Bronchial Thermoplasty a Procedure for Severe Asthma

Product Overview – A Revolutionary Procedure for Severe Asthma

Bronchial Thermoplasty (BT) delivered by the Alair™ System, is a safe outpatient procedure for the treatment of severe asthma in adult patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

How BT Works

- BT, delivered by the Alair™ System, uses mild heat to actually reduce the amount of excess smooth muscle tissue in the airways. Less muscle tissue means less airway constriction during an asthma attack. The majority of treated patients can thus breathe more easily and are less likely to have an asthma attack.
- BT does not replace asthma medication but works with these medications to give added, long-lasting protection from serious asthma symptoms.

The BT Procedure

- BT, delivered by the Alair™ System, is a safe outpatient procedure performed in three sessions to ensure safety and optimal results. The sessions are typically scheduled three weeks apart.
- Each session is routinely performed under moderate sedation and typically takes less than an hour to complete.
- No incision is needed because the procedure is performed with a bronchoscope inserted through the mouth or nose. A bronchoscope is a long, flexible tube with a camera on one end that allows the physician to see inside the airways.
- The first session treats the airways in the right lower lobe of the lungs, the second treats the airways in the left lower lobe, and the third procedure treats the airways in both upper lobes of the lungs.
- After all three procedures are performed, treatment is complete. The patient will return to their regular doctor to continue managing their asthma.
- As with any procedure, there are risks, and individual results may vary. The most common side effect of BT is temporary worsening of respiratory-related symptoms. This side effect typically occurs within a day of the procedure and resolves within seven days on average with standard care. There is a small (3.4% per procedure) risk of these symptoms requiring hospitalization.
Market Potential – An Unmet Clinical Need

Asthma is a serious public health problem. It is one of the top five chronic diseases globally, which includes heart disease, stroke, cancer, and diabetes. Some patients with severe asthma, who are on the highest doses of standard of care medications (inhaled corticosteroids and long-acting bronchodilators) taken daily, may still experience frequent and life-threatening asthma attacks. The increased burden of severe asthma can lead to a substandard quality of life for these patients, and few treatment options exist to adequately control their disease.

In the United States, asthma affects almost 25 million Americans, five to ten percent of whom are estimated to have severe asthma. U.S. government data reported, in one year:

- 12.8 million people experiencing asthma attacks
- 1.75 million emergency room visits
- 456,000 hospitalizations
- 3,447 asthma-related deaths


Severe asthma can have a dramatic impact on a person’s quality of life:

- In 2008, affected adults missed an average of five days of work due to asthma.¹
- On average, a person will spend four days in the hospital each time they are admitted for asthma treatment.²
- Patients who are severely affected by asthma are four times as likely to experience negative outcomes, such as emergency room visits and use of oral steroids.³
- Patients with severe asthma experience frequent symptoms such as coughing, wheezing, shortness of breath, chest tightness, mucus production, and exacerbations (asthma attacks) caused by a narrowing of the lungs’ airways.⁴

Clinical Results – At Year One

The AIR2 Trial evaluated the safety and effectiveness of the Alair™ Bronchial Thermoplasty System in patients with severe asthma. At one year, patients with severe asthma treated with BT, showed significant improvement compared to sham controlled patients.

- **32 percent fewer** severe asthma attacks
- **84 percent fewer** emergency room visits for respiratory symptoms
- **66 percent fewer** days lost from work, school, and other activities due to asthma symptoms

In addition,

- **79 percent** of patients treated with Bronchial Thermoplasty (BT), delivered by the Alair™ System, saw a **significant improvement** in their asthma-related quality of life.

Long-Lasting Clinical Results – Out to Five Years

In September 2013, the article, “Benefits of Bronchial Thermoplasty Persist Out to 5 Years in Patients with Severe Asthma,” by Michael Wechsler and colleagues appeared in the Journal of Allergy and Clinical Immunology. In Press

The AIR2 Trial 5-Year Extension Study was conducted to evaluate the sustained effectiveness of BT beyond 1 year, and the long-term safety of BT out to five years in BT-treated patients from the AIR2 Trial.

Safety & Effectiveness Maintained Out to Five Years

- The reduction in severe asthma attacks was maintained out to five years.
- The reduction in emergency room visits for respiratory symptoms was maintained out to five years.
- No increase in hospitalizations, asthma symptoms, or respiratory adverse events over the course of 5 years


Scientific Evidence

Experience with Bronchial Thermoplasty has been described in more than 15 peer reviewed publications including the New England Journal of Medicine, Journal of Allergy and Clinical Immunology, CHEST, Annals of Allergy, Asthma and Immunology and the American Journal of Respiratory and Critical Care Medicine. During the course of four clinical trials in patients with asthma over 800 Bronchial Thermoplasty procedures have been performed, in more than 275 patients in over 30 institutions around the world. Bronchial Thermoplasty is now available in over 270 medical centers in 28 countries and over 2000 patients have been treated. Clinical data show Bronchial Thermoplasty provides long lasting asthma control in patients with severe asthma.

Regulatory Status

The Alair™ Bronchial Thermoplasty System is approved by the FDA and 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™ Bronchial Thermoplasty System is approved by Health Canada and has received a CE Mark for use in the European Union, and is approved for use in a number of countries in Latin America and the Asia Pacific region.

Procedure Cost

The cost of the procedure will vary by provider. Boston Scientific supplies the device required to perform each procedure ($2,500 each), but the hospitals will also have additional costs for the equipment, supplies and staffing to perform the procedure. Patients are expected to receive three procedures in total. The cost for a patient to undergo Bronchial Thermoplasty treatment, inclusive of all 3 procedures, is estimated to range between $14,000 and $20,000.
Reimbursement Status
Like any new technology, insurance coverage policies and payment vary by payer until insurance companies get more experience with the procedure. As of January 1, 2013, there were two Category I CPT codes (for established procedures) to describe Bronchial Thermoplasty. Physicians can thus be paid more consistently for performing BT when the procedure is covered. Physician payment under Medicare is comparable to payment for other complex bronchoscopy procedures, providing a strong benchmark for private payers.

Many national payers and large regional payers (i.e., United Healthcare, Anthem, Humana CIGNA and many Blue Cross and Blue Shield plans,) are already covering Bronchial Thermoplasty on a case-by-case basis, even when they have non-coverage policies in place. In addition, we are aware of at least five regional health plans (SelectHealth (UT), HealthPartners (MN), Preferred One (MN), Avmed (FL) and Priority Health (MI)) that have decided to cover the procedure, thereby making Bronchial Thermoplasty available to their members.

Currently Medicare covers Bronchial Thermoplasty in all states therefore Medicare beneficiaries can be treated based on medical necessity. This means that Medicare beneficiaries should have access to Bronchial Thermoplasty.

Patients are encouraged to work with their physicians to contact their individual payers prior to having Bronchial Thermoplasty to confirm coverage.

About Boston Scientific
Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. In 2010, Boston Scientific acquired Asthmatx, Inc., which developed the Alair™ Bronchial Thermoplasty System. For more information about Boston Scientific, visit: www.bostonscientific.com. For more information about Bronchial Thermoplasty, visit www.BTforAsthma.com.


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Rx Only. CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions and warnings can be found with product labeling.

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Notes for reporters, editors and news anchors:

Facts about Bronchial Thermoplasty:

Bronchial Thermoplasty is only indicated or appropriate for **adults with severe asthma**

Bronchial Thermoplasty complements, **but does not replace**, asthma medications by providing long lasting asthma control.

Bronchial Thermoplasty is a treatment option for severe asthma patients who continue to be symptomatic despite taking their asthma medications.

Bronchial Thermoplasty offers long lasting asthma control, resulting in:
- Improved asthma-related quality of life
- Decreased severe asthma attacks
- Reduction in emergency room visits for respiratory symptoms
- Reduction in days lost from work, school or other activities due to asthma

Recent data demonstrated that the effectiveness of Bronchial Thermoplasty persists for at least 5 years. “Provides years of improved asthma control”.

Bronchial Thermoplasty is a novel approach of attacking asthma at the source, by reducing the airway smooth muscle that causes the constriction of the airways. This reduces but does not eliminate asthma attacks.

Like any new technology, insurance coverage policies and payment vary by payer initially. Bronchial Thermoplasty is currently being covered and paid for by a number of insurance companies on a case by case basis for appropriate patients.

**What Bronchial Thermoplasty DOES NOT do:**

Bronchial Thermoplasty does not allow asthma patients to stop taking their asthma medications; (Patients CAN NOT say goodbye to a life time of prescriptions, etc.)

Bronchial Thermoplasty does not eliminate all asthma symptoms.

Bronchial Thermoplasty is not permanent.

Bronchial Thermoplasty does not cure or eliminate asthma.