>
<tr>
<td>M00564111</td>
<td>Transbronchial Aspiration Needle 20 15 130 1.8 Box 5</td>
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<tr>
<td>M00564121</td>
<td>Transbronchial Aspiration Needle 21 15 130 1.8 Box 5</td>
</tr>
</tbody>
</table>

*Needle packaged with 20cc Syringe.

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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

<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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<tbody>
<tr>
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<td>M00558731</td>
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<td>Expect Pulmonary Needle Adaptor – Olympus Scope Compatible</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.*
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

Cellebrity Single-Use Cytology Brushes

<table>
<thead>
<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>Product Description</th>
<th>Required Working Channel (mm)</th>
<th>Bristle O.D. (mm)</th>
<th>Sheath Length (cm)</th>
<th>Units</th>
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<tr>
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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

### 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>
<th>Minimum Working Channel (mm)</th>
<th>Units</th>
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<tr>
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<tr>
<td>M00515191</td>
<td>06714729792871</td>
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<td>M00515192</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

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 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>M00550300</td>
<td>08714729456186</td>
<td>12</td>
<td>13.5 @ 4.5 atm</td>
<td>15 @ 8 atm</td>
<td>5.5</td>
<td>110</td>
<td>Each</td>
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<tr>
<td>M00550310</td>
<td>08714729456193</td>
<td>15</td>
<td>16.5 @ 4.5 atm</td>
<td>18 @ 7 atm</td>
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<td>110</td>
<td>Each</td>
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<tr>
<td>M00550320</td>
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<td>18</td>
<td>19 @ 4.5 atm</td>
<td>20 @ 6 atm</td>
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<td>110</td>
<td>Each</td>
</tr>
<tr>
<td>M00550330</td>
<td>08714729456216</td>
<td>8</td>
<td>9 @ 5.5 atm</td>
<td>10 @ 9 atm</td>
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<td>110</td>
<td>Each</td>
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<tr>
<td>M00550340</td>
<td>08714729456223</td>
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<td>110</td>
<td>Each</td>
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<tr>
<td>M00550350</td>
<td>08714729456230</td>
<td>12</td>
<td>13.5 @ 4.5 atm</td>
<td>15 @ 8 atm</td>
<td>3.0</td>
<td>110</td>
<td>Each</td>
</tr>
</tbody>
</table>

Inflation/Deflation Devices and Accessories

**Alliance II Inflation System**
- Inflation Handle
- Single-Use Syringe/Gauge Assembly

**CRE SteriFlate Disposable Inflation Device**
- CRE SteriFlate Disposable Inflation Device

**Jagwire Single-Use Pulmonary Guidewire**
- D.O. (in) Length (cm)
- Box 2

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 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

### Therapeutic Devices

**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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<tbody>
<tr>
<td>M00513200</td>
<td>08714729414995</td>
<td>Zero Tip Airway Retrieval Basket</td>
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<td>120</td>
<td>12</td>
<td>Polyimide / PTFE</td>
<td>Each</td>
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<tr>
<td>M00513210</td>
<td>08714729415008</td>
<td>Zero Tip Airway Retrieval Basket</td>
<td>1.0</td>
<td>120</td>
<td>16</td>
<td>Polyimide / PTFE</td>
<td>Each</td>
</tr>
</tbody>
</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.
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

<table>
<thead>
<tr>
<th>Order Number</th>
<th>GTIN</th>
<th>Description</th>
<th>OD (in)</th>
<th>Length (mm)</th>
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<tr>
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<td>08714729842323</td>
<td>Amplatz Super Stiff Guidewire</td>
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<td>260</td>
<td>Straight</td>
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</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.

Ultraflex Tracheobronchial Stent Delivery 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.
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
- Trachoesophageal fistula and airway complications such as anastomosis and stenosis

**Placement Technique**
- The Polyflex Airway Stent requires rigid bronchoscopy

**Radiopaque Delivery System**
- Helps facilitate precise positioning and controlled use

**Gentle, Radial Force**
- Designed to adapt to airway anatomy and helps maintain patency

**Full-length Silicone Coating**
- Helps prevent tumor in-growth
- Designed to seal trachoesophageal and bronchoesophageal fistulae

**Engineered to Elongate when Stretched Lengthwise**
- Facilitates stent change or removal

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.

*Image courtesy of Dr. David R. Riker*
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

INDICATIONS:
Airway complications such as anastomosis and stenosis following lung transplantation; Tracheomalacia; 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.

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

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*Image courtesy of Gaetane Michaud, MS, MD, FCCP

Pulmonary Stents
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

**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.

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

### Alair Bronchial Thermoplasty Catheter and Radiofrequency Controller

#### Alair Bronchial Thermoplasty Catheter

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<thead>
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<th>GTIN</th>
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<td>Alair ATS 2-5</td>
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*Note: Initial stocking order requires a minimum order of 6 catheters (covering the complete treatment of 2 patients)*

#### Alair Radiofrequency Controller

<table>
<thead>
<tr>
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<th>Model Number</th>
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<th>Units</th>
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**Alair**

Bronchial Thermoplasty Catheter and Radiofrequency Controller

12 Bronchial Thermoplasty