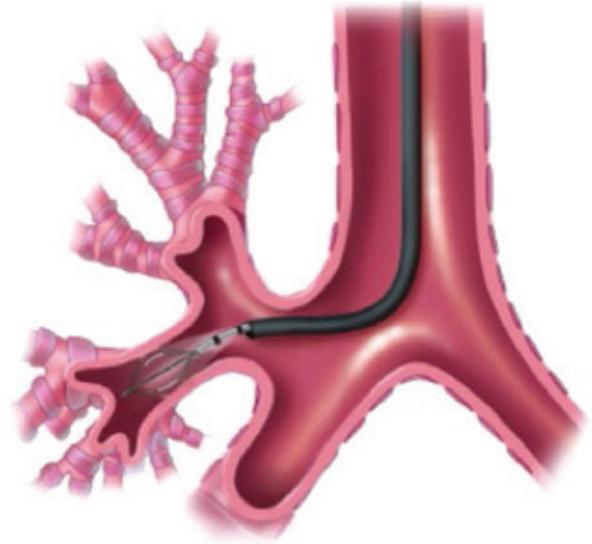


Patient information sheet and consent form Bronchial Thermoplasty (BT)

You have been recommended by your Respiratory Specialist to undergo a Bronchial Thermoplasty.

This is a procedure that may be recommended for adults with severe, persistent asthma that is not well controlled on inhaled steroids combined with a long-acting bronchodilator medicine.



What is bronchial thermoplasty (BT)?

There is often excess smooth muscle in the airways with severe persistent asthma. A bronchoscope is a small tube that allows the doctor to look inside the airways in the lungs. The Alair® bronchial thermoplasty system can be placed thru the bronchoscope. The Alair System then delivers controlled thermal energy (heat) to the airway wall in the lung. This controlled thermal energy helps to reduce excess airways smooth muscle. When the excess airway smooth muscle is reduced, the airways are less likely to constrict. This may reduce the frequency of asthma attacks. Bronchial thermoplasty is a procedure that is done in three visits; each visit is two to three weeks apart.

During the bronchial thermoplasty, the bronchoscope will be placed through the nose into the lungs. The Alair System will be placed through the bronchoscope to a specific section of the lungs to be treated. Once the Alair System is near the end of an airway, controlled thermal energy is applied along the airway. This is repeated with all the airways in the section of the lungs to be treated.

Over the three bronchoscopy visits, a different section of the lungs will be treated during each of the three visits. After the third procedure, all the lung sections will have been treated except the right middle portion, which is not supposed to be treated.

The preparation for the bronchial thermoplasty will take about one hour. The bronchial thermoplasty will take from 45 minutes to 60 minutes. The recovery may take from two to four hours. Sometimes, an overnight stay is required.

What are the benefits of BT?

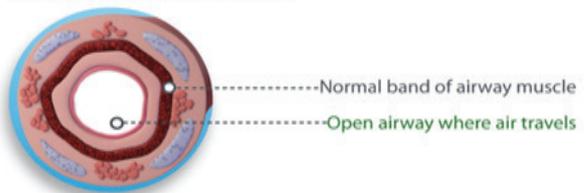
In clinical trials, BT has been shown to improve asthma-related quality of life in 79% of people who received treatment.

People treated with BT also had:

- 84% fewer asthma-related emergency room visits
- 66% fewer days lost from work, school, and other activities due to asthma symptoms
- 32% fewer severe asthma attacks.

Airways Before and After Bronchial Thermoplasty Treatment

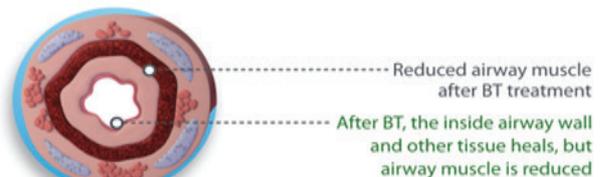
Airway of Person without Asthma



Airway of Person with Severe Asthma



Airway of Person with Severe Asthma after Treatment



■ Who are suitable candidates?

You **may be** a good candidate if:

- Age 18 years or over
- Be a non smoker for at least the past year
- You have severe asthma
- And your symptoms are not well controlled despite the use of inhaled corticosteroids and long acting beta-agonists.

You **are not** a candidate if:

- You have a pacemaker, internal defibrillator, or some other types of implantable electronic device
- You have sensitivities to the medications used when performing a bronchoscopy, including benzodiazepines, atropine and lignocaine
- You have been previously treated with BT

■ What do I need to do to prepare for the BT?

You should not eat anything for 6 hours before the test. Clear fluids (not containing milk) can be drunk up until 2 hours before the test.

If you are on warfarin, clopidogrel, aspirin or other blood thinning medications you will need to stop this before the test 7 days before the procedure. This is to minimise the risks of bleeding following taking the biopsy.

If you have been on warfarin, you will need a blood test (INR) on the day of the biopsy to check your blood is clotting.

If you are taking warfarin following a heart valve procedure, you will probably require injections to ensure your blood is thinned sufficiently - please discuss this with your doctor.

If you are diabetic, please discuss your diabetes medicines with your doctor.

Take all other medications (including tablets or inhalers etc) at the usual time of day on the day of the test. These can be taken with a sip of water until 1 hour before the procedure.

■ How is sedation achieved?

About 1 hour before the procedure you will usually have some pain-killing medication. You will usually be given some sedation through an intravenous (IV) drip and more pain relief during the procedure. The sedative will help you to relax, and may make you feel sleepy. The sedative may also help you to forget any unpleasant sensations felt during the test.

You will not require a general anaesthetic.

Procedural sedation involves the use of short-acting analgesic and sedative medications. This is not a general anaesthetic.

Serious complications rarely occur and no deaths had been reported in multiple studies. **Significant respiratory compromise**, the most concerning potential complication, develops in less than 1% of cases.

Adverse outcomes may include **respiratory depression** with (which are often short-lived, and resolve with patient stimulation or supplemental oxygen), **cardiovascular instability** including low blood pressure or heart rate (usually transient without intervention needed), **vomiting** (about 5% and may need medication) and **aspiration, emergence reactions, and inadequate sedation** preventing completion of the procedure.

■ What are the risks?

There are few side effects from the BT procedure, but people may experience temporary worsening of respiratory symptoms within one to seven days following the procedure. The most frequent side effects from BT include:

- Coughing
- Wheezing
- Shortness of breath

There is a small risk (3.4%) of these symptoms requiring hospitalisation.

■ What happens after the procedure?

Patients vary in their wake-up times. You will be taken to a recovery area until the sedation wears off. If you require an overnight stay, you will then be taken back to the respiratory ward.

Once discharged, you will be given an appointment with your specialist to discuss the results. You will also be called on the telephone by our RCCP (Respiratory Coordinated Care Program) nurse 24 hours, 48 hours and 7 days after the procedure to see how you are doing.

You will be given on written instruction when you leave the hospital. Please follow these carefully.

What will happen on the day?

Please come to the reception desk at the Preadmission Clinic on level 3 at the time you have been given. You should not have anything to eat for 6 hours before your appointment time and nothing to drink for up to 2 hours before.

Please bring with you any medication you take and your spectacles if you wear them.

Please do not wear jewellery, nail varnish or make-up.

Please let us know before you come for your procedure if you will need an interpreter.

When you arrive a member of staff will take your name and a few other details and let the bronchoscopy staff know that you have arrived.

A nurse will greet you and make you comfortable and take your blood pressure, temperature and pulse, and ask you questions about your medical history. The nurse or doctor will insert a small plastic tube into your hand or arm so that we can give you sedation and any other medication during the procedure.

Please let the nurse know if you are taking any medication which thins the blood, such as Heparin, Aspirin, or Warfarin. Please also tell us if you have any allergies or if you may be pregnant.

Please also let us know if you are diabetic.

SUMMARY GUIDE

You are scheduled to have a bronchial thermoplasty, an innovative, new, non-drug procedure developed for the treatment of severe persistent asthma.

- ☑ Do not eat for 6 hours or drink for 2 hours before the procedure.
- ☑ Review your medication schedule and smoking activity with your doctor.
- ☑ After the procedure, do not drink for ½ to 1 hour or until the numbness completely wears off.
- ☑ Do not drive home by yourself for 24 hours after the procedure; arrange for a family member or friend to take you home.
- ☑ Contact your doctor immediately if you have shortness of breath or chest pain, or you cough up more than a few tablespoons of blood at home.

If you have any questions or concerns, please contact:

Your respiratory consultant or registrar on call via switch

Sutherland Hospital

Tel: 02 9540 7111

Patient Instruction after Bronchial Thermoplasty

The responsible adult escorting you home should also be aware of the following instructions.

The effect of the sedation can take some time to wear off and your memory loss may persist longer than the sedation. Your escort needs to know that you may not carry out instruction even though you appear to acknowledge them.

You can resume eating a normal diet after discharge unless the doctor today advises otherwise.

**SEDATION WILL AFFECT YOUR JUDGMENT FOR ABOUT 24 HOURS.
DURING THIS TIME FOR YOUR OWN SAFETY AND IN SOME CASES LEGALLY:**

- DO NOT drive any type of car, bike or other vehicle and take extra care as a pedestrian
- DO NOT operate machinery
- DO NOT drink alcohol
- DO NOT use cooking appliances or handle dangerous items such as boiling water
- DO NOT make critical decisions or sign a legal document
- DO NOT do activities that require coordination or balance
- Ensure that you have a responsible adult to care for you until tomorrow
- Rest at home for the remainder of the day

Your doctor may prescribe you medication for pain or other indications:

- Take medication prescribed

SEEK MEDICAL ADVICE FROM YOUR GP or HOSPITAL IF YOU NOTICE ANY OF THE FOLLOWING:

- Have trouble swallowing / breathing / speaking
- Sharp pain in the throat or chest
- Begin coughing up more than a few tablespoons of blood
- Have a high temperature or fever $>38^{\circ}\text{C}$
- Have redness, pain or swelling for more than 48 hours where you had the injection for sedation (hand or arm)
- Any symptoms that you think is related to today's procedure and is causing you serious concern

Please ensure you have an arranged follow up with your respiratory specialist within 3 weeks of the procedure.

If you have any questions or concerns, please contact:

Your respiratory consultant or registrar on call via switch

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Tel: 02 9540 7111