

The Alair™ Bronchial Thermoplasty System - Factsheet

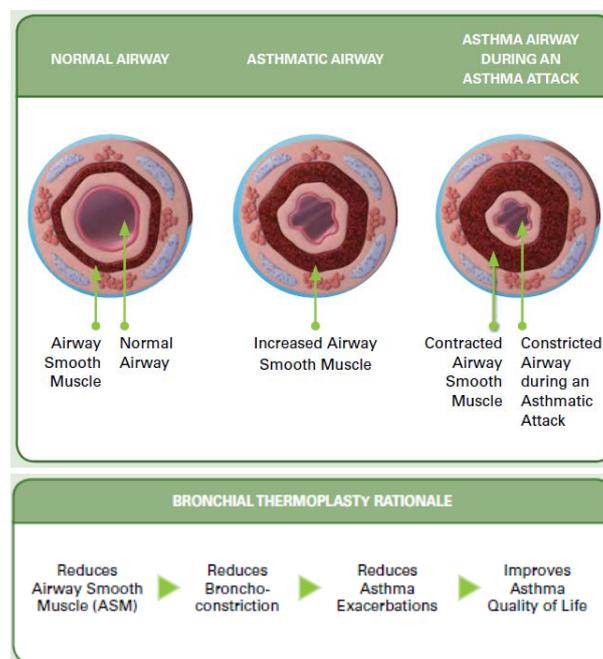
Bronchial thermoplasty, a novel therapy option for severe asthma

As a result of limitations of existing medications, there remains a significant unmet medical need to improve the care for patients with severe asthma, by better controlling their asthma symptoms. Bronchial thermoplasty (BT), delivered by the Alair™ System, is a long-lasting treatment option for this well-defined patient population.

BT is a non-drug procedure for severe asthma in patients 18 years and older. This minimally invasive procedure is expected to complement conventional asthma drug treatments, thereby improving symptom control and the quality of life of patients with severe asthma.

Benefit of reducing airway smooth muscle

The new Alair™ Bronchial Thermoplasty System is designed to help control asthma by reducing the mass of airway smooth muscle (ASM). ASM is located within the walls of the airways in the lung and there is typically an increase in the amount of ASM in the lungs of patients with asthma. Although current medications are reasonably successful in controlling inflammation and contraction of ASM in the majority of patients with asthma, some patients with severe asthma continue to suffer from excessive bronchoconstriction that plays an integral role in asthma attacks. Reducing ASM decreases the ability of the airways to constrict, thereby reducing the frequency and severity of asthma symptoms.



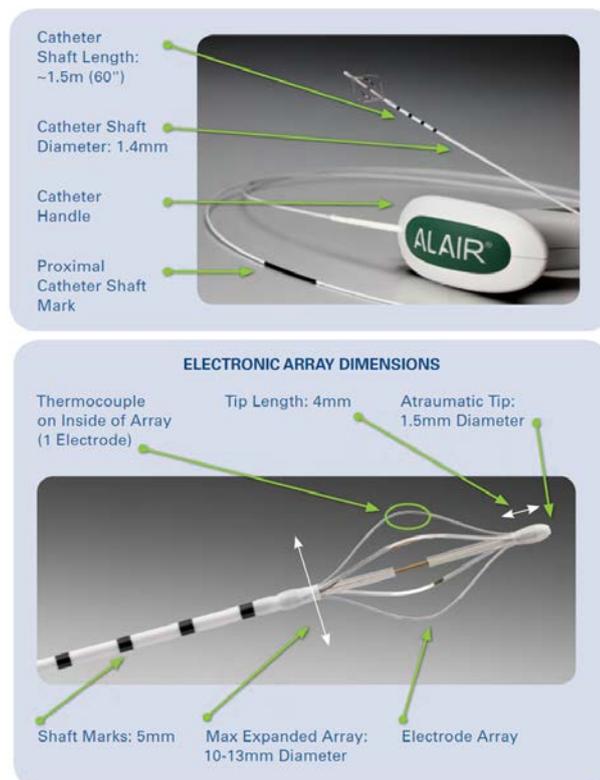
Treatment performed over three procedures

BT is performed using the Alair™ System in three procedure visits, each scheduled approximately three weeks apart. The first procedure treats the airways of the right lower lobe, the second treats the airways of the left lower lobe and the third and final procedure treats the airways in both upper lobes. Each session lasts about one hour, and following a brief period of recovery from the moderate sedation, the patient can go about their everyday activities at home.

The Alair™ Bronchial Thermoplasty System consists of two parts

The Alair™ Bronchial Thermoplasty System, which is comprised of two primary components, delivers thermal energy to the airway wall, heating the tissue in a controlled manner in order to reduce ASM mass.

1. The Alair™ Bronchial Thermoplasty Catheter is a single-use device designed to be delivered via a standard bronchoscope through the nose or mouth. The catheter delivers radiofrequency energy along the length of the airway walls in a controlled ten-second burst, causing a reduction in the excessive ASM that narrows the airways in patients with asthma.



2. The Alair™ Bronchial Thermoplasty Radiofrequency (RF) Controller is designed with a set of control parameters and algorithms to deliver the correct intensity and duration of thermal energy sufficient to reduce the mass of ASM tissue, while limiting long-term impact to surrounding tissues.



The Alair™ Bronchial Thermoplasty System has proven long-term benefits

BT has an excellent long-term safety and effectiveness profile, with evidence of long-term safety up to at least five years^{2,4} and durability of effect up to at least five years.^{3,4}

Clinical Results – At one year

In the pivotal AIR2 clinical trial, adults with severe asthma who underwent BT demonstrated that treatment with the Alair™ Bronchial Thermoplasty System resulted in improved quality of life, as well as the following benefits over a sham procedure. Benefits from the AIR2 trial include:

- 32 percent reduction in asthma attacks¹
- 84 percent reduction in emergency room visits for respiratory symptoms¹
- 73 percent reduction in hospitalisations for respiratory symptoms¹
- 66 percent reduction in days lost from work/school or other daily activities due to asthma¹
- 79 percent of patients treated with BT saw a significant improvement in their asthma-related quality of life¹

Proven long-term benefits at five years

In September 2013, results from the AIR2 Trial 5-Year Extension Study appeared in the Journal of Allergy and Clinical Immunology. The extension study was conducted to evaluate the sustained effectiveness of BT beyond one year, and the long-term safety of BT out to five years in BT-treated patients from the AIR2 Trial. 85 percent of patients who underwent BT treatment in the AIR2 Trial completed the five-year follow-up.

Key findings reported at five years following BT include:

- Improvement in asthma control for up to five years
- 48 percent reduction in asthma attacks
- 88 percent reduction in emergency room visits for respiratory symptoms
- No increase in hospitalisations for respiratory symptoms
- No increase in respiratory adverse events
- No difference in the percentage of patients experiencing severe exacerbations, ER visits and asthma symptoms over five years based on patient reported allergy status

In the period immediately following BT, there was an expected transient increase in the frequency and worsening of respiratory-related symptoms, including asthma (multiple symptoms), respiratory tract infections, wheezing, dyspnea, and chest pain, which were of the type expected following bronchoscopy in patients with asthma. These events typically occurred within a day of the procedure and were resolved on average within seven days with standard care. In the long-term after treatment, fewer BT treated patients reported respiratory adverse events. Investigators in the AIR2 trial concluded that the increased risk of adverse events in the short-term following BT was outweighed by the benefits, which persisted for at least five years⁴.

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References

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2. Thomson N, et al., Long-term (5 year) Safety of Bronchial Thermoplasty: Asthma Intervention Research (AIR) Trial, *BMC Medicine*, 2011.
3. Castro M, et al., Persistence of Effectiveness of Bronchial Thermoplasty in Patients with Severe Asthma, *Annals of Asthma, Allergy and Immunology*, 2011;107:65-70.
4. Wechsler M, et al., Benefits of Bronchial Thermoplasty Persist Out to 5 Years in Patients with Severe Asthma, *Journal of Asthma and Clinical Immunology*, August 2013..

Brief Statement of Relevant Indications for Use, Contraindications, Warnings, and Adverse Events: The Alair™ bronchial thermoplasty system is indicated for the treatment of severe asthma in patients 18 years and older . The Alair™ System is not for use in patients with an active implantable electronic device or known sensitivity to medications used in bronchoscopy. Previously treated airways of the lung should not be retreated with the Alair™ System. Patients should be stable and suitable to undergo bronchoscopy. The most common side effect of BT is an expected transient increase in the frequency and worsening of respiratory-related symptoms. Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.