

Diagnostic Devices

3 Radial Jaw 4™

Pulmonary Biopsy Forceps Single-Use Device

4 Cellebrity[™]

Cytology Brush Single-Use Device

5 eXcelon™

Transbronchial Aspiration Needle Single-Use Device

6 Expect™ Pulmonary

Endobronchial Ultrasound
Transbronchial Aspiration Needle

Therapeutic Devices

8 CRE™

Pulmonary Balloon Dilatation Catheter Single-Use Device

9 ZeroTip™

Airway Retrieval Basket

Pulmonary Stents

10 Ultraflex™

Tracheobronchial Stent System Single-Use Device

13 Polyflex™

Self-Expanding Silicone Airway Stent

15 Dynamic[™] (Y)

Bifurcated Tracheobronchial Stent

Bronchial Thermoplasty

16 The Alair™ System

Bronchial Thermoplasty 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, dilatation 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.



This brochure
is also available
for download. Please
contact your local
sales representative.

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 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[™]

Pulmonary Biopsy Forceps - Single-Use Device

Order		Jaw	Working	Minimum Working	
Number	Description	O.D. (mm)	Length (cm)	Channel (mm)	Units
M005 1518 1	Radial Jaw 4 Standard Capacity	1.8	100	2.0	Box 5
M005 1518 2	Radial Jaw 4 Standard Capacity	1.8	100	2.0	Box 20
M005 1519 1	Radial Jaw 4 Standard Capacity w/Needle	1.8	100	2.0	Box 5
M005 1519 2	Radial Jaw 4 Standard Capacity w/Needle	1.8	100	2.0	Box 20
M005 1520 1	Radial Jaw 4 Large Capacity	2.2	100	2.8	Box 5
M005 1520 2	Radial Jaw 4 Large Capacity	2.2	100	2.8	Box 20

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





Cytology Brush

Cellebrity[™]

Cytology Brush - Single-Use Device

Order		Required Working	Bristle	Sheath Length	
Number	Description	Channel (mm)	O.D. (mm)	(cm)	Units
M005 1600 1	Cellebrity Cytology Brush	2.0	1.0	140	Box 10
M005 1601 1	Cellebrity Cytology Brush	2.0	1.5	140	Box 10
M005 1607 1	Cellebrity Cytology Brush	2.0	1.9	100	Box 10
M005 1615 1	Cellebrity Cytology Brush	2.0	1.9	150	Box 10

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

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™

Transbronchial Aspiration Needle with Syringe – Single-Use Device

						*Needle p	ackaged with 2	Occ Syringe.
Order Number	Description*	Gauge	···· Needle ·· O.D. (mm)	I.D. (mm)	Needle Length (mm)	Catheter Length (cm)	Sheath. O.D. (mm)	Units
M005 6410 1	eXcelon Transbronchial Aspiration Needle w/Syringe	19	1.07	0.69	15	130	1.8	Box 5
M005 6411 1	eXcelon Transbronchial Aspiration Needle w/Syringe	20	0.90	0.58	15	130	1.8	Box 5
M005 6412 1	eXcelon Transbronchial Aspiration Needle w/Syringe	21	0.81	0.50	15	130	1.8	Box 5

Expect[™] **Pulmonary**

Endobronchial Ultrasound Transbronchial Aspiration Needle

The Expect Needle is designed to be used with endobronchial ultrasound bronchoscopes for ultrasound guided fine needle aspiration (FNA) of the submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract.

Durability

Cobalt chromium needle provides benefits over some stainless steel alloys including greater needle hardness and excellent tensile properties to deliver*:

- ➤ Superior needle penetration*
- ➤ Improved pushability and kink resistance*
- Increased resistance to needle damage or deformation after multiple passes*
- Thin wall of needle aids in flexibility while maximizing inner diameter for improved sample collection

Pass 1



Pass 18



Expect Pulmonary Endobronchial
Ultrasound Transbronchial
Aspiration Needle

^{*} Catheter and Specialty Needle Alloys, an abstract from Materials & Processes for Medical Devices Conference & Exposition, Minneapolis, MN, August 10-12, 2009.

This study compared a cobalt-chromium alloy with nanoflex and 304 stainless steels.

Bench test results may not necessarily be indicative of clinical performance.

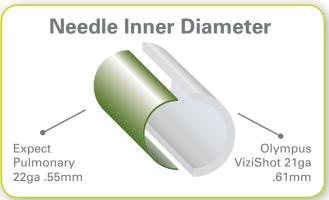
Reliability

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

Thin Wall Design

Inner diameter of the 22ga Expect Needle is only 10% smaller than the Olympus 21ga needle.[†]





For illustrative purposes only

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

Expect[™] **Pulmonary**

Endobronchial Ultrasound Transbronchial Aspiration Needle

Product Code	Gauge	Minimum Working Channel (mm)	Sheath Diameter (mm)	Packaging
M005 5822 0	Expect Pulmonary 22ga – Olympus	2.0	1.6	Each
M005 5822 1	Expect Pulmonary 22ga — Olympus	2.0	1.6	Box 5
M005 5825 0	Expect Pulmonary 25ga — Olympus	2.0	1.4	Each
M005 5825 1	Expect Pulmonary 25ga — Olympus	2.0	1.4	Box 5
M005 5873 1	Expect Pulmonary Needle Adaptor – Olympus	N/A	N/A	Box 10

^{**} Data on file. Bench test results may not necessarily be illustrative of clinical performance. † Endo Bronchial Ultrasound Transbronchial Needle Aspiration (EBUS-TBNA) Competitor Device Testing. #91043238. Milan Vidovic, Molly Phillips - Hungerford. Page 32, 2013-2015.

Pulmonary Balloon Dilatation Catheter Single-Use Device

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



Alliance II Inflation System

CRE[™] Pulmonary Balloon Dilatation Catheter – Single-Use Device

Order		Balloon	Initial Balloon	Intermediate	Maximum	Working Catheter
Number	Description	Length (cm)	0.D. (mm)	Balloon O.D. (mm)	Balloon O.D. (mm)	Length (cm)
M005 5030 0	CRE Balloon	5.5	12	13.5	15	75
M005 5031 0	CRE Balloon	5.5	15	16.5	18	75
M005 5032 0	CRE Balloon	5.5	18	19.0	20	75
M005 5033 0	CRE Balloon	3.0	8	9.0	10	75
M005 5034 0	CRE Balloon	3.0	10	11.0	12	75
M005 5035 0	CRE Balloon	3.0	12	13.5	15	75

Alliance™	II Inflation System	
Order Number	Description	Units
M005 5062 0	Alliance™ II Inflation Handle	Box 1
M005 5060 1	60ml Syringe/Gauge Assembly	Box 5

Jagwire™ Pulmonary Guidewire						
Order Number	Description	O.D. (in) / (mm)	Length (cm)	Units		
M005 1517 1	Jagwire	.035 / 0.89	180	Box 2		

ZeroTip[™]

Airway Retrieval Basket

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

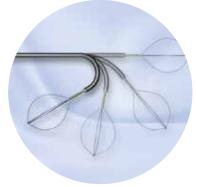
ace

ZeroTip
Airway Retrieval Basket

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



Nitinol wire construction for enhanced scope deflection



Engineered for foreign body retrieval, even in the upper lobes

ZeroTip[™] Airway Retrieval Basket

Order Number	Description	Sheath O.D. (mm)	Working Length (cm)	Basket Opening (mm)	Sheath Material	Units
M005 1320 0	ZeroTip Airway Retrieval Basket	0.8	120	12	Polyimide / PTFE	Each
M005 1321 0	ZeroTip Airway Retrieval Basket	1.0	120	16	Polyimide / PTFE	Each

Ultraflex[™]

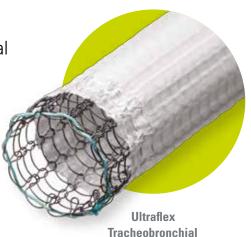
Tracheobronchial Stent System Single-Use Device

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



Covered Stent System

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

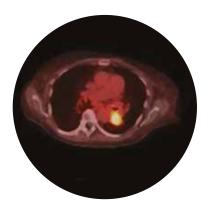
Ultraflex Tracheobronchial

Uncovered Stent System

Resist Tumor Ingrowth

Polyurethane Covering

> On the covered version, covering helps resist tumor growth



PET Scan



LLL Tumor



Post Stent

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 Stent

Delivery System

Ultraflex™ Covered TracheoBronchial NG Stents - Distal Release

Tracheal St	ents			
Order Number	Description	Maximum Stent O.D. (mm)	Expanded Stent Length (mm)	Covered Length (mm)
M005 6482 0	Ultraflex Tracheal NG Stent	14	80	65
M005 6483 0	Ultraflex Tracheal NG Stent	16	40	25
M005 6484 0	Ultraflex Tracheal NG Stent	16	60	45
M005 6485 0	Ultraflex Tracheal NG Stent	16	80	65
M005 6486 0	Ultraflex Tracheal NG Stent	18	40	25
M005 6487 0	Ultraflex Tracheal NG Stent	18	60	45
M005 6488 0	Ultraflex Tracheal NG Stent	18	80	65
M005 6489 0	Ultraflex Tracheal NG Stent	20	40	25
M005 6490 0	Ultraflex Tracheal NG Stent	20	60	45
M005 6491 0	Ultraflex Tracheal NG Stent	20	80	65

Bronchial Stents						
Order Number	Description	Maximum Stent O.D. (mm)	Expanded Stent Length (mm)	Covered Length (mm)		
M005 6474 0	Ultraflex Bronchial NG Stent	8	40	25		
M005 6475 0	Ultraflex Bronchial NG Stent	10	30	15		
M005 6476 0	Ultraflex Bronchial NG Stent	10	40	25		
M005 6477 0	Ultraflex Bronchial NG Stent	12	30	15		
M005 6478 0	Ultraflex Bronchial NG Stent	12	40	25		
M005 6479 0	Ultraflex Bronchial NG Stent	14	30	15		
M005 6480 0	Ultraflex Bronchial NG Stent	14	40	25		
M005 6481 0	Ultraflex Bronchial NG Stent	14	60	45		

Ultraflex[™]

Tracheobronchial Stent System Single-Use Device

Ultraflex[™] Non-covered Tracheobronchial NG Stents - Proximal Release

Tracheal Stents						
Order Number	Description	Maximum Stent O.D. (mm)	Expanded Stent Length (mm)			
M005 6471 0	Ultraflex Tracheal NG Stent	14	40			
M005 6472 0	Ultraflex Tracheal NG Stent	14	60			

Bronchial S	Stents		
Order Number	Description	Maximum Stent O.D. (mm)	Expanded Stent Length (mm)
M005 6464 0	Ultraflex Bronchial NG Stent	8	20
M005 6465 0	Ultraflex Bronchial NG Stent	8	40
M005 6466 0	Ultraflex Bronchial NG Stent	10	20
M005 6467 0	Ultraflex Bronchial NG Stent	10	40
M005 6468 0	Ultraflex Bronchial NG Stent	12	20
M005 6469 0	Ultraflex Bronchial NG Stent	12	40
M005 6470 0	Ultraflex Bronchial NG Stent	14	20

Packaged one per box

Ultraflex™ Non-covered Tracheobronchial NG Stents - Distal Release

Tracheal St	ents		
Order Number	Description	Maximum Stent O.D. (mm)	Expanded Stent Length (mm)
M005 6453 0	Ultraflex Tracheal NG Stent	16	40
M005 6454 0	Ultraflex Tracheal NG Stent	16	60
M005 6456 0	Ultraflex Tracheal NG Stent	18	40
M005 6457 0	Ultraflex Tracheal NG Stent	18	60
M005 6459 0	Ultraflex Tracheal NG Stent	20	40
M005 6460 0	Ultraflex Tracheal NG Stent	20	60

Bronchial Stents					
Order Number	Description	Maximum Stent O.D. (mm)	Expanded Stent Length (mm)		
M005 6450 0	Ultraflex Bronchial NG Stent	10	30		
M005 6451 0	Ultraflex Bronchial NG Stent	12	30		
M005 6452 0	Ultraflex Bronchial NG Stent	14	30		

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



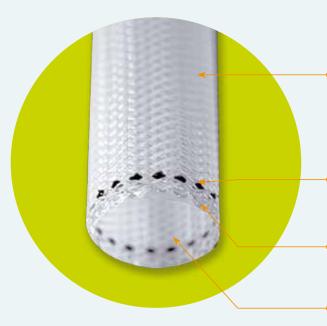


Polyflex Airway Stent in benign tracheal stenosis – shows adaptation to irregularities of the tracheal lumen

Note: Polyflex Airway is contraindicated for operable benign tracheal stenosis

Polyflex™

Self-Expanding Silicone Airway Stent



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 Stents

Order Number	Description	Stent I.D. (mm)	Stent Length (mm)	Delivery System Diameter (mm)
M005 7000 0	Polyflex Airway Stent	8	20	7
M005 7001 0	Polyflex Airway Stent	8	30	7
M005 7002 0	Polyflex Airway Stent	10	20	8
M005 7003 0	Polyflex Airway Stent	10	30	8
M005 7004 0	Polyflex Airway Stent	10	40	8
M005 7005 0	Polyflex Airway Stent	10	50	8
M005 7006 0	Polyflex Airway Stent	12	20	9
M005 7007 0	Polyflex Airway Stent	12	30	9
M005 7008 0	Polyflex Airway Stent	12	40	9
M005 7009 0	Polyflex Airway Stent	12	50	9
M005 7010 0	Polyflex Airway Stent	14	20	9
M005 7011 0	Polyflex Airway Stent	14	30	9
M005 7012 0	Polyflex Airway Stent	14	40	9
M005 7013 0	Polyflex Airway Stent	14	50	9
M005 7014 0	Polyflex Airway Stent	14	60	9
M005 7015 0	Polyflex Airway Stent	16	30	10
M005 7016 0	Polyflex Airway Stent	16	40	10

Order Number	Description	Stent I.D. (mm)	Stent Length (mm)	Delivery System Diameter (mm)
M005 7017 0	Polyflex Airway Stent	16	50	10
M005 7018 0	Polyflex Airway Stent	16	60	10
M005 7019 0	Polyflex Airway Stent	16	70	10
M005 7020 0	Polyflex Airway Stent	18	30	11
M005 7021 0	Polyflex Airway Stent	18	40	11
M005 7022 0	Polyflex Airway Stent	18	50	11
M005 7023 0	Polyflex Airway Stent	18	60	11
M005 7024 0	Polyflex Airway Stent	18	70	11
M005 7025 0	Polyflex Airway Stent	18	80	11
M005 7026 0	Polyflex Airway Stent	20	40	12
M005 7027 0	Polyflex Airway Stent	20	50	12
M005 7028 0	Polyflex Airway Stent	20	60	12
M005 7029 0	Polyflex Airway Stent	20	70	12
M005 7030 0	Polyflex Airway Stent	20	80	12
M005 7031 0	Polyflex Airway Stent	22	50	13
M005 7032 0	Polyflex Airway Stent	22	60	13
M005 7033 0	Polyflex Airway Stent	22	80	13

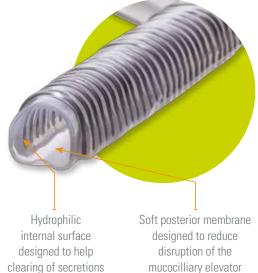
Dynamic[™] (Y)

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







Post-operative chest radiograph confirming proper stent position

Dynamic[™] **(Y)**Bifurcated Tracheobronchial Stent

Order Number	Description	Tracheal Width (Internal) (mm)	Bronchial Width (Internal) (mm)	Tracheal Length (mm)	Bronchial Lengths (Right / Left) (mm)
M005 7067 0	Dynamic (Y) Stent	11	8	110	25 / 40
M005 7068 0	Dynamic (Y) Stent	13	10	110	25 / 40
M005 7069 0	Dynamic (Y) Stent	15	12	110	25 / 40

The Alair[™] System

Bronchial Thermoplasty 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
(18W) or mild heat (65C) 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



Alair RF energy electrode array



Alair Bronchial Thermoplasty Radiofrequency Controller

Indications for use approved in EU are: The Alair™ System is intended for use in the treatment of asthma in patients 18 years and older.

Alair[™] Bronchial Thermoplasty (BT) System

Order Number	Model	Description	Active Electrode Length (mm)	Tip Diameter (mm)	Minimum Working Channel (mm)
M005ATS 2502 0	ATS 2-5	Alair BT Catheter – Global	5.0	~1.5	2.0
M005ATS 2501 0	ATS 2-5	Alair BT Catheter – North America	5.0	~1.5	2.0
M005ATS 2000 0	ATS 200	Alair RF Controller – monopolar (return electrode not included)			

Notes	

Notes	





www.bostonscientific.eu