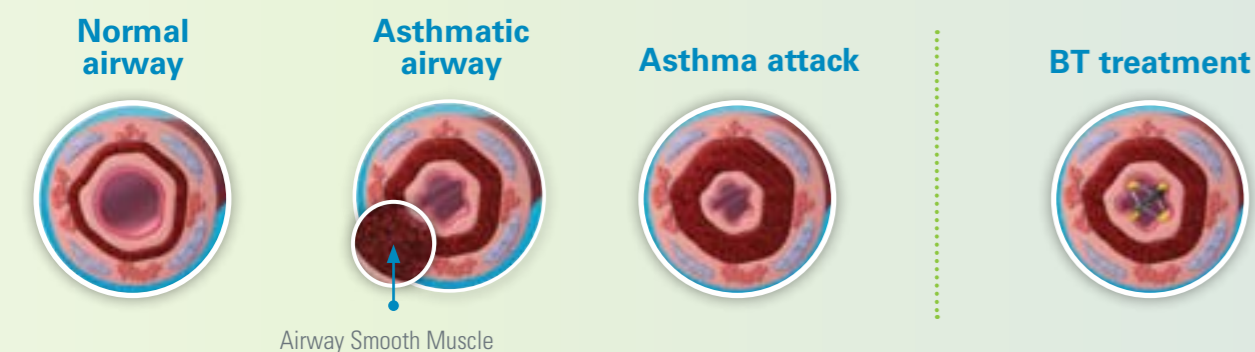


# What is Bronchial Thermoplasty?

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>

## 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

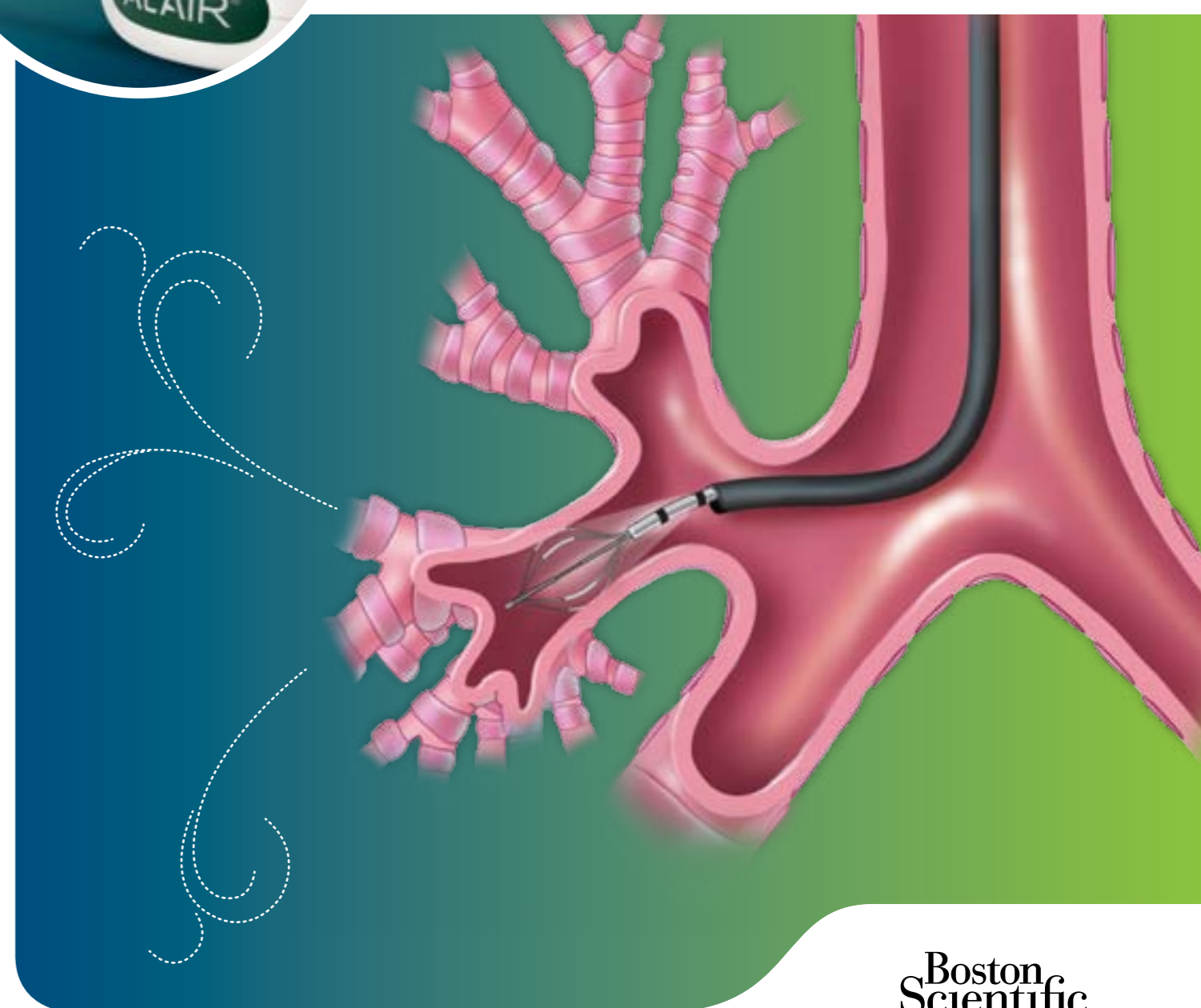
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- 2) Castro M, et al., Two-Year Persistence of Effect of Bronchial Thermoplasty (BT) in Patients With Severe Asthma: AIR2 Trial, *Chest.* 2010; 138:768A
- 3) Pavord I, et al., 5-Year Safety of Bronchial Thermoplasty Demonstrated in Patients with Severe Persistent Refractory Asthma: Research in Severe Asthma (RISA) Trial, *AJRCCM* 183; 2011: A6382
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- 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
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- 7) Braman SS. The global burden of asthma. *Chest* 2006; 130: 4S-12S

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# Bronchial Thermoplasty: A New Procedure for Severe Asthma



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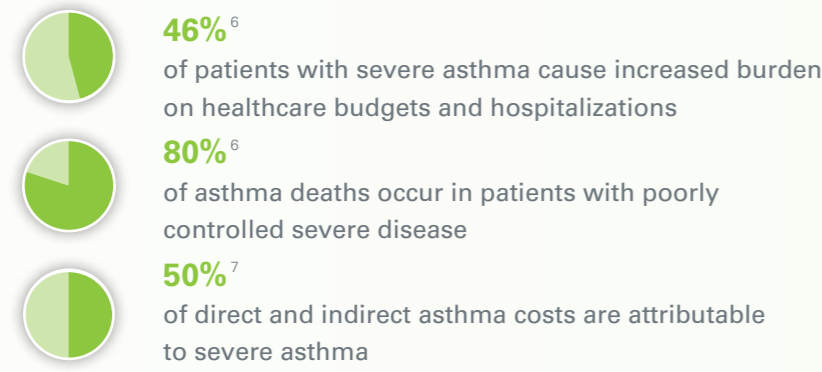
# Severe Asthma

## 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.



## 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
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/>

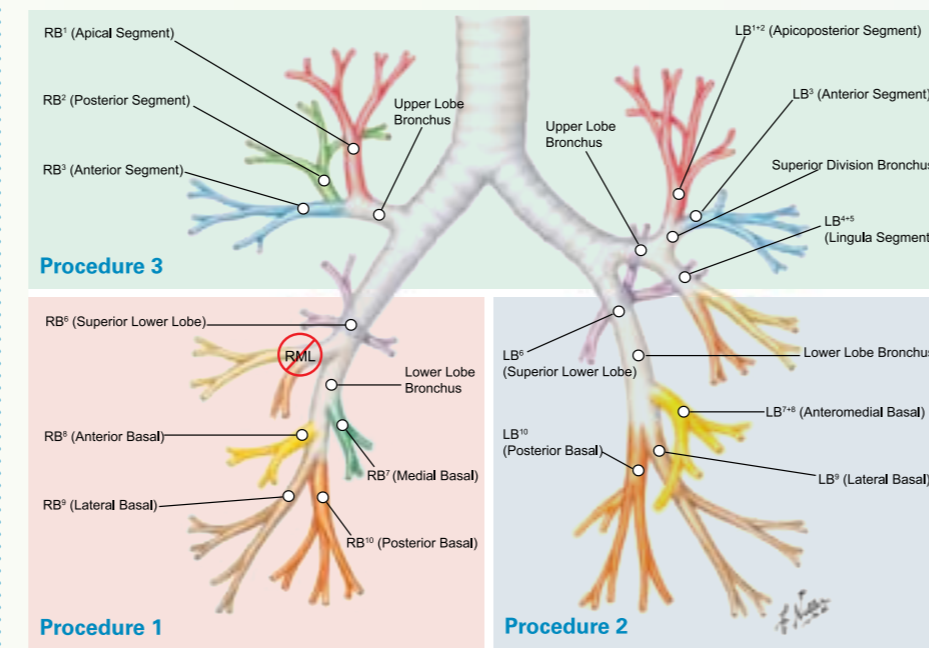
# Bronchial Thermoplasty: The Procedure

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



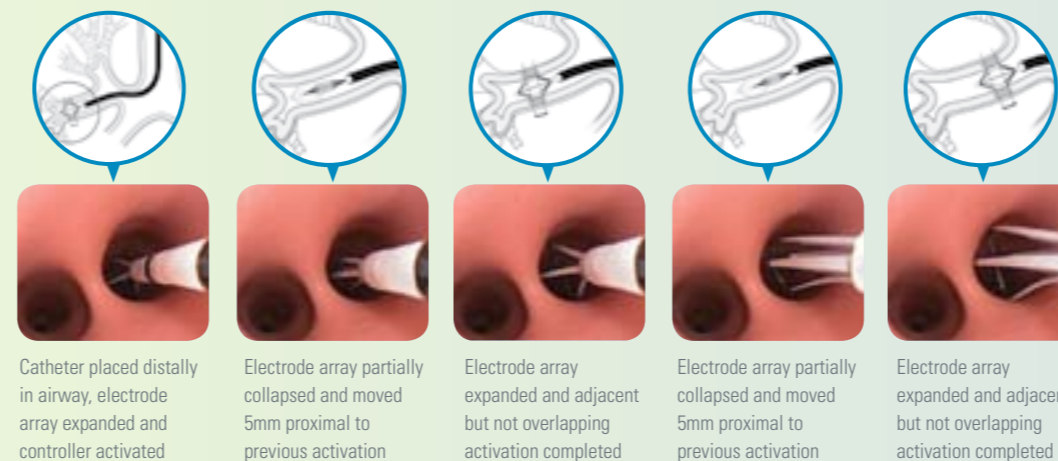
### Bronchial Thermoplasty complements current drug therapy

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

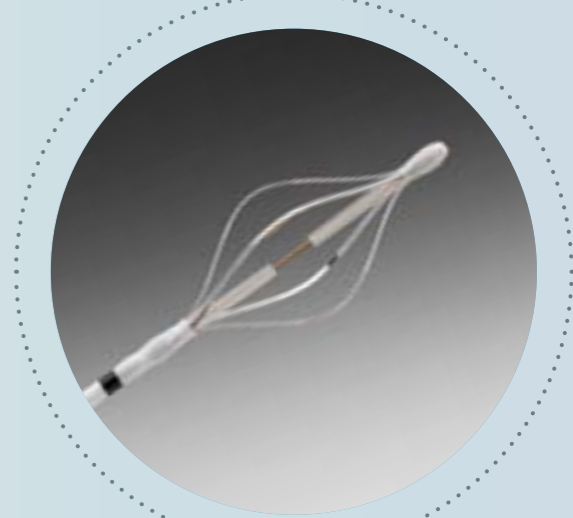
Bronchial Thermoplasty (BT) delivered by the Alair™ System is a non-drug procedure for long lasting control of severe asthma in adults over the age of 18. The Alair System is a means to deliver thermal energy to the airway via a bronchoscope to reduce airway smooth muscle.

### 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.

