Pulmonary Endoscopy

- Ultraflex™ Tracheobronchial Stent System
- Alair™ Bronchial Thermoplasty Catheter
- Radial Jaw 4™ Pulmonary Biopsy Forceps
- CRE™ Pulmonary Balloon Dilatation Catheter
- 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 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 one of the globally recognized leaders in the management of pulmonary disease. We are fully dedicated to developing devices and procedures to improve the quality of life for patients.

Radial Jaw 4™ Pulmonary Biopsy Forceps – Single-Use Device

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 Distal End Tube
➤ Improved visibility
➤ Prevents inadvertent lodging of the cap in the scope working channel

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

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

Diagnostic Devices

1 Radial Jaw 4™ Pulmonary Biopsy Forceps – Single-Use Device
2 Cellebrity™ Cytology Brushes – Single-Use Device
3 eXcelon™ TransBronchial Aspiration Needle – Single-Use Device

Therapeutic Devices

4 CRE™ Pulmonary Balloon Dilatation Catheter – Single-Use Device
5 Zero Tip™ Airway Retrieval Basket

Tracheobronchial Stents

6 Ultraflex™ TracheoBronchial Pulmonary Stent System – Single-Use Device
9 Polyflex™ Airway Stent
11 Dynamic™ (Y) Stent – Bifurcated TracheoBronchial Stent

Bronchial Thermoplasty

12 The Alair™ System – Bronchial Thermoplasty System

Radial Jaw 4™ Pulmonary Biopsy Forceps

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

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### eXcelon™

**TransBronchial Aspiration Needle**

Single-Use 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 hub and needle configuration is designed to help prevent needle detachment
- Clear catheter designed for visualization if blood is drawn during aspiration

---

### Cellebrity™

**Cytology Brush**

Single-Use Device

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

**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

---

### Cellebrity™

**Endoscopic Cytology Brushes – Bronchoscope**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Required Working Channel (mm)</th>
<th>Bristle O.D. (mm)</th>
<th>Sheath Length (mm)</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>M00516001</td>
<td>Cellebrity Cytology Brush</td>
<td>2.0</td>
<td>1.0</td>
<td>140</td>
<td>box 10</td>
</tr>
<tr>
<td>M00516011</td>
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<td>1.5</td>
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<tr>
<td>M00516001</td>
<td>Cellebrity Cytology Brush</td>
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<tr>
<td>M00516015</td>
<td>Cellebrity Cytology Brush</td>
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<td>1.9</td>
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<td>box 10</td>
</tr>
</tbody>
</table>

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### eXcelon™

**TransBronchial Aspiration Needle with Syringe**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Needle Gauge</th>
<th>Needle O.D. (mm)</th>
<th>Needle L.D. (mm)</th>
<th>Syringe Length (mm)</th>
<th>Syringe O.D. (mm)</th>
<th>Units</th>
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<tbody>
<tr>
<td>M00564101</td>
<td>eXcelon Transbronchial Aspiration Needle w/Syringe</td>
<td>19</td>
<td>1.07</td>
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<td>15</td>
<td>130</td>
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<tr>
<td>M00564121</td>
<td>eXcelon Transbronchial Aspiration Needle w/Syringe</td>
<td>21</td>
<td>0.81</td>
<td>0.52</td>
<td>15</td>
<td>130</td>
<td>1.8</td>
</tr>
</tbody>
</table>
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 waistning

**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

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ZeroTip™ 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

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### CRE™ Pulmonary Balloon Dilatation Catheter – Single-Use Device

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Balloon Length (cm)</th>
<th>Initial Balloon O.D. (mm)</th>
<th>Intermediate Balloon O.D. (mm)</th>
<th>Maximum Balloon O.D. (mm)</th>
<th>Working Catheter Length (cm)</th>
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</thead>
<tbody>
<tr>
<td>M0050300</td>
<td>CRE Balloon</td>
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<td>13.5</td>
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<td>CRE Balloon</td>
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<tr>
<td>M0050340</td>
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<td>11.0</td>
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<tr>
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<td>12</td>
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<td>75</td>
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</table>

### Alliance™ II Inflation System

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Units</th>
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<tbody>
<tr>
<td>M0050620</td>
<td>Alliance™ II Inflation Handle</td>
<td>box 1</td>
</tr>
<tr>
<td>M0050601</td>
<td>60ml Syringe/Luer Assembly</td>
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</table>

### Jagwire™ Pulmonary Guidewire

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>O.D. (mm)</th>
<th>Length (cm)</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>M00515171</td>
<td>Jagwire</td>
<td>0.035</td>
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</tbody>
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### ZeroTip™ Airway Retrieval Baskets

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Sheath O.D. (mm)</th>
<th>Working Length (cm)</th>
<th>Basket Opening (mm)</th>
<th>Sheath Material</th>
<th>Units</th>
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<tbody>
<tr>
<td>M0051320</td>
<td>ZeroTip Airway Retrieval Basket</td>
<td>0.8</td>
<td>120</td>
<td>12</td>
<td>Polyimide / PTFE</td>
<td>Each</td>
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<td>M0051321</td>
<td>ZeroTip Airway Retrieval Basket</td>
<td>1.0</td>
<td>120</td>
<td>16</td>
<td>Polyimide / PTFE</td>
<td>Each</td>
</tr>
</tbody>
</table>
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™ Covered TracheoBronchial NG Stents**

**– Distal Release**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Maximum Stent O.D. (mm)</th>
<th>Expanded Stent Length (mm)</th>
<th>Covered Stent Length (mm)</th>
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</thead>
<tbody>
<tr>
<td>M00564810</td>
<td>Ultraflex Tracheal NG Stent</td>
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<td>80</td>
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<tr>
<td>M00564812</td>
<td>Ultraflex Tracheal NG Stent</td>
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<td>M00564814</td>
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<td>M00564817</td>
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<td>60</td>
<td>45</td>
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<tr>
<td>M00564818</td>
<td>Ultraflex Tracheal NG Stent</td>
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<td>80</td>
<td>65</td>
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<tr>
<td>M00564820</td>
<td>Ultraflex Tracheal NG Stent</td>
<td>20</td>
<td>40</td>
<td>25</td>
</tr>
<tr>
<td>M00564821</td>
<td>Ultraflex Tracheal NG Stent</td>
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<tr>
<td>M00564822</td>
<td>Ultraflex Tracheal NG Stent</td>
<td>20</td>
<td>80</td>
<td>65</td>
</tr>
</tbody>
</table>

**Ultraflex™ TracheoBronchial Stent 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

**Pulmonary Stents**

---

PET Scan
LLL Tumor
Post Stent

Packaged one per box
Ultraflex™ TracheoBronchial
Pulmonary Stent System
Single-Use Device

Ultraflex™ Non-covered TracheoBronchial NG Stents
– Proximal Release

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Maximum Stent O.D. (mm)</th>
<th>Expanded Stent Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M00564710</td>
<td>Ultraflex Tracheal NG Stent</td>
<td>14</td>
<td>40</td>
</tr>
<tr>
<td>M00564720</td>
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<td>14</td>
<td>60</td>
</tr>
</tbody>
</table>

Ultraflex™ Non-covered TracheoBronchial NG Stents
– Distal Release

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Maximum Stent O.D. (mm)</th>
<th>Expanded Stent Length (mm)</th>
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</thead>
<tbody>
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<td>M00564540</td>
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<tr>
<td>M00564560</td>
<td>Ultraflex Tracheal NG Stent</td>
<td>18</td>
<td>40</td>
</tr>
<tr>
<td>M00564570</td>
<td>Ultraflex Tracheal NG Stent</td>
<td>18</td>
<td>60</td>
</tr>
<tr>
<td>M00564590</td>
<td>Ultraflex Tracheal NG Stent</td>
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<td>40</td>
</tr>
<tr>
<td>M00564600</td>
<td>Ultraflex Tracheal NG Stent</td>
<td>20</td>
<td>60</td>
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Bronchial Stents

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Maximum Stent O.D. (mm)</th>
<th>Expanded Stent Length (mm)</th>
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<tbody>
<tr>
<td>M00564640</td>
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<td>20</td>
</tr>
<tr>
<td>M00564650</td>
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<tr>
<td>M00564700</td>
<td>Ultraflex Bronchial NG Stent</td>
<td>14</td>
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</tr>
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</table>

Polyflex™
Airway Stent
Self-Expanding Silicone Device

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

Note: Polyflex Airway is contraindicated for operable benign tracheal stenosis
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.
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.

**Alair™**
Bronchial Thermoplasty 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

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Model</th>
<th>Description</th>
<th>Active Electrode Length (mm)</th>
<th>Tip Diameter (mm)</th>
<th>Minimum Working Channel (mm)</th>
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<tbody>
<tr>
<td>M005ATS50620</td>
<td>ATS 2-5</td>
<td>Alair BT Catheter – Global</td>
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<td>~1.5</td>
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<td>Alair BT Catheter – North America</td>
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<tr>
<td>M005ATS50000</td>
<td>ATS 200</td>
<td>Alair RF Controller – monopolar (return electrode not included)</td>
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</tbody>
</table>

Packaged one per box