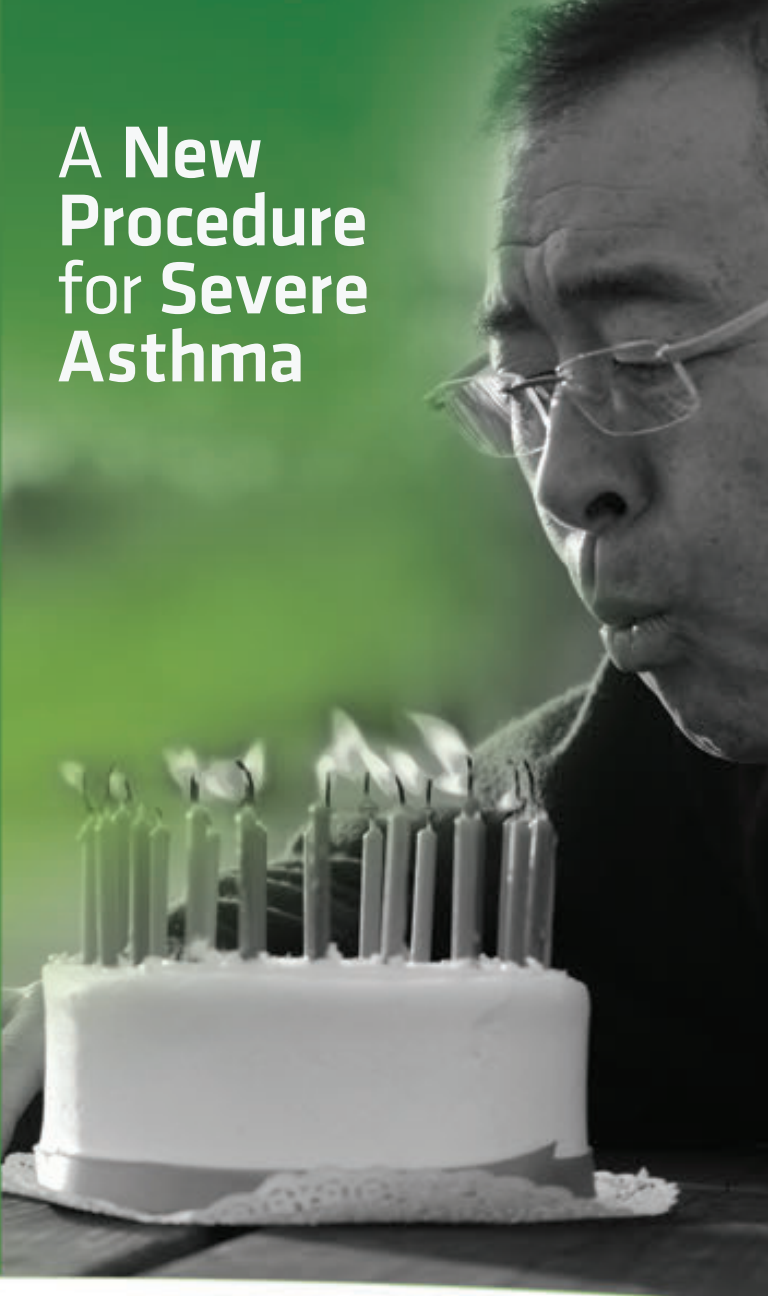



A New Procedure for Severe Asthma



 This brochure describes a new procedure for treating severe asthma in adults.



**Bronchial
Thermoplasty**

DELIVERED BY THE ALAIR® SYSTEM



Contents

About Severe Asthma	2
Why do doctors do this treatment?	2
What is the Alair® System?	2
What is Bronchial Thermoplasty (BT)?	3
Who can have this treatment?	3
(Indication for Use)	
Who cannot have this treatment?	3-4
(Contraindications)	
What are the risks and side effects of BT?	5-6
What are the benefits of BT?	7
What will happen if you decide to have the BT treatment for your severe asthma?	8-9
What happens after each BT treatment?	10
When to call the doctor?	10



About Severe Asthma

What happens when you have severe asthma?

Air travels in and out of your lungs through airways, which are tubes. There are tiny muscles in the walls of the airways. People who have severe asthma have larger muscles in their airways than other people. The airways close down when these muscles contract.

What happens when your airways close down?

When airways close down it can be harder to breathe. Your chest may feel tight. You may wheeze or cough. Asthma medicines usually open up the airways. These medicines do not always work well in patients who have severe asthma.

Why do doctors do this treatment?

You have severe asthma. Your asthma is severe because the asthma drugs you take now do not control your asthma symptoms.

Your doctor wants to use the Alair[®] System to treat your severe asthma. This treatment is called Bronchial Thermoplasty (BT). BT is a procedure and not an asthma medicine. Your doctor thinks your health is good enough to have this treatment.

If you decide to have this treatment, you will need to do what your doctor asks you to do or you may be harmed.

What is the Alair[®] System?

The Alair[®] System is the tool that your doctor will use to perform BT. The Alair[®] System has two main parts:

- A small tube with 4 wires at the end. See Figure 1.

Figure 1: Actual size of tip of Alair tube

- A machine that heats the wires

You need to decide if BT is right for you. You will be treated by a doctor who has been trained and knows how to use it correctly.



What is Bronchial Thermoplasty?

The Alair® System mildly heats your airway walls. This heating reduces some of the extra muscle present in the airways. This may allow your airways to stay more open and help you breathe better.

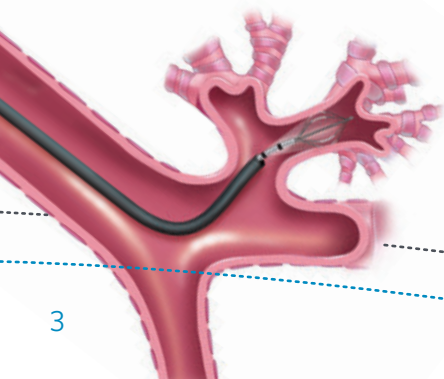
Who can have this treatment? (Indication for Use)

The Alair® Bronchial Thermoplasty System 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.

Who cannot have this treatment? (Contraindications)

You cannot have this treatment if you have:

- **An implant with electronics.** Tell your doctor if you have any implants with electronics, such as a pacemaker. BT may keep the implant from working correctly.
- **Problems taking certain medicines.** Tell your doctor if you have ever had a problem taking any kind of medicines. Your doctor will use some medicines to perform BT. Your doctor needs to make sure the medicine he or she uses will not hurt you.
- **Have had this treatment before.** Tell your doctor if you have had BT before.
- **You cannot have this treatment if you are less than 18 years old.** No one has tested BT in patients younger than 18 years.



You cannot have this treatment while the following conditions are present:

- **An active respiratory infection.** Tell your doctor if you think you have an infection, fever, or your asthma is worse than usual. If your infection is in your lungs or airway, BT may harm you.
- **Have had an asthma attack or changed your oral corticosteroid dose in the last 2 weeks.** Tell your doctor if either of these happened in the last 2 weeks. If you have had an asthma attack or changed your oral corticosteroid dose in the last 2 weeks, BT may harm you.
- **A blood clotting problem.** Tell your doctor if you take any drugs to keep your blood from clotting. Some call these drugs blood thinners. If you have a blood clotting problem, BT may harm you.

Clinical Study

In 2007, doctors studied nearly 300 patients who had severe asthma. In this study, they saw how well BT worked and what side effects patients had. Doctors treated about 200 people with BT. This was the “BT Group”. Doctors treated another group in a similar way, but they did not heat their airways. This was the “Sham Group”. Patients did not know which group they were in. Doctors studied these patients for a year after their last treatment. We do not know how well patients did beyond one year. This is still being studied.



What are the risks and side effects of BT?

Right after their doctors treated them, many patients in the study had side effects. [Table 1](#) shows how many people had each side effect. The table shows side effects that occurred in 1 or more out of every 100 patients, and occurred more often in the BT group.

How to read this table:

- Short Term: from start of first treatment until 6 weeks after third treatment.
- Long Term: from 6 weeks after last treatment until 1 year after last treatment.
- In the table, some patients had more than one side effect.
- [Look at Table 1.](#)
 - Think of a group of 100 patients.
 - Look at the column that says “Short Term Period”.
 - Go down that column to the row that reads “more than one symptom of asthma.”
 - This row means that 52 out of every 100 patients in the BT Group had “more than one symptom of asthma” sometime after their first treatment until 6 weeks after their third treatment.
 - On the same row, now look at the “Long Term Period” column.
 - You see there were 27 out of every 100 patients in the BT Group who had “more than one symptom of asthma” in the long term period.
 - The 52 and the 27 are not separate groups of patients. Some patients may be counted in both groups:
 - One or more patients who had a “Short Term Period” effect may have also had a “Long Term Period” effect. Meaning he or she did not get better.
 - One or more patients who did not have a “Short Term Period” effect may have had a “Long Term Period” effect. Meaning he or she got worse later.
 - One or more patients who had a “Short Term Period” effect may not have had a “Long Term Period” effect. Meaning their problem went away.
 - We do not know how well patients will do beyond a year after their treatment.

Table 1: Short Term and Long Term Side Effects

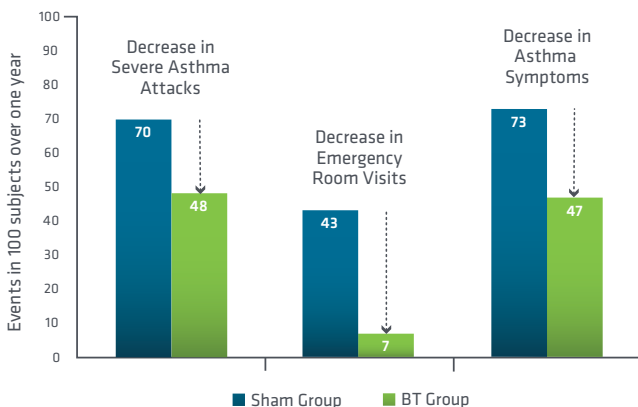
Type of Side Effect	Short-Term Period		Long-Term Period	
	BT Group	Sham Group	BT Group	Sham Group
Related to Breathing	OUT OF EVERY 100 PATIENTS			
More than one symptom of asthma	52	39	27	43
Wheezing	15	6	4	3
Chest pain	14	13	3	1
Shortness of breath	11	6	2	1
Chest discomfort	9	10	2	1
Infection in the lower airways	8	2	3	6
Collapse of part of the lung	5	0	0	0
Swelling of the airways	4	2	7	5
Bleeding*	3	0	0	0
Blocked airways	3	0	0	0
Pneumonia	2	0	3	2
Blood in mucus	2	1	1	1
Abnormal breath sounds	2	0	0	0
Intense swelling of airways	1	0	0	0
Infection in the lower airways caused by a virus	1	0	0	0
Narrowing of airways	1	0	0	0
Fluid in lungs	1	0	0	0
Related to Ear, Nose and Throat				
Infection in the upper airways	20	11	30	26
Swelling of the nose and/or throat	5	7	11	5
Infection in the upper airways caused by a virus	4	2	6	7
Acute Sinusitis	3	2	4	8
Rhinitis	2	0	4	6
Swelling of throat	2	1	1	1
Increased mucus in upper airways	1	0	0	0
All Other				
Headaches	14	9	5	3
Fever	4	2	0	1
Influenza	4	2	4	12
Upset stomach	4	2	2	4
Anxiety	4	0	1	2
Nausea	3	4	1	1
High blood pressure	3	2	3	3
Urinary tract infection	1	1	3	1
Bleeding during the procedure	1	0	0	0

*One instance of bleeding occurred 31 days after a BT treatment and was treated with a medical procedure.

What are the benefits of BT?

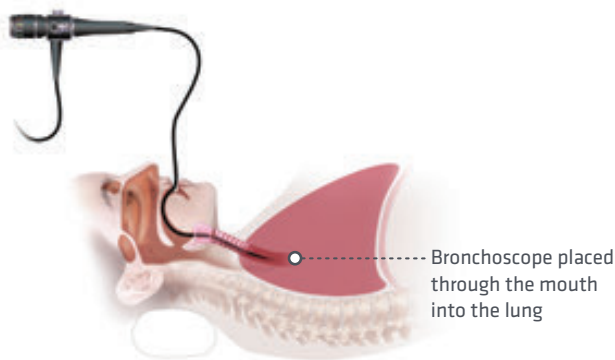
The study showed that the people in the BT Group had fewer severe asthma attacks, visits to the emergency room, and asthma symptoms as shown in [Figure 2](#).

Figure 2. Benefits of BT



The BT Group also lost on average 3 fewer days per patient from work, school, or other daily activities due to asthma symptoms. This was for one year after treatment compared to the Sham Group. This is not shown in [Figure 2](#).

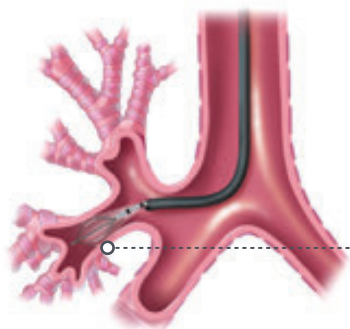
Figure 3. Placement of Bronchoscope into your lungs



What will happen if you decide to have the BT treatment for your severe asthma?

- There will be 3 treatments. There will be 3 weeks in between each treatment.
- You will prepare for each treatment by taking a 50-mg steroid pill by mouth once a day for 3 days before the treatment.
- You will also take a 50-mg steroid pill on the day of the treatment.
- On each BT treatment day, your doctor will test your lungs. He or she will do this by checking how much air you can blow out.
- Your doctor will make sure you don't have an infection. An infection would delay the treatment.
- Your doctor will tell you what he or she will do during BT.
- Your doctor will:
 1. Give you medicines to make you sleepy.
 2. Put a small tube called a bronchoscope through your mouth into your airways. [See Figure 3.](#)
 3. Put the smaller Alair tube through the bronchoscope. The wires on its end will touch your airways. [See Figure 4.](#)

Figure 4. Placement of Alair tube in your lungs

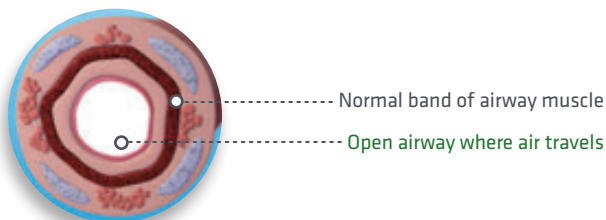


Wires of Alair tube opened to contact the inside of your airways

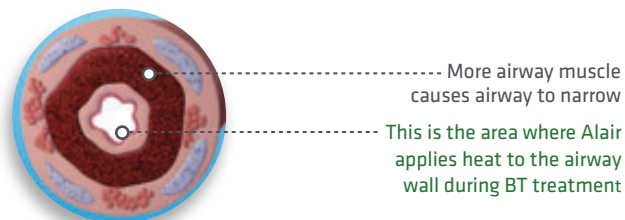
- Heat the wires on the end of the small Alair tube to reduce some of the airway muscle tissue. You won't feel this because your doctor gave you medicines. See Figure 5 for how airways look before and after BT treatment.

Figure 5. Airways Before and After BT Treatment

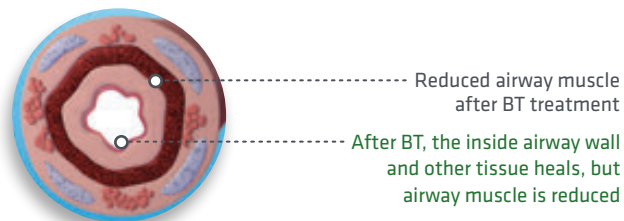
Airway of Person without Asthma



Airway of Person with Severe Asthma



Airway of Person with Severe Asthma after Treatment



- Move the small Alair tube to more places and treat them the same way.
- Take the small Alair tube and the bronchoscope out.
- Watch over you as you wake up and recover.

What happens after each BT treatment?

- You have to take a 50-mg steroid pill the day after.
- Your doctor will contact you by phone to check on you:
 - The day after your treatment
 - The day after that, and
 - A week after your treatment
- You will still have to take your asthma medicine.

After your airways heal from your first treatment, you will go back to your doctor for your second treatment. Your doctor will treat more of your airways. After you get well from that, your doctor will treat the rest of your airways in your third treatment.

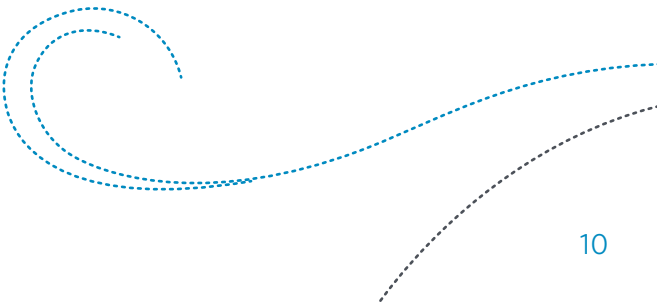
Use your rescue inhaler if your asthma symptoms get bad. Tell your doctor if you needed to use your rescue inhaler.

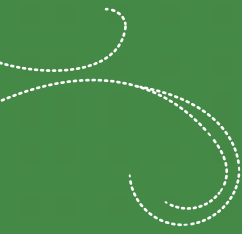
When to call the doctor?

If you have this treatment, contact your doctor if your asthma symptoms get worse and do not get better after taking your rescue inhaler.

Brief Statement of Relevant Indications for Use, Contraindications, Warnings, and Adverse Events:


The Alair[®] Bronchial Thermoplasty System 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[®] 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.





Thank you for considering this
important new treatment for
severe asthma.

www.BTforAsthma.com



▶ Where to learn more
about the Alair[®] System
and BT

- Contact your doctor, or
- Call:

Boston Scientific
Toll Free: 877.810.6060

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