Bronchial Thermoplasty

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications 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.

Contraindications

Patients with the following conditions should not be treated:

- Presence of a pacemaker, internal defibrillator, or other implantable electronic devices,
- Known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines,
- Patients previously treated with the Alair® System should not be retreated in the same area(s). No clinical data are available studying the safety and/or effectiveness of repeat treatments.

Patients should not be treated while the following conditions are present:

- Active respiratory infection,
- Asthma exacerbation or changing dose of systemic corticosteroids for asthma (up or down) in the past 14 days,
- Known coagulopathy,
- As with other bronchoscopic procedures, patients should stop taking anticoagulants, antiplatelet agents, aspirin and NSAIDS before the procedure with physician guidance.

Potential Adverse Events

Adverse events that may occur during the Treatment Period (from first bronchoscopy until 6 weeks after final bronchoscopy) or in the first year Post-Treatment with ≥ 3% incidence include upper respiratory tract infection, nasopharyngitis, throat irritation, viral upper respiratory tract infection, sinusitis, acute sinusitis, pharyngolaryngeal pain, allergic rhinitis, rhinitis, asthma (multiple symptoms)*, wheezing, chest pain, cough, dyspnea, chest discomfort, lower respiratory tract infection, productive cough, atelectasis, bronchitis, hemoptysis, headaches, anxiety, dyspepsia, nausea, influenza, pyrexia (fever), back pain, hypertension, and urinary tract infection.

* “ Asthma (multiple symptoms)” is defined as occurrence or worsening of shortness of breath, wheeze, cough, productive cough, or some combination of these.

Respiratory adverse events that may occur during the Treatment Period or in the first year Post-Treatment with < 3% and ≥ 1% incidence include abnormal breath sounds, acute bronchitis, bronchial obstruction, bronchospasm, discolored sputum(blood-tinged sputum), epistaxis, hypoxia, increased upper airway secretion, nasal congestion, operative hemorrhage, pneumonia, pulmonary congestion, rhinorrhea, viral lower respiratory tract infection, and viral pharyngitis.

Non-respiratory adverse events that may occur during the Treatment Period or in the first year Post-Treatment with < 3% and ≥ 1% incidence include abdominal pain, acne, allergic dermatitis, arthralgia, back injury, candidiasis, conjunctivitis, cystitis, depression, diarrhea, dizziness, fatigue, food poisoning, gastritis, gastroenteritis, gastroesophageal reflux disease, gastrointestinal infection, heart palpitations, herpes simplex, hiccups, hyperglycemia, hypersensitivity, hypotension, injury, insomnia, intervertebral disc protrusion, joint sprain, ligament rupture, migraine, muscle strain, musculoskeletal pain, nephrolithiasis, oral candidiasis, pain in extremity, peripheral edema, procedural pain, rash, skin laceration, tendonitis, tonsillitis, tooth abscess, tooth extraction, tooth infection, toothache, tremor, viral tonsillitis, and vomiting.

There may be other risks associated with the procedure and attendant anesthesia and medications. Please consult the manufacturers' directions for use for the equipment and medications used in association with the bronchial thermoplasty procedure for relevant indications, warnings, precautions, and adverse events.

Precautions

Caution should be taken in patients with the following conditions due to a potential increased risk of adverse events that may be associated with the procedure. Patients with these conditions were not studied in the pivotal trial and the safety of Alair® treatment for such patients has not been determined:

- Post-bronchodilator FEV1 < 65%.
- Other respiratory diseases including emphysema, vocal cord dysfunction, mechanical upper airway obstruction, cystic fibrosis or uncontrolled obstructive sleep apnea.
- Use of short acting bronchodilator in excess of 12 puffs per day within 48 hours of bronchoscopy (excluding prophylactic use for exercise).
- Use of oral corticosteroids in excess of 10 milligrams per day for asthma.
- Increased risk for adverse events associated with bronchoscopy or anesthesia, such as pregnancy, insulin dependent diabetes, epilepsy or other significant co-morbidities, such as uncontrolled coronary artery disease, acute or chronic renal failure, and uncontrolled hypertension.
- Intubation for asthma, or ICU admission for asthma within the prior 24 months.
- Any of the following within the past 12 months:
    - 4 or more lower respiratory tract infections (LRTI)
    - 3 or more hospitalizations for respiratory symptoms
    - 4 or more OCS pulses for asthma exacerbation