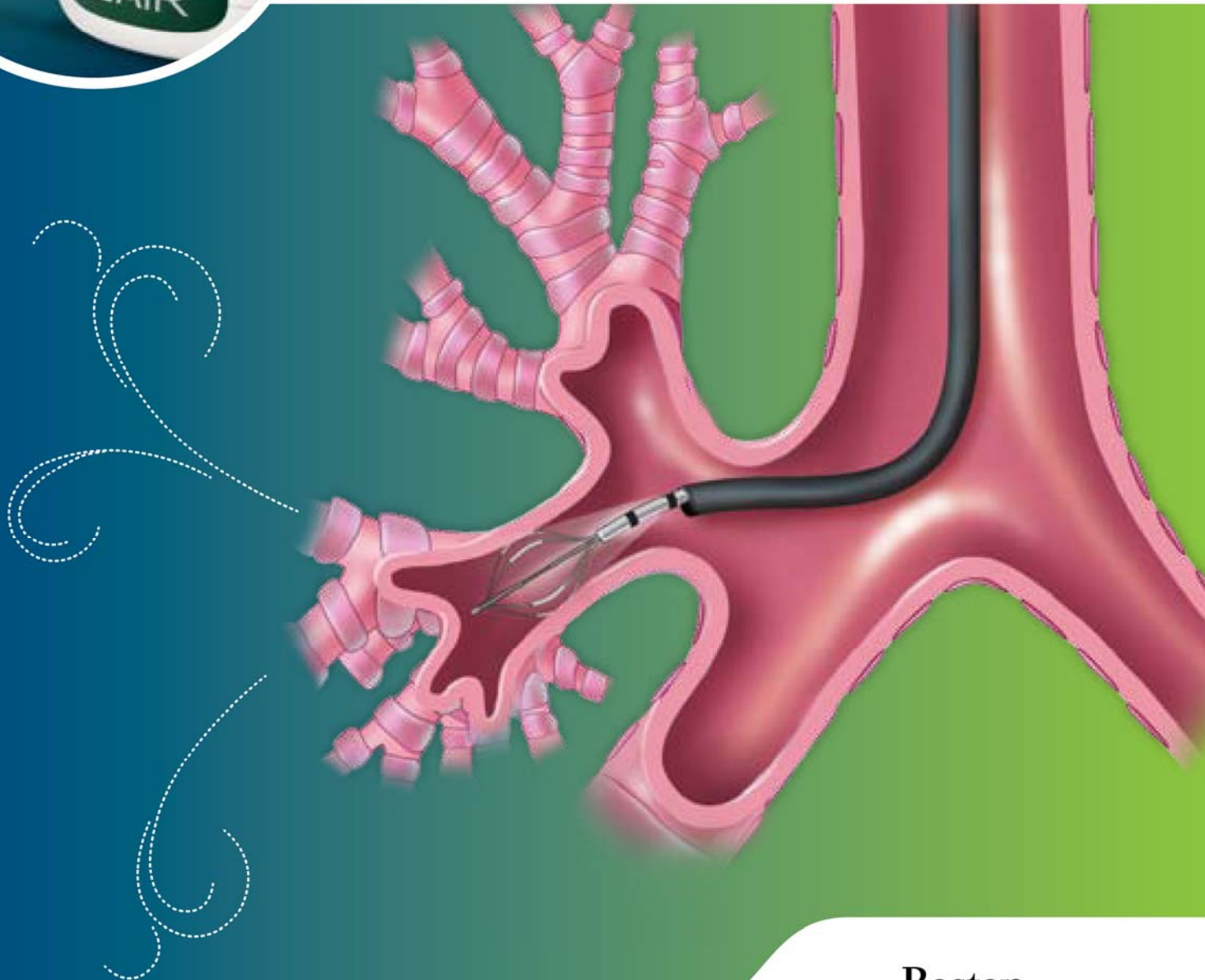




## ***Bronchial Thermoplasty:*** *A New Procedure for Severe Asthma*



## Ordering Information

Alair Catheter ATS 2-5					
Order Number	Model	Description	Active Electrode Length (mm)	Tip Diameter (mm)	Minimum Working Channel (mm)
M005ATS25020	ATS 2-5	Alair BT Catheter – Global	5.0	~1.5	2.0
M005ATS25010	ATS 2-5	Alair BT Catheter – North America	5.0	~1.5	2.0

Alair RF Controller ATS 200		
Order Number	Model	Description
M005ATS20000	ATS 200	Alair RF Controller – monopolar (return electrode not included)

Alair Controller Accessory Kits ATS 201*		
Order Number	Model	Description
M005ATS20130	ATS 201	EU Hybrid Type E/F Plug
M005ATS20110	ATS 201	North American Plug
M005ATS20120	ATS 201	British Type G Plug
M005ATS20140	ATS 201	Australian Type I Plug
M005ATS20150	ATS 201	Danish Type K Plug
M005ATS20160	ATS 201	Brazil IEC 60906-1 Plug
M005ATS20170	ATS 201	Chinese CPCS-CCC (Chinese 10 A/250 V) Plug
M005ATS20180	ATS 201	Swiss Type J Plug
M005ATS20190	ATS 201	Israel Type H Plug

\* All accessory kits include power cord with moulded plug, foot switch; and operating manual

- 1) Castro M, Rubin AS, Lavolette M, et al.; AIR2 Trial Study Group. Effectiveness and safety of Bronchial Thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-blind, shamcontrolled clinical trial. *Am J Respir Crit Care Med*. 2010 Jan 15;181(2):116-24
- 2) Castro M, et al., Two-Year Persistence of Effect of Bronchial Thermoplasty (BT) in Patients With Severe Asthma: AIR2 Trial, *Chest*. 2010; 138:768A
- 3) Pavord I, et al., 5-Year Safety of Bronchial Thermoplasty Demonstrated in Patients with Severe Persistent Refractory Asthma: Research in Severe Asthma (RISA) Trial, *AJRCCM* 183; 2011: A6382
- 4) Thomson et al. Long-term (5 year) safety of Bronchial Thermoplasty: Asthma Intervention Research (AIR) trial. *BMC Pulmonary Medicine* 2011, 11:8
- 5) Rabe KF, Vermeire PA, Soriano JB, Maier WC. Clinical management of asthma in 1999: the Asthma Insights and Reality in Europe (AIRE) study. *Eur Respir J* 2000;16:802-807
- 6) Rabe KF, Adachi M, Lai CK, Soriano JB, Vermeire PA, Weiss KB, et al. Worldwide severity and control of asthma in children and adults: the global asthma insights and reality surveys. *J Allergy Clin Immunol* 2004;114:40-47
- 7) Braman SS. The global burden of asthma. *Chest* 2006; 130: 4S-12S

### European Distribution Centre –

#### The Netherlands

T: +31 45 54 67 700 F: +31 45 54 67 800

#### European Headquarters –

#### Paris

T: +33 1 57 66 80 00 F: +33 1 57 66 84 99

#### Argentina (Freephone)

T: 0800 555 2678 F: +5411 4896 8517

#### Australia/New Zealand

T: +61 2 8063 8100 F: +61 2 9330 1404

#### Austria

T: +43 1 60 810 F: +43 1 60 810 60

#### Belgium (Freephone)

T: 0800 94 494 F: 0800 93 343

#### Brazil

T: +55 11 5502 8500 F: +55 11 5103 2212

#### Canada

T: +1 888 359 9691 F: +1 888 575 73965

#### Chile

T: +562 445 4904 F: +562 445 4915

#### China – Beijing

T: +86 10 8525 1588 F: +86 10 8525 1566

#### China – Guangzhou

T: +86 20 8767 9791 F: +86 20 8767 9789

#### China – Shanghai

T: +86 21 6141 5959 F: +86 21 6141 5900

#### Colombia

T: +57 1 629 5045 F: +57 1 612 4761

#### Czech Republic

T: +420 296 331 901 F: +420 296 331 935

#### Denmark (Freephone)

T: 80 30 80 02 F: 80 30 80 05

#### Eire (Freephone)

T: 1800 882 969 F: 1800 882 968

#### Finland

T: +358 20 762 8882 F: +358 20 762 8883

#### France

T: +33 1 39 30 49 00 F: +33 1 39 30 49 01

#### Germany (Freephone)

T: 08000 723300 F: 08000 723319

#### Greece

T: +30 210 9542 300 F: +30 210 9542 310

#### Hong Kong

T: +852 2360 7100 F: +852 2563 5276

#### Hungary

T: +36 1 456 30 40 F: +36 1 456 30 41

#### India – Bangalore

T: +91 80 2212 4928/9 F: +91 80 2207 5153

#### India – Chennai

T: +91 44 2220 1879 F: +91 44 2220 0716

#### India – Delhi

T: +91 11 4243 2222 F: +91 11 2610 0808

#### India – Mumbai

T: +91 22 4030 9165 F: +91 22 4040 9199

#### Italy

T: +39 010 60 60 1 F: +39 010 60 60 200

#### Korea

T: +82 2 3476 2121 F: +82 2 3476 1776

#### Mexico

T: +52 55 5687 63 90 F: +52 55 5687 62 28

#### Middle East/Gulf/North Africa

T: +961 1 805 410 F: +961 1 805 445

#### The Netherlands

T: +31 30 602 55 44 F: +31 30 602 55 05

#### Norway (Freephone)

T: 800 104 04 F: 800 101 90

#### Poland

T: +48 22 435 14 14 F: +48 22 435 14 10

#### Portugal

T: +351 1 381 25 40 F: +351 21 381 25 58

#### South Africa

T: +27 11 840 8600 F: +27 11 463 6077

#### South East Asia – Malaysia

T: +60 3 2283 3813 F: +60 3 2284 3813

#### South East Asia – Philippines

T: +63 2 687 6994 F: +63 2 687 3047

#### South East Asia – Singapore

T: +65 6418 8888 F: +65 6418 8899

#### South East Asia – Thailand

T: +66 2 6380 100 F: +66 2 6380 400

#### South East Europe

T: +30 210 9542 300 F: +30 210 9542 310

#### Spain

T: +34 901 11 12 15 F: +34 91 319 50 03

#### Sweden

T: +46 42 25 69 00 F: +46 42 25 69 69

#### Switzerland

T: +41 32 626 57 00 F: +41 32 626 57 01

#### Taiwan

T: +886 2 2747 7278 F: +886 2 2747 7270

#### Turkey

T: +90 216 464 36 66 F: +90 216 464 36 67

#### UK (Freephone)

T: +59 82 900 6212 F: 0844 800 4513

#### Uruguay

T: +59 82 900 6212 F: +59 82 900 6212

#### Venezuela

T: +58 212 959 6275 F: +58 212 959 5328

**Boston Scientific**

*Defining tomorrow, today.™*

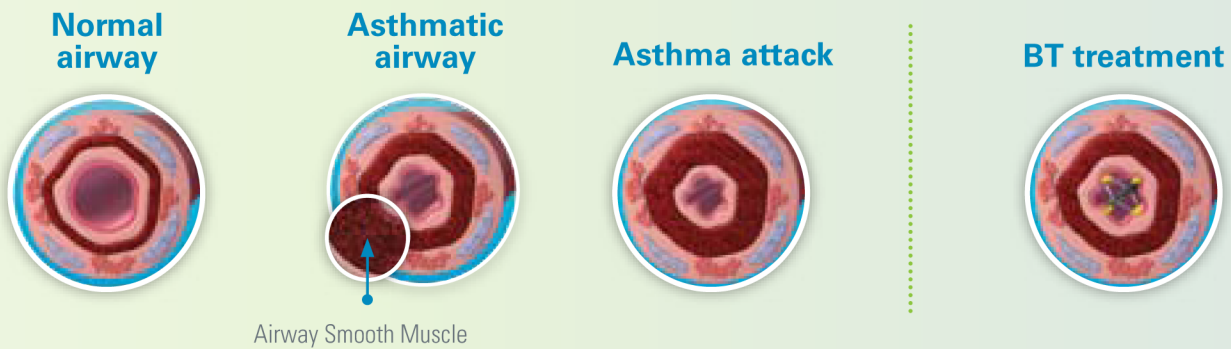
[www.bostonscientific-international.com](http://www.bostonscientific-international.com)

# What is Bronchial Thermoplasty?

*Bronchial Thermoplasty is a new, long lasting, non-drug treatment for adult asthma patients, over the age of 18, whose asthma is not well controlled despite conventional therapy.*

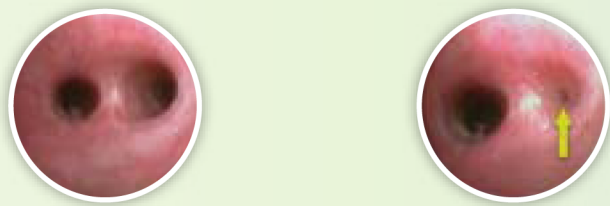
Bronchial Thermoplasty is a bronchoscopy based procedure that uses radiofrequency (RF) energy to reduce the amount of excess airway smooth muscle (ASM) present in the airways and limit its ability to contract and narrow the airways.

## Airway cross-section



## Treatment Effect

Local Methacholine Challenge (Canine Airway).



Airway on the left above is treated with BT, airway on the right is not treated with BT.

The same airways are given methacholine after the bronchial thermoplasty treatment. BT treated airway on the left remains open.

Reduces Airway Smooth Muscle (ASM)

Reduces bronchoconstriction

Reduces asthma exacerbations

Improves asthma quality of life

## Benefits of BT

**32% reduction**  
in asthma attacks<sup>1</sup>

**84% reduction**  
in emergency room visits from  
respiratory symptoms<sup>1</sup>

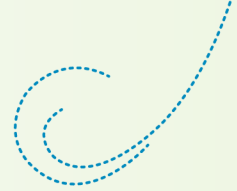
**73% reduction**  
in hospitalizations for respiratory  
symptoms<sup>1</sup>

**66% reduction**  
in days lost from work, school and  
other daily activities due to asthma<sup>1</sup>

Persistent effects observed up to  
**2 years**<sup>2</sup>

Stable safety profile observed up to  
**5 years**<sup>3,4</sup>

# Severe Asthma



## The Unmet Need

**32 million**<sup>5</sup>  
in Europe  
have asthma

**6 million**<sup>5</sup>  
of these have  
severe asthma

**1,2 million**<sup>6</sup>  
of adults  
with severe  
asthma have  
uncontrolled  
asthma and  
respond poorly  
to treatment.



**46%**<sup>6</sup>  
of patients with severe asthma cause increased burden on healthcare budgets and hospitalizations



**80%**<sup>6</sup>  
of asthma deaths occur in patients with poorly controlled severe disease



**50%**<sup>7</sup>  
of direct and indirect asthma costs are attributable to severe asthma

## Bronchial Thermoplasty (BT): Targeting the Unmet Need

*Patients with severe asthma experience a poor quality of life and account for a substantial portion of the overall economic burden of asthma given frequent physician/ER visits, hospitalizations and lost time from work.*

### Alternatives are needed to better control asthma symptoms

since **20%** of patients with severe asthma cannot gain control despite high intensity treatment with existing options

Existing Drug Therapies		Severity of Asthma
Alternatives needed	⑤ Oral Corticosteroids +/- Anti IgE treatment	Severe
	④ Medium or high-dose ICS + LABA +/- Leukotriene modifier +/- sustained release theophylline	Severe
	③ Low-dose ICS + Long-acting Beta2-agonists(LABA) or Medium-dose ICS or Low dose ICS + Leukotriene modifier	Moderate
	② Low-dose Inhaled Corticosteroids (ICS) Leukotriene modifier	Moderate
	① Short-acting Beta2-agonists (SABA)	Mild

Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2010; <http://www.ginasthma.org/>

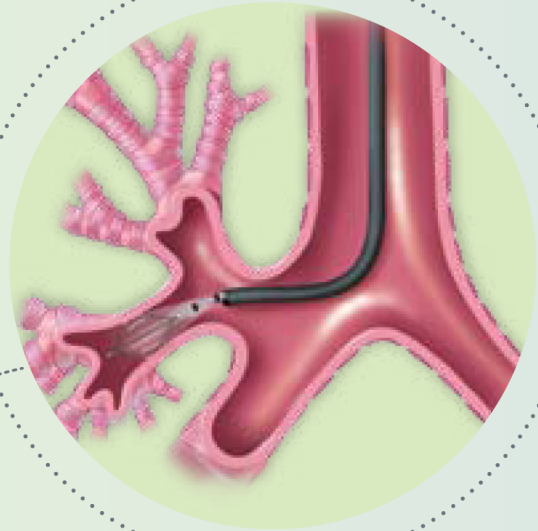




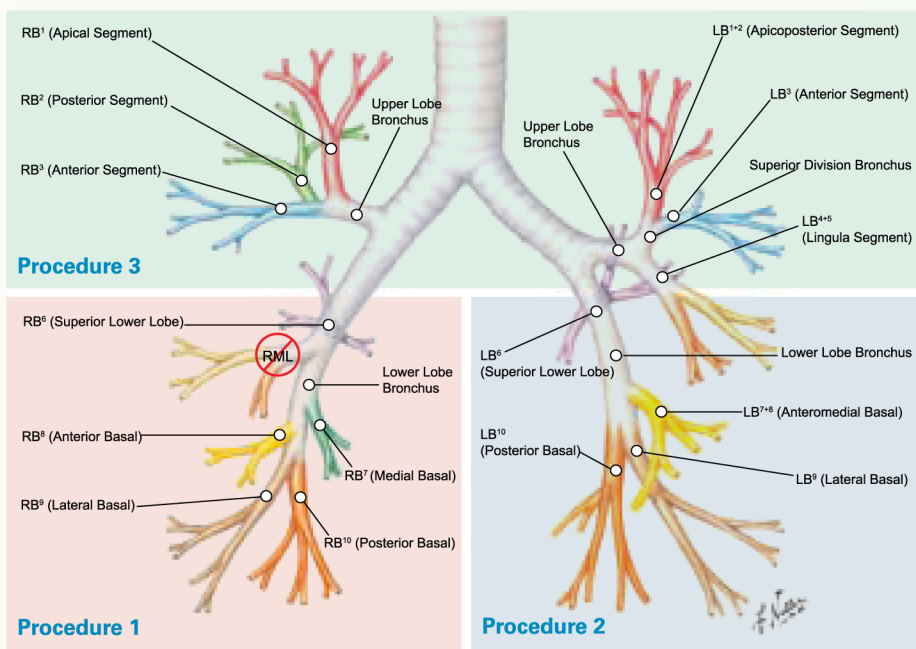
# Bronchial Thermoplasty: The Procedure

Treatment is performed by a trained physician over three procedures, each scheduled approximately three weeks apart and treating a different section of the lung.

Each procedure takes approximately 45-60 minutes and patients should be monitored post procedure in the same way as they would be following other bronchoscopy procedures.



## BT Procedure Process



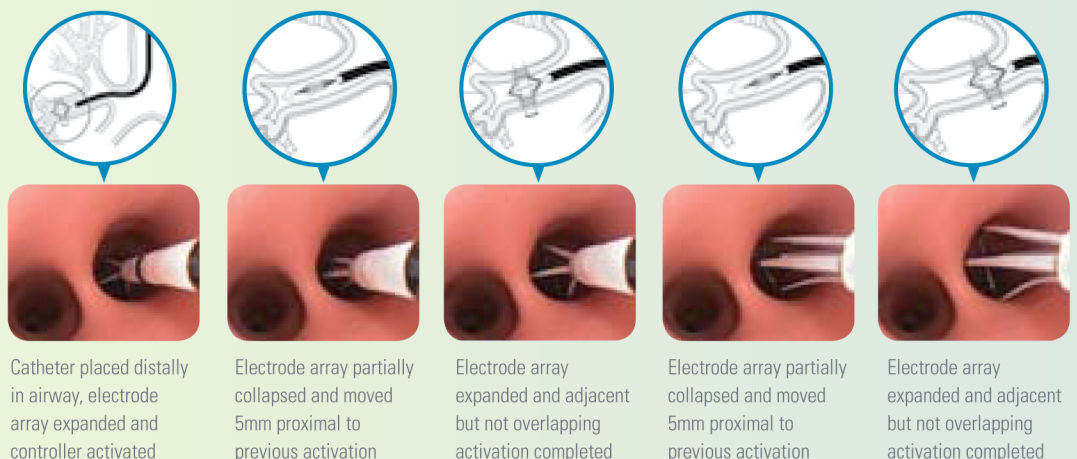
## Bronchial Thermoplasty complements current drug therapy

Bronchial Thermoplasty complements asthma maintenance medications by providing long lasting asthma control and improving asthma-related quality of life of patients with severe asthma.

It will not replace daily asthma medications and patients will continue to be monitored on their daily asthma medications by their asthma care physicians.

## Treating the Airways

A single activation of the Alair catheter delivers RF energy over a distance of 5mm to airways  $\geq 3$ mm in diameter and distal to the main stem bronchi.



# Bronchial Thermoplasty delivered by the Alair™ System

Bronchial Thermoplasty (BT) delivered by the Alair™ System is a non-drug procedure for long lasting control of severe asthma in adults over the age of 18. The Alair System is a means to deliver thermal energy to the airway via a bronchoscope to reduce airway smooth muscle.

**It is comprised of two primary components:**

## 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
- ▶ Requires a minimum 2.0mm working channel diameter bronchoscope, and maximum 5.0mm outer diameter

## Alair Radiofrequency (RF) Controller

Designed with proprietary control parameters and algorithms to deliver the correct intensity and duration of thermal energy sufficient to reduce excess ASM, while limiting long-term impact to surrounding tissues.

