ALAIR™

Bronchial Thermoplasty
Radiofrequency Controller Model ATS 200

Boston Scientific
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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.

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 this operator's manual in conjunction with the Alair Catheter Model ATS 2-5 directions for use 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.

Controller/RF Energy Warnings:

1. Do not use RF energy in the presence of flammable anesthesia or other flammable gases, flammable liquids (such as skin prepping agents and tinctures), or flammable objects. Non-flammable agents should be used for cleaning and disinfecting whenever possible. Flammable agents used for cleaning, disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of RF energy.
2. While using this device in oxygen-enriched atmospheres, nitrous oxide (N2O) atmospheres, or in the presence of other oxidizing agents, follow appropriate guidelines for reducing the risk of surgical fires.

Warnings

3. Do not cut a patient return electrode to make it smaller as reducing the size of the patient return electrode may result in patient burns due to high current density.
4. Do not wrap the power cord, patient return electrode cord, or Catheter cable around metal objects as hazardous currents may be induced leading to harm or injury (e.g. shock) to the patient or medical personnel, or fire.
5. While using this device, the patient should not be allowed to come into contact with grounded metal objects as harm or injury to the patient may result. Antistatic sheeting is recommended to prevent the patient from coming into contact with metal parts which are connected to earth or which have an appreciable capacitance to earth.
6. Skin-to-skin contact (e.g. contact between the arms and body of the patient) should be avoided by inserting dry gauze.
7. The electrical cord supplied for the Controller must be connected to a properly grounded receptacle. Do not use extension cords or adapters.
8. Exposing the Controller to liquids may result in harm or injury (e.g. electrical shock) to the patient and/or user or damage to the Controller.
9. Failure of the Controller may result in an unintended increase of output power.
10. When the Controller and physiological monitoring equipment are used simultaneously on the patient, any monitoring electrodes should be placed as far as possible from the patient return electrode. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating high frequency current-limiting devices are recommended.
11. The Controller should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Controller should be observed to verify normal operation in the configuration in which it will be used. When RF energy is delivered, conducted and radiated electrical fields may interfere with other electrical medical equipment stacked with or placed adjacent to the Controller.
12. Do not open the Controller enclosure or tamper with the Controller in any way. Harm or injury (e.g. electrical shock) or damage to the Controller may result. Contact BSC for repair/replacement.
13. Use of the Controller with a non-Alair catheter may result in harm or injury to the patient and/or operator, or may result in product malfunction.
14. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
15. The use of RF energy can produce unintended neuromuscular stimulation. Appropriate precautions, including continuous monitoring of the patient during treatment, should be taken to minimize the risk of patient injury.
16. No modification of this equipment is allowed.

4. Do not use the Catheter if the marker bands are not visible.

Warnings

Catheter Warnings:

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. No modification of this equipment is allowed.

Precautions

Controller/RF Energy Precautions:

1. Alair™ System components and accessories need to be rated for at least the maximum peak output voltage as specified in the Technical Specifications section of this manual. The Catheter designed for use with this Controller is rated for the maximum peak output voltage as specified in the Technical Specifications section of this manual.
2. Use a Valleylab™ E7506, ConMed™ 51-7310, or a similar gel-type patient return electrode that is compliant with the applicable portions of IEC 60601-2-2 and/or CE marked. Use only patient return electrodes indicated for use with adults or patients weighing more than 15 kg (33 lbs).
3. Verify that all oxygen circuit connections are leak-free before and during the use of RF energy. Verify that the endotracheal tube (if used) is leak-free, and that the cuff is properly sealed to prevent oxygen leaks.
4. The RF delivery tones and indicator lights on the front panel are important safety features. Do not obstruct your view of the Controller's front panel.

Precautions

5. Proper placement of a patient return electrode is required for the use of this device. Ensure the entire patient return electrode is securely placed on a suitably prepared area on the patient in accordance with themanufacturer's instructions. Check the patient return electrode before and periodically during system use to ensure that it is in firm contact with the skin, especially whenever the patient is repositioned.
6. The Catheter cable should be positioned in such a way that contact with the patient return electrode cable or other wires is avoided.
7. The Alair System needs special precautions regarding Electromagnetic Compatibility ("EMC"). Portable and mobile communications devices can affect proper operation of the Alair System. The Alair System should be installed and used in accordance with the EMC information provided in this Operator's Manual.
8. The use of components or accessories other than an Alair Catheter, or as suggested by BSC, may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Controller.
9. Follow local governing ordinances and your institution's biohazard procedures egarding disposal of the Alair Controller, Footswitch, and Power Cords.
10. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Alair System, including cables specified by the manufacturer. Otherwise, degradation of the performance of the equipment could result.
11. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting equipment.

Catheter Precautions:

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 re-sterilize, 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.
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.
8. Before delivering energy, make certain that all electrodes are in contact with the airway wall.

Precaution

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:

        i. 4 or more lower respiratory tract infections (LRTI)

        ii. 3 or more hospitalizations for respiratory symptoms

        iii. 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.*

Adverse Events in Pivotal Study

Patient Population
The Alair System was evaluated in a randomized, double-blind, sham-controlled, multi-center clinical study – the Asthma Intervention Research 2 (AIR2) Trial. A total of 297 subjects with severe persistent asthma who were still symptomatic despite being managed on conventional therapy of high dose ICS and LABA were randomized – 196 subjects in the Alair group and 101 subjects in the Sham group. (See the Clinical Data section for key entry criteria.) The Sham procedure was identical to the Alair procedure except that no energy was delivered to the Catheter in the sham procedure.

Safety analyses were performed for the Intent-to-Treat (ITT) population (288 subjects) that consisted of all randomized subjects who have been administered at least one bronchoscopy.

Observed Adverse Events
The safety of the Alair System was assessed by comparing adverse event profiles of the Alair and Sham group subjects. Adverse event profiles are compared for the Treatment Phase (day of first bronchoscopy procedure to 6 weeks after the last bronchoscopy procedure) and Post Treatment Phase (6 weeks after the last bronchoscopy to the 12 month follow-up visit).

Adverse events (whether considered procedure-related or not procedure related by the investigator) occurring with ≥ 3% incidence in the Alair group are presented for 288 patients in Table 3 (ALAIR Bronchial Thermoplasty Radiofrequency Controller Model ATS 200 Operations Manual).

Respiratory adverse events occurring in either the Treatment Phase or in the first year Post-Treatment at a rate of < 3% and ≥ 1% (whether considered procedure-related or not procedure-related by the investigator) in the Alair™ group included 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 occurring in either the Treatment Phase or in the first year Post-Treatment at a rate of < 3% and ≥ 1% (whether considered procedure-related or not procedure-related by the investigator) in the Alair group included 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.

During the Treatment Phase in the AIR2 Trial, there was a transient increase in respiratory adverse events, including asthma (multiple symptoms), upper respiratory tract infection, atelectasis, lower respiratory tract infection, wheezing, hemoptysis, and anxiety in the Alair group compared to the Sham group. There was a lower incidence of throat irritation in the Alair group compared to the Sham group. There were 7 instances of hemoptysis defined as > 5.0 mL (1.3% of bronchoscopies) of which 2 occurred on the day of the procedure, 2 occurred within 3 days, 2 occurred at 2 weeks, and one occurred on Day 31 after the procedure. The greatest amount of hemoptysis observed was a cumulative total of 150 mL that occurred over 5 days and was treated with bronchial artery embolization. During the Treatment Phase (~12 weeks period), the rate of Unscheduled Physician Office visits (events / subject / 12 weeks) in the Alair group was 0.230 compared to 0.133 in the Sham group. The rate of Hospitalizations for respiratory symptoms (events / subject / 12 weeks) was 0.086 in the Alair group compared to 0.028 in the Sham group. The rate of Emergency Room visits for respiratory symptoms (events / subject / 12 weeks) was 0.062 in the Alair group compared to 0.075 in the Sham group. During the Post-Treatment Phase in the AIR2 Trial, there was a lower incidence of respiratory symptoms in the Alair group compared to the Sham group, including a 36% reduction in asthma (multiple symptoms) events and proportion of subjects with asthma (multiple symptoms) events. There was also a lower incidence of influenza, and a greater incidence of nasopharyngitis,