ALAIR™

Bronchial Thermoplasty Catheter

Boston Scientific
Advancing science for life™

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

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

For Professional Use Only:
The Alair Catheter must be used by a physician who has training and experience in performing bronchoscopic procedures.

Warning

Contents supplied STERILE using a Radiation process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific Corporation (BSC) representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

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.

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.

Warnings

Read these directions for use in conjunction with the Alair RF Controller Model ATS 200 Operator's Manual before using the Alair Bronchial Thermoplasty System. Failure to follow any instructions or failure to heed any warnings or precautions may result in harm or injury to patient.

1. Prior to performing the procedure, ensure appropriate training, equipment, medications and staff are in place to handle any potential bronchoscopic, respiratory or anesthesia related emergencies. The Alair System should only be used in a fully equipped bronchoscopy suite with access to full resuscitation equipment to handle hemoptysis, pneumothorax, and other respiratory complications including acute exacerbation of asthma and respiratory failure requiring intubation.
2. Do not deliver energy if the Catheter's electrode array is in contact with a metal object. This may result in harm or injury to the patient and/or operator.
3. Do not advance the Catheter within the bronchoscope if significant resistance is felt, as this may result in harm or injury to the patient and/or cause damage to the Catheter and/or bronchoscope.
4. Do not advance the Catheter into bronchi in which the Catheter cannot be seen under bronchoscopic vision. Advancing the Catheter beyond this region may cause patient harm or injury such as pneumothorax or pneumomediastinum.
5. Do not reposition the bronchoscope with the Catheter advanced beyond the distal end of the bronchoscope as this may result in patient harm or injury.
6. Use of the Alair Catheter with a non-Alair Controller may result in harm or injury to the patient and/or operator, or may result in product malfunction.
7. Do not treat the right middle lobe because of the potential susceptibility of the right middle lobe to transient obstruction as a result of inflammation or edema due to certain anatomical characteristics. The narrow diameter of the lobar bronchus and acute take-off angle may create poor conditions of drainage that may cause patient harm or injury such as atelectasis or difficulty in re-inflation (Right Middle Lobe Syndrome).
8. No modification of this equipment is allowed.

Precaution

1. The Alair Catheter is provided sterile and is SINGLE USE ONLY. Do not use the Catheter if the package is opened, torn, or damaged. Use of a Catheter from damaged packaging may result in patient harm or injury. Do not resterilize, reprocess or reuse the Catheter, as this may result in patient harm or injury, transmittal of infectious disease or product malfunction.
2. Do not use the Catheter if it comes in contact with a surface that is not aseptic (e.g. floor). This may result in patient infection.
3. Do not use the Catheter if it is damaged or irregular. Use of a damaged or irregular Catheter may result in patient harm or injury.
4. Do not use the Catheter if the marker bands are not visible.

Precaution

5. Use care when handling the Catheter to avoid kinking the Catheter shaft.
6. Avoid deflecting the bronchoscope while the electrode array is within the bend of the bronchoscope's working channel as this may result in damage to the Catheter and failure of the Catheter to operate properly.
7. Before inserting or removing the Catheter from the bronchoscope, ensure the electrode array is relaxed. Do not use the Catheter if the electrode array does not expand or relax properly (See Operational Instructions, Figures 4 and 5).
8. Before delivering energy, make certain that all electrodes are in contact with the airway wall.
9. 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% predicted.
    - 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:
        A. 4 or more lower respiratory tract infections (LRTI)
        B. 3 or more hospitalizations for respiratory symptoms
        C. 4 or more OCS pulses for asthma exacerbation
10. The Alair™ System should only be used by clinicians who are experienced in bronchoscopy and have undergone adequate training with the device.
11. The Alair System should only be used in patients stable enough to undergo bronchoscopy in the judgment of their clinician.
12. Follow local governing ordinances and your institution's biohazard procedures regarding disposal of the Alair Catheter and patient return electrode.

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.

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