

ESTTA Tracking number: **ESTTA682020**

Filing date: **07/06/2015**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91215699
Party	Defendant Holaira, Inc.
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Filer's e-mail	dhansen@oppenheimer.com, bgrahn@oppenheimer.com, trademarks@oppenheimer.com
Signature	/Dennis Hansen/
Date	07/06/2015
Attachments	Affidavit of Dennis Hansen Introducing Evidence Pursuant to Stipulation.pdf(126650 bytes) Affidavit of Service Dennis Hansen Affidavit.pdf(44208 bytes) Applicant Non-Confidential Exhibit 82 to Affidavit of Dennis Hansen.pdf(190710 bytes) Applicant Non-Confidential Exhibit 83 to Affidavit of Dennis Hansen.pdf(819949 bytes) Applicant Non-Confidential Exhibit 84 to Affidavit of Dennis Hansen.pdf(1030623 bytes) Applicant Non-Confidential Exhibit 85 to Affidavit of Dennis Hansen.pdf(66895 bytes) Applicant Non-Confidential Exhibit 86 to Affidavit of Dennis Hansen.pdf(231486 bytes) Applicant Non-Confidential Exhibit 87 to Affidavit of Dennis Hansen.pdf(198291 bytes) Applicant Non-Confidential Exhibit 88 to Affidavit of Dennis Hansen.pdf(82906 bytes) Applicant Non-Confidential Exhibit 89 to Affidavit of Dennis Hansen.pdf(112824 bytes) Applicant Non-Confidential Exhibit 90 to Affidavit of Dennis Hansen.pdf(106289 bytes) Applicant Non-Confidential Exhibit 91 to Affidavit of Dennis Hansen.pdf(243031 bytes) Applicant Non-Confidential Exhibit 92 to Affidavit of Dennis Hansen.pdf(177058 bytes) Applicant Non-Confidential Exhibit 93 to Affidavit of Dennis Hansen.pdf(234807 bytes) Applicant Non-Confidential Exhibit 94 to Affidavit of Dennis Hansen.pdf(199476 bytes) Applicant Non-Confidential Exhibit 95 to Affidavit of Dennis Hansen.pdf(1403444 bytes) Applicant Non-Confidential Exhibit 97 to Affidavit of Dennis Hansen.pdf(2938775 bytes)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

In the matter of Application Serial No.: 85/806,379
Filed: December 19, 2012
For the mark: HOLAIRA
Published in the *Trademark Official Gazette* on December 3, 2013

Boston Scientific Corporation and
Asthmatx, Inc.

Opposition No. 91215699

Opposers,

v.

**AFFIDAVIT OF
DENNIS HANSEN**

Holaira, Inc.

Applicant.

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

Dennis Hansen, being first duly sworn and warned that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements and the like may jeopardize the validity of this document, states the following:

1. I am an attorney representing Holaira, Inc. (“Applicant”) in the above-captioned matter (“Opposition”).
2. The information contained in this Affidavit is based upon my personal knowledge.
3. Boston Scientific Corp. and Asthmatix, Inc. (“Opposers”) and Applicant entered into a stipulation regarding the submission of evidence in the Opposition (the “Stipulation”), which was executed by Opposers and Applicant on March 3, 2015 and March 6, 2015,

respectively. A copy of the Stipulation was submitted by Opposers as Exhibit 25 to the Affidavit of Timothy D. Sitzmann.

4. The Parties stipulated that the following documents may be admitted into evidence through declaration as reflected in the Stipulation.

5. Attached as Exhibit 82 is a true and correct copy of a document entitled "Answer" and produced at BSC000727 – BSC000731.

6. Attached as Exhibit 83 is a true and correct copy of a document entitled "Alair Directions For Use" and produced at BSC000662 – BSC000675.

7. Attached as Exhibit 84 is a true and correct copy of a document entitled "Alair™ Bronchial Thermoplasty Radiofrequency Controller Model ATS 200 Operator's Manual" and produced at BSC000677 – BSC000692.

8. Attached as Exhibit 85 is a true and correct copy of a screenshot of the BTforAsthma website produced at BSC000794.

9. Attached as Exhibit 86 is a true and correct copy of a screenshot of the BTforAsthma website produced at BSC000797 – BSC000799.

10. Attached as Exhibit 87 is a true and correct copy of a screenshot of the BTforAsthma website produced at BSC000803 – BSC000805.

11. Attached as Exhibit 88 is a true and correct copy of a screenshot of the BTforAsthma website produced at BSC000812 – BSC000813.

12. Attached as Exhibit 89 is a true and correct copy of a screenshot of the BTforAsthma website produced at BSC000814 – BSC000816.

13. Attached as Exhibit 90 is a true and correct copy of a screenshot of the BTforAsthma website produced at BSC000817 – BSC000818.

14. Attached as Exhibit 91 is a true and correct copy of a screenshot of the BTforAsthma website produced at BSC000819 – BSC000821.

15. Attached as Exhibit 92 is a true and correct copy of a screenshot of the BTforAsthma website produced at BSC000822 – BSC000824.

16. Attached as Exhibit 93 is a true and correct copy of a screenshot of the BTforAsthma website produced at BSC000825 – BSC000827.

17. Attached as Exhibit 94 is a true and correct copy of a screenshot of the BTforAsthma website produced at BSC000828 – BSC000829.

18. Attached as Exhibit 95 is a true and correct copy of a document entitled “A New Procedure for Severe Asthma” and produced at BSC000558 – BSC000569.

19. Attached as Exhibit 96 is a true and correct copy of a document entitled “Stratagem Healthcare Communications – Asthmatx” and produced at BSC000623 – BSC000643, (SUBMITTED UNDER SEAL).

20. Attached as Exhibit 97 is a true and correct copy of a document entitled “Trademark Search Report” and produced at BSC000454 – BSC000548.

21. Attached as Exhibit 98 is a true and correct copy of a document entitled “Trademark Coexistence Agreement” and produced at BSC000031 – BSC000063, (SUBMITTED UNDER SEAL).

FURTHER YOUR AFFAIANT SAYETH NOT

Dated: July 6, 2015

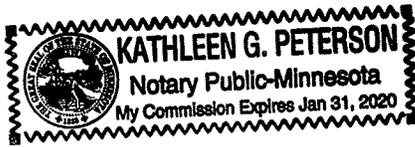


Dennis Hansen

Subscribed and sworn to before me
this 6th day of July, 2015.



Notary Public



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the matter of Application Serial No.: 85/806,379
Filed: December 19, 2012
For the mark: HOLAIRA
Published in the *Trademark Official Gazette* on December 3, 2013

Boston Scientific Corporation and
Asthmatx, Inc.

Opposition No. 91215699

Opposers,

v.

**AFFIDAVIT OF SERVICE
BY UNITED STATES MAIL**

Holaira, Inc.

Applicant.

STATE OF MINNESOTA)
) *ss.*
COUNTY OF HENNEPIN)

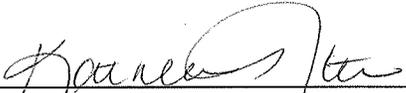
Kathleen Peterson, being first duly sworn upon oath, states that on July 6, 2015, she served the attached:

1. Affidavit of Dennis Hansen (with Exhibits)

upon the within named counsel by United States Mail, using an envelope addressed as set forth below, with postage prepaid, and depositing the same in the United States Mail at Minneapolis, Minnesota:

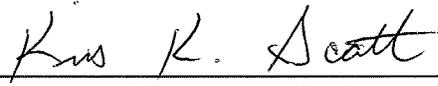
Timothy D. Sitzmann, Esq.
Stephen R. Baird, Esq
Bradley J. Walz, Esq.
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Capella Tower, Suite 3500
225 South Sixth Street
Minneapolis, MN 55402-4629

Attorneys for Opposers

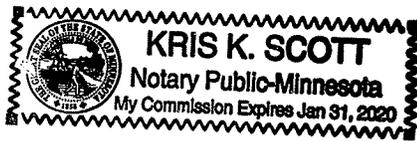


KATHLEEN PETERSON

Subscribed and sworn to before
this 6th day of July, 2015



Notary Public – State of Minnesota



APPLICANT'S EXHIBIT 82

ESTTA Tracking number: **ESTTA304077**

Filing date: **09/01/2009**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92051129
Party	Defendant ASTHMATX, INC.
Correspondence Address	ASTHMATX, INC. 888 Ross Drive, 1st Floor Sunnyvale, CA 94089 UNITED STATES lperry@perryip.com
Submission	Answer
Filer's Name	E. Lynn Perry
Filer's e-mail	lperry@perryip.com
Signature	/elp/
Date	09/01/2009
Attachments	Answer to Pet to Cancel 090901.pdf (4 pages)(38022 bytes)

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

ALERE MEDICAL CORPORATION,)	Cancellation No. 92051129
)	
Petitioner,)	
)	Mark: ALAIR
v.)	Reg. Nos. 2856168 and 3380080
)	
ASTHMATX, INC.,)	
)	
Respondent.)	
)	

ANSWER

ASTHMATX, INC., Respondent, hereby answers the Petition to Cancel filed by ALERE MEDICAL CORPORATION, Petitioner, as follows. Respondent is without sufficient knowledge or information concerning the corporate status and place of business of Petitioner, and on that basis denies the same, and denies that Petitioner is or would be damaged by registration of ALAIR Reg. Nos. 2856168 and 3380080 (the "Registrations"). Further answering, Respondent alleges:

1. Respondent admits the allegations in paragraph 1 of the Petition.
2. Respondent admits the allegations in paragraph 2 of the Petition.
3. Respondent is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 3 of the Petition, and on that basis denies the same.
4. Respondent is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 4 of the Petition, and on that basis denies the same.
5. Respondent admits that copies of print-outs from the USPTO TARR, TESS, and Assignment databases for Reg. Nos. 2659940 and 3530814 are attached to the Petition. Respondent is without knowledge or information sufficient to form a belief as to the truth or

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6. Petitioner is estopped from prevailing in this action by the equitable defense of laches.

7. Petitioner is estopped from prevailing in this action by the equitable defense of acquiescence.

8. Petitioner is estopped from prevailing in this action by the equitable defense of unclean hands in that Petitioner's sole purpose in filing the Petition is to stop Respondent's Reg. No. 2856168 from becoming incontestable and to use the Petition as leverage concerning non-U.S. matters.

WHEREFORE, Respondent prays that the Cancellation be dismissed with prejudice.

Respectfully submitted,



E. Lynn Perry
Attorneys for Respondent
ASTHMATX, INC.

Perry IP Group ALC
4 Embarcadero Center
39th Floor
San Francisco, CA 94111
415-398-6300 (tel.)
415-398-6306 (fax)

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CERTIFICATE OF SERVICE BY MAIL

I am over the age of 18 and not a party to the within action. I am employed in the County of San Francisco, State of California by Perry IP Group ALC. My business address is 4 Embarcadero Center, 39th Floor, San Francisco, California 94111.

On the date indicated below, I served the following entitled document:

ANSWER

by placing a true and correct copy thereof in a sealed envelope addressed as follows:

Charles E. Weinstein, Esq.
Foley Hoag LLP
Seaport West
155 Seaport Boulevard
Boston, MA 02210-2600

I am readily familiar with the firm's business practice for collection and processing of correspondence for mailing with the United States Postal Service. On this day, I placed for collection and processing the above document to be deposited with the United States Postal Service in the ordinary course of business. And in the ordinary course of the firm's business, such correspondence is deposited with the United States Postal Service the same day that it is collected.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on September 1, 2009 at San Francisco, California.



E. Lynn Perry

APPLICANT'S EXHIBIT 83

**Boston
Scientific**

ALAIR™
Bronchial Thermoplasty Catheter

Directions for Use

3

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ALAIR™

Bronchial Thermoplasty Catheter

Rx ONLY

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.

ALAIR BRONCHIAL THERMOPLASTY SYSTEM DESCRIPTION

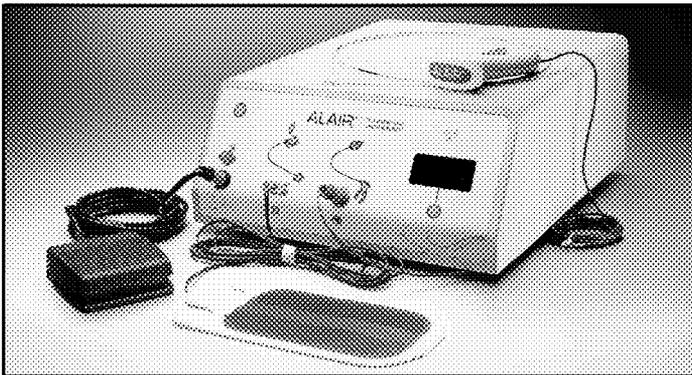


Figure 1. The Alair Bronchial Thermoplasty System

The Alair Bronchial Thermoplasty System ("Alair System"), manufactured by Boston Scientific Corporation, consists of the Alair Catheter and the Alair Controller System, as described below:

Alair Catheter: The Alair Catheter Model ATS 2-5 ("Catheter") is provided sterile and is a SINGLE-USE ONLY, disposable device. The Catheter delivers energy from the Controller to the desired site in the airway and relays temperature feedback to the Controller. The Alair Catheter Model ATS 2-5 is designed to be used with the Alair RF Controller Model ATS 200.

Alair Controller System

Alair Radiofrequency (RF) Controller: The Alair RF Controller Model ATS 200 ("Controller") is designed to provide controlled delivery of RF energy to the Alair Catheter. Energy from the Controller is delivered to the Catheter through the electrical cable attached to the proximal end of the Catheter handle. Actual power delivered is automatically modulated by the Controller based on temperature control algorithms. The Controller delivers low-power, temperature controlled RF energy to the airway at a predetermined temperature setting for a predetermined time period. The Controller incorporates hardware and software features that limit current, voltage, power, energy, time and temperature during each application of RF energy. The Controller is not intended to come in contact with the patient and therefore is not provided as a sterile device. For information on the installation, use, and other technical specifications, please read the Alair Radiofrequency Controller Operator's Manual for Model ATS 200.

Footswitch: The Controller is used with a footswitch that allows the operator to start and stop the delivery of RF energy. The Controller is designed to be used with the compatible footswitch provided by BSC. The footswitch is not intended to come into contact with the patient and therefore is not provided as a sterile device.

Patient Return Electrode: The Controller is designed to be used with a gel-type patient return electrode that is compliant with the applicable portions of IEC 60601-2-2 and/or CE marked. The patient return electrode is used to complete the return path for the electrical current. Use only patient return electrodes indicated for use with adults or patients weighing more than 15 kg (33 lbs). Examples of acceptable patient return electrodes include Valleylab™ E7506 and ConMed™ 51-7310. Follow the directions for use (DFU) packaged with the patient return electrode.

Contents

One (1) ALAIR Catheter Model ATS 2-5

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.

BRONCHOSCOPE REQUIREMENTS

The Catheter is designed to be used with high-frequency compatible flexible bronchoscopes that have a minimum 2.0 mm working channel, and recommended 5.3 mm or less outer diameter.

MECHANISM OF ACTION

Airway smooth muscle (ASM) consists of muscle tissue within the airway walls in the lung. Contraction of the ASM is a main cause of airway constriction that leads to difficulty in breathing during asthma attacks. Severe asthma patients also experience an increase in ASM mass. This increase, together with inflammation of the airways, combines to thicken airway walls, which decreases the inside diameter of the airways when the ASM contracts. The resulting decrease in airway diameter causes increased resistance to airflow and further contributes to difficulty in breathing during asthma attacks.

The Alair™ System is used to deliver thermal energy to the airway wall, to heat the tissue in a controlled manner in order to reduce ASM mass. Bronchial thermoplasty is intended to reduce, debulk, or partially eliminate smooth muscle tissue. In preclinical studies (Danek et al. 2004¹, Brown et al. 2005²), the reduction of ASM has been shown to decrease the ability of the airways to constrict/contract, reduce resistance to airflow and responsiveness of the airway, and increase the resting diameter of the airway.

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.

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 (See Operational Instructions, Figure 5).
- 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 6 and 7).
- 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:
 - 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.

CLINICAL STUDIES

Objectives

The pivotal study was a multi-center, randomized, double-blind, sham-controlled study to demonstrate the safety and effectiveness of the Alair System in a population of subjects with severe asthma.

Effectiveness Endpoints

The primary effectiveness endpoint was the difference between treatment (Alair) and control (Sham) groups in the change in the Asthma Quality of Life Questionnaire (AQLQ) score between baseline and the average of 6-, 9-, and 12-month follow-up visits (integrated AQLQ score). Other endpoints included: rates of severe asthma exacerbations, proportions of patients with severe asthma exacerbations, and days lost from work, school, or other daily activities due to asthma symptoms. In addition, several safety endpoints were considered for effectiveness; these endpoints included rates of asthma (multiple symptoms)* adverse events, Unscheduled Physician Office visits for respiratory symptoms, Emergency Room visits for respiratory symptoms, and Hospitalizations for respiratory symptoms.

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

Methods

This was a multicenter, randomized (2 Alair, 1 Sham), double-blind, sham-controlled clinical trial comparing the effects of treatment with the Alair System to a Sham treatment in subjects that were optimized to conventional therapy of inhaled corticosteroids (ICS) and long-acting β_2 -agonists (LABA). All subjects included in the Study were taking ICS (> 1000 μg beclomethasone or equivalent per day) and LABA (≥ 100 μg salmeterol or equivalent per day), and were still symptomatic. Subjects in the Alair and Sham groups were administered the Alair treatment and Sham bronchoscopies, respectively, by an unblinded bronchoscopy team in 3 separate bronchoscopy sessions. Each bronchoscopy session was separated by at least 3 weeks. All bronchoscopy sessions were administered under local anesthesia with sedation. Subjects had follow-up visits with blinded asthma assessment teams at 6-weeks, 12-weeks, 6-months, 9-months, and 12-months after the final bronchoscopy session. All subjects were prescribed to take 50 mg of oral prednisone or prednisolone (or equivalent) each day for 5 days covering the 3 days before the bronchoscopy session, the day of the bronchoscopy session, and the day after the bronchoscopy session (prophylactic indication).

Statistical Plan

Primary and secondary endpoints, as well as adverse events were analyzed using Bayesian statistics. The Posterior Probability of Superiority was calculated for the primary and secondary endpoints, as well as safety outcomes.

Patient Population

Enrollment was limited to patients with severe persistent asthma who were still symptomatic despite being managed on conventional therapy of high dose ICS and LABA. Subjects may have been taking up to 10 milligrams of oral corticosteroids per day. Study subjects were required to meet the following patient selection criteria:

Key Entry Criteria

Inclusion

1. Adult; age 18-65 years.
2. Asthma requiring regular maintenance medication that includes inhaled corticosteroids (greater than 1000 μg beclomethasone per day or equivalent) and long-acting β_2 -agonists (at least 100 μg salmeterol per day or equivalent), with or without other asthma medications. Oral corticosteroids at a dosage of up to, but not greater than 10 mg per day, or 20 mg every other day are acceptable.
3. Asthma Quality of Life Questionnaire Score during the Baseline Phase of 6.25 or less.
4. Pre-bronchodilator forced expiratory volume in one second $\geq 60\%$ predicted (after patients stabilized on inhaled corticosteroids and long-acting β_2 -agonists during the Baseline Phase).
5. Non-smoker x 1 year or greater (if former smoker, less than 10 pack years total smoking history).

Exclusion

1. Post-bronchodilator FEV₁ < 65% predicted.
2. Three or more hospitalizations for exacerbations of asthma in the previous year; OR a history of life-threatening asthma, defined by past intubations for asthma, or intensive care unit admission for asthma within the prior 24 months.
3. History of recurrent lower respiratory tract infection requiring antibiotics (more than 3 in the past 12-Months).
4. History of recurrent oral steroid use for asthma (4 or more pulses of oral steroids in the past 12-Months).

Demographics

A total of 297 subjects between the ages of 18 and 65 were enrolled and randomized (2 Alair: 1 Sham) in this study. One hundred and ninety (190) subjects received the Alair treatment and 98 subjects received the Sham control treatment (Intent-to-Treat population). The Sham procedure was identical to the Alair procedure except that no energy was delivered through the Catheter.

There were no statistical differences in demographic measures between the Alair and Sham groups. Subject demographics are described in Table 1.

	Alair (n=190)	Sham (n=98)
Age (years) (Mean ± SD)	41 ± 12	41 ± 12
Gender		
Male	81 (43%)	38 (39%)
Female	109 (57%)	60 (61%)
Race/Ethnicity		
Caucasian	151 (80%)	72 (74%)
African American / Black	19 (10%)	15 (15%)
Hispanic	6 (3%)	4 (4%)
Asian	4 (2%)	1 (1%)
Other	10 (5%)	6 (6%)
Height (cm) (Mean ± SD)	167 ± 9	167 ± 10
Weight (kg) (Mean ± SD)	82 ± 18	82 ± 20

Table 1: Subject Demographics (Intent-to-Treat Population)

Effectiveness Results

Effectiveness analyses were performed for both the Intent-to-Treat (ITT) population and Per-Protocol (PP) population. The ITT population consisted of all randomized subjects who have been administered at least one bronchoscopy. The PP population excluded all subjects in the ITT population who met any of the following criteria:

- Have taken any interfering concomitant medications.
- Have undergone other interfering treatments.
- Did not attend one of the 6-, 9-, 12-month visits, with the exception of a discontinuation from the Study due to an adverse event related to Study treatment.
- Had missed one or more bronchoscopy procedures.

Effectiveness Endpoints

Although the clinical study was powered only for the primary effectiveness endpoint (see below), several effectiveness endpoints and safety endpoints that could also be considered effectiveness endpoints demonstrated clinically meaningful differences in favor of the Alair group compared to the Sham group. The effectiveness endpoints were rates of severe asthma exacerbations, proportions of patients with severe asthma exacerbations, and days lost from work, school, or other daily activities due to asthma symptoms. The safety endpoints considered for effectiveness were rates of asthma, emergency room visits for respiratory symptoms, and hospitalization rates for respiratory symptoms.

Steroid Exacerbations^a (Severe Exacerbations Requiring Systemic Corticosteroids) (ITT Population)

During the Post-Treatment Phase, the severe exacerbation rate for the Steroid Exacerbations was 0.48 exacerbations/subject/year in the Alair group and 0.70 exacerbations/subject/year in the Sham group [95% CI (Sham - Alair): -0.031, 0.520]. During the Post-Treatment Phase, the proportion of subjects experiencing Steroid Exacerbations was 26% in the Alair group and 40% in the Sham group [95% CI (Sham - Alair): 2.1%, 25.1%].

Steroid Exacerbation rates (annualized rate) and proportion of patients experiencing Severe Exacerbations for the Post-Treatment Phase are presented graphically in Figure 2.

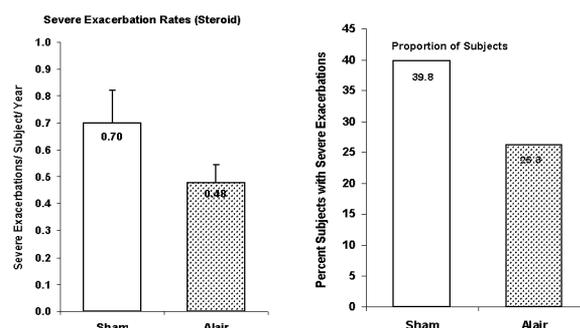


Figure 2: Severe Exacerbations during the Post-Treatment Phase

^a**Steroid Exacerbations** = Exacerbations treated with oral or intravenous corticosteroids, OR a doubling of the baseline inhaled corticosteroid dose for at least 3 days, OR any temporary increase in the dosage of oral corticosteroids for a subject taking maintenance oral corticosteroids at Study entry.

Annualized rates of exacerbations per subject are extrapolated from the 46 week Post-Treatment Phase from 6 weeks after the last bronchoscopy procedure to the 12 month follow-up visit.

Days Lost from Work, School, or Other Daily Activities due to Asthma Symptoms (ITT Population)

During the Post-Treatment Phase, subjects in the Alair group lost an average of 1.3 days/year/subject from work, school, or other daily activities due to asthma symptoms, compared to the Sham group that lost 3.9 days/year/subject (annualized rates per subject are extrapolated from the 46 week Post-Treatment Phase from 6 weeks after the last bronchoscopy procedure to the 12 month follow-up visit) [95% CI (Sham - Alair): 0.425, 6.397].

Safety Endpoints that Demonstrated Effectiveness

Measures such as Emergency Room visits and Hospitalizations for respiratory symptoms are generally considered to be important measures of safety, especially if an intervention results in an increase in the rate of one or more of these events. However, these measures can also be considered important measures of effectiveness if an intervention results in a measurable decrease in the rate of one or more of these events. During longer-term follow-up (> 6 weeks after the last Alair™ treatment), there was a reduction in asthma (multiple symptoms) adverse events [95% CI (Sham - Alair): -0.01, 0.001], Emergency Room visits for respiratory symptoms [95% CI (Sham - Alair): 0.11, 0.83], and Hospitalizations for respiratory symptoms (event rate per group) [95% CI (Sham - Alair): 0.025, 0.172], presented graphically in Figure 3.

There was a reduction in the proportion of subjects having asthma (multiple symptoms) adverse events [95% CI (Sham - Alair): 4.0%, 27.3%], and in the proportion of subjects having Emergency Room visits for respiratory symptoms in the Alair group (3.7% in the Alair group compared to 15.3% in the Sham group) [95% CI (Sham - Alair): 4.6%, 19.7%].

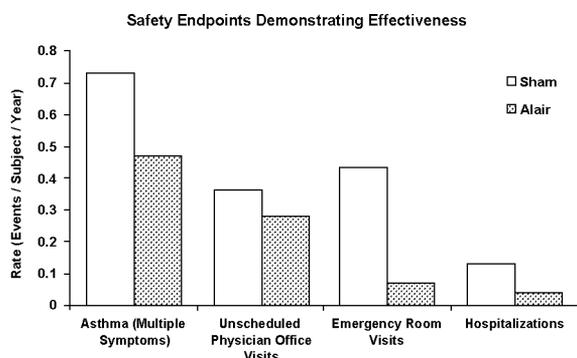


Figure 3: Safety Endpoints demonstrating Effectiveness (ITT Population)

Primary Effectiveness Endpoint – Integrated AQLQ Score

The difference between the Alair and Sham groups in the average change in AQLQ score from Baseline at the 6-, 9-, and 12-month follow-up visits was 0.210 [95% CI (Alair - Sham): -0.025, 0.445]. The pre-specified Posterior Probability of Superiority for the difference between the groups was 96.4%. For the ITT population, the difference between the groups had a Posterior Probability of Superiority of 96.0%, and for the PP population, the difference between the groups had a Posterior Probability of Superiority of 97.9%, demonstrating an improvement in the Asthma Quality of Life in the Alair group compared to Sham. The results for the change from Baseline of the Integrated AQLQ score for the Intent-to-Treat and Per Protocol populations are summarized in Table 2.

Population	Difference Between Groups in Integrated AQLQ Score (Posterior Mean, 95% CI)	Posterior Probability of Superiority (%)
ITT (Intent-to-Treat) (Alair N=190, Sham N=98)	0.210 (-0.025, 0.445)	96.0
PP (Per Protocol) (Alair N=173, Sham N=95)	0.244 (0.009, 0.478)	97.9

Table 2: Primary Effectiveness Endpoint: Integrated AQLQ Score

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.

Adverse Event	Treatment*		Post-Treatment**	
	Alair (N=190) %	Sham (N=98) %	Alair (N=187) %	Sham (N=98) %
Average duration of period (days)	84		322	
Ear, Nose, and Throat				
Upper respiratory tract infection	20	11	30	26
Nasopharyngitis	5	7	11	5
Throat irritation	5	12	1	3
Viral upper respiratory tract infection	4	2	6	7
Sinusitis	3	5	6	7
Acute Sinusitis	3	2	4	8
Pharyngolaryngeal pain	3	5	1	2
Allergic rhinitis	2	3	4	4
Rhinitis	2	0	4	6
Lower Respiratory				
Asthma (Multiple Symptoms)	52	39	27	43
Wheezing	15	6	4	3
Chest pain	14	13	3	1
Cough	12	14	3	5
Dyspnea	11	6	2	1
Chest discomfort	9	10	2	1
Lower respiratory tract infection	8	2	3	6
Productive cough	7	9	3	4
Atelectasis	5	0	0	0
Bronchitis	4	2	7	5
Hemoptysis	3	0	0	0
Neurology				
Headaches	14	9	5	3
Anxiety	4	0	1	2
Gastrointestinal				
Dyspepsia	4	2	2	4
Nausea	3	4	1	1

Adverse Event	Treatment*		Post-Treatment**	
	Alair (N=190) %	Sham (N=98) %	Alair (N=187) %	Sham (N=98) %
Non-site specific				
Influenza	4	2	4	12
Pyrexia (fever)	4	2	0	1
Other				
Back pain	5	6	3	5
Hypertension	3	2	3	3
Urinary tract infection	1	1	3	1

Table 3: Adverse Events with ≥ 3% Incidence (% of subjects) in the Alair Group

* Treatment phase represents adverse events reported between the first bronchoscopy and 6-weeks post last bronchoscopy.

** Post-Treatment phase represents adverse events reported between 6-weeks post last bronchoscopy and the 12 month visit.

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, in the Alair group compared to the Sham group.

High Resolution Computed Tomography (HRCT) Results

In the 150 subjects (100 Alair group and 50 Sham group) assigned to HRCT scan examinations, at 1-year, there were no difference in signs of gas trapping or consolidation and there was no evidence of bronchiectasis. A difference was seen in bronchial wall thickening without gas trapping which occurred only in the Sham subjects (4%).

Summary of Clinical Findings

Results from the clinical study which evaluated the effectiveness and safety of the Alair™ System in subjects with severe asthma demonstrated that Alair treatment resulted in clinically significant reductions in severe exacerbations that required systemic steroids, the percent of subjects experiencing the severe exacerbations, the number of Emergency Room visits for respiratory symptoms, the percent of subjects experiencing Emergency Room visits for respiratory symptoms, Hospitalizations for respiratory symptoms, and days lost from school/work/other daily activities due to asthma symptoms. Although bronchial thermoplasty was associated with an increased rate of respiratory adverse events during the Treatment Phase (primarily related to asthma), in the Post-Treatment Phase, a smaller proportion of patients treated with bronchial thermoplasty experienced respiratory adverse events, including asthma (multiple symptoms).

HOW SUPPLIED

The Alair Bronchial Thermoplasty System Catheter Model ATS 2-5 is supplied sterile and is for SINGLE USE ONLY. 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. Store in a cool, dry, dark place. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible. Rotate inventory so that product is used prior to the expiration date on package label.

OPERATIONAL INSTRUCTIONS

Alair Catheter Inspection and Preparation

1. The Alair System should only be used by a physician trained in bronchoscopy. These instructions do not explain bronchoscopic procedures.
2. Please read the Operator's Manual for the Alair RF Controller Model ATS 200 before beginning the procedure.
3. Visually inspect the package for damage before removing the Catheter from the package. Do not use the Catheter if the package is damaged or has been previously opened or torn.

4. Aseptically remove the Catheter from the package tray and inspect for any damage. The Catheter is packaged with the electrode array retracted within the protective, removable orange-colored Catheter tip sheath. Before use, remove the protective orange sheath. Inspect the Catheter for any damage such as broken or crushed areas of the Catheter, sharp or protruding edges at the distal tip, or any excessive bends or kinks in the Catheter shaft. Do not use the Catheter if any damage or irregularity is found. See Figure 4.

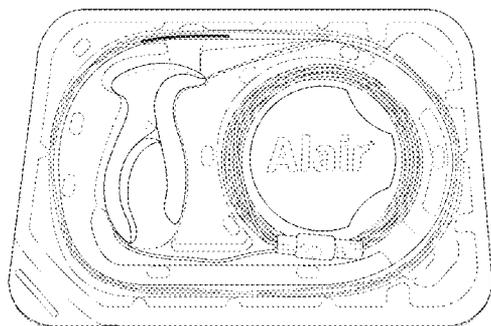


Figure 4. Alair™ Catheter in Tray

5. The distal portion of the Catheter shaft has marker bands that are spaced 5 mm apart to aid in the positioning of the Catheter electrode array. Do not use the Catheter if the marker bands are not visible. See Figure 5.

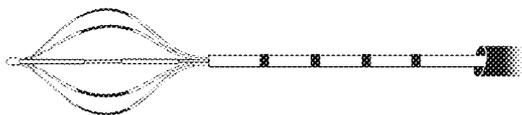


Figure 5. Alair Catheter with its four Marker Bands, spaced 5 mm apart

6. Hold the Catheter handle in the palm of your hand, with the thumb and forefinger just below the Alair logo. Then, squeeze the forward handle back towards the back handle, ensuring that the electrode array expands properly. Verify that the electrode array opens fully and evenly. See Figure 6.

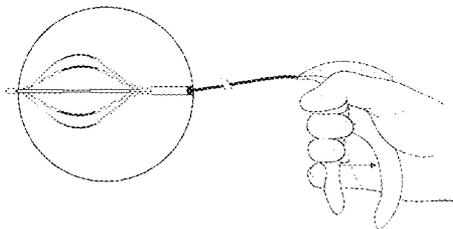


Figure 6: Alair Catheter Electrode Array Expanded

7. Relax the electrode array by releasing the front handle. See Figure 7. Do not use the Catheter if the electrode array does not expand or relax properly.

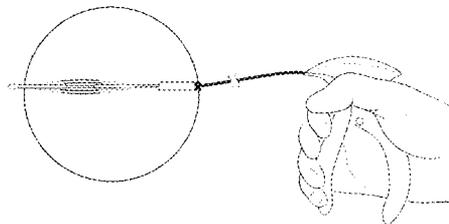


Figure 7: Alair Catheter Electrode Array Relaxed

Alair Bronchial Thermoplasty System Set-up and Operation

The Alair Catheter is intended to be used in conjunction with the Alair Controller. Please read the Alair RF Controller Model ATS 200 Operator's Manual before using the Alair System.

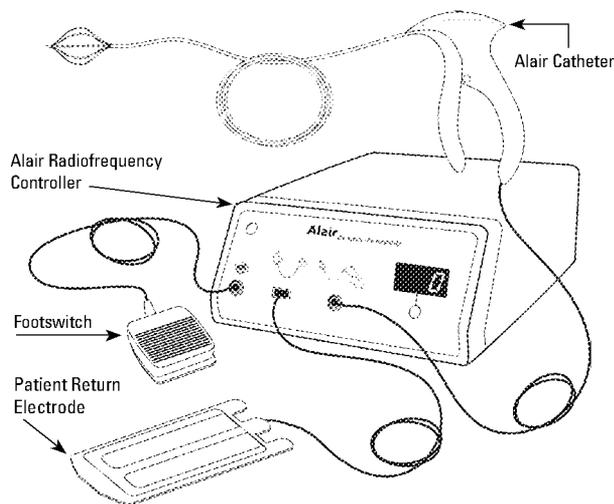


Figure 8: Alair RF Controller Model ATS 200 set up

Consult the Alair RF Controller Model ATS 200 Operator's Manual for specific instructions on:

- Controller Installation;
- Controller Power-Up;
- Connection of Components and Accessories;
- Controller Modes;
- Periodic Maintenance and Repair;
- Troubleshooting; and
- Technical Specifications.

Patient Preparation

1. Administer prophylactic prednisone or equivalent at a dosage of 50 mg/day for the 3 days before the procedure, the day of the procedure and the day after the procedure to minimize post procedure inflammation.

2. Pre-procedure spirometry: On the day of procedure, perform a post-bronchodilator (BD) FEV₁ to assess patient stability pre and post procedure. Pre-procedure FEV₁ value should be greater than or equal to 85% of normal value.
3. Verify the patient remains a good candidate for bronchoscopy under moderate sedation prior to initiation of the procedure (Mayse et al 2007)⁵. Postpone the procedure if any of the following conditions apply:
 - Prescribed prednisone was not taken on the 3 days before bronchoscopy.
 - SpO₂ is less than 90% on room air.
 - Increase in asthma symptoms in last 48 hours requiring more than 4 puffs/day on average of rescue bronchodilator over pretreatment usage.
 - Asthma exacerbation or changing dose of systemic corticosteroids for asthma (up or down) in the past 14 days.
 - Active respiratory infection, active allergic sinusitis, or other clinical instability.
 - Physician feels for any reason the procedure should be postponed.
4. Prepare the patient for bronchoscopy. Administration of an anticholinergic (glycopyrrolate or atropine) is recommended to reduce airway secretions during procedure to improve visibility. Follow patient management protocols according to staffing, training, and individual institution-specific policies and guidelines for bronchoscopy.
5. Place the patient return electrode securely on the patient in accordance with manufacturer's instructions.
6. Introduce the flexible bronchoscope through the nose or mouth as appropriate. See Figure 9 below.

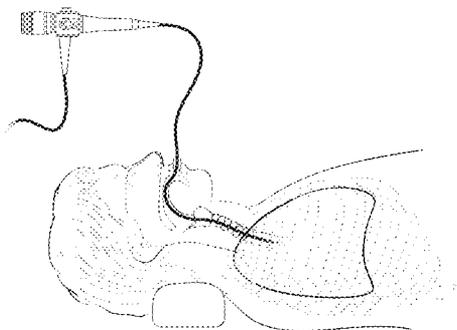


Figure 9: Bronchoscope navigation into patient's airways

7. Navigate the bronchoscope to the targeted site and position the bronchoscope so that the targeted site is in bronchoscopic view.

Alair™ Catheter Use

1. Before inserting the Catheter into the bronchoscope, ensure the Catheter is connected, the Controller is set up properly, and the electrode array is relaxed.
2. Advance the Catheter into the bronchoscope working channel being careful not to kink the Catheter shaft. Kinking of the Catheter shaft could result in failure of the Catheter electrode array to open fully in tortuous anatomy. See PRECAUTIONS.

3. Avoid deflecting the bronchoscope while the electrode array is within the bend of the bronchoscope's working channel as this could result in damage to the Catheter and failure of the Catheter to operate properly. See PRECAUTIONS.
4. Advance the Catheter through the bronchoscope until the distal tip of the Catheter shaft is in bronchoscopic view. If the device encounters significant resistance during insertion, do not force it. In especially tortuous anatomy it may be necessary to relax the bronchoscope's deflection mechanism until the device passes smoothly. See Figure 10 below.

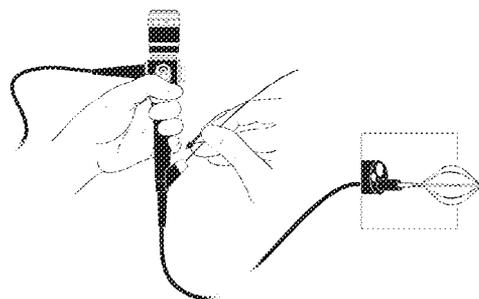


Figure 10: Alair Catheter introduced through working channel of bronchoscope

5. Advance the Catheter to the targeted site under bronchoscopic vision. Do not advance the Catheter into bronchi in which the Catheter cannot be seen under bronchoscopic vision. Advancing the Catheter under such conditions may result in pneumothorax, pneumomediastinum or other harm or injury to the patient. See WARNINGS.
6. 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). See WARNINGS.
7. Do not reposition the bronchoscope with the Catheter advanced beyond the distal end of the bronchoscope as this may result in harm or injury to the patient. See WARNINGS.
8. Once at the targeted site, squeeze the handle together to expand the electrode array partially so that the electrodes are close to or just touching the targeted site. With the electrode array partially expanded, adjust the axial position of the electrodes in the airway to position the active electrodes (exposed 5 mm center region of the array electrodes) as desired. Expand the array until all four electrodes firmly contact the airway wall. *Do not over-expand the electrode array* as this may cause one or more of electrodes to deploy inward or 'invert'. In most cases, contact with the airway wall will NOT require the Catheter handle to be squeezed completely. If an electrode inverts, relax the electrode array and then re-expand the array in a large, straight airway, confirming proper deployment before returning to the area being treated.
9. Proper contact of the electrodes with the airway wall should be confirmed visually. See Figure 11.

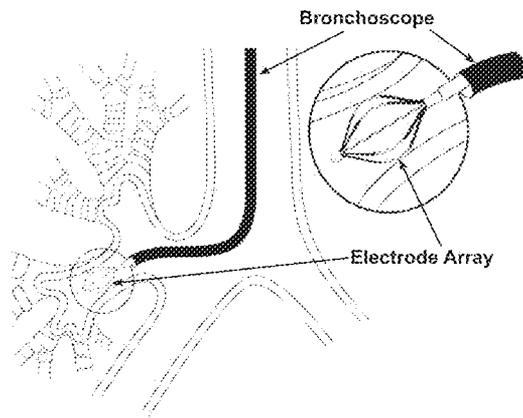


Figure 11: Alair™ Catheter in the Airway

10. Before delivering RF energy, make certain that all electrodes are in contact with the airway wall. See PRECAUTIONS.
11. Deliver RF energy to the targeted region by pressing and releasing the footswitch once. The Controller will deliver energy automatically according to preset parameters for time, energy, power, and temperature.
12. To manually terminate RF energy delivery, if necessary, press and release the footswitch again.

Note: The Controller will automatically shut off the RF energy if it detects atypical energy delivery or temperature response.

13. The Controller is programmed to alert the user with both audible and visual cues if re-deployment of the electrode array or replacement of the Catheter is required. Please refer to the Alair RF Controller Model ATS 200 Operator's Manual for more detailed instructions on these audible sounds and light displays.

Note: If RF energy delivery ends prematurely, it may be necessary to re-deploy the electrode array and begin RF energy delivery again. If the problem persists, replace the Catheter.

14. Reposition the Catheter and repeat the steps above making 5 mm proximally placed contiguous treatments. The Catheter's marker bands are spaced 5 mm apart to assist with contiguous placement. See Figure 12.

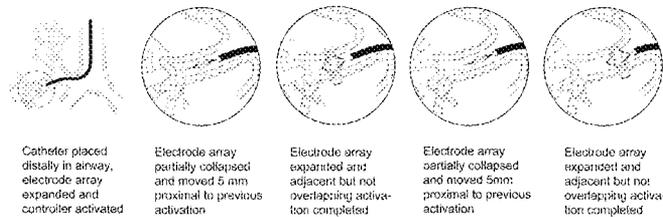


Figure 12: Contiguous Placement and Activation

15. It may be necessary to clean the electrode array if accumulated material on the array impairs visibility. To clean the electrode array follow these steps:
 - Remove the Catheter from the bronchoscope.
 - Expand the electrode array and vigorously swish the electrode array in a sterile container filled with ROOM TEMPERATURE saline.
 - DO NOT CLEAN THE ARRAY WITH COLD SALINE as this may trigger the Catheter failure alarm.
 - If further cleaning is necessary, wipe the array gently using a cotton swab or gauze.
16. Once the procedure is complete, relax the Catheter handle to relax the electrode array before removing the Catheter from the bronchoscope or before withdrawing the Catheter into the bronchoscope for airway navigation. To manipulate the bronchoscope with the Catheter in the working channel, withdraw the Catheter approximately 10 cm into the bronchoscope so the electrode array is proximal to the bend in the distal tip of the bronchoscope.
17. Once the treatment is complete, remove the Catheter from the bronchoscope. Disconnect the Catheter from the Controller, and dispose of the used Catheter per your institution's biohazard procedures. Remove the return electrode from the patient. Disconnect the patient return electrode from the Controller, and dispose of the patient return electrode per your institution's biohazard procedures.

Post Procedure Care

1. Follow appropriate institutional guidelines for post procedure care. It is recommended that patients should be carefully monitored and discharged only after they are deemed to be stable and have adequate (comparable to pre-procedure) lung function, mental status, and are able to adequately take liquids.
2. Recommended post procedure assessments are based on the criteria that were used in clinical trials of bronchial thermoplasty (Mayse et al 2007) and include:
 - 2 to 4 hour recovery/monitoring period following each procedure
 - Spirometry, breath sounds, and vital signs (heart rate, blood pressure, temperature, respiratory rate, pulse oximetry) before discharge
 - Discharge if post bronchodilator FEV₁ is within 80% of the pre procedure value and patient is feeling well
 - Verify patient has gag reflex and is able to take liquids
 - Remind patient to take prophylactic prednisone or equivalent the day following bronchoscopy
 - Caution patient about the potential adverse events that they might experience including hemoptysis, fever, cough, and worsening of asthma symptoms. Patients should be advised to consult their physician if they experience any of these adverse events, or asthma symptoms that are not controlled by their reliever medications.
 - Contact patient via phone calls at 1, 2 and 7 days to assess post procedure status
 - Office visit at 2 to 3 weeks to assess clinical stability and schedule subsequent bronchial thermoplasty procedures as appropriate

MAINTENANCE AND TROUBLESHOOTING

- If mucus builds up in the airways and obscures visualization, remove the Catheter from the bronchoscope, provide irrigation with sterile saline, and suction the resulting fluid from the airways.
- If the Catheter handle alarm (red light) appears on the Controller front panel the Catheter should be replaced. The only exception to this instruction occurs if the Catheter electrode array has been exposed to a low (<16 °C) temperature. In these limited cases (e.g., cleaning the array in iced saline or exposing a wet array to cold air resulting in evaporative cooling) the electrode array should be returned to room temperature and the Catheter connector should be unplugged and re-connected to the Controller. If the Catheter handle alarm persists, replace the Catheter and continue with the bronchial thermoplasty procedure.
- If the electrode array does not expand or relax properly, remove the Catheter from the bronchoscope and squeeze and relax the Catheter handle to visually confirm that the electrode array is functioning properly. If it is not functioning properly, replace the Catheter and continue with the bronchial thermoplasty procedure.
- If you are alerted to auditory or visual cues from the Controller, consult the Alair™ Bronchial Thermoplasty RF Controller Model ATS 200 Operator's Manual for operating and troubleshooting guidelines for the Controller.
- If an electrode inverts, relax the electrode array and then re-expand the array in a large, straight airway, confirming proper deployment before returning to the area being treated. In most cases, contact with the airway wall will NOT require the Catheter handle to be squeezed completely.

REFERENCES

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- 3 Mayse ML, Laviolette M, Rubin AS, Lampron N, Simoff M, Duhamel D, Musani, AI, Yung RC, Mehta AC. Clinical Pearls for Bronchial Thermoplasty. *J Bronchol.* 2007, 14:115-123.

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WARRANTY

Catheter - Warranty

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APPLICANT'S EXHIBIT 84

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Model ATS 200

Operator's Manual

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ALAIR™

Bronchial Thermoplasty Radiofrequency Controller

Rx ONLY

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



FOR PROFESSIONAL USE ONLY

The Alair Radiofrequency Controller must be used by a physician who has training and experience in performing bronchoscopic procedures.

ALAIR BRONCHIAL THERMOPLASTY SYSTEM DESCRIPTION

This Operator's Manual provides instructions for using the Alair Radiofrequency (RF) Controller Model ATS 200. The Alair RF Controller Model ATS 200 is intended to be used with the Alair Catheter. The Alair RF Controller is designed to provide controlled delivery of radiofrequency energy to the Alair Catheter.

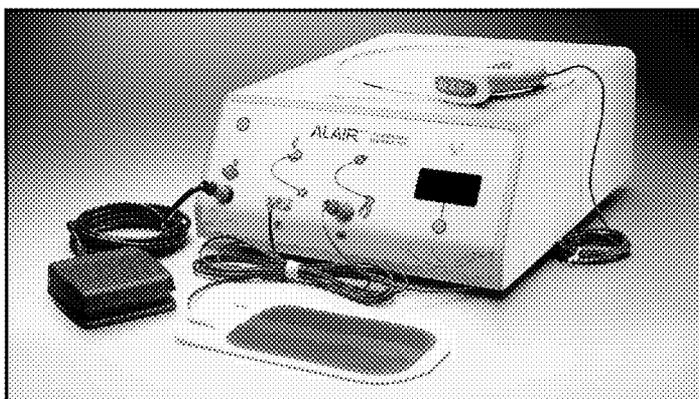


Figure 1. The Alair Bronchial Thermoplasty System

The Alair Bronchial Thermoplasty System ("Alair System"), manufactured by Boston Scientific Corporation (BSC), consists of the Alair Controller System and the Alair Catheter, as described below:

Alair Controller System

Alair Radiofrequency (RF) Controller: The Alair RF Controller Model ATS 200 ("Controller") is designed to provide controlled delivery of RF energy to the Alair Catheter. Energy from the Controller is delivered to the Catheter through the electrical cable attached to the proximal end of the Catheter handle. Actual power delivered is automatically modulated by the Controller based on temperature control algorithms. The Controller delivers low-power, temperature-controlled RF energy to the airway at a predetermined temperature setting for a predetermined time period. The Controller incorporates hardware and software features that limit current, voltage, power, energy, time and temperature during each application of

RF energy. The Controller is not intended to come in contact with the patient and therefore is not provided as a sterile device.

Footswitch: The Controller is used with a footswitch that allows the operator to start and stop the delivery of RF energy. The Controller is designed to be used with the compatible footswitch provided by BSC. The footswitch is not intended to come into contact with the patient and therefore is not provided as a sterile device.

Patient Return Electrode: The Controller is designed to be used with a gel-type patient return electrode that is compliant with the applicable portions of IEC 60601-2-2 and/or CE marked. The patient return electrode is used to complete the return path for the electrical current. Use only patient return electrodes indicated for use with adults or patients weighing more than 15 kg (33 lbs). Examples of acceptable patient return electrodes include Valleylab™ E7506 and ConMed™ 51-7310. Follow the directions for use (DFU) packaged with the patient return electrode.

Alair Catheter

The Alair Catheter Model ATS 2-5 ("Catheter") is provided sterile and is a SINGLE-USE ONLY, disposable device. The Catheter delivers energy from the Controller to the desired site in the airway and relays temperature feedback to the Controller. The Alair Catheter Model ATS 2-5 is designed to be used with the Alair RF Controller Model ATS 200. For information on the preparation, use and other technical specifications, please refer to the Alair Catheter directions for use (DFU) that is supplied with Model ATS 2-5.

Contents

- One (1) Alair Radiofrequency Controller Model ATS 200
- One (1) Alair Radiofrequency Controller Accessory Kit Model ATS 201
 - One (1) Footswitch
 - One (1) Power cord

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.

MECHANISM OF ACTION

Airway smooth muscle (ASM) consists of muscle tissue within the airway walls in the lung. Contraction of the ASM is a main cause of airway constriction that leads to difficulty in breathing during asthma attacks. Severe asthma patients also experience an increase in ASM mass. This increase, together with inflammation of the airways, combines to thicken airway walls, which decreases the inside diameter of the airways when the ASM contracts. The resulting decrease in airway diameter causes increased resistance to airflow and further contributes to difficulty in breathing during asthma attacks.

The Alair System is used to deliver thermal energy to the airway wall, to heat the tissue in a controlled manner in order to reduce ASM mass. Bronchial thermoplasty is intended to reduce, debulk, or partially eliminate smooth muscle tissue. In preclinical studies (Danek et al. 2004¹, Brown et al. 2005²), the reduction of ASM has been shown to decrease the ability of the airways to constrict/contract, reduce resistance to airflow and responsiveness of the airway, and increase the resting diameter of the airway.

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.
- 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.

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.

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.
- 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 the manufacturer'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 regarding disposal of the Alair Controller, Footswitch, and Power Cords.

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.

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.

CLINICAL STUDIES

Objectives

The pivotal study was a multi-center, randomized, double-blind, sham-controlled study to demonstrate the safety and effectiveness of the Alair System in a population of subjects with severe asthma.

Effectiveness Endpoints

The primary effectiveness endpoint was the difference between treatment (Alair) and control (Sham) groups in the change in the Asthma Quality of Life Questionnaire (AQLQ) score between baseline and the average of 6-, 9-, and 12-month follow-up visits (integrated AQLQ score). Other endpoints included: rates of severe asthma exacerbations, proportions of patients with severe asthma exacerbations, and days lost from work, school, or other daily activities due to asthma symptoms. In addition, several safety endpoints were considered for effectiveness; these endpoints included rates of asthma (multiple symptoms)* adverse events, Unscheduled Physician Office visits for respiratory symptoms, Emergency Room visits for respiratory symptoms, and Hospitalizations for respiratory symptoms.

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

Methods

This was a multicenter, randomized (2 Alair, 1 Sham), double-blind, sham-controlled clinical trial comparing the effects of treatment with the Alair System to a Sham treatment in subjects that were optimized to conventional therapy of inhaled corticosteroids (ICS) and long-acting β_2 -agonists (LABA). All subjects included in

the Study were taking ICS (> 1000 µg beclomethasone or equivalent per day) and LABA (≥ 100 µg salmeterol or equivalent per day), and were still symptomatic.

Subjects in the Alair and Sham groups were administered the Alair treatment and Sham bronchoscopies, respectively, by an unblinded bronchoscopy team in 3 separate bronchoscopy sessions. Each bronchoscopy session was separated by at least 3 weeks. All bronchoscopy sessions were administered under local anesthesia with sedation. Subjects had follow-up visits with blinded asthma assessment teams at 6-weeks, 12-weeks, 6-months, 9-months, and 12-months after the final bronchoscopy session.

All subjects were prescribed to take 50 mg of oral prednisone or prednisolone (or equivalent) each day for 5 days covering the 3 days before the bronchoscopy session, the day of the bronchoscopy session, and the day after the bronchoscopy session (prophylactic indication).

Statistical Plan

Primary and secondary endpoints, as well as adverse events were analyzed using Bayesian statistics. The Posterior Probability of Superiority was calculated for the primary and secondary endpoints, as well as safety outcomes.

Patient Population

Enrollment was limited to patients with severe persistent asthma who were still symptomatic despite being managed on conventional therapy of high dose ICS and LABA. Subjects may have been taking up to 10 milligrams of oral corticosteroids per day. Study subjects were required to meet the following patient selection criteria:

Key Entry Criteria

Inclusion

1. Adult; age 18-65 years.
2. Asthma requiring regular maintenance medication that includes inhaled corticosteroids (greater than 1000 µg beclomethasone per day or equivalent) and long-acting β₂-agonists (at least 100 µg salmeterol per day or equivalent), with or without other asthma medications. Oral corticosteroids at a dosage of up to, but not greater than 10 mg per day, or 20 mg every other day are acceptable.
3. Asthma Quality of Life Questionnaire Score during the Baseline Phase of 6.25 or less.
4. Pre-bronchodilator forced expiratory volume in one second ≥ 60% predicted (after patients stabilized on inhaled corticosteroids and long-acting β₂-agonists during the Baseline Phase).
5. Non-smoker x 1 year or greater (if former smoker, less than 10 pack years total smoking history).

Exclusion

1. Post-bronchodilator FEV₁ < 65% predicted.
2. Three or more hospitalizations for exacerbations of asthma in the previous year; OR a history of life-threatening asthma, defined by past intubations for asthma, or intensive care unit admission for asthma within the prior 24 months.
3. History of recurrent lower respiratory tract infection requiring antibiotics (more than 3 in the past 12-Months).
4. History of recurrent oral steroid use for asthma (4 or more pulses of oral steroids in the past 12-Months).

Demographics

A total of 297 subjects between the ages of 18 and 65 were enrolled and randomized (2 Alair: 1 Sham) in this study. One hundred and ninety (190) subjects received the Alair treatment and 98 subjects received the Sham control treatment (Intent-to-Treat population). The Sham procedure was identical to the Alair procedure except that no energy was delivered through the Catheter.

There were no statistical differences in demographic measures between the Alair and Sham groups. Subject demographics are described in Table 1.

	Alair (n=190)	Sham (n=98)
Age (years) (Mean ± SD)	41 ± 12	41 ± 12
Gender		
Male	81 (43%)	38 (39%)
Female	109 (57%)	60 (61%)
Race/Ethnicity		
Caucasian	151 (80%)	72 (74%)
African American / Black	19 (10%)	15 (15%)
Hispanic	6 (3%)	4 (4%)
Asian	4 (2%)	1 (1%)
Other	10 (5%)	6 (6%)
Height (cm) (Mean ± SD)	167 ± 9	167 ± 10
Weight (kg) (Mean ± SD)	82 ± 18	82 ± 20

Table 1: Subject Demographics (Intent-to-Treat Population)

Effectiveness Results

Effectiveness analyses were performed for both the Intent-to-Treat (ITT) population and Per-Protocol (PP) population. The ITT population consisted of all randomized subjects who have been administered at least one bronchoscopy. The PP population excluded all subjects in the ITT population who met any of the following criteria:

- Have taken any interfering concomitant medications.
- Have undergone other interfering treatments.
- Did not attend one of the 6-, 9-, 12-month visits, with the exception of a discontinuation from the Study due to an adverse event related to Study treatment.
- Had missed one or more bronchoscopy procedures.

Effectiveness Endpoints

Although the clinical study was powered only for the primary effectiveness endpoint (see below), several effectiveness endpoints and safety endpoints that could also be considered effectiveness endpoints demonstrated clinically meaningful differences in favor of the Alair group compared to the Sham group. The effectiveness endpoints were rates of severe asthma exacerbations, proportions of patients with severe asthma exacerbations, and days lost from work, school, or other daily activities due to asthma symptoms. The safety endpoints considered for effectiveness were rates of asthma, emergency room visits for respiratory symptoms, and hospitalization rates for respiratory symptoms.

Steroid Exacerbations^a (Severe Exacerbations Requiring Systemic Corticosteroids) (ITT Population)

During the Post-Treatment Phase, the severe exacerbation rate for the Steroid Exacerbations was 0.48 exacerbations/subject/year in the Alair group and 0.70 exacerbations/subject/year in the Sham group [95% CI (Sham - Alair): -0.031, 0.520]. During the Post-Treatment Phase, the proportion of subjects experiencing Steroid Exacerbations was 26% in the Alair group and 40% in the Sham group [95% CI (Sham - Alair): 2.1%, 25.1%].

Steroid Exacerbation rates (annualized rate) and proportion of patients experiencing Severe Exacerbations for the Post-Treatment Phase are presented graphically in Figure 2.

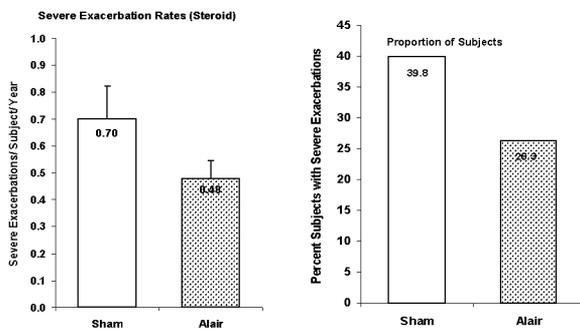


Figure 2: Severe Exacerbations during the Post-Treatment Phase

^a **Steroid Exacerbations** = Exacerbations treated with oral or intravenous corticosteroids, OR a doubling of the baseline inhaled corticosteroid dose for at least 3 days, OR any temporary increase in the dosage of oral corticosteroids for a subject taking maintenance oral corticosteroids at Study entry.

Annualized rates of exacerbations per subject are extrapolated from the 46 week Post-Treatment Phase from 6 weeks after the last bronchoscopy procedure to the 12 month follow-up visit.

Days Lost from Work, School, or Other Daily Activities due to Asthma Symptoms (ITT Population)

During the Post-Treatment Phase, subjects in the Alair group lost an average of 1.3 days/year/subject from work, school, or other daily activities due to asthma symptoms, compared to the Sham group that lost 3.9 days/year/subject (annualized rates per subject are extrapolated from the 46 week Post-Treatment Phase from 6 weeks after the last bronchoscopy procedure to the 12 month follow-up visit) [95% CI (Sham - Alair): 0.425, 6.397].

Safety Endpoints that Demonstrated Effectiveness

Measures such as Emergency Room visits and Hospitalizations for respiratory symptoms are generally considered to be important measures of safety, especially if an intervention results in an increase in the rate of one or more of these events. During longer-term follow-up (> 6 weeks after the last Alair treatment), there was a reduction in asthma (multiple symptoms) adverse events [95% CI (Sham - Alair): -0.01, 0.001], Emergency Room visits for respiratory symptoms [95% CI (Sham - Alair): 0.11, 0.83], and Hospitalizations for respiratory symptoms (event rate per group) [95% CI (Sham - Alair): 0.025, 0.172], presented graphically in Figure 3.

There was a reduction in the proportion of subjects having asthma (multiple symptoms) adverse events [95% CI (Sham - Alair): 4.0%, 27.3%], and in the proportion of subjects having Emergency Room visits for respiratory symptoms in the Alair group (3.7% in the Alair group compared to 15.3% in the Sham group) [95% CI (Sham - Alair): 4.6%, 19.7%].

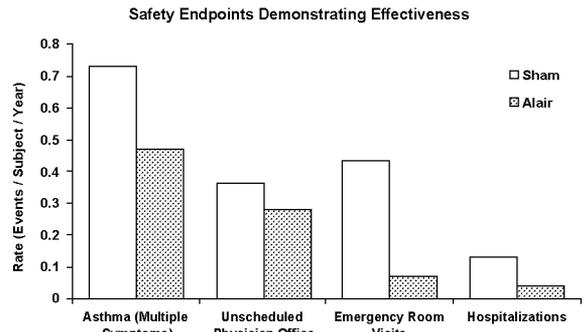


Figure 3: Safety Endpoints demonstrating Effectiveness (ITT Population)

Primary Effectiveness Endpoint – Integrated AQLQ Score

The difference between the Alair and Sham groups in the average change in AQLQ score from Baseline at the 6-, 9-, and 12-month follow-up visits was 0.210 [95% CI (Alair - Sham): -0.025, 0.445]. The pre-specified Posterior Probability of Superiority for the difference between the groups was 96.4%. For the ITT population, the difference between the groups had a Posterior Probability of Superiority of 96.0%, and for the PP population, the difference between the groups had a Posterior Probability of Superiority of 97.9%, demonstrating an improvement in the Asthma Quality of Life in the Alair group compared to Sham.

The results for the change from Baseline of the Integrated AQLQ score for the Intent-to-Treat and Per Protocol populations are summarized in Table 2.

Population	Difference Between Groups in Integrated AQLQ Score (Posterior Mean, 95% CI)	Posterior Probability of Superiority (%)
ITT (Intent-to-Treat) (Alair N=190, Sham N=98)	0.210 (-0.025, 0.445)	96.0
PP (Per Protocol) (Alair N=173, Sham N=95)	0.244 (0.009, 0.478)	97.9

Table 2: Primary Effectiveness Endpoint: Integrated AQLQ Score

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.

Adverse Event	Treatment*		Post-Treatment**	
	Alair (N=190) %	Sham (N=98) %	Alair (N=187) %	Sham (N=98) %
Average duration of period (days)	84		322	
Ear, Nose, and Throat				
Upper respiratory tract infection	20	11	30	26
Nasopharyngitis	5	7	11	5
Throat irritation	5	12	1	3
Viral upper respiratory tract infection	4	2	6	7
Sinusitis	3	5	6	7
Acute Sinusitis	3	2	4	8
Pharyngolaryngeal pain	3	5	1	2
Allergic rhinitis	2	3	4	4
Rhinitis	2	0	4	6
Lower Respiratory				
Asthma (Multiple Symptoms)	52	39	27	43
Wheezing	15	6	4	3
Chest pain	14	13	3	1
Cough	12	14	3	5
Dyspnea	11	6	2	1
Chest discomfort	9	10	2	1
Lower respiratory tract infection	8	2	3	6
Productive cough	7	9	3	4
Atelectasis	5	0	0	0
Bronchitis	4	2	7	5
Hemoptysis	3	0	0	0
Neurology				
Headaches	14	9	5	3
Anxiety	4	0	1	2

Adverse Event (Continued)	Treatment*		Post-Treatment**	
	Alair (N=190) %	Sham (N=98) %	Alair (N=187) %	Sham (N=98) %
Dyspepsia	4	2	2	4
Nausea	3	4	1	1
Non-site specific				
Influenza	4	2	4	12
Pyrexia (fever)	4	2	0	1
Other				
Back pain	5	6	3	5
Hypertension	3	2	3	3
Urinary tract infection	1	1	3	1

Table 3: Adverse Events with ≥ 3% Incidence (% of subjects) in the Alair Group

* Treatment phase represents adverse events reported between the first bronchoscopy and 6-weeks post last bronchoscopy.

** Post-Treatment phase represents adverse events reported between 6-weeks post last bronchoscopy and the 12 month visit.

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, in the Alair group compared to the Sham group.

High Resolution Computed Tomography (HRCT) Results

In the 150 subjects (100 Alair group and 50 Sham group) assigned to HRCT scan examinations, at 1-year, there were no difference in signs of gas trapping or consolidation and there was no evidence of bronchiectasis. A difference was seen in bronchial wall thickening without gas trapping which occurred only in the Sham subjects (4%).

Summary of Clinical Findings

Results from the clinical study which evaluated the effectiveness and safety of the Alair™ System in subjects with severe asthma demonstrated that Alair treatment resulted in clinically significant reductions in severe exacerbations that required systemic steroids, the percent of subjects experiencing the severe exacerbations, the number of Emergency Room visits for respiratory symptoms, the percent of subjects experiencing Emergency Room visits for respiratory symptoms, Hospitalizations for respiratory symptoms, and days lost from school/work/other daily activities due to asthma symptoms. Although bronchial thermoplasty was associated with an increased rate of respiratory adverse events during the Treatment Phase (primarily related to asthma), in the Post-Treatment Phase, a smaller proportion of patients treated with bronchial thermoplasty experienced respiratory adverse events, including asthma (multiple symptoms).

INSTALLATION

Inspect the Controller for any signs of physical damage. If physical damage is found, do not use. Please contact BSC for repair/replacement.

Preparing the Alair Controller for Use

The Controller should be placed on a sturdy cart, table, or platform. Provide at least four to six inches of space around the sides and top of the Controller to allow adequate ventilation. It is normal for the top and rear panel to be warm under continuous use.

Power Cord

The Controller is intended for use with a Boston Scientific approved power cord. Do not use extension cords or adapters. The power cord is to be used to isolate the Alair Controller from the supply mains. Do not position the Alair Controller so that it is difficult to disconnect.

Proper Grounding

To ensure patient safety, the Controller must be properly grounded. The ground wire in the power cord is connected to the Controller chassis and ensures that no dangerous currents will flow from the Controller chassis in the event of internal electrical failure.

Routine Inspections and Maintenance

The power cord assembly should be periodically checked for damage to the insulation or connectors. In the event that the Controller requires repair/replacement, please contact BSC. If needed, only your institution's biomedical engineering representatives should replace the Controller fuses. Routine maintenance and calibration of the Controller are not required.

Cleaning and Disinfecting Instructions

Disconnect the power cord before cleaning or disinfecting the unit. Use a mild non-abrasive detergent or cleaning/disinfecting solution and damp cloth to clean the Controller enclosure, front panel, and power cable. Do not allow fluids to enter the enclosure, power cable connections, or component/accessory connections. Do not attempt to clean the unit while it is plugged into an electrical outlet.

Note: Do not spray or pour liquid onto the Controller. Exposure of the Controller to liquids may result in electrical shock to the user or damage to the Controller.

Front Panel Indicators, Display, and Receptacles

A description of the front panel indicators, control buttons and their functions is given below. Please refer to Figure 4 for the location of each item on the front panel.

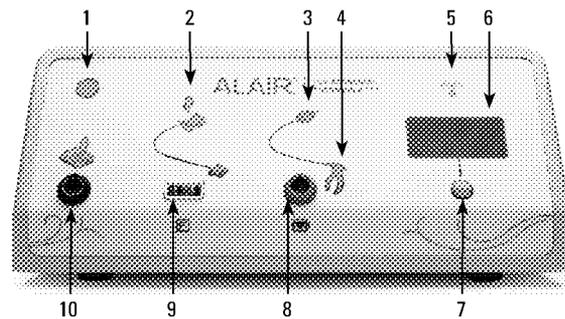
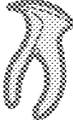
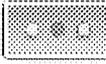


Figure 4. Alair Controller Front Panel

INDICATORS	
	<p>1. Status Indicator – This indicator gives the user a signal about the overall readiness of the Alair System. When the Status Indicator light is <i>green</i> the Controller is in READY mode and able to deliver RF energy.</p> <p>When the Status Indicator light is <i>amber</i> the Controller is in STANDBY mode and is not capable of delivering RF energy. More detail on the Controller modes is provided below.</p>
	<p>2. Patient Return Electrode Icon – When the Patient Return Electrode Icon light is <i>amber</i> the user should ensure that the patient return electrode gel pad is correctly applied to the patient.</p> <p>After ensuring proper electrode placement, proceed by re-expanding the Catheter electrode array, taking care to ensure proper contact of all electrodes with the airway wall, and ensuring minimal movement of the electrode array during delivery of RF energy; then, continue.</p>

INDICATORS (continued)	
	<p>3. Catheter Electrode Array Icon – When the Catheter Electrode Array Icon light is <i>amber</i> the user should re-expand the Catheter electrode array, taking care to ensure proper placement and contact of all electrodes with the airway wall and ensuring minimal movement of the electrode array during delivery of RF energy; then, continue.</p>
	<p>4. Catheter Handle Icon – When the Catheter Handle Icon is flashing <i>red</i> the Catheter should be discarded and replaced with a new Catheter.</p> <p>The only exception to this instruction occurs if the Catheter array has been exposed to a low (<16 °C) temperature. In these limited cases (e.g., cleaning the array in iced saline or exposing a wet array to cold air resulting in evaporative cooling), the electrode array should be returned to room temperature and the catheter connector should be unplugged and re-connected to the Controller. If the Catheter Handle alarm persists, replace Catheter and continue with the bronchial thermoplasty procedure.</p>
	<p>5. RF Energy Icon – When the RF Energy Icon light is <i>blue</i> the Controller is delivering RF energy. This icon lights only while RF energy is being delivered.</p>
DISPLAY	
	<p>6. Activation Counter Digital Display – Displays the number of complete activations performed during device use.</p>
	<p>7. Activation Counter Button – When the counter button is depressed and released, the counter displays the number of incomplete activations for 5 seconds.</p> <p>When the counter button is depressed and held for 4 seconds, the complete and incomplete activation counters are reset to zero.</p> <p>Note: <i>The activation counter will not reset during the display of incomplete activations. Reset the activation counter only during the display of complete activations.</i></p>
RECEPTACLES	
	<p>8. Catheter Receptacle – The <i>grey</i> receptacle accepts Catheter connectors and is keyed to ensure proper orientation. This connector is isolated from ground and AC mains to protect the patient from electrical hazards.</p>
	<p>9. Patient Return Electrode Receptacle – This receptacle accepts any standard, 2-pin patient return electrode connector. This connector is isolated from ground and AC mains to protect the patient from electrical hazards.</p>
	<p>10. Footswitch Receptacle – The <i>black</i> footswitch receptacle accepts the footswitch connector and is keyed to insure proper orientation. A single activation of the footswitch will turn the RF output ON if it was OFF, and turn the RF output OFF if it was ON.</p>

Rear Panel Indicators and Functions

A description of the rear panel indicators and functions is given below. Please refer to Figure 5 for the location of each item on the rear panel.

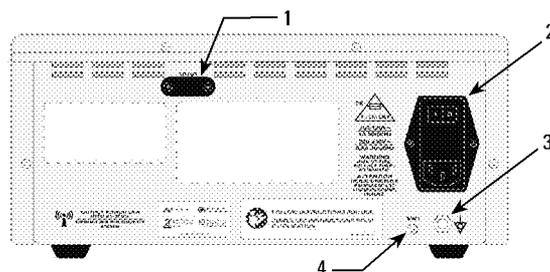


Figure 5. Alair™ Controller Rear Panel

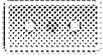
- 1. Serial Communication Port** – For service by authorized personnel only. Not for use by user.
- 2. Power Entry Module** – This module contains both the ON/OFF switch (I/O) and the power connection.
- 3. Equipotentiality Connector** – Provides a means of securely linking the chassis of the Controller to the potential equalization system at the installation site.
- 4. Program Memory Enable Screw** – For service by authorized personnel only. Not for use by user.

OPERATIONAL INSTRUCTIONS

Alair Controller Power-Up

- Plug the Controller into a grounded receptacle. Do not use extension cords or adapters.
- Turn the power on using the ON/OFF switch that is located on the Power Entry Module on the rear panel of the Controller (**see Figure 5 above**). The Controller will perform a number of internal self-tests: a tone will sound and all indicators will light for approximately 1 second. Do not use the Controller if any of the indicators fails to light or this tone is not heard. In the event of malfunction, contact BSC for repair or replacement.
- Once the self-test is completed, the Controller will enter STANDBY mode with the digital display showing zero [0] and the Status Indicator illuminated *amber* (**refer to Figure 4 above for the location of all controls and indicators**).
- The Status Indicator light will transition from *amber* to *green* once all component and accessory connections have been made.
- If the Controller goes directly into FAULT mode with all lights flashing upon start-up (see the Controller Modes section below for explanation of FAULT mode conditions), turn the Controller power switch OFF and ON again. If the Controller continues to enter the FAULT mode contact BSC for repair or replacement information.

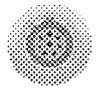
Connection of Alair™ System Components and Accessories



1. Connect a suitable, 2-pin patient return electrode to the corresponding electrode receptacle on the front panel of the Controller following the manufacturer's DFU (**see illustration at left**). This receptacle has a patient return electrode icon directly above it. Place the patient return electrode securely on the patient in accordance with the patient return electrode manufacturer's instructions.



2. Connect the *black* footswitch cable connector supplied with the Controller to the matching *black* footswitch receptacle on the front panel of the Controller (**see illustration at left**). The appropriate receptacle has a footswitch icon directly above it. Ensure that the connector is securely attached to the Alair Controller before proceeding.



3. Connect the *grey* Catheter electrical cable to the matching *grey* Catheter receptacle on the Controller front panel (**see illustration at left**). The appropriate receptacle has a Catheter icon directly above it. Ensure that the connector is securely attached to the Alair Controller before proceeding.



4. If all the component and accessory connections have been made and the Controller has been powered ON, the Status Indicator light will be *green* (**see illustration at left**). If the Catheter, or footswitch, or return electrode connections described above have not been completed, the Controller will remain in the STANDBY mode and the Status Indicator light will remain *amber*.

Alair Controller Modes

SELF-TEST Mode – This mode lasts approximately 2 seconds and occurs automatically upon turning on the power to the Controller. The Controller performs a number of internal tests to verify correct functioning of the Controller, including:

- the function of all displays and the "RF On" tone
- the accuracy of the power, voltage, and current measurements
- the return pad current measurement accuracy
- the A/D calibration accuracy
- RAM functionality
- Firmware cyclical redundancy checks on the software

All of the indicators should light and the digital display should show [188]. A long tone should be heard during the SELF-TEST. This mode automatically transitions to either STANDBY or READY mode when it is completed.

STANDBY Mode – The STANDBY mode indicates that the Controller has passed its SELF-TEST and is standing by for component and accessory connections to be made in preparation for use. The Status Indicator light is *amber* when the Controller is in STANDBY mode. This mode is entered automatically after the SELF-TEST mode if any of the components or accessories (Catheter, footswitch, or patient return electrode) are not connected to the Controller.

READY Mode – The READY mode indicates that all required component and accessory connections (Catheter, footswitch, and patient return electrode) have been made and that the Controller is ready to deliver energy. The Status Indicator light is *green* when the Controller is in READY mode.

RF ON Mode – RF energy is being delivered in this mode. The RF Energy Icon light is *blue* when RF energy is being delivered. When the footswitch is depressed a short tone signals the start of RF energy delivery, and an intermittent dual tone sounds at 2-second intervals during RF energy delivery. The Controller delivers energy until the activation is complete or until the footswitch is depressed a second time, discontinuing RF energy delivery. After the completion of each activation, a long tone signals the termination of RF energy delivery and the Controller returns to the READY mode.

FAULT Mode – This mode indicates that a safety algorithm has been triggered or a non-recoverable error has occurred. In the case of a non-recoverable error, the digital display will flash [188] and all other indicators will flash. A non-recoverable error can only be reset by turning the Controller off, then on again. If FAULT mode persists, please contact BSC for repair or replacement information.

ALAIR CONTROLLER SHUT DOWN

Turn the power off using the ON/OFF switch that is located on the Power Entry Module on the rear panel of the Controller (See Figure 5).

MAINTENANCE AND TROUBLESHOOTING

Routine maintenance and calibration of the Controller are not required since the SELF-TEST Mode, activated automatically upon turning on the power to the Controller, verifies correct functioning of the Controller. The power cord assembly should be periodically checked for damage to the insulation or connectors.

In the event that the Controller requires repair or replacement, please contact BSC.

Only a qualified biomedical engineering representative at your institution should replace the Controller fuses.

If you encounter problems while using the Controller, check the following:

Problem/Error Message	Check the following
Controller does not power on	<ul style="list-style-type: none"> • Ensure that the switch at the rear of the Controller is in the "ON" position • Check power cord connection at the rear of the Controller • Check that the Controller power cord is connected to an appropriate power supply (see the Technical Specifications Section). • Have a qualified biomedical engineering representative at your institution check the Controller fuses or contact BSC for repair or replacement information.
The status indicator does not transition from the Standby Mode (<i>amber</i>) to the Ready Mode (<i>green</i>)	<ul style="list-style-type: none"> • Ensure that the Alair Catheter, patient return electrode and footswitch are all properly connected to the Controller
RF Energy is not delivered when the footswitch pedal is depressed	<ul style="list-style-type: none"> • Check that the Controller is powered on • Ensure that the Alair Catheter, the patient return electrode and footswitch are all properly connected to the Controller

Problem/Error Message	Check the following
Catheter icon on Controller is flashing <i>red</i> and the Controller is not responding	<ul style="list-style-type: none"> Replace the Alair™ Catheter with a new Alair Catheter The only exception to this instruction occurs if the Catheter array has been exposed to a low (<16 °C) temperature. In these limited cases (e.g., cleaning the array in iced saline or exposing a wet array to cold air resulting in evaporative cooling), the electrode array should be returned to room temperature and the catheter connector should be unplugged and re-connected to the Controller. If the Catheter Handle alarm persists, replace Catheter and continue with the bronchial thermoplasty procedure.
If any of these problems persist, please contact BSC for repair or replacement information.	

TECHNICAL SPECIFICATIONS

According to the IEC 60601-1 standard for medical devices, the Controller is classified as Class 1 equipment.

RF OUTPUT (not user adjustable)

Waveform - 461 kHz, sinusoidal

Maximum Output Values

- Power: 25 Watts; limited by software to 18 watts
- Voltage: 85 Vrms, 120 V peak, 240 V peak-to-peak
- Current: 0.90 Arms

Maximum Power Output over the Range of Load Resistance (see Figure 6): Actual power delivered will be automatically adjusted by the Controller based on temperature control algorithms.

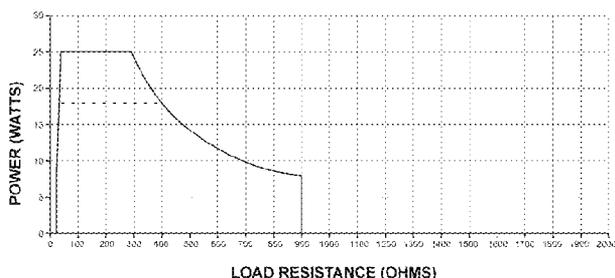


Figure 6: Maximum Power Given Load Resistance

Shutdown Limits

- Measured Temperature: < 10 °C or > 15 °C above set temperature
- Measured Impedance: < 25Ω, or > 900Ω

Mechanical Specifications

- Size: 5.3 in x 12.3 in x 15.4 in (13.5 cm x 31.2 cm x 39.1 cm)
- Measured Temperature Accuracy: ± 0.5% ± 2.5 °C
- Weight: 12.5 lbs. (5.6 kg)

Environmental Storage and Transport Conditions

- Storage temperature: 10 °C to 40 °C
- Transportation conditions: -40 °C to 70 °C
- Ensure that the unit is at room temperature for one hour before use if unit has been exposed to extreme temperature conditions

Operational Conditions

- Temperature: 18 °C to 40 °C
- Humidity: 30% to 75% (non-condensing)
- Pressure: ≥ 800 millibars

AC Input Specifications

- 100 – 120 V~ 50/60 Hz, 1.0 A
- 220 – 240 V~ 50 Hz, 0.5 A

Replace mains fuses as marked: 1.25 A/250 V, T-lag, 5x20 mm

EMC TEST LEVELS, COMPLIANCE LEVELS, AND ENVIRONMENTAL GUIDANCE

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
The Alair RF Controller Model ATS 200 is intended for use in the electromagnetic environment specified below. The user of the Controller should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	EMC Environmental Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines NA - no input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (Continued)			
The Alair™ RF Controller Model ATS 200 is intended for use in the electro-magnetic environment specified below. The customer or the user of the Controller should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test Level	Compliance Level	EMC Environmental Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Controller requires continued operation during power interruptions, it is recommended that the Controller be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (Continued)			
Immunity Test	IEC 60601 Test Level	Compliance Level	EMC Environmental Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{rms} 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Controller, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = [1.17]\sqrt{P} \text{ MHz to 800 MHz}$ $d = [1.17]\sqrt{P} \text{ MHz to 800 MHz}$ $d = [2.33]\sqrt{P} \text{ MHz to 2.5 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Alair RF Controller Model ATS 200 or any of its components or accessories are used exceeds the applicable RF compliance level above, the Controller should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating components or accessories or the entire Alair Bronchial Thermoplasty System.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
The Controller is intended for use in the electromagnetic environment specified below. The customer or the user of the Controller should assure that it is used in such an environment.		
Emissions Test	Compliance Level	EMC Environmental Guidance
RF Emissions CISPR 11	Group 1	The Controller must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The Controller is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

IEC Recommended Separation of RF Communication Equipment			
Recommended separation distances between portable and mobile RF communications equipment and the Alair™ RF Controller Model ATS 200 System			
The Alair RF Controller Model ATS 200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Controller can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Controller as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3 V_1 is 3 V_{rms} per the conducted emissions compliance level indicated in the table above

NOTE 4 E_1 is 3 V/m per the radiated emissions compliance level indicated in the table above

REFERENCES

- 1 Danek CJ, Lombard CM, Dungworth DL, Cox PG, Miller JD, Biggs MJ, Keast TM, Loomas BE, Wizeman WJ, Hogg JC, Leff AR. Reduction in airway hyperresponsiveness to methacholine by the application of RF energy in dogs. J Appl Physiol. 2004, 97(5):1946-53.
- 2 Brown RH, Wizeman W, Danek C, Mitzner W. Effect of bronchial thermoplasty on airway distensibility. Eur Respir J. 2005 Aug;26(2):277-82.

NO IMPLIED LICENSE

The purchase or rental of the Alair™ Controller does not grant a license, either expressly, by implication, estoppel or otherwise under any Boston Scientific patent right or patent covering or relating to any method or process in which the Alair Controller might be used. An implied license only exists for the Alair Controller used in conjunction with the Alair ATS 2-5 Catheter. Nothing herein shall be construed as a right or license to (a) make, use, sell, offer to sell, import, lease or distribute the Alair Controller with a non-Alair catheter or (b) sell or offer to sell the Alair Controller to customers that plan to make, have made, use, sell, offer to sell, import, lease or distribute the Alair Controller with a non-Alair catheter.

WARRANTY

Boston Scientific Corporation (BSC) warrants for one year from the date of purchase that reasonable care has been used in the design and manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, cleaning and storage of the product as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Boston Scientific Corporation's control may directly affect the product and results obtained from it. Boston Scientific Corporation shall repair or replace, at its option, any part of the product that Boston Scientific Corporation determines was defective at time of shipment if notice thereof is received within one year of shipment. Boston Scientific Corporation shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of the product.

Boston Scientific Corporation neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the product. BSC assumes no liability with respect to product use by a non-qualified physician; use contrary to documentation; use with a non-Alair catheter.

Buyer shall be responsible for the ongoing support and maintenance of the product not covered by this one-year warranty and after the one year warranty period has expired. Buyer may, at its sole cost and expense, purchase an extended warranty from Boston Scientific Corporation (BSC) to extend the term of this warranty.

Valleylab is a trademark of Covidien AG.

ConMed is a trademark of ConMed Corporation.

	Footswitch		Contents
	Serial Communication Port		Do not use if package is damaged
	Date of Manufacture		Consult Instructions For Use

SYMBOL LEGEND

	Defibrillation-Proof Type CF Applied Part		Serial Number
	Neutral Electrode Isolated from Earth at High Frequencies		For Prescription use only
	Caution		Program Memory Enable, for Use Only by Qualified Service Personnel
	Alternating Current		[Blue Safety Sign] Follow Instructions For Use
	Equipotentiality Connector		Catalog Number
	Fuses		Legal Manufacturer
	Power Off, Disconnected from the Mains		Lot Number
	Power On, Connected to the Mains		Product Number
	Catheter		Minimum Required Working Channel
	Patient Return Electrode		Recyclable Package
	Transmits and Accepts Radiofrequency Signals		Separate Collection

Boston Scientific (Master Brand DPU Template 8in x 8in Global, 90106041AL), User Manual, MB, Alair Radiofrequency Controller, Canada/Mexico, 90795407-01B_pretrans



**Legal
Manufacturer**
Manufactured for:
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

 **Do not use if package
is damaged.**

 **Recyclable
Package**

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2013-02



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Black (K) ΔE ≤5.0

BSC000692

APPLICANT'S EXHIBIT 85

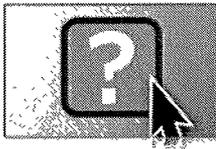


NEW 5 YEAR DATA For Health Care Professionals

UNITED STATES

BRONCHIAL THERMOPLASTY REAL PEOPLE, REAL RESULTS ARE YOU A BT CANDIDATE?

FIND A BT CLINIC Zip Code



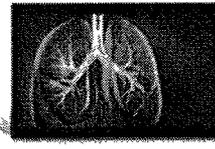
How much does asthma limit your choices?

Take this short quiz to find out.



"It's amazing to see the difference. I feel like the sky's the limit."

Hear patients with severe asthma talk about life before and after BT.



See how BT works

View an animation of the BT procedure in: English, Français, Deutsch, Italiano, or Español.



Start your BT journey today!

Request a FREE ASTHMA DVD and connect with the BT 1-2-3 Support Program.

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APPLICANT'S EXHIBIT 86

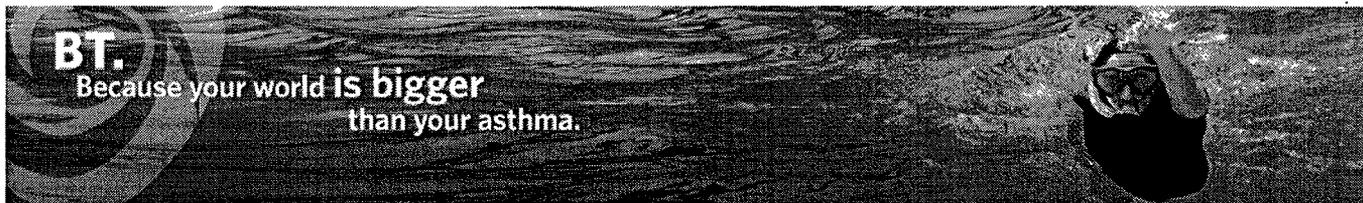


NEW 5 YEAR DATA For Health Care Professionals

UNITED STATES

BRONCHIAL THERMOPLASTY REAL PEOPLE, REAL RESULTS ARE YOU A BT CANDIDATE?

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Support for patients

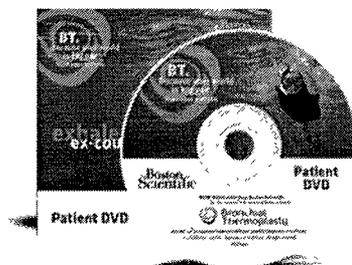
Physician information request

Home > Request more information > Support for patients

Start your BT journey with a FREE DVD and continued support

Ready for a bigger world with fewer asthma attacks?

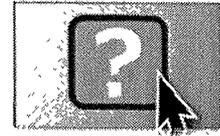
Complete the fields below to request your FREE DVD and connect with the BT 1-2-3 Support Program



Thank you for your interest in Bronchial Thermoplasty (BT). Your requested information is on its way to you. In the meantime, we invite you to explore the BTforAsthma.com website to learn more about this revolutionary procedure. If you have questions about BT, talk to your doctor or call our patient support line at 1-877-810-6060.

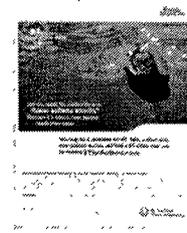
If you have any questions, please call our patient support line at 877-810-6060.

[BSC Privacy Policy](#)



How much does asthma limit your choices?

Take this short quiz to [find out](#).



[Download the BT Pamphlet for Patients.](#)



"It's amazing to see the difference. I feel like the sky's the limit."

[Hear patients with severe asthma talk about life before and after BT.](#)

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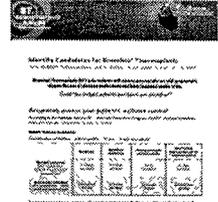
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Help your patients recognize severe asthma by downloading the [Asthma Impact Survey](#).

Support for physicians
Request more information [about BT, BT training opportunities, and referring patients for treatment.](#)

To assist patients in finding a BT Clinic, [click here.](#)



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NEW 5 YEAR DATA For Health Care Professionals

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BRONCHIAL THERMOPLASTY REAL PEOPLE, REAL RESULTS ARE YOU A BT CANDIDATE? FIND A BT CLINIC Zip Code



Take the Asthma Impact Survey

Are you a BT candidate?

About asthma

Current treatment options

Connect to the BT 1-2-3 SUPPORT PROGRAM

Ready for a life less defined by asthma? Get the support and information you need!

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Home > Are you a BT candidate? > Current treatment options

Current treatment options for severe asthma

Many drugs can be prescribed to manage asthma symptoms. The severity of a patient's asthma often plays a large role in how successful a medication will be.

Some major types of currently-used asthma medications include:

<http://www.btforasthma.com/is-it-right-for-you/current-treatment-options>

Anti-inflammatory drugs. Inhaled corticosteroids are the key drugs used for controlling the underlying inflammation in asthma.

Bronchodilators widen the airways by relaxing airway smooth muscle, though they do not reverse airway inflammation. Bronchodilators come in 2 basic forms:

Maintenance medications, such as long-acting beta-agonists that work up to 12 hours.

Rescue (short-acting) medications that work quickly to ease severe asthma symptoms for 4 to 6 hours.

Medications for long-term control, including methylxanthines, anticholinergics, leukotriene inhibitors, and IgE inhibitors such as Xolair®.

Oral corticosteroids such as prednisone, when used for maintenance, are reserved for patients with severe asthma. These drugs typically serve as maintenance medications.

Medications have limitations

These medications treat asthma symptoms, but there are limitations—especially for patients with severe asthma. Studies show how hard it can be to manage asthma:

Limited efficacy in patients with severe asthma: A number of recent surveys show that symptoms are poorly controlled by asthma medications in patients with severe asthma. These patients often continue to experience frequent and serious symptoms despite taking regular doses of asthma medications.¹ Even this limited efficacy is only possible when the patient takes his or her medicine as prescribed, typically twice a day, every day.

Not taking medications as prescribed

A 2012 report by the Global Initiative for Asthma estimated that approximately 50% of patients with asthma do not take their medications as prescribed.² Non-compliance may be a reason for an increase in emergency room visits and hospitalizations among patients with severe asthma.

Side effects

Asthma medications can have potentially serious side effects. As with any medication, side effects become a greater concern when treatment is ongoing and as dosages increase, which is the case for patients with severe asthma.

Corticosteroids (oral steroids): Side effects of prednisone and other oral corticosteroids range from mild annoyances to serious, irreversible damage. These side effects occur more frequently with higher doses and longer treatment. Side effects with ongoing use include suppression of the immune system, adrenal system, and growth; osteoporosis; skin thinning; hypertension; cataracts; glaucoma; muscle weakness; and increased risk of infection. Short-term side effects include stomach upset, headache, dizziness, trouble sleeping, fluid retention, weight gain, high blood pressure, loss of potassium, elevation of cholesterol levels and vision changes.

Bronchodilators: The possible side effects of short-acting rescue medications include rapid heartbeat, skeletal muscle tremor, potassium deficiency, increased lactic acid, headache and hyperglycemia. Long-acting beta-agonists may even cause severe asthma symptoms in some patients, and death when those episodes occur.²

Other drugs: The side effects of omalizumab (Xolair®) include anaphylaxis, injection-site reactions, and viral infections.

Lifestyle burdens

Because existing medications provide poor symptom control for some patients with severe asthma, they often must miss work or school. In addition, severe symptoms can require unscheduled doctor office visits, emergency room visits, and hospitalizations.

References:

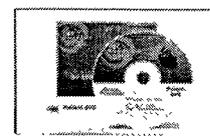
1. Partridge MR. Examining the unmet need in adults with severe asthma *Eur Respir Rev.* 2007;16:104,67-72.
2. GINA (Global Initiative for Asthma) 2012 Global Strategy for Asthma Management and Prevention Workshop report in collaboration with National Institutes of Health (NIH) National Heart, Lung, and Blood Institute NHLB/WHO 2007.

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How much does asthma limit your choices?

[Take this short quiz to find out.](#)



[Learn more about BT with this FREE DVD for patients with asthma.](#)



“It’s amazing to see the difference. I feel like the sky’s the limit.”

[Hear patients with severe asthma talk about life before and after BT.](#)

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APPLICANT'S EXHIBIT 88



NEW 5 YEAR DATA For Health Care Professionals

UNITED STATES

BRONCHIAL THERMOPLASTY REAL PEOPLE, REAL RESULTS ARE YOU A BT CANDIDATE?

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Take the Asthma Impact Survey

Are you a BT candidate?

About asthma

Current treatment options



Ready for a life less defined by asthma? Get the support and information you need!

START HERE

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Home > Are you a BT candidate? > Are you a BT candidate?

Are you a BT candidate?

You may be eligible for Bronchial Thermoplasty (BT) treatment if:

You are 18 years or older with severe asthma, AND

You have asthma symptoms despite taking inhaled corticosteroids and long-acting beta-agonists such as Advair™, Dulera™, or Symbicort™.

Take the Asthma Impact Survey to discover more about how asthma symptoms may be affecting your life.

You are not a candidate for BT if:

- You have a pacemaker, internal defibrillator, or other implantable electronic device.
- You have a known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines.
- You've been treated previously with BT.

Who performs the BT procedure?

BT is performed by a specially trained pulmonologist. If your regular doctor currently managing your asthma is an allergist, family practice physician, general practitioner, internist or other physician, he or she will be able to refer you to a BT Clinic for a consultation with a pulmonologist. After your BT treatment is completed, you will return to your regular asthma doctor to manage your asthma.

For help with discussing this treatment with your doctor:

- Complete the **Asthma Impact Survey**.
- Share your survey results with the physician who manages your asthma.

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Learn more about BT with this FREE DVD for patients with asthma.



"It's amazing to see the difference. I feel like the sky's the limit."

Hear patients with severe asthma talk about life before and after BT.



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NEW 5 YEAR DATA For Health Care Professionals

UNITED STATES

BRONCHIAL THERMOPLASTY REAL PEOPLE, REAL RESULTS ARE YOU A BT CANDIDATE?

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Take the Asthma Impact Survey

Are you a BT candidate?

About asthma

Current treatment options

Connect to the
BT 1-2-3
 SUPPORT PROGRAM

Ready for a life less defined by asthma? Get the support and information you need!

START HERE

Home > Are you a BT candidate? > Take the Asthma Impact Survey

How much does asthma affect your quality of life?

See for yourself: If asthma is limiting the choices you make in life, perhaps it's time to look beyond medication alone. The following survey was created by a doctor and can help you recognize the many ways severe asthma may be affecting your life.

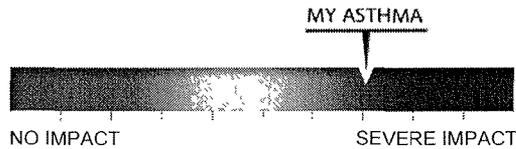
<http://www.btforasthma.com/is-it-right-for-you/self-assessment?q=11,11,11,11,11,11>

Be sure to share your answers with your doctor—and discover how Bronchial Thermoplasty (BT) may help you live a fuller life. BT, delivered by the Alair™ System, is not another medication—it's a revolutionary and safe procedure proven to provide a long-lasting reduction in asthma attacks.

THE ASTHMA IMPACT SURVEY™

Congratulations on taking an important step toward a new life with fewer asthma attacks

Your responses indicate that asthma has a **severe impact** on your quality of life



Print my Survey results and letter to my doctor here.

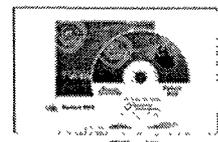
This survey is a diagnostic tool to assess the impact asthma has on your daily lifestyle. You should check with your doctor to make sure that you are taking your medication appropriately and consistently. Your medication dosage may need to be adjusted to help provide better symptom control. If you are taking the maximum tolerated medication regularly and continue to have asthma symptoms that impact your daily life, you may be a candidate for the BT treatment and you should consult an asthma specialist to learn more about your options.

Take this survey and the letter with you to your doctor. It will help your doctor determine whether you might be a candidate for BT.

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References:

1. Wechsler M, et al, for the AIR2 Trial Study Group. *J Allergy Clin Immunol.* 2013;132:1295-1302.



Learn more about BT with this FREE DVD for patients with asthma.



[Download the BT Pamphlet for Patients.](#)

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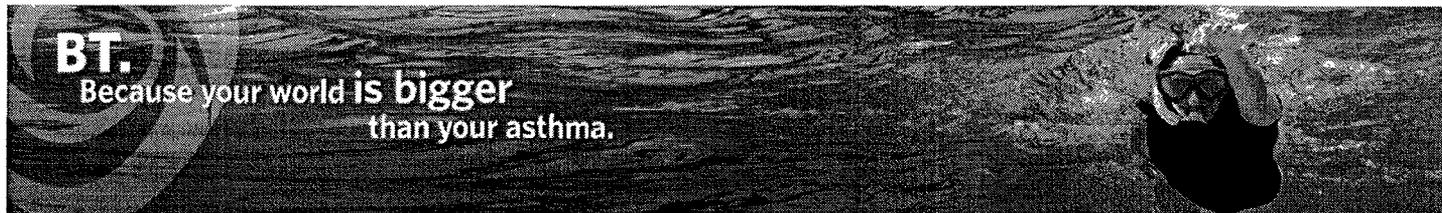


NEW 5 YEAR DATA For Health Care Professionals

UNITED STATES

BRONCHIAL THERMOPLASTY REAL PEOPLE, REAL RESULTS ARE YOU A BT CANDIDATE?

FIND A BT CLINIC Zip Code



US availability

International Availability



Ready for a life less defined by asthma? Get the support and information you need!

START HERE

By submitting, I agree to receive occasional, relevant information about BT.

Home > Find a BT Clinic > US availability

Find a BT Clinic

Type in your zip code or click on a state on the US map to see a list of physicians offering Bronchial Thermoplasty (BT) in that state.

Boston Scientific maintains an updated list of physicians who are trained to perform BT. The list is based upon location only.

http://www.btforasthma.com/find-clinic/physician-locator

If there isn't a BT Clinic in your area, [contact Boston Scientific.](#)

Not in the United States? [View a list of hospitals outside of the US with BT Clinics](#)

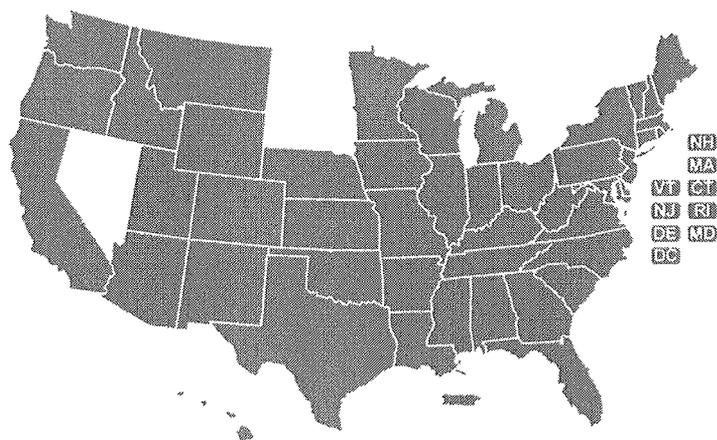
(* Required)

Zip Code: *

How far are you willing to travel? *

OR

Find Physicians in your state:



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NEW 5 YEAR DATA For Health Care Professionals

UNITED STATES

BRONCHIAL THERMOPLASTY

REAL PEOPLE, REAL RESULTS

ARE YOU A BT CANDIDATE?

FIND A BT CLINIC Zip Code



Patient stories

Physician stories

In the news

Press releases



Ready for a life less defined by asthma? Get the support and information you need!

START HERE

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Home > Real people, real results > Patient stories

Real people, real results

Listen and watch as people with severe asthma discuss the dramatic difference Bronchial Thermoplasty (BT) has made in their lives.

Please note that individual BT treatment results may vary. BT is an add-on therapy that supplements your current asthma medications. BT, delivered by the Alair[®] System, is

indicated for the treatment of severe asthma in people 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.



Angel's Story

"I've been able to cut the grass. I've been able to work on my car. I wasn't able to travel. I've been able to travel, something I haven't done for years."

[VIEW VIDEO](#)



Laretta's Story

"Now I can live life and go and do those fun activities that I hadn't done before. If you really want to live life and you really don't want a disease that's controlling your life or defining you, have BT."

[VIEW VIDEO](#)



Mike's and Jenny's Story

"I just feel like I'm free... I feel like the sky's the limit."

[VIEW VIDEO](#)



Chris's Story

"It was a moment of revelation. It's that sun breaking through the clouds and you go, 'It worked.'"

[VIEW VIDEO](#)



Debbie's Story

"I noticed doing things around the house, things that I would get out of breath with before. Like carrying up laundry from the basement, just something as simple as that... I wasn't as winded."

[VIEW VIDEO](#)



John's Story

"I've gone from torture to being able to live my life, I feel like I've got a second chance."

[VIEW VIDEO](#)



Brenda's Story

"I would highly recommend this to somebody else. It's just a simple procedure and it's a great benefit."

[VIEW VIDEO](#)

Jeff's Story



"My life has changed due to the treatment in a way that I'm not afraid to go hiking in the mountains."

[VIEW VIDEO](#)



How much does asthma limit your choices?

[Take this short quiz to find out.](#)



[Learn more about BT with this FREE DVD for patients with asthma.](#)

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REAL PEOPLE, REAL RESULTS

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Patient stories

Physician stories

In the news

Press releases



Ready for a life less defined by asthma? Get the support and information you need!

START HERE

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Home > Real people, real results > Physician stories

Physician stories

Listen and watch as physicians discuss the positive results they've seen in their patients with this revolutionary treatment for severe asthma.

Please note that individual BT treatment results may vary. BT is an add-on therapy to current asthma medications. BT, delivered by the Alair™ System, is indicated for the

treatment of severe asthma in people 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.



[VIEW VIDEO](#)

Dr. Mario Castro

Washington University, St. Louis, MO

"The benefits that we have seen with Bronchial Thermoplasty include an improvement in their quality of life, an improvement in their asthma symptoms, a decrease in the frequency that they end up in the emergency room and in turn towards decreased hospitalizations as well, and we also see that they are missing less work or school after the treatment itself."



[VIEW VIDEO](#)

Dr. Gerard P. Cox

McMaster University, St. Joseph's Healthcare, Hamilton, Ontario, Canada

"Bronchial Thermoplasty represents an opportunity, different from anything that's been done before therapeutically for these patients to help control asthma."



[VIEW VIDEO](#)

Dr. David R. Duhamel

Virginia Hospital Center, Arlington, VA

"I'm very excited about this new technology. I really think it offers a new opportunity to greatly impact our patient's lives."



[VIEW VIDEO](#)

Dr. Jeff B. Hales

Virginia Hospital Center, Arlington, VA

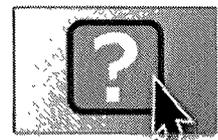
"The patients that I followed as an assessment physician through this AIR2 trial are walking on cloud nine."



[VIEW VIDEO](#)

Dr. Armin Ernst and Patricia DiGiusto

"Patricia was the perfect first patient for any new procedure that you want to introduce into a hospital. She was looking for other options and really came to us to get a better idea of what Bronchial Thermoplasty was all about."



How much does asthma limit your choices?

[Take this short quiz to find out.](#)



**Learn more about BT with
this FREE DVD for
patients with asthma.**

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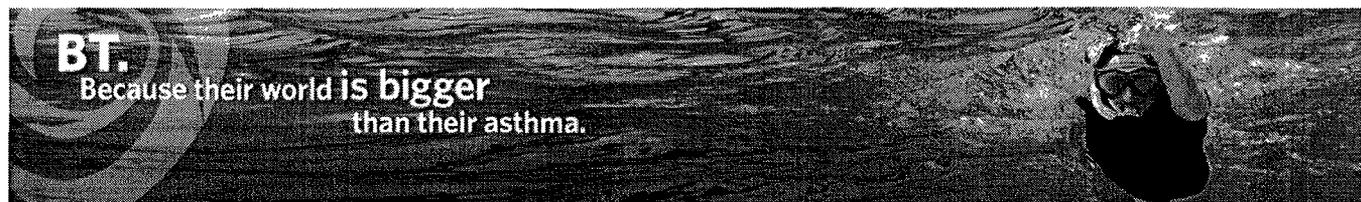


BRONCHIAL THERMOPLASTY

REAL PEOPLE, REAL RESULTS

ARE YOU A BT CANDIDATE?

UNITED STATES

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Overview for Physicians

Performing BT

The Alair™ System

Clinical Studies

AIR2 Trial

RISA Trial

Bibliography

[Home](#) > [Healthcare Professionals](#) > [Overview for Physicians](#)

Do your asthma patients know what they are missing?

Now, a revolutionary procedure can help them lead a fuller life.

Frequent asthma exacerbations can have a profound impact on a patient's lifestyle. Severe asthma places limitations on work, school, and other activities. However, patients may not acknowledge—or even recognize—that their asthma symptoms are severe. Over time, these patients may try to avoid exacerbations by modifying daily activities—even those that they enjoy.

Bronchial Thermoplasty (BT), delivered by the Alair™ System, is a safe, minimally invasive outpatient procedure for the treatment of severe asthma in adults. If you have patients who you believe may benefit from this procedure, the information in this section will help you identify the appropriate BT candidates.

Who is appropriate for BT?

Adult patients with severe asthma (at least 18 years old)

Patients whose asthma is not well controlled despite taking a combination of inhaled corticosteroids and long-acting beta-agonists such as Advair™, Symbicort™, or Dulera™

Patients able to safely undergo bronchoscopy per hospital guidelines

Help your patients recognize severe asthma: The online [Asthma Impact Survey](#) is intended to help you determine how asthma may be influencing the choices your patient makes every day.

A recent study has shown that the interference of asthma with daily activities is a key predictor for the risk of future exacerbations.¹ In fact, in an analysis of the quality-of-life survey you see here, patients with severe health impairment related to asthma were 70% to 4 times as likely to manifest adverse outcomes like ER visits and oral corticosteroid use.²

Who is *not* appropriate for BT?

Patients who have a pacemaker, internal defibrillator, or other implantable electronic device

Patients who have a known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines

Patients who have previously been treated with BT

BT should be delayed when any of the following conditions are present:

Active respiratory infection

Asthma exacerbation or changing dose of systemic corticosteroids (up or down) in the past 14 days

Known coagulopathy

Patient is unable to stop taking anticoagulants, antiplatelet agents, aspirin, or non-steroidal anti-inflammatory medications (NSAIDs) before the procedure with physician guidance

Who performs the BT procedure?

Pulmonologists who are experienced in bronchoscopy

BT training is required, and includes:

- Review of Alair System Catheter Directions for Use and Controller Operator's Manual
- Guided didactic instruction in computer simulation-based Bronchial Thermoplasty Learning Center
- Detailed in-service training of the Alair System
- Hands-on training with Alair System in a lung model prior to initial cases
- Proctoring of initial cases by Boston Scientific Health Care Industry Representative (HCIR)
- Ongoing support of cases when requested

Where is the procedure performed?

At facilities that are appropriately equipped to perform bronchoscopy and are equipped to handle respiratory emergencies

How is the procedure performed?

[Click here to view the video](#)

Review a complete list of [indications for use, contraindications and precautions](#).

If you would like to refer a patient for BT or are interested in performing the procedure yourself, please complete the [Physician information request form](#).

References.

1. Schatz M, et al *Chest* 2012;41:66-72
2. Schatz M, et al *J Allergy Clin Immunol*. 2011;128;1:44-49.e1.

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See how BT works
View an animation of the BT procedure in: [English](#), [Français](#), [Deutsch](#), [Italiano](#), or [Español](#)

[Find out why physicians are excited about bringing BT to patients with severe asthma.](#)



Help your patients recognize severe asthma by

downloading the
[Asthma Impact Survey.](#)

Support for
physicians
[Request more information
about BT, BT training
opportunities, and
referring patients for
treatment.](#)

To assist patients in finding
a BT Clinic, [click here.](#)

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ENDO-142305-AE April 2014

APPLICANT'S EXHIBIT 94

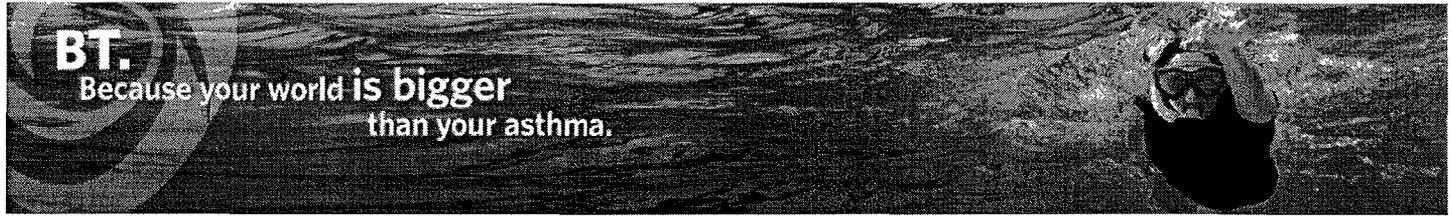


NEW 5 YEAR DATA For Health Care Professionals

UNITED STATES

BRONCHIAL THERMOPLASTY REAL PEOPLE, REAL RESULTS ARE YOU A BT CANDIDATE?

FIND A BT CLINIC Zip Code



Support for patients

Physician information request

Connect to the BT 1-2-3 SUPPORT PROGRAM

Ready for a life less defined by asthma? Get the support and information you need!

START HERE

By submitting, I agree to receive occasional, relevant information about BT.

Home > Request more information > Physician information request

Physician information request

If you would like more information on Bronchial ThermoPlasty (BT), please complete the information requested below and a representative from Boston Scientific will follow up with you.

<http://www.btforasthma.com/get-more-info/physician-info-request>

Please select one of the following:

- I am interested in referring patients for Bronchial Thermoplasty treatment.
- I currently provide or am interested in providing Bronchial Thermoplasty treatments to patients.

(* Required)

Title

Specialty

First Name *

Last Name *

Hospital/Clinic *

Address 1 *

Address 2

City *

State *

Zip/Postal code*

Country

Phone

Email *

I currently perform bronchoscopy Yes No

I perform approximately the following number of bronchoscopies per month

I see in my office the following number of severe asthma patients per month

How did you hear about us? *

I am interested in learning more about the BT training program

I am interested in referring a patient(s) for BT

I would like to receive more information on BT

Comments:

Boston Scientific Corporation
 150 Baytech Drive
 San Jose, CA 95134
 T: 877-810-6060 F: 408-419-0199



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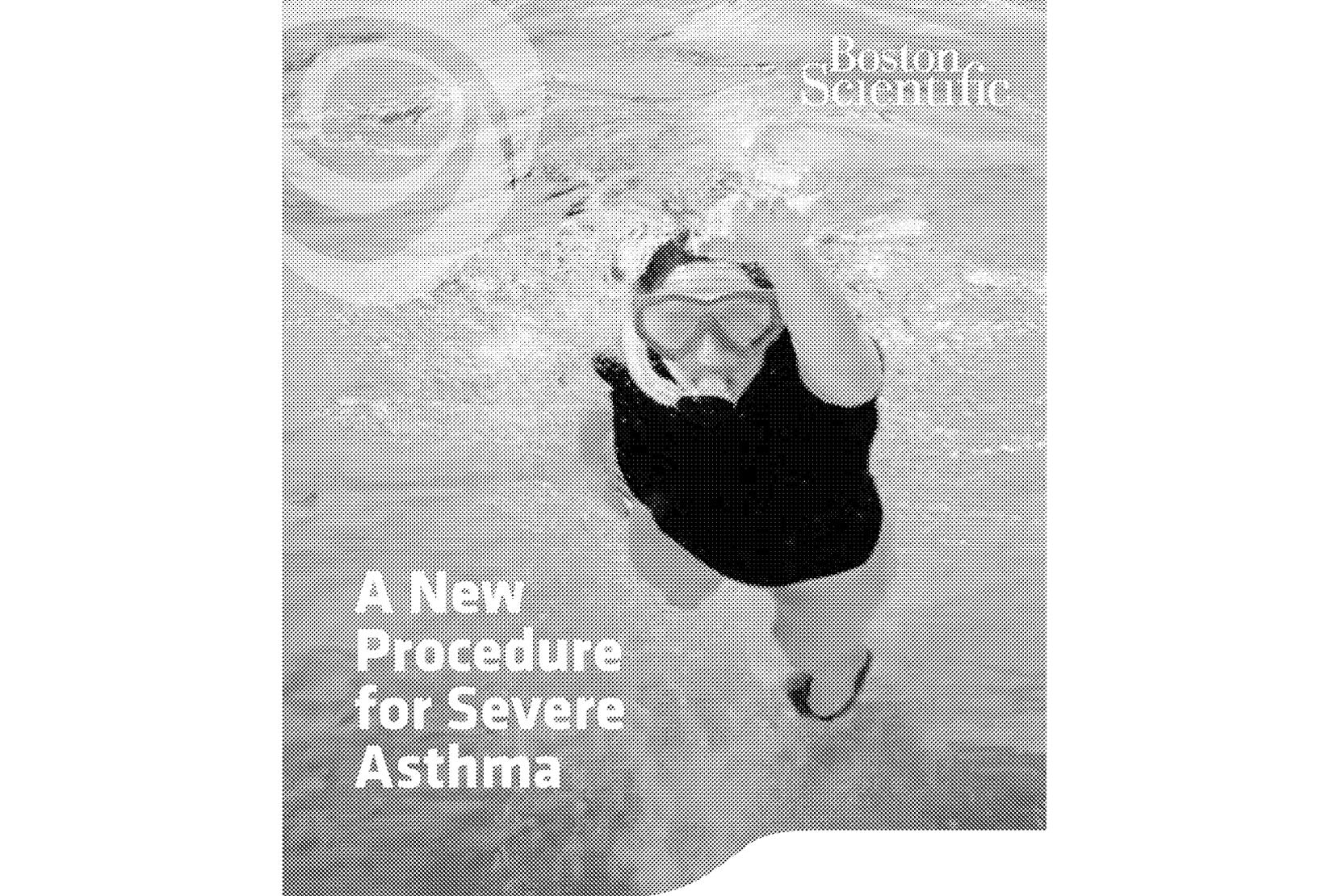
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ENDO-142305-AE April 2014

APPLICANT'S EXHIBIT 95

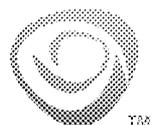


Boston
Scientific

A New Procedure for Severe Asthma

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

*NOW AVAILABLE from Boston Scientific
for the treatment of severe asthma in adults*



**Bronchial
Thermoplasty**

BSC000558

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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**.
- ✦ 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.

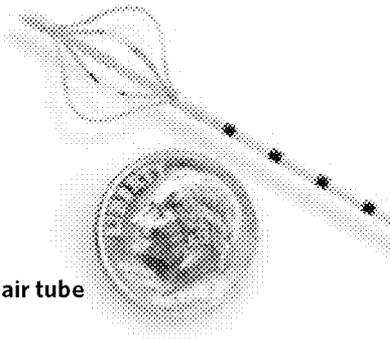


Figure 1: Actual size of tip of Alair tube

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)

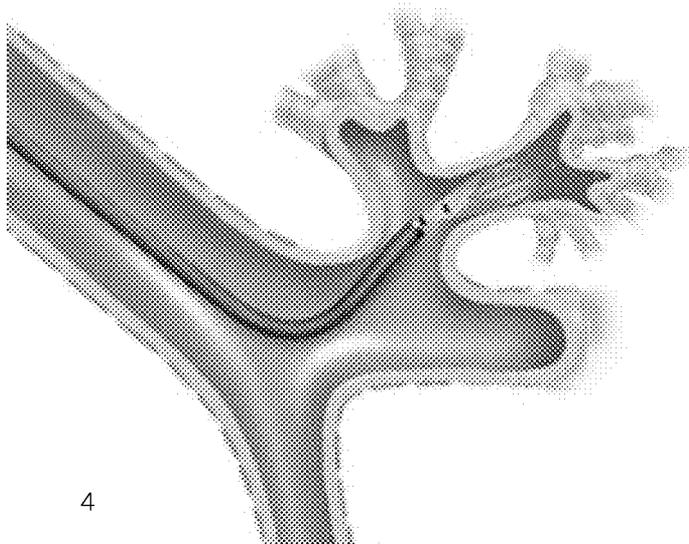
The Alair Bronchial Thermoplasty System is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists.

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 medicine. 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 has 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 3 or more in every 100 patients 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.

Other side effects related to the lungs, ear, nose, and throat occurred in the short-term or long-term periods in the BT group. The following side effects occurred in 1 or more in every 100 patients in the BT group, but less often than the side effects in **Table 1**: abnormal breath sounds, acute swelling of the airways, blocked airways, bleeding during the procedure, bloody mucus, bloody nose, chest

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
Cough	12	14	3	5
Shortness of breath	11	6	2	1
Chest discomfort	9	10	2	1
Infection in the lower airways	8	2	3	6
Productive cough	7	9	3	4
Collapse of part of the lung	5	0	0	0
Swelling of the airways	4	2	7	5
Bleeding	3	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
Throat irritation	5	12	1	3
Infection in the upper airways caused by a virus	4	2	6	7
Sinusitis	3	5	6	7
Acute sinusitis	3	2	4	8
Sore throat	3	5	1	2
Allergic rhinitis	2	3	4	4
Rhinitis	2	0	4	6
All Other				
Headaches	14	9	5	3
Back pain	5	6	3	5
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

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

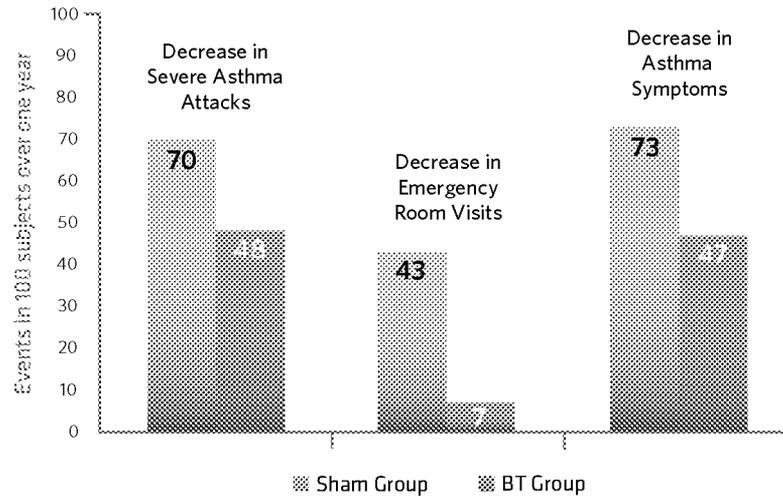
congestion, increased mucus in upper airways, infection in the lower airways caused by a virus, low oxygen in the blood, narrowing of airways, nasal congestion, pneumonia, runny nose, and swelling of the throat caused by a virus.

Ask your doctor about other uncommon side effects that are not related to the lungs, ear, nose, and throat.

What are the benefits of BT?

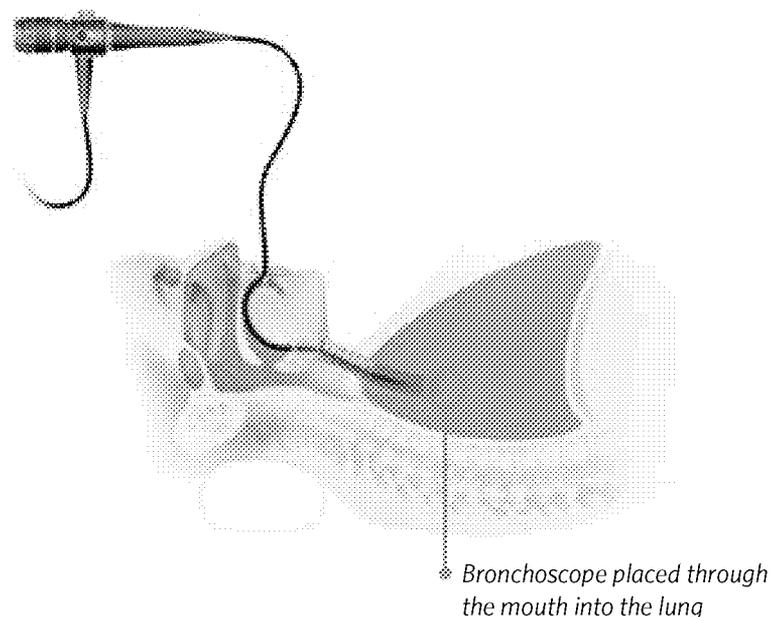
The study showed that the people in the BT Group had fewer severe asthma attacks, visits to the emergency room, and asthma symptoms, as shown in **Figure 2**.

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**.

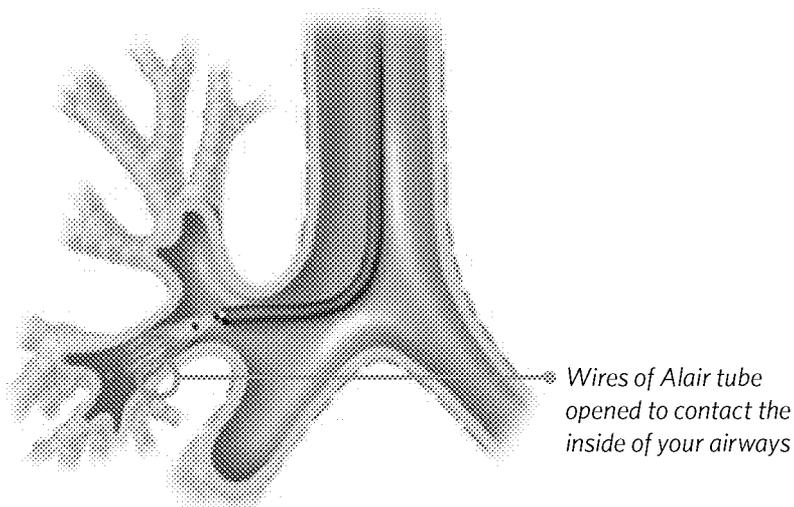
Figure 3. Placement of bronchoscope into your lungs



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 medicine 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**.

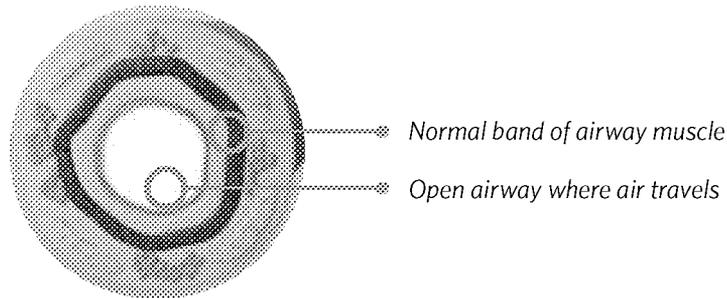
Figure 4. Placement of Alair tube in your lungs



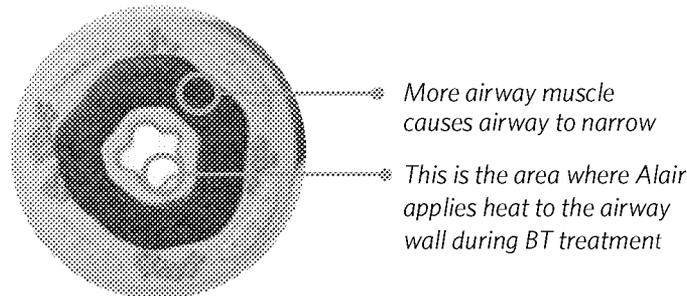
4. Heat the wires on the end of the small Alair™ tube to reduce some of the airway muscle tissue. You won't feel this because your doctor gave you medicine. See **Figure 5** for how airways look before and after Bronchial Thermoplasty treatment.

Figure 5. Airways before and after BT treatment

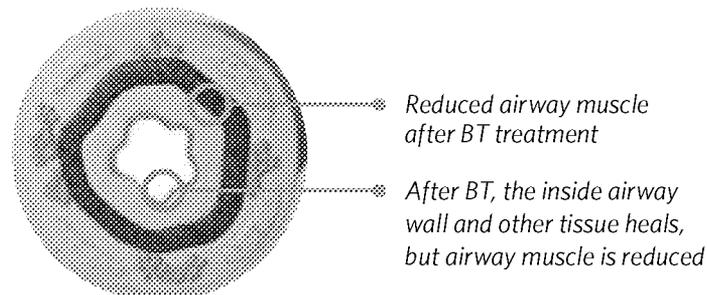
Airway of person without asthma



Airway of person with severe asthma



Airway of person with severe asthma after treatment



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

What happens after each BT treatment?

- * You need 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 need 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 using 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

**Boston
Scientific**

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
www.BTforAsthma.com

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BSC000569

APPLICANT'S EXHIBIT 97

TRADEMARK SEARCH REPORT

MELISA FRICK

FENWICK & WEST
2 PALO ALTO SQUARE
SUITE 800
PALO ALTO, CA, 94306
(650) 494-0600 Ext. 0000

Order Number: 9913814

ALAIR

MEDICAL EQUIPMENT PREPARATIONS AND
PROCEDURES INCLUDING MEDICAL SERVICES

Date Ordered:	August 12, 1999	Reference:	20766-070
Date Completed:	August 18, 1999	Delivery:	FEDEX NEXT DAY

JURISDICTIONS SEARCHED

US Federal
US State
US Common Law
Domain Names

RESEARCHER

Anna Arakelyan

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Contents: CORBASE (Federal)

The following records were found through an all-class search for the letter string ...ALAIR... (or its phonetic equivalents) and look/sound similar to your proposed mark.

1.	ALLAIRE	2
	Status: Notice of Allowance - Issued	
	Int'l Classes: 005, 010	
2.	ALLAIRE SPIROS	3
	Status: Notice of Allowance - Issued	
	Int'l Classes: 005, 010	
3.	ELARE	4
	Status: Notice of Allowance - Issued	
	Int'l Classes: 005	
4.	ALARE	4
	Status: Publication/Registration review complete	
	Int'l Classes: 009	
5.	ALLAIRE	5
	Status: Non-final action - Mailed	
	Int'l Classes: 009	
6.	ALLAIRE	5
	Status: New Application - Record initialized not assigned to examiner	
	Int'l Classes: 042	
7.	D'ALLAIRD'S	6
	Status: Section 8 - Accepted	
	Int'l Classes: 042	
8.	ALAREN	7
	Status: Abandoned - Failure to Respond	
	Int'l Classes: 029	
9.	ALLAIRE	7
	Status: Abandoned - Failure to Respond	
	Int'l Classes: 031	
10.	ALLAIRE	8
	Status: Cancelled - Section 8	
	Int'l Classes: 031	

ALAIR

11.	ALAIR	9
	Status: Cancelled - Section 8	
	Int'l Classes: 003	
12.	ALAREN	10
	Status: Cancelled - Section 8	
	Int'l Classes: 029	
13.	DUSTALAYR	11
	Status: Expired	
	Int'l Classes: 003	
14.	D'ALLAIRD'S	12
	Status: Cancelled - Section 8	
	Int'l Classes: 025	
15.	THERMALAIRE	13
	Status: Expired	
	Int'l Classes: 025	

The following records were found in your classes and contain A...LAIR... (or its phonetic equivalents) list goods/services related to your and look/sound similar to your proposed mark.

16.	ALAIR	14
	Status: Section 8 & 15 - Accepted and acknowledged	
	Int'l Classes: 005	
17.	AMILAIR	15
	Status: Abandoned - No Statement of Use filed	
	Int'l Classes: 005	

The following records were found in your classes for AL...AIR... (or their phonetic equivalents) list goods/services related to yours and look/sound similar to your proposed mark.

18.	ALTAIR	16
	Status: Section 8 & 15 - Accepted and acknowledged	
	Int'l Classes: 010	
19.	ALTAIR	18
	Status: Registered	
	Int'l Classes: 010	
20.	ALVAIR	19
	Status: Abandoned - Failure to Respond	
	Int'l Classes: 005	
21.	ALEVAIRE	20
	Status: Expired	
	Int'l Classes: 005	
22.	ALPARE	22
	Status: Expired	
	Int'l Classes: 005	

The following record was found in your classes for A...AIR... (or their phonetic equivalents) lists goods/services related to yours and looks/sounds very similar to your proposed mark.

23.	ADVAIR	23
	Status: Publication/Registration review complete	
	Int'l Classes: 005	

ALAIR

The following records were found in your classes for the suffix ...LAIR(S)(or their phonetic equivalents), list goods/services related to yours and look/sound similar to your proposed mark.

24.	BLAIR	24
	Status: Renewed	
	Intl Classes: 005	
25.	ZOLAIR	27
	Status: Publication/Registration review complete	
	Intl Classes: 005	
26.	ISOLAIR	28
	Status: Section 8 & 15 - Accepted and acknowledged	
	Intl Classes: 010	
27.	VENTILAIR	29
	Status: Section 8 & 15 - Accepted and acknowledged	
	Intl Classes: 010	
28.	FLAIR	30
	Status: Section 8 & 15 - Accepted and acknowledged	
	Intl Classes: 010	
29.	SINGULAIR	31
	Status: Registered	
	Intl Classes: 005	
30.	XOLAIR	31
	Status: First Extension - Granted	
	Intl Classes: 005	
31.	FLAIR	32
	Status: Notice of Allowance - Issued	
	Intl Classes: 010	
32.	RHEO BLAIR	33
	Status: Publication/Registration review complete	
	Intl Classes: 005	
33.	CLARALAIR	33
	Status: New Application - Record initialized not assigned to examiner	
	Intl Classes: 005	
34.	GLARE DROPS	34
	Status: Registered	
	Intl Classes: 005	
35.	LATERAL FLARE	34
	Status: Non-final action - Mailed	
	Intl Classes: 010	
36.	QUANTEC FLARE SERIES	35
	Status: Publication/Registration review complete	
	Intl Classes: 010	
37.	CARBOLAIR	35
	Status: Cancelled - Section 8	
	Intl Classes: 005	
38.	FLARE	36
	Status: Cancelled - Section 8	
	Intl Classes: 010	

ALAIR

39.	BELAIR	37
	Status: Cancelled - Section 8	
	Int'l Classes: 005	
40.	FLARE	38
	Status: Abandoned - No Statement of Use filed	
	Int'l Classes: 010	
41.	PENTOLAIR	39
	Status: Cancelled - Section 8	
	Int'l Classes: 005	
42.	SOLAIR	40
	Status: Cancelled - Section 8	
	Int'l Classes: 010	
43.	NARE FLARE	41
	Status: Abandoned - No Statement of Use filed	
	Int'l Classes: 010	
44.	FLAIR	42
	Status: Abandoned - No Statement of Use filed	
	Int'l Classes: 010	
45.	NASALFLAIR	42
	Status: Abandoned - Failure to Respond	
	Int'l Classes: 010	
46.	CLARALAIR	43
	Status: Abandoned - After Publication	
	Int'l Classes: 005	
47.	THOMPSON-BLAIR	43
	Status: Abandoned - Failure to Respond	
	Int'l Classes: 010, 020	
48.	ANTI-SHEAR LAYER	44
	Status: Abandoned - Failure to Respond	
	Int'l Classes: 005	
49.	FLAIR DENTAL ARTS	44
	Status: Abandoned - Failure to Respond	
	Int'l Classes: 010	
50.	FLAIR	45
	Status: Cancelled - Section 8	
	Int'l Classes: 005	

ALAIR

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Contents: CORSTATE (State)

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51.	ALAIRCO	46
	State: California	
52.	ALLAIRE VILLAGE INC	46
	State: New Jersey	
53.	ALLAIRE VILLAGE INC	47
	State: New Jersey	
54.	ALLAIRE AIRCRAFT SERVICES	47
	State: New Jersey	
55.	THERALAIR, INC.	47
	State: Arizona	

Contents: Common Law

Common Law Section.....48

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Contents: Domain Names

56.	ALAIR.COM	80
57.	ALEIR.COM	80
58.	ALAYRE.COM	80
59.	ELAIR.COM	80
60.	ALARE.COM	81
61.	ALARE.NET	81
62.	ALARES.COM	81
63.	ALARES.NET	81
64.	ALLAER.COM	82
65.	ALLAIR.COM	82
66.	ALLAIRE.COM	82
67.	ALLAIRE.NET	82
68.	ALLAIRE.ORG	83
69.	ALLARE.COM	83
70.	ALLARE.NET	83
71.	ALLEAR.COM	83
72.	ALLEARS.COM	84
73.	ALLEARS.NET	84
74.	ELLAIRE.COM	84
75.	ALLAREA.COM	84

Comments

This report covers records through the following dates:

To be Registered, Published or Canceled: September 14, 1999
 Most Recently Filed Application: July 23, 1999
 Most Recent Registration: July 27, 1999

Due to processing delays at the USPTO, not all applications filed by the date specified as Most Recently Filed Application are available for review.

The following character replacements may have been used in your search report:

^ = Any single character
 ~ = Vowel~A~Tilde@(a, e, i, o, u, y)
 @ = a, e, i, o, u, y, w
 # = Any single digit

When necessary to restrict the search by classes, the following classes were searched:

Intl Class 005	(Pharmaceuticals)
Intl Class 010	(Medical Apparatus)
Intl Class 035	(Advertising and Business)
Intl Class 042	(Miscellaneous Services)
Intl Class 200	(Collective Membership)
Intl Class A	(Certification of Goods)
Intl Class B	(Certification of Services)
US Class 018	(Medicines and Pharmaceutical Preparations)
US Class 044	(Dental, Medical, and Surgical Appliances)
US Class 100	(Miscellaneous)
US Class 101	(Advertising and Business)
US Class 200	(Collective Membership)
US Class A	(Certification of Goods)
US Class B	(Certification of Services)

ALAIR

The following records were found through an all-class search for the letter string ...ALAIR... (or its phonetic equivalents) and look/sound similar to your proposed mark.

1. ALLAIRE

Goods/Services:	(INT. 005) Pharmaceutical preparations for the treatment of diseases of the human respiratory, cardiovascular, endocrine, reproductive, neurologic, immune, gastrointestinal and musculo-skeletal systems, for the treatment of hematologic and bone disorders, infectious diseases and for metabolic and oncologic diseases
Status:	(INT. 010) Inhalers for powder pharmaceuticals Notice of Allowance - Issued, as of April 13, 1999
Serial No.:	75-426146
History:	Filed January 30, 1998 Published January 19, 1999
Extra Status:	Intent To Use
Ownership:	
At Filing:	Dura Pharmaceuticals, Inc. 7475 Lusk Boulevard San Diego, CA 921214204
Attorney:	Kenneth H Ohriner
Correspondent:	Kenneth H Ohriner Lyon & Lyon LLP 633 W 5th St Ste 4700 Los Angeles CA 90071-2066

ALAIR

2. ALLAIRE SPIROS

Goods/Services: (INT. 005) Pharmaceutical preparations for the treatment of diseases of the human respiratory, cardiovascular, endocrine, reproductive, neurologic, immune, gastrointestinal and musculo-skeletal systems, for the treatment of hematologic and bone disorders, infectious diseases and for metabolic and oncologic diseases

Status: (INT. 010) Inhalers for powder pharmaceuticals
Notice of Allowance - Issued, as of April 13, 1999

Serial No.: 75-426390

History: Filed January 30, 1998
Published January 19, 1999

Extra Status: Intent To Use

Ownership:

At Filing: Dura Pharmaceuticals, Inc.
7475 Lusk Boulevard
San Diego, CA 921214204

Attorney: Kenneth H Ohrinex

Correspondent: Kenneth H Ohrinex
Lyon & Lyon LLP
633 W 5th St Ste 4700
Los Angeles CA 90071-2066

ALAIR

3. ELARE

Goods/Services: (INT. 005) Pharmaceutical, namely, transdermal contraceptives
Status: Notice of Allowance - Issued, as of March 9, 1999
Serial No.: 75-457738
History: Filed March 27, 1998
Published December 15, 1998
Extra Status: Intent To Use
Ownership:
At Filing: Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 089337001
Attorney: Michael J Ryan Jr
Correspondent: Michael J Ryan Jr
Johnson & Johnson
1 Johnson & Johnson Plz
New Brunswick NJ 08933-7001

4. ALARE

ALARE

Goods/Services: (INT. 009) Computer peripherals for picture archiving communication systems
Status: Publication/Registration review complete, as of July 7, 1999
Serial No.: 75-570270
History: Filed October 14, 1998
Extra Status: Intent To Use
Ownership:
At Filing: Alare Systems Corporation
10 Sandra Lane
Sparta, NJ 078710847
Attorney: Scott S. Packman
Correspondent: Scott S Packman
O'Melveny & Myers LLP
1999 Ave Of The Stars 7th FL
Los Angeles CA 90067-6035
Design: Illustration, including words/letters/numbers in Stylized Form

ALAIR

5. ALLAIRE

Goods/Services: (INT. 009) Computer software for internet and other computer network applications
Status: Non-final action - Mailed, as of June 14, 1999
Serial No.: 75-579460
History: Filed October 29, 1998
Date of First Use: May 11, 1995 (INT CL. 009)
Ownership:
 At Filing: Allaire Corporation
 One Alewife Center
 Cambridge, MA 02140
Attorney: Charles E. Weinstein
Correspondent: Charles E. Weinstein
 Foley, Hoag & Eliot LLP
 One Post Office Square
 Boston, Massachusetts 02109

6. ALLAIRE

Goods/Services: (INT. 042) Consultation services in the field of computer hardware and software
Status: New Application - Record initialized not assigned to examiner, as of July 1, 1999
Serial No.: 75-737396
History: Filed October 29, 1998
Date of First Use: May 11, 1995 (INT CL. 042)
Ownership:
 At Filing: Allaire Corporation
 One Alewife Center
 Cambridge, MA 02140
Attorney: Susan Barbieri Montgomery
Correspondent: Susan Barbieri Montgomery
 Foley Hoag & Eliot LLP
 1 Post Office Sq
 Boston MA 02109

ALAIR

7. D'ALLAIRD'S

Goods/Services: (INT. 042) Retail department store services
Status: Section 8 - Accepted, as of May 14, 1997
Serial No.: 73-675144 **Registration No.:** 1482031
History: Filed July 29, 1987
Published December 29, 1987
Registered March 22, 1988
Date of First Use: March, 1987 (INT CL. 042)
Ownership:
At Filing: Marks & Spencer Canada, Inc.
3770 Nashua Drive
Mississauga, Ontario, Canada L4V 1M6
(Canada Corporation), DBA Marks & Spencer,
And DBA D'Allaird'S
At Publication: Marks & Spencer Canada, Inc.
3770 Nashua Drive
Mississauga, Ontario, Canada L4V 1M6
At Registration: Marks & Spencer Canada, Inc.
3770 Nashua Drive
Mississauga, Ontario, Canada L4V 1M6
Attorney: Barth X Derosa
Domestic Rep.: Watson Cole Grindle & Watson
Correspondent: Barth X Derosa
Watson Cole Grindle & Watson
1400 K St NW
Washington DC 20005-2477
Affidavits Filed: Section 8
Assignment: Deed 1825/0051, recorded December 8, 1998
Assignor: Marks & Spencer Canada, Inc., CAX, signed
August 2
Assignee: Comark Inc., 586 Argus Road, Oakville Ontario,
CAX, L6J 7S1, CAX
Text: Nunc pro tunc

ALAIR

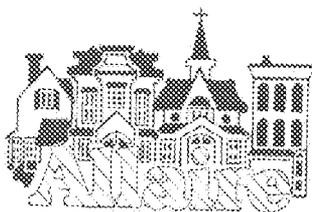
8. ALAREN

Goods/Services: (INT. 029) Casein
Status: Abandoned - Failure to Respond, as of March 5, 1984
Serial No.: 73-391492
History: Filed September 28, 1982
Abandoned February 24, 1984
Date of First Use: June 29, 1982 (INT CL. 029)
Ownership:
At Filing: New Zealand Milk Products, Inc.
6300 River Rd.
Rosemont, IL 60018
Attorney: Frank A. Neal
Correspondent: Frank A. Neal
4237 Bettina & Ulkern
San Mateo, Calif. 94403

9. ALLAIRE

Goods/Services: (INT. 031) Grass seed
Status: Abandoned - Failure to Respond, as of December 1, 1987
Serial No.: 73-643071
History: Filed February 5, 1987
Abandoned October 24, 1987
Date of First Use: August 5, 1986 (INT CL. 031)
Ownership:
At Filing: Turf Merchants, Inc.
P.O. BOX 1467
Albany, OR 97321
Attorney: Paul S. Angello
Correspondent: Paul S. Angello
Stoel, Rives, Boley, Fraser & Wyse
900 SW Fifth Avenue
Portland, Oregon 97204

10. ALLAIRE



Goods/Services: (INT. 031) Grass seed
Status: Cancelled - Section 8, as of September 4, 1995
Serial No.: 73-716322 **Registration No.:** 1527244
History: Filed March 14, 1988
 Published December 6, 1988
 Registered February 28, 1989
 Cancelled September 4, 1995
Date of First Use: August 5, 1986 (INT CL. 031)
Ownership:
 At Filing: Stanford Seed CO., The
 560 Fulton Street
 Buffalo, NY 14240
 At Publication: Stanford Seed CO., The
 560 Fulton Street
 Buffalo, NY 14240
 At Registration: Stanford Seed CO., The
 560 Fulton Street
 Buffalo, NY 14240
Attorney: Paul S. Angello
Correspondent: Paul S. Angello
 Steel Rives Boley Jones & Grey
 900 SW Fifth Avenue
 Suite 2300
 Portland, OR 97204
Disclaimer: No claim is made to the exclusive right to use
 "ALLAIRE", apart from the mark as shown.
Assignment: Deed 0686/0875, recorded December 22, 1989
 Assignor: Stanford Seed CO., The, NY, signed September
 Assignor: Borderland Warehouse Corporation, NY
 Assignor: Whitney-Dickinson Seeds, Inc., NY
 Assignor: Stanford Seed Export, Inc., NY
 Assignor: Whitney-Dickinson Seed Growers, Inc., ID
 Assignor: Turf Merchants, Inc., (Merged Into), OR
 Assignee: New Stanford, Inc., DE
 Text: Merger
Lining/Stippling: The lining shown in the portion of the mark
 consisting of four vintage buildings is a feature
 of the mark and does not indicate color. The
 word "ALLAIRE" is lined for the color green,
 but no claim is made to the color.
Design: Illustration, including words/letters/numbers

ALAIR

11. ALAIR

Goods/Services: (INT. 003) Beauty and perfumery products, namely hairdressing and scalp cleansing preparations, hair tonics, hair dyes, face creams, cold creams, ointments, emulsions, toilet powder, perfumes, toilet soap, lotions, and beauty oil for the body and face

Status: Cancelled - Section 8, as of September 29, 1997

Serial No.: 73-808927 **Registration No.:** 1638804

History: Filed June 26, 1989
Published January 1, 1991
Registered March 26, 1991
Cancelled September 29, 1997

Extra Status: Foreign Priority Claimed

Ownership:

At Filing: Alair Laboratories Ltd.
17 Wainwright Avenue
Richmond Hill, Ontario, Canada L4C 5R4

At Publication: Alair Laboratories Ltd.
17 Wainwright Avenue
Richmond Hill, Ontario, Canada L4C 5R4

At Registration: Alair Laboratories Ltd.
17 Wainwright Avenue
Richmond Hill, Ontario, Canada L4C 5R4

Attorney: Nancy A. Miller

Domestic Rep.: Sughrue, Mion, Zinn, Macpeak And Seat

Correspondent: Nancy A. Miller
Rogers, Bereskin & Parr
Scotia Plaza, 40 King Street West
Suite 4000, BOX 401
Toronto, Ontario, Canada M5h 3y2

Foreign Reg.: Canada, Reg. No.: 371277, Appl. No.: 628725,
Registered: July 27, 1990, Expiration: July 27,
2005, Foreign Priority Claimed

ALAIR

12. ALAREN

Goods/Services: (INT. 029) Edible caseins
Status: Cancelled - Section 8, as of April 12, 1999
Serial No.: 74-242272 Registration No.: 1722221
History: Filed February 3, 1992
Published July 14, 1992
Registered October 6, 1992
Cancelled April 12, 1999
Date of First Use: 1980 (INT CL. 029)
Ownership:
At Filing: New Zealand Dairy Board
Pastoral House, 25 The Terrace
Wellington, New Zealand
At Publication: New Zealand Dairy Board
Pastoral House, 25 The Terrace
Wellington, New Zealand
At Registration: New Zealand Dairy Board
Pastoral House, 25 The Terrace
Wellington, New Zealand
Attorney: Norman H. Zivin
Domestic Rep.: Norman H. Zivin
Correspondent: Norman H. Zivin
Cooper & Durham
1185 Avenue Of The Americas
New York, NY 10036

ALAIR

13. DUSTALAYR

Goods/Services: (U.S. 052) Liquid floor treatment oil preparation used for cleaning and sweeping floors and as a dust remover

INTL Class: 003 Cosmetics and Cleaning Preparations

Status: Expired, as of April 2, 1996

Serial No.: 71-664112 **Registration No.:** 0608108

History: Filed April 7, 1954
Registered June 28, 1955
Renewed June 28, 1975

Extra Status: Section 2(f)

Date of First Use: January 1, 1914 (US CL. 052)

Ownership:
At Registration: West Disinfecting Company
42-16 West St.
Long Island City, NY

Affidavits Filed: Sections 8 & 15

Assignment: Deed 0042/0281, recorded June 19, 1958

Assignor: West Disinfecting Company, Incorporated July 14, 1899., signed April

Assignee: West Chemical Products, Inc.

Text: Change of name

Assignment: Deed 0945/0343, recorded December 22, 1992

Assignor: West Chemical Products, Inc., signed November 30

Assignee: United Jersey Bank, 210 Main Street, Hackensack, NJ, 07068, NJ

Text: Security Interest

14. D'ALLAIRD'S



Goods/Services: (INT. 025) Ladies' wearing apparel, namely, dresses, jackets, suits, coats, simulated fur coats, raincoats, car coats, capes, vests, blouses, sweaters, tops, pants, skirts, shorts, swimsuits, beachwear, housecoats, kimonos, robes, negligees, negligee sets, nightgowns, pajamas, sleepcoats, slips, half slips, panties, briefs, petticoats, belts, gloves, scarves and hats

Status: Cancelled - Section 8, as of July 18, 1994

Serial No.: 73-633477 **Registration No.:** 1472371

History: Filed December 2, 1986
Published October 20, 1987
Registered January 12, 1988
Cancelled July 18, 1994

Ownership:

At Filing: Marks & Spencer Canada Inc.
3770 Nashua Drive
Mississauga, Ontario, Canada L4V 1M6

At Publication: Marks & Spencer Canada Inc.
3770 Nashua Drive
Mississauga, Ontario, Canada L4V 1M6

At Registration: Marks & Spencer Canada Inc.
3770 Nashua Drive
Mississauga, Ontario, Canada L4V 1M6

Attorney: Philip T. Shannon

Domestic Rep.: Pennie & Edmonds

Correspondent: Philip T. Shannon
Pennie & Edmonds
1155 Avenue Of The Americas
New York, New York 10036

Foreign Reg.: Canada, Reg. No.: 192286, Registered: June 29, 1973, Expiration: June 29, 1988

Assignment: Deed 0602/0070, recorded May 12, 1988

Assignor: Marks & Spencer Canada Inc., 3770 Nashua Drive, Mississauga, Ontario, CAN, L4V 1M6, signed May 2

Assignee: D'Allaird'S U.S. Inc., 1209 Orange Street, Wilmington, DE, 19801

Text: Assigns the entire interest and goodwill

Design: Illustration, including words/letters/numbers

ALAIR

15. THERMALAIRE

Goods/Services: (U.S. 039) Undershirts
INTL. Class: 025 Clothing
Status: Expired, as of July 20, 1998
Serial No.: 72-023678 Registration No.: 0653123
History: Filed February 4, 1957
Registered October 15, 1957
Renewed October 15, 1977
Date of First Use: January 14, 1957 (US CL. 039)
Ownership:
At Registration: Cluett, Peabody & CO., Inc.
433 River St.
Troy, NY
Affidavits Filed: Sections 8 & 15

ALAIR

The following records were found in your classes and contain A..LAIR.. (or its phonetic equivalents) list goods/services related to your and look/sound similar to your proposed mark.

16. ALAUR

Goods/Services: (INT. 005) Face cream to control blemishes
Status: Section 8 & 15 - Accepted and acknowledged, as of April 17, 1996
Serial No.: 73-689298 **Registration No.:** 1565395
History: Filed October 13, 1987
Published January 10, 1989
Registered November 14, 1989
Date of First Use: February 18, 1987 (INT CL. 005)
Ownership:
At Filing: Lefkovits, Albert M.
715 Park Avenue
New York, NY 10021
At Publication: Lefkovits, Albert M.
715 Park Avenue
New York, NY 10021
At Registration: Lefkovits, Albert M.
715 Park Avenue
New York, NY 10021
Attorney: Myron Amer
Correspondent: Myron Amer
Bauer & Amer
114 Old Country Road
Suite 310
Mineola, NY 11501
Affidavits Filed: Sections 8 & 15

ALAIR

17. AMILAIR

Goods/Services: (INT. 005) Pharmaceutical preparations and substances for the prevention, treatment and/or alleviation of respiratory disorders and cystic fibrosis

Status: Abandoned - No Statement of Use filed, as of March 10, 1994

Serial No.: 74-248455

History: Filed February 21, 1992
Published December 15, 1992

Extra Status: Intent To Use

Ownership:

At Filing: Glaxo Inc.
Five Moore Drive
P. O. BOX 13408
Research Triangle Park, NC 27709

At Publication: Glaxo Inc.
Five Moore Drive
P. O. BOX 13408
Research Triangle Park, NC 27709

Attorney: Dickerson M. Downing

Correspondent: Dickerson M. Downing
Morgan & Finnegan
345 Park Avenue
New York, NY 10154

ALAIR

The following records were found in your classes for AL...AIR... (or their phonetic equivalents) list goods/services related to yours and look/sound similar to your proposed mark.

18. ALTAIR

Goods/Services: (INT. 010) Electrocardiographic data acquisition and analysis apparatus
Status: Section 8 & 15 - Accepted and acknowledged, as of August 23, 1997
Serial No.: 74-168050 **Registration No.:** 1691338
History: Filed May 20, 1991
Published March 17, 1992
Registered June 9, 1992
Date of First Use: January, 1989 (INT CL. 010)
Ownership:
At Filing: Diagnostic Medical Instruments, Inc.
6724 Thompson Road
Syracuse, NY 13211
At Publication: Diagnostic Medical Instruments, Inc.
6724 Thompson Road
Syracuse, NY 13211
At Registration: Diagnostic Medical Instruments, Inc.
6724 Thompson Road
Syracuse, NY 13211
At Renewal: Burdick, Inc.
15 Plumb Street
Milton, WI 53563
Attorney: Stanley Sacks
Correspondent: Stanley Sacks
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210
Affidavits Filed: Sections 8 & 15
Assignment: Deed 1160/0462, recorded June 6, 1994
Assignor: Diagnostic Medical Instruments, Inc., NY,
signed May 2
Assignee: M&I Marshall & Hsley Bank, 770 N. Water
Street Milwaukee, WI 53202, WI
Text: Security Interest
Assignment: Deed 1611/0730, recorded July 18, 1997

Continued On Following Page ⇨

ALAIR

	Assignor:	Diagnostic Medical Instruments, Inc., NY, signed June 2
Assignee:		Burdick, Inc., 15 Plumb Street, Milton, WI, 53563, DE
Text:		Assigns the entire interest and goodwill

ALAIR

19. ALTAIR

Goods/Services: (INT. 010) Air mattress bed apparatus with integral control unit for therapeutic use
Status: Registered, as of June 10, 1997
Serial No.: 75-022229 **Registration No.:** 2070739
History: Filed October 19, 1995
Published July 23, 1996
Registered June 10, 1997
Extra Status: Intent To Use
Date of First Use: November 13, 1996 (INT CL. 010)
Ownership:
At Filing: Lumex, Inc.
81 Spence Street
Bay Shore, NY 11706
At Publication: Lumex, Inc.
81 Spence Street
Bay Shore, NY 11706
At Registration: Mul Acquisition Corp. II
900 Market Street
Suite 200
Wilmington, DE 19801
Attorney: Janet E. Witt
Correspondent: Janet E Witt
Alston & Bird
One Atlantic Ctr
1201 W Peachtree St
Atlanta GA 30309-3424
Assignment: Deed 1455/0336, recorded April 26, 1996
Assignor: Lumex, Inc., NY, signed April
Assignee: Mul Acquisition Corp. II, Suite 200, 900 Market Street, Wilmington, DE, 19801, DE
Text: Assigns the entire interest and goodwill
Assignment: Deed 1671/0307, recorded January 9, 1998
Assignor: Mul Acquisition Corp. II, DE, signed December 30,
Assignee: Ibj Schroder Business Credit Corporation, As Agent, One State Street, New York, NY, 10004, NY
Text: Security agreement

ALAIR

20. ALVAIR

Goods/Services: (INT. 005) Pharmaceutical preparations
Status: Abandoned - Failure to Respond, as of April 29, 1995
Serial No.: 74-512392
History: Filed April 13, 1994
Abandoned March 7, 1995
Extra Status: Intent To Use
Ownership:
At Filing: Riker Laboratories, Inc.
3m Center
Saint Paul, MN 55144
Attorney: Michelle M. Michel
Correspondent: Michelle M. Michel
3m Office Of Intellectual Prop. Counsel
3m Center, P.O. BOX 33427
St. Paul, MN 55133-3427

ALAIR

21. ALEVAIRE

Goods/Services: (U.S. 018) Preparation for aerosol inhalation in bronchopulmonary disorders
INTL Class: 005 Pharmaceuticals
Status: Expired, as of September 19, 1994
Serial No.: 71-642193 **Registration No.:** 0583675
History: Filed February 12, 1953
 Registered December 15, 1953
 Renewed December 15, 1973
Date of First Use: January 19, 1953 (US CL. 018)
Ownership:
At Registration: Winthrop-Stearns Inc.
 1450 Broadway
 New York, NY
Affidavits Filed: Sections 8 & 15

Assignment: Deed 0014/0431, recorded February 21, 1956
Assignor: Winthrop-Stearns Inc., signed Fe
Assignee: Winthrop Laboratories Inc.
Text: Change of name

Assignment: Deed 0014/0434, recorded February 21, 1956
Assignor: Winthrop Laboratories Inc., signed December 30,

Assignee: Sterling Drug Inc.
Text: Merger

Assignment: Deed 0824/0354, recorded October 23, 1991
Assignor: Sterling Drug Inc., DE, signed September
Assignee: Sterling Winthrop Inc., DE
Text: Change of name

Assignment: Deed 1381/0403, recorded December 8, 1995
Assignor: Sterling Winthrop Inc., DE, signed September
Assignee: Sanofi Winthrop, Inc., 90 Park Avenue, New York, NY, 10016, DE
Text: Assigns the entire interest and goodwill

Assignment: Deed 1556/0155, recorded February 5, 1997
Assignor: Sanofi Winthrop, Inc., DE, signed December 20,
Assignee: Sanofi Pharmaceuticals, Inc., 90 Park Avenue, New York, NY, 10016, DE
Text: Change of name

Opposition: Proceeding 055003, filed November 1, 1973

Continued On Following Page =>

ALAIR

Applicant: Beecham Inc., SN 72-451764, data not provided
by PTO

Outcome: Terminated as of May 13, 1974

ALAIR

22. ALPARE

Goods/Services: (U.S. 018) Allergenic extracts
INTL Class: 005 Pharmaceuticals
Status: Expired, as of December 5, 1994
Serial No.: 72-465048 Registration No.: 0979314
History: Filed August 7, 1973
Registered February 26, 1974
Date of First Use: July 2, 1973 (US CL. 018)
Ownership:
At Registration: Miles Laboratories, Inc.
1127 Myrtle St.
Elkhart, IN 46514
Affidavits Filed: Section 8
Assignment: Deed 0353/0446, recorded July 2, 1979
Assignor: Miles Laboratories, Inc., -Merged into-, IN,
signed May 2
Assignee: Miles Laboratories, Inc.
Text: Merger and change of name
Assignment: Deed 0589/0225, recorded October 13, 1987
Assignor: Miles Laboratories, Inc., DE, signed September
Assignee: Miles Inc., IN
Text: Merger

ALAIR

The following record was found in your classes for ALAIR (or their phonetic equivalents) lists goods/services related to yours and looks/sounds very similar to your proposed mark.

23. ADVAIR

Goods/Services:	(INT. 005) Pharmaceutical preparations and substances for the treatment and/or alleviation of respiratory ailments
Status:	Publication/Registration review complete, as of June 22, 1999
Serial No.:	75-595007
History:	Filed November 24, 1998
Extra Status:	Intent To Use
Ownership:	
At Filing:	Glaxo Group Limited Berkeley Avenue Greenford Middlesex UB6 0UN, United Kingdom
Attorney:	Maury M. Tepper, III
Domestic Rep.:	Glaxo Wellcome Inc.
Correspondent:	Maury M. Tepper, III Intellectual Property Group - Mai-476 Five Moore Drive Research Triangle Park, NC 27709

BLAIR

The following records were found in your classes for the suffix
...LAIR(S)(or their phonetic equivalents), list goods/services related to
yours and look/sound similar to your proposed mark.

24. BLAIR

Goods/Services: (U.S. 018) Liniment, bitter herb compound, laxative chewing gum, cough syrup, vitamin tablets, medicated salve for the chest and throat, castoria, hygienic powder, antiseptic skin ointment, liniment and camminative, toothache drops, burn ointment, milk of magnesia tablets, aspirin tablets, a. P. C. Tablets, corn remedy, foot comfort salve, athlete's foot aid salve, antiseptic mouth wash, and antiseptic medicated skin cream

INTL Class: 005 Pharmaceuticals

Status: Renewed, as of April 1, 1991

Serial No.: 71-588649 **Registration No.:** 0541104

History: Filed December 1, 1949
Registered April 17, 1951
Renewed April 17, 1991

Extra Status: Section 2(f)

Date of First Use: January 1, 1949 (US CL. 018)

Ownership:

At Registration: Morton Manufacturing Corp.
2101 Hudson Street
Lynchburg, VA
(Virginia Corporation), DBA Blair Of Virginia

At Renewal: Trend Media, Inc.
1000 Robins Road
Lynchburg, VA 24506

Correspondent: Kelvin G. Smith
Kimmel, Crowell & Weaver
Suite 1203
2001 Jefferson Davis Highway
Arlington, VA. 22202

Affidavits Filed: Section 8

Assignment: Deed 0114/0730, recorded June 24, 1964

Assignor: Morton Manufacturing Corporation Intco, signed May 2

Assignee: Morton Manufacturing Corporation

Text: Merger and change of name

Continued On Following Page ⇨

BLAIR

Assignor: Trend Media, Inc., DE, signed August 7
Assignee: Tri-Tech Laboratories, Inc., 1000 Robins Road
Lynchburg, VA 24506, DE
Text: Assigns the entire interest and goodwill

Assignment: Deed 1381/0954, recorded July 20, 1995
Assignor: Nationsbank Of Georgia, N.A. (Formerly Central
Fidelity Bank, Manufacturers Hanover Trust
Company, Sovran Bank & The Citizens And
Southern National Bank), signed July 18
Assignee: Trend Media, Inc., 3397 Rilmann Rd., N.W.,
Atlanta, GA, 30327, DE
Assignee: Trend Laboratories, Inc. (Formerly Frances
Denney Companies, Inc. And Frances Denney,
Inc.), 3397 Rilmann Road, N.W., Atlanta, GA,
30327, DE
Text: Release of security interest and assignment of
assignor's interest nunc pro tunc august 17, 1992.

Assignment: Deed 1395/0231, recorded October 11, 1995
Assignor: Tri-Tech Laboratories, Inc., DE, signed October
2,
Assignee: Blair Holdings, Inc., 700 Barksdale Road, Suite
15, Newark, DE, 19711, DE
Text: Assignment of a part of assignor interest

Cancellation: Proceeding 014444, filed August 2, 1984
Respondent: New Process Company, citing trademark
"BLAIR", SN 73-402356, RN 1283914
Outcome: Terminated as of December 18, 1986
Design: Illustration, including words/letters/numbers in
Stylized Form

ALAIR

25. ZOLAIR

Goods/Services:	(INT. 005) Pharmaceutical preparations for use in the treatment of rhinitis
Status:	Publication/Registration review complete, as of June 21, 1999
Serial No.:	75-597662
History:	Filed December 10, 1998
Extra Status:	Intent To Use
Ownership:	
At Filing:	Novartis Ag 4002 Ch Basel, Switzerland
Domestic Rep.:	Chris Doninger
Correspondent:	Chris Doninger 564 Morris Avenue Summit New Jersey 07901

26. ISOLAIR

Goods/Services: (INT. 010) Surgical filtering masks
Status: Section 8 & 15 - Accepted and acknowledged, as of March 8, 1989
Serial No.: 73-359541 **Registration No.:** 1227425
History: Filed April 12, 1982
 Published November 23, 1982
 Registered February 15, 1983
Date of First Use: November 1, 1981 (INT CL. 010)
Date of First Use:
In Commerce: December 1, 1981 (INT CL. 010)
Ownership:
At Filing: Louis M. Gerson CO., Inc.
 15 Sproat St.
 Middleboro, MA
At Publication: Louis M. Gerson CO., Inc.
 15 Sproat St.
 Middleboro, MA
At Registration: Louis M. Gerson CO., Inc.
 15 Sproat St.
 Middleboro, MA
Attorney: Stanley Sacks
Correspondent: Stanley Sacks
 Wolf, Greenfield & Sacks
 201 Devonshire
 Boston MA 02110
Affidavits Filed: Sections 8 & 15

ALAIR

27. VENTILAIR

Goods/Services: (INT. 010) Medical air compressor for respiratory therapy
Status: Section 8 & 15 - Accepted and acknowledged, as of June 10, 1996
Serial No.: 73-665774 **Registration No.:** 1566967
History: Filed June 10, 1987
Published August 29, 1989
Registered November 21, 1989
Date of First Use: October 20, 1986 (INT CL. 010)
Ownership:
At Filing: Hamilton Medical, Inc.
P.O. BOX 30008
Reno, NV 89520
At Publication: Hamilton Medical, Inc.
P.O. BOX 30008
Reno, NV 89520
At Registration: Hamilton Medical, Inc.
P.O. BOX 30008
Reno, NV 89520
Attorney: William K. Wells, Jr.
Correspondent: William K. Wells, Jr.
Kenyon & Kenyon
1025 Connecticut Avenue, N.W.
Washington, D.C. 20036
Affidavits Filed: Sections 8 & 15

ALAIR

28. FLAIR

Goods/Services: (INT. 010) Dental prophylaxis instruments, namely, brushes and cups
Status: Section 8 & 15 - Accepted and acknowledged, as of March 30, 1998
Serial No.: 74-148710 **Registration No.:** 1676672
History: Filed March 18, 1991
Published December 3, 1991
Registered February 25, 1992
Date of First Use: February 1, 1991 (INT CL. 010)
Ownership:
At Filing: Dentsply International Inc.
570 West College Ave.
York, PA 17404
At Publication: Dentsply International Inc.
570 West College Ave.
York, PA 17404
At Registration: Dentsply International Inc.
570 West College Ave.
York, PA 17404
At Renewal: Dentsply Research And Development Corp.
Lakeview And Clarke Avenue
Milford, DE 19963
Attorney: Edward J Hanson Jr
Correspondent: Edward J Hanson Jr
Dentsply International Inc
570 W College Ave
York PA 17405-0872
Affidavits Filed: Sections 8 & 15
Assignment: Deed 1131/0445, recorded April 1, 1994
Assignor: Dentsply International Inc., DE, signed Mar
Assignee: Dentsply Research And Development Corp.,
Lakeview And Clarke Avenue Milford, DE
19963, DE
Text: Assigns the entire interest and goodwill

ALAIR

29. SINGULAIR

Goods/Services: (INT. 005) Pharmaceutical preparations for the treatment of respiratory disorders
Status: Registered, as of March 25, 1997
Serial No.: 74-589438 **Registration No.:** 2048127
History: Filed October 24, 1994
Published September 12, 1995
Registered March 25, 1997
Extra Status: Intent To Use
Date of First Use: May 15, 1996 (INT CL. 005)
Ownership:
At Filing: Merck & CO., Inc.
One Merck Drive, P.O. BOX 100
Whitehouse Station, NJ 088890100
At Publication: Merck & CO., Inc.
One Merck Drive, P.O. BOX 100
Whitehouse Station, NJ 088890100
Attorney: Kevin M. Dugan
Correspondent: Kevin M. Dugan
Merck & CO., Inc.
P. O. BOX 100
One Merck Drive
Whitehouse Station, NJ 08889-0100

30. XOLAIR

Goods/Services: (INT. 005) Pharmaceutical preparations for use in the treatment of rhinitis
Status: First Extension - Granted, as of June 28, 1999
Serial No.: 75-388270
History: Filed November 12, 1997
Published September 15, 1998
Extra Status: Intent To Use
Ownership:
At Filing: Novartis Ag
4002 Basle, Switzerland
Attorney: Barry A Solomon
Domestic Rep.: Novartis Corporation
Correspondent: Barry A Solomon
Novartis Corp
556 Morris Ave
Summit NJ 07901

ALAIR

31. FLAIR

Goods/Services: (INT. 010) Nasal support device for use on non-human domestic mammals

Status: Notice of Allowance - Issued, as of March 2, 1999

Serial No.: 75-423380

History: Filed January 21, 1998
Published December 8, 1998

Extra Status: Intent To Use

Ownership:

At Filing: Blach, Edward L.
 P.O. BOX 1901
 Roswell, NM 88202

At Publication: Winease, Llc
 856 Great Oaks Trail
 Eagan, MN 55123

Attorney: James R Chiapetta

Correspondent: James R Chiapetta
Merchant Gould Smith Edell Welter Et AL
3100 Norwest Ctr
90 S 7th St
Minneapolis MN 55402-4131

Assignment: Deed 1716/0005, recorded April 13, 1998

Assignor: Blach, Edward L., signed Apri

Assignee: Winease, Llc, 856 Great Oaks Trail, Eagan, MN, 55123

Text: Assigns the entire interest and goodwill

ALAIR

32. RHEO BLAIR

Goods/Services: (INT. 005) Dietary and nutritional supplements
Status: Publication/Registration review complete, as of
May 12, 1999
Serial No.: 75-536104
History: Filed August 13, 1998
Extra Status: Intent To Use
Ownership:
At Filing: Next Nutrition, Inc.
6231 Yarrow Drive
Suite C
Carlsbad, CA 92009
Attorney: Jay H Geller
Correspondent: Jay H Geller
Law Offices Of Jay H Geller
East Twr Ste 600
2425 W Olympic Blvd
Santa Monica CA 90404

33. CLARALAIR

CLARALAIR

Goods/Services: (INT. 005) Antihistamine preparation
Status: New Application - Record initialized not
assigned to examiner, as of May 10, 1999
Serial No.: 75-657408
History: Filed March 10, 1999
Extra Status: Intent To Use
Ownership:
At Filing: Schering Corporation
2000 Galloping Hill
Kenilworth, NJ 07033
Attorney: Joel Wiener
Correspondent: Joel Wiener
Schering Corp
2000 Galloping Hill
Kenilworth NJ 07033

ALAIR

34. GLARE DROPS

Goods/Services: (INT. 005) Eye lubricating drops
Status: Registered, as of November 25, 1997
Serial No.: 75-146971 Registration No.: 2116994
History: Filed August 8, 1996
Published April 29, 1997
Registered November 25, 1997
Extra Status: Intent To Use
Date of First Use: August 18, 1997 (INT CL. 005)
Ownership:
At Filing: Ergovision, Inc.
1 Fairchild Court
Plainview, NY 11803
At Publication: Ergovision, Inc.
1 Fairchild Court
Plainview, NY 11803
Attorney: Leonard W. Suroff
Correspondent: Leonard W. Suroff
12 Tompkins Avenue
Jericho, NY 11753
Disclaimer: No claim is made to the exclusive right to use
"DROPS", apart from the mark as shown.

35. LATERAL FLARE

Goods/Services: (INT. 010) Hip prosthesis
Status: Non-final action - Mailed, as of May 24, 1999
Serial No.: 75-213485
History: Filed December 16, 1996
Extra Status: Supplemental Register
Date of First Use: 1990 (INT CL. 010)
Ownership:
At Filing: Felto, Joseph F.
530 First Avenue, Suite 5b
New York, NY 10016
Attorney: Lawrence E. Abelman
Correspondent: Lawrence E. Abelman
Abelman Frayne & Schwab
150 E 42nd St
New York NY 10017

ALAIR

36. QUANTEC FLARE SERIES

Goods/Services: (INT. 010) Endodontic instruments, namely, endodontic files and reamers, handles for endodontic instruments and root canal therapy instruments

Status: Publication/Registration review complete, as of June 17, 1999

Serial No.: 75-539272

History: Filed August 19, 1998

Extra Status: Intent To Use

Date of First Use: May 1, 1998 (INT CL. 010)

Ownership:
At Filing: Ormco Corporation
1717 West Collins Avenue
Orange, CA 92867

Correspondent: Wood Herron & Evans Llp
2700 Carew Twr
441 Vine St
Cincinnati OH 45202

Disclaimer: No claim is made to the exclusive right to use "SERIES", apart from the mark as shown

37. CARBOLAIR

Goods/Services: (INT. 005) Bronchodilator pharmaceutical preparation

Status: Cancelled - Section 8, as of February 28, 1984

Serial No.: 73-116017 **Registration No.:** 1074426

History: Filed February 16, 1977
Registered October 4, 1977
Cancelled February 28, 1984

Date of First Use: January 28, 1977 (INT CL. 005)

Ownership:
At Registration: Riker Laboratories, Inc.
Northridge, CA

38. FLARE

Goods/Services: (INT. 010) Medical goods-namely, infant diapers for use in the treatment of hyperbilirubenemia; surgical clothing covers-namely, headwear, shoe covers, and surgical gowns
Status: Cancelled - Section 8, as of August 14, 1990
Serial No.: 73-389301 **Registration No.:** 1272547
History: Filed September 27, 1982
 Published January 10, 1984
 Registered April 3, 1984
 Cancelled August 14, 1990
Date of First Use: February 10, 1980 (INT CL. 010)
Date of First Use:
In Commerce: May 14, 1980 (INT CL. 010)
Ownership:
At Filing: Flare Products, Inc.
 P.O. BOX 2155
 2881 Nogales, Tucson Hwy.
 Nogales, AZ
At Publication: Flare Products, Inc.
 P.O. BOX 2155
 2881 Nogales, Tucson Hwy.
 Nogales, AZ
At Registration: Flare Products, Inc.
 P.O. BOX 2155
 2881 Nogales, Tucson Hwy.
 Nogales, AZ
Attorney: Harry M. Weiss
Correspondent: Harry M. Weiss
 4204 N. Brown Ave.
 Scottsdale AZ 85251

ALAIR

39. BELAIR

Goods/Services: (INT. 005) Bronchodilator
Status: Cancelled - Section 8, as of May 2, 1994
Serial No.: 73-651813 Registration No.: 1462486
History: Filed March 27, 1987
Published August 4, 1987
Registered October 27, 1987
Cancelled May 2, 1994
Date of First Use: March 6, 1987 (INT CL. 005)
Ownership:
At Filing: Purdue Frederick Company
100 Connecticut Avenue
Norwalk, CT 06856
At Publication: Purdue Frederick Company
100 Connecticut Avenue
Norwalk, CT 06856
At Registration: Purdue Frederick Company
100 Connecticut Avenue
Norwalk, CT 06856
Attorney: Samuel Kriegel
Correspondent: Samuel Kriegel
P.O. BOX 5600
100 Connecticut Avenue
Norwalk, CT 06856

ALAIR

40. FLARE

Goods/Services: (INT. 010) Massage tools
Status: Abandoned - No Statement of Use filed, as of November 21, 1991
Serial No.: 74-008166
History: Filed December 5, 1989
Published August 28, 1990
Extra Status: Intent To Use
Ownership:
 At Filing: Flare Company Limited
70, Kimigasa Sakaecho 1 -Chome
Yokosuka, Kanagaga, Japan
 At Publication: Flare Company Limited
70, Kimigasa Sakaecho 1 -Chome
Yokosuka, Kanagaga, Japan
Attorney: L. Lawton Rogers, III
Domestic Rep.: L. Lawton Rogers, III, Joseph M. Killeen And
Thomas W. Perkins
Correspondent: L. Lawton Rogers, III
Rogers & Killeen
510 King Street, Suite 408
Alexandria, VA 22314
Design: Illustration, including words/letters/numbers

ALAIR

41. PENTOLAIR

Goods/Services: (INT. 005) Ophthalmic solutions
Status: Cancelled - Section 8, as of April 6, 1998
Serial No.: 74-108243 Registration No.: 1658787
History: Filed October 19, 1990
Published July 9, 1991
Registered October 1, 1991
Cancelled April 6, 1998
Date of First Use: January, 1989 (INT CL. 005)
Ownership:
At Filing: Bausch & Lomb Pharmaceuticals, Inc.
8500 Hidden River Parkway
Tampa, FL 33637
At Publication: Bausch & Lomb Pharmaceuticals, Inc.
8500 Hidden River Parkway
Tampa, FL 33637
At Registration: Bausch & Lomb Pharmaceuticals, Inc.
8500 Hidden River Parkway
Tampa, FL 33637
Attorney: Jon O. Webster
Correspondent: Jon O. Webster
One Lincoln First Square
Rochester, NY 14604

ALAIR

42. SOLAIR

Goods/Services: (INT. 010) Medical heated canopies for infant care
Status: Cancelled - Section 8, as of June 28, 1999
Serial No.: 74-159647 Registration No.: 1742226
History: Filed April 22, 1991
Published February 25, 1992
Registered December 22, 1992
Cancelled June 28, 1999
Extra Status: Intent To Use
Date of First Use: May 30, 1992 (INT CL. 010)
Ownership:
At Filing: Air-Shields, Inc.
330 Jacksonville Road
Hathoro, PA 19040
At Publication: Air-Shields, Inc.
330 Jacksonville Road
Hathoro, PA 19040
At Registration: Air-Shields, Inc.
330 Jacksonville Road
Hathoro, PA 19040
Attorney: Andrew L. Ney
Correspondent: Andrew L. Ney
Ratner & Prestia
500 North Gulph Road
Post Office BOX 980
Valley Forge, PA 19482

ALAIR

43. NARE FLARE

Goods/Services: (ENT. 010) External nasal dilator
Status: Abandoned - No Statement of Use filed, as of
May 11, 1993
Serial No.: 74-243055
History: Filed February 4, 1992
Published August 18, 1992
Extra Status: Intent To Use
Ownership:
 At Filing: Cns, Inc.
 1250 Park Road
 Chanhassen, MN 553179260
 At Publication: Cns, Inc.
 1250 Park Road
 Chanhassen, MN 553179260
Attorney: Theodore F. Neils
Correspondent: Theodore F. Neils
 Kinney & Lange
 Suite 1500
 625 Fourth Avenue South
 Minneapolis, MN 55415-1659

ALAIR

44. FLAIR

Goods/Services: (INT. 010) Medical devices, namely, infusion catheters for the heart
Status: Abandoned - No Statement of Use filed, as of November 7, 1997
Serial No.: 75-131638
History: Filed July 9, 1996
Published February 11, 1997
Extra Status: Intent To Use
Ownership:
At Filing: Interventional Innovations Corp.
2670 Patton Road
St. Paul, MN 55113
At Publication: Interventional Innovations Corp.
2670 Patton Road
St. Paul, MN 55113
Attorney: Janal M. Kalis
Correspondent: Janal M. Kalis
Oppenheimer Wolff & Donnelly
3400 Plaza VII, 45 South Seventh Street
Minneapolis, MN 55402

45. NASALFLAIR

Goods/Services: (INT. 010) Medical apparatus, namely, nasal positive airway pressure devices
Status: Abandoned - Failure to Respond, as of May 29, 1998
Serial No.: 75-257162
History: Filed March 14, 1997
Abandoned April 3, 1998
Extra Status: Intent To Use
Ownership:
At Filing: Vital Signs, Inc.
20 Campus Road
Totowa, NJ 07512
Attorney: Joseph A. Giampapa
Correspondent: Joseph A. Giampapa
20 Campus Rd
Totowa NJ 07512

ALAIR

46. CLARALAIR

Goods/Services: (INT. 005) Antihistamine/anti-inflammatory preparation
Status: Abandoned - After Publication, as of June 10, 1999
Serial No.: 75-422270
History: Filed January 23, 1998
Published December 8, 1998
Abandoned March 31, 1999
Extra Status: Intent To Use
Ownership:
At Filing: Schering Corporation
200 Galloping Hill Road
Kenilworth, NJ 07033
At Publication: Schering Corporation
200 Galloping Hill Road
Kenilworth, NJ 07033
Attorney: Joel Wiener
Correspondent: Joel Wiener
Schering Corp
2000 Galloping Hill Rd
Kenilworth NJ 07033

47. THOMPSON-BLAIR

Goods/Services: (INT. 010) Beds for surgical and medical use
(INT. 020) Beds, hospital beds, home care beds
Status: Abandoned - Failure to Respond, as of August 26, 1985
Serial No.: 73-509635
History: Filed November 19, 1984
Abandoned August 6, 1985
Date of First Use: June, 1978 (INT CL. 010, 020)
Ownership:
At Filing: Ev-Jen Medical
3233 E. Mission Oaks Blvd.
Camarillo, CA 93010
Correspondent: Pastoriza & Kelly
21031 Ventura Boulevard
Suite 919
Woodland Hills, California 91364

ALAIR

48. ANTI-SHEAR LAYER

Goods/Services: (INT. 005) Medical devices, namely wound dressings
Status: Abandoned - Failure to Respond, as of June 8, 1992
Serial No.: 74-155150
History: Filed April 8, 1991
Abandoned April 11, 1992
Date of First Use: March 1, 1991 (INT CL. 005)
Date of First Use:
In Commerce: April 2, 1991 (INT CL. 005)
Ownership:
At Filing: Fraass Survival Systems, Inc.
3830 Boston Road
Bronx, NY 10475
Attorney: Dennis J. Helms
Correspondent: Dennis J. Helms
Mathews, Woodbridge & Collins, P.A.
Suite 306
100 Thayer Circle
Princeton, New Jersey 08540-3662

49. FLAIR DENTAL ARTS



Goods/Services: (INT. 010) Artificial teeth
Status: Abandoned - Failure to Respond, as of January 26, 1999
Serial No.: 75-369185
History: Filed October 6, 1997
Abandoned November 30, 1998
Date of First Use: July 31, 1997 (INT CL. 010)
Ownership:
At Filing: Maynard, Michael William
104 N. Missouri Ave.
Roswell, NM 88201-1016
Correspondent: Michael William Maynard
104 N Missouri Ave
Roswell NM 88201-1016
Design: Illustration, including words/letters/numbers

ALAIR

50. FLAIR

Goods/Services: (INT. 005) Veterinary preparations - namely, an insecticide and repellent for fleas, ticks and lice on dogs and cats

Status: Cancelled - Section 8, as of July 4, 1994

Serial No.: 73-620604 **Registration No.:** 1470376

History: Filed September 18, 1986
Published October 6, 1987
Registered December 29, 1987
Cancelled July 4, 1994

Date of First Use: July 10, 1986 (INT CL. 005)

Ownership:

At Filing: Coopers Animal Health Inc.
520 West 21st Street
Kansas City, MO 64108

At Publication: Coopers Animal Health Inc.
520 West 21st Street
Kansas City, MO 64108

At Registration: Coopers Animal Health Inc.
520 West 21st Street
Kansas City, MO 64108

Attorney: Robert D. Hovey

Correspondent: Robert D. Hovey
Schmidt, Johnson, Hovey & Williams
1400 Mercantile Bank Tower
1101 Walnut Street
Kansas City, Missouri 64106

In a search through *Shepard's United States Citations on CD-ROM Edition*, for references similar to ALAIR, the following citations were found and may be relevant to your proposed mark.

PTTMA,Alair

Published for December 1998 - August 1999

There are no citing references to this legal authority for this period.

Published prior to December 1998

Cancelled 690 OGT 158

Cancelled 1204 OGT(2) 548

ALAIR

.....
The following records were found through an all-class search for the letter
string ...ALAIR... (or their phonetic equivalents) and look/sound similar
to your proposed mark.
.....

51. ALAIRCO

State: California
Goods/Services: Air conditioning heating refrigeration etc
INTL Class: 035 Advertising and Business
036 Insurance and Financial
042 Miscellaneous Services
US Class: 101 Advertising and Business
Status: Renewed
Registration No.: S9110
History: Renewed December 18, 1989
Owner: Albert Edward Keen Tarzana CA

52. ALLAIRE VILLAGE INC

State: New Jersey
Goods/Services: Rings spoons mugs
INTL Class: 016 Paper Goods and Printed Matter
017 Rubber Goods
020 Furniture and Articles Not Otherwise
Classified
022 Cordage and Fibers
028 Toys and Sporting Goods
US Class: 050 Merchandise Not Otherwise Classified
Status: Registered
Registration No.: C4607
History: Registered June 16, 1986
Owner: Allaire Village Inc Farmingdale NJ

ALAIR

53. ALLAIRE VILLAGE INC

State: New Jersey
Goods/Services: Rings spoons mugs stationery t-shirts
INTL Class: 035 Advertising and Business
036 Insurance and Financial
042 Miscellaneous Services
US Class: 101 Advertising and Business
Status: Registered
Registration No.: C7227
History: Registered June 19, 1986
Owner: Allaire Village Inc Farmingdale NJ

54. ALLAIRE AIRCRAFT SERVICES

State: New Jersey
Goods/Services: Advertising and business
INTL Class: 035 Advertising and Business
036 Insurance and Financial
042 Miscellaneous Services
US Class: 101 Advertising and Business
Status: Registered
Registration No.: C6910
History: Registered July 26, 1983
Owner: Monmouth Aircraft Service Inc Farmingdale NJ

55. THERALAIR, INC.

State: Arizona
Goods/Services: Heating, ventilating and air conditioning
INTL Class: 011 Environmental Control Apparatus
Status: Registered
Registration No.: 177871
History: Filed July 14, 1997
Registered July 14, 1997
Date of First Use: July 9, 1997 (in state)
Owner: Thermalair, Inc.
1140 Red Gum St.
Anaheim, CA 92806

ALAIR

THE FOLLOWING FILES WERE SEARCHED FOR COMPANY NAMES, TRADE NAMES, OR PRODUCT NAMES SIMILAR TO YOURS:

File 16:Gale Group PROMT(R) 1972-1999/Aug 09 (c) 1999 The Gale Group
File 47:Gale Group Magazine DB(TM) 1959-1999/Aug 09 (c) 1999 The Gale group
File 111:TGG Natl.Newspaper Index(SM) 1979-1999/Aug 09 (c) 1999 The Gale Group
File 116:Brands & Their Companies 1998/Dec (c) 1999 Gale Research
File 148:Gale Group Trade & Industry DB 1976-1999/Aug 09 (c)1999 The Gale Group
File 211:Gale Group Newsearch(TM) 1997-1999/Aug 09 (c) 1999 The Gale Group
File 570:Gale Group MARS(R) 1984-1999/Aug 09 (c) 1999 The Gale Group
File 621:Gale Group New Prod.Annou.(R) 1985-1999/Aug 09 (c) 1999 The Gale Group
File 15:ABI/INFORM(R) 1971-1999/Aug 09 (c) 1999 Bell & Howell
File 75:TGG Management Contents(R) 86-1999/Aug W1 (c) 1999 The Gale Group
File 535:Thomas Register Online(R) 1999/Q1 (c) 1999 Thomas Publishing Co.
Dun and Bradstreet

Pharmaceutical Specialty Files

File 72:EMBASE 1993-1999/Jul W4 (c) 1999 Elsevier Science B.V.
File 73:EMBASE 1974-1999/Jul W4 (c) 1999 Elsevier Science B.V.
File 74:In.Pharm.Abs. 1970-1999/Apr (c) 1999 Amer.Soc.of Health-System Pharm.
File 149:TGG Health&Wellness DB(SM) 1976-1999/Aug W2 (c) 1999 The Gale Group
File 158:DIOGENES(R) 1976-1999/May W3 (c) 1999 DIOGENES
File 187:F-D-C Reports 1987-1999/Aug W1 (c) 1999 F-D-C Reports Inc.
File 188:Health Devices Sourcebook (1999) ECRI (A nonprofit agency)
File 198:Health Devices Alerts(R) 1977-1999/Aug W2 (c) 1999 ECRI-nonprft agncy

ALAIR

5/8/1 (Item 1 from file: 16)
DIALOG(R)File 16(c) 1999 The Gale Group. All rts. reserv.

08462354 SUPPLIER NUMBER: 55394804
Best Of Show At Internet World Australia 99 08/06/99.
August 6, 1999
FULL TEXT AVAILABLE IN FORMAT 7 OR 9 WORD COUNT: 262

COMPANY:

*Creative Digital Technology
Allaire Corp.
Cable and Wireless Optus Ltd.
Harvest Software Inc.

PRODUCT: *Network Software (7372620); Data Encryption Software (7372691);
Internet Access Providers (4811522); Multimedia Authoring Software
(7372453); Technology & Information (9122800)
EVENT: *Marketing procedures (240); Product standards, safety, & recalls
(350)
COUNTRY: *Australia (9AUS)

8/2/1 (Item 1 from file: 116)
DIALOG(R)File 116:Brands & Their Companies
(c) 1999 Gale Research. All rts. reserv.

09936725

TRADE NAME: ALLAIRE

SIC Code: 0139 - Field Crops Except Cash Grains Nec
DESCRIPTION: Flowers, plants, and seeds

COMPANY:

JONATHAN GREEN, INC.

ALAIR

8/2/3 (Item 3 from file: 116)
DIALOG(R)File 116:Brands & Their Companies
(c) 1999 Gale Research. All rts. reserv.

09778424

TRADE NAME: COLD FUSION

SIC Code: 7372 - Prepackaged Software
DESCRIPTION: Computer software

COMPANY:
ALLAIRE, LLC

10/8/1 (Item 1 from file: 16)
DIALOG(R)File 16:(c) 1999 The Gale Group. All rts. reserv.

07777687 SUPPLIER NUMBER: 50341569
Allaire lets code-driven developers take control
Sept 28, 1998
FULL TEXT AVAILABLE IN FORMAT 7 OR 9 WORD COUNT: 367

COMPANY:
*Allaire

PRODUCT: *Internet Software (7372680)
EVENT: *Product introduction (336)
COUNTRY: *United States (JUSA)

ALAIR

10/8/43 (Item 1 from file: 47)
DIALOG(R)File 47:(c) 1999 The Gale group. All rts. reserv.

05339209 SUPPLIER NUMBER: 54195649 (USE FORMAT 7 OR 9 FOR FULL TEXT)
No HTML required.(web authoring software)(Brief Article)(Evaluation)
July, 1998
WORD COUNT: 757 LINE COUNT: 00061

DESCRIPTORS: World Wide Web sites--Design and construction; Software--
Evaluation; Computer software industry--Products
PRODUCT/INDUSTRY NAMES: 7372682 (Internet Server Software)
SIC CODES: 7372 Prepackaged software
NAICS CODES: 51121 Software Publishers
TRADE NAMES: Netscape Composer (Web authoring software)--Evaluation;
Adobe PageMill (Web authoring software)--Evaluation; Allaire HomeSite
3.0 (Web authoring software)--Evaluation; Microsoft FrontPage (Web
authoring software)--Evaluation
FILE SEGMENT: MI File 47

10/8/47 (Item 2 from file: 148)
DIALOG(R)File 148:(c)1999 The Gale Group. All rts. reserv.

06498207 SUPPLIER NUMBER: 14154630 (USE FORMAT 7 OR 9 FOR FULL TEXT)
A cat above the competition. (Allaire)
June, 1993
WORD COUNT: 808 LINE COUNT: 00063

SPECIAL FEATURES: illustration; photograph
COMPANY NAMES: Allaire--Production management
INDUSTRY CODES/NAMES: FASH Fashion, Accessories and Textiles
DESCRIPTORS: Women's clothing industry--Production management
SIC CODES: 2330 Women's and Misses' Outerwear
FILE SEGMENT: TI File 148

ALAIR

10/8/48 (Item 3 from file: 148)
DIALOG(R)File 148:(c)1999 The Gale Group. All rts. reserv.

06443651 SUPPLIER NUMBER: 13676884 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Quality environment. (clothing industry working environment) (Editorial)
April, 1993
WORD COUNT: 523 LINE COUNT: 00041

COMPANY NAMES: Allaire --Buildings, facilities, etc.; Mendes Worldwide--
Buildings, facilities, etc
INDUSTRY CODES/NAMES: FASH Fashion, Accessories and Textiles
DESCRIPTORS: Clothing industry--Buildings, facilities, etc.
SIC CODES: 2300 APPAREL AND OTHER TEXTILE PRODUCTS
FILE SEGMENT: TI File 148

5/3/1
DIALOG(R)File 187:F-D-C Reports
(c) 1999 F-D-C Reports Inc. All rts. reserv.

00245693 F-D-C Accession Number 06040020373
Pharmaceutical Approvals Monthly
February 1, 1999
Volume 4, Issue 2

Allaire Spiros (Product name from Weekly Trademark Review published Jan.
19, 1999.)

TRADEMARK NAME: Allaire Spiros
SERIAL NUMBER: 75-426,390
NAME OF FIRM: Dura Pharmaceuticals
FILING DATE: 1-30-98
CLASS NUMBERS: 6, 18, 44, 46, 51 & 52
COMMENT: Owner of U.S. Reg. No. 2,127,647. For pharmaceutical
preparations for the treatment of diseases of the human respiratory,
cardiovascular, endocrine, reproductive, neurologic, immune,
gastrointestinal and musculo-skeletal systems, for the treatment of
hematologic and bone disorders, infectious diseases and for metabolic
and oncologic diseases. Class 10 - Medical Apparatus.
CATEGORY OF ENTRY: Marks Published For Opposition In More Than One Class

ALAIR

5/3/2

DIALOG(R)File 187:F-D-C Reports

(c) 1999 F-D-C Reports Inc. All rts. reserv.

00245692 F-D-C Accession Number 06040020372

Pharmaceutical Approvals Monthly

February 1, 1999

Volume 4, Issue 2

Allaire (Product name from Weekly Trademark Review published Jan. 19, 1999.)

TRADEMARK NAME: Allaire

SERIAL NUMBER: 75-426,146

NAME OF FIRM: Dura Pharmaceuticals

FILING DATE: 1-30-98

CLASS NUMBERS: 6, 18, 44, 46, 51 & 52

COMMENT: For pharmaceutical preparations for the treatment of diseases of the human respiratory, cardiovascular, endocrine, reproductive, neurologic, immune, gastrointestinal and musculoskeletal systems, for the treatment of hematologic and bone disorders, infectious diseases and for metabolic and oncologic diseases. Class 10 - Medical Apparatus.

CATEGORY OF ENTRY: Marks Published For Opposition In More Than One Class

ALAIR

5/3/3
DIALOG(R)File 187:F-D-C Reports
(c) 1999 F-D-C Reports Inc. All rts. reserv.

00064768 F-D-C Accession Number 09120148
The Rose Sheet
January 7, 1991
Volume 12, Issue 1

WEEKLY TRADEMARK REVIEW

ISSUE DATE: Issued Jan. 1, 1991
TRADEMARK NAME: Alair
SERIAL NUMBER: 73-808,927
NAME OF FIRM: Alair Labs
FILING DATE: 6-26-89
CLASS NUMBERS: 51 & 52
COMMENT: Priority claimed under Sec. 44(d) on Canada Application No. 628725, filed 4-3-1989, Reg. No. 371277, dated 7-27-1990, expires 7-27-2005. For beauty and perfumery products, namely hairdressing and scalp cleansing preparations, hair tonics, hair dyes, face creams, cold creams, ointments, emulsions, toilet powder, perfumes, toilet soap, lotions and beauty oil for the body and face.
CATEGORY OF ENTRY: marks published for opposition in one class
RECIPIENT INSTITUTION: 01/07/91

ALAIR

5/3/1999
DIALOG(R)File 535:Thomas Register Online(R)
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08896025
Kloster Steel Corp.
224 N. Justine St.
Chicago, IL 60607 USA

TELEPHONE: 312-421-3450
FAX: 312-421-2067 FAX
OTHER: 800-621-2212

DESCRIPTION OF BUSINESS:

THOMAS REGISTER OF AMERICAN MANUFACTURERS
Tool Steel.

TRADENAMES:

Air-Chrom (Air Hardening Steel)
Chiz-~~Alair~~ (Air Hardening Shock Steel)
Chiz-Alloy (Chisel Steel)
Clipper (High Speed Steel)
Hi-Run (High Chrome High Carbon Steel)
Pure-Ore (Tool Steel)
Super-Alloy (Shock Steel)
Swedoil (Oil Hardening)

[Record S1.1--Dun & Bradstreet #73815]

C M ALLAIRE & SON INC
CEO: CHARLES M ALLAIRE, PRESIDENT
105 UXBRIDGE RD
MENDON, MA 01756-1223
(508) 478-9606

SIC Codes:
15219901 New construction, single-family houses
DUNS Number: 04-347-1580
Sales Volume: \$250,000 - \$500,000

ALLAIR

[Record S1.2--Dun & Bradstreet #174189]

ALLAIRE CORP
ALLAIRE SOFTWARE
CEO: DAVID ORFAO, PRESIDENT
1 ALEWIFE CTR
CAMBRIDGE, MA 02140-2327
(617) 761-2000

SIC Codes:
73720000 Prepackaged software
DUNS Number: 83-578-2699
Sales Volume: \$5,000,000+

[Record S1.3--Dun & Bradstreet #199326]

A F ALLAIRE DMD
CEO: A F ALLAIRE, OWNER
839 PLEASANT ST
BROCKTON, MA 02301-3052
(508) 583-3530

SIC Codes:
80210202 Dentists' office
DUNS Number: 60-801-6323
Sales Volume: \$99,000 - \$249,000

[Record S1.4--Dun & Bradstreet #207726]

ALLAIRE PROPERTIES CORP
CEO: JOHN ALLAIRE JR, PRINCIPAL
690 DEPOT ST
NORTH EASTON, MA 02356-2700
(508) 230-8600

SIC Codes:
65310000 Real estate agents and managers
DUNS Number: 02-011-1642
Sales Volume: \$99,000 - \$249,000

ALAIR

[Record S1.5--Dun & Bradstreet #314474]

RUDY ALLAIRE

CEO: RUDY ALLAIRE, OWNER
30 TRUPELL RD
HOLLIS, NH 03049-6271
(603) 465-7537

SIC Codes:

17610103 Roofing contractor
DUNS Number: 16-873-2220
Sales Volume: \$250,000 - \$500,000

[Record S1.6--Dun & Bradstreet #348793]

NORMAN R ALLAIRE

CEO: NORMAN ALLAIRE, PRINCIPAL
25 WILLOW ST
LITTLETON, NH 03561-4216
(603) 444-5286

SIC Codes:

17110000 Plumbing, heating, air-conditioning
DUNS Number: 96-511-3863
Sales Volume: \$99,000 - \$249,000

[Record S1.7--Dun & Bradstreet #382315]

RON ALLAIRE CONSTRUCTION INC

CEO: RONALD L ALLAIRE, PRESIDENT
52 RAILROAD AVE
SPRINGVALE, ME 04083
(207) 324-8135

SIC Codes:

17949901 Excavation and grading, building construction
17719903 Flooring contractor
DUNS Number: 06-503-3532
Sales Volume: \$250,000 - \$500,000

ALAIR

[Record S1.8--Dun & Bradstreet #397081]

ALLAIRE DRYWALL
CEO: DAN ALLAIRE, OWNER
37 BIRCHWOOD DR
SABATTUS, ME 04280-4708
(207) 375-8072

SIC Codes:
17420101 Drywall
DUNS Number: 62-764-7563
Sales Volume: \$99,000 - \$249,000

[Record S1.9--Dun & Bradstreet #397435]

ALLAIRE DRYWALL
CEO: LEO ALLAIRE, OWNER
RR 4
TURNER, ME 04282-9804
(207) 225-2969

SIC Codes:
17420000 Plastering, drywall, and insulation
DUNS Number: 16-643-9232
Sales Volume: \$50,000 - \$99,000

[Record S1.10--Dun & Bradstreet #458934]

RUGGIERO ZIOGAS AND ALLAIRE
CEO: STEVEN ALLAIRE, PARTNER
271 FARMINGTON AVE
BRISTOL, CT 06010-3901
(860) 584-2384

SIC Codes:
51119901 General practice attorney, lawyer
DUNS Number: 06-925-8069
Sales Volume: \$250,000 - \$500,000

ALAIR

[Record S1.11--Dun & Bradstreet #459165]

D H ALLAIRE INC
HUBBARDS FLORIST
CEO: DAVID H ALLAIRE, PRESIDENT
133 NORTH ST
BRISTOL, CT 06010-4154
(860) 583-4184

SIC Codes:

59929901 Flowers, fresh

59470104 Gift shop

DUNS Number: 05-418-6572

Sales Volume: \$250,000 - \$500,000

[Record S1.12--Dun & Bradstreet #541487]

EMORY R ALLAIRE
CEO: EMORY R ALLAIRE, OWNER
623 AVON DR
ORANGE, CT 06477-1904
(203) 389-0412

SIC Codes:

17110405 Warm air heating and air conditioning contractor

DUNS Number: 94-515-2833

Sales Volume: \$99,000 - \$249,000

[Record S1.13--Dun & Bradstreet #642789]

ELAIRES INC
CEO: PHILLIP SERIALE, PRESIDENT
804 WILLOW AVE
HOBOKEN, NJ 07030-2900
(201) 798-5889

SIC Codes:

65130000 Apartment building operators

DUNS Number: 07-714-2826

Sales Volume: \$500,00 - \$999,000

ALAIR

[Record S1.14--Dun & Bradstreet #644703]

ALLAIRE ENTERPRISES INC
ALLAIRE PHOTOGRAPHY
CEO: RICHARD ALLAIRE, PRESIDENT
P O BOX 75
KEARNY, NJ 07032-0075
(201) 991-3357

SIC Codes:
72219903 Photographer, still or video
DUNS Number: 96-674-9152
Sales Volume: \$99,000 - \$249,000

[Record S1.15--Dun & Bradstreet #778504]

ALLAIRE LOUNGE & LIQUORS INC
SPIRITS UNLIMITED
CEO: ROCCO LOPRESTI, PRESIDENT
56 NEWMAN SPRINGS RD
RED BANK, NJ 07701-1428
(732) 747-4053

SIC Codes:
59210000 Liquor stores
DUNS Number: 17-502-8182
Sales Volume: \$1,000,000 - \$4,999,000

[Record S1.16--Dun & Bradstreet #783698]

ALLAIRE RACQUET CLUB INC
CEO: MOSHE SHUSTER, PRESIDENT
S S STATE HWY 38
BELMAR, NJ 07719
(732) 681-3366

SIC Codes:
79970504 Tennis club, membership
59410303 Tennis goods and equipment
DUNS Number: 06-869-3258
Sales Volume: \$250,000 - \$500,000

ALAIR

[Record S1.17--Dun & Bradstreet #784068]

GARY DESARNO
ALLAIRE PAVING
CEO: GARY DESARNO, OWNER
P O BOX 152 B ST
BELMAR, NJ 07719-2442
(732) 681-6868

SIC Codes:
17710300 Driveway, parking lot, and blacktop contractors
DUNS Number: 87-831-4988
Sales Volume: \$99,000 - \$249,000

[Record S1.18--Dun & Bradstreet #784508]

ALLAIRE TRAVEL INC
CEO: EVELYN STEINHEIM, PRESIDENT
1937 HIGHWAY 35
BELMAR, NJ 07719-3512
(732) 449-3600

SIC Codes:
47249901 Tourist agency arranging transport, lodging and car rental
47290101 Airline ticket offices
DUNS Number: 08-761-7015
Sales Volume: \$1000 - \$50,000

[Record S1.19--Dun & Bradstreet #784517]

ALLAIRE WINDSHIELD REPAIRS
CEO: FELIX KOHN, PRESIDENT
1900 RTE 35
BELMAR, NJ 07719-3513
(732) 223-0258

SIC Codes:
75360000 Automotive glass replacement shops
DUNS Number: 62-182-4614
Sales Volume: \$99,000 - \$249,000

ALAIR

[Record S1.20--Dun & Bradstreet #784736]

ALLAIRE STUDIO OF PHOTOGRAPHY INC
CEO: DON LORDI, PRESIDENT
3209 BRIGHTON AVE
BELMAR, NJ 07719-4458
(732) 681-3138

SIC Codes:

73350000 Commercial photography
DUNS Number: 13-166-3239
Sales Volume: \$50,000 - \$99,000

[Record S1.21--Dun & Bradstreet #784809]

VICTOR AT ALLAIRE INC
CEO: MOSHE SHUSTER, PRESIDENT
444 DEUCE DR
BELMAR, NJ 07719-9481
(732) 280-8181

SIC Codes:

15210000 Single-family housing construction
15220000 Residential construction, nec
DUNS Number: 87-805-8494
Sales Volume: \$5,000,000+

[Record S1.22--Dun & Bradstreet #784813]

STAR PIZZAZ INC
ALLAIR CHAMDRY
CEO: BRIAN FLAHERTY, PRESIDENT
2149 PARKWOOD DR
BELMAR, NJ 07719-9514
(732) 681-1222

SIC Codes:

72170000 Carpet and upholstery cleaning
DUNS Number: 19-708-6283
Sales Volume: \$50,000 - \$99,000

ALAIR

[Record S1.23--Dun & Bradstreet #784842]

ALTERNATIVE CARE INC

ALLAIRE

CEO: GEORGE MERVINE, PRESIDENT

1983 HIGHWAY 34

BELMAR, NJ 07719-9750

(732) 974-7666

SIC Codes:

83510000 Child day care services

DUNS Number: 79-954-2220

Sales Volume: \$99,000 - \$249,000

[Record S1.24--Dun & Bradstreet #789075]

ALLAIRE VILLAGE INC

HISTORIC ALLAIRE VILLAGE

CEO: SCOTT PETERS

P O BOX 220

FARMINGDALE, NJ 07727-0220

(732) 938-2253

SIC Codes:

84129901 Historical society

DUNS Number: 01-126-2334

Sales Volume: \$99,000 - \$249,000

[Record S1.25--Dun & Bradstreet #789135]

ALLAIRE LIMOUSINE SERVICE INC

CEO: MICHAEL RENEHAN, PRESIDENT

P O BOX 627

FARMINGDALE, NJ 07727-0627

(732) 938-4700

SIC Codes:

41190103 Limousine rental, with driver

DUNS Number: 02-299-2234

Sales Volume: \$1,000,000 - \$4,999,000

ALAIR

[Record S1.26--Dun & Bradstreet #789332]

ALLAIRE PUBLISHING INC
HERALD NEWSPAPER THE
CEO: ROBERT MCKENNA, PRESIDENT
P O BOX 2487
FARMINGDALE, NJ 07727-2487
(732) 938-3131

SIC Codes:

27110101 Commercial printing and newspaper publishing combined
DUNS Number: 13-512-2463
Sales Volume: \$1,000,000 - \$4,999,000

[Record S1.27--Dun & Bradstreet #789337]

CAFE ALLAIRE INC
CEO: JAMES CONROY, PRESIDENT
P O BOX 2511
FARMINGDALE, NJ 07727-2511
(732) 938-7533

SIC Codes:

58120500 Family restaurants
DUNS Number: 03-166-8486
Sales Volume: \$99,000 - \$249,000

[Record S1.28--Dun & Bradstreet #793106]

A-MART
ALLAIRE MART
CEO: MICHAEL WANG, OWNER
75 SQUANKUM RD
HOWELL, NJ 07731
(732) 938-2181

SIC Codes:

54119905 Grocery stores, independent
59470104 Gift shop
DUNS Number: 09-424-4753
Sales Volume: \$99,000 - \$249,000

ALAIR

[Record S1.29--Dun & Bradstreet #794289]

ALLAIRE -ARGENT

CEO: TRACEY THOMPSON, PRINCIPAL
1150 US HIGHWAY 9
HOWELL, NJ 07731-3781
(732) 431-1909

SIC Codes:

57310000 Radio, television, and electronic stores
DUNS Number: 86-851-8796
Sales Volume: \$99,000 - \$249,000

[Record S1.30--Dun & Bradstreet #801067]

POLETIS INC

THE ALLAIRE SCHOOL II
CEO: PETER POLETIS, PRESIDENT
160 OLD COUNTRY RD
MIDDLETOWN, NJ 07748-1722
(732) 671-8567

SIC Codes:

83510000 Child day care services
82110000 Elementary and secondary schools
DUNS Number: 16-230-9223
Sales Volume: \$1000 - \$50,000

[Record S1.31--Dun & Bradstreet #801469]

ALLEIRE HAIR SALON INC

CEO: JILL BRENER, OWNER
757 HIGHWAY 35
MIDDLETOWN, NJ 07748-3407
(732) 706-9339

SIC Codes:

72319902 Unisex hair salons
DUNS Number: 79-619-9750
Sales Volume: \$50,000 - \$99,000

ALAIR

[Record S1.32--Dun & Bradstreet #801717]

THE ALLAIRE SENIOR CENTER
CEO: RICHARD SCHAEDEL
33 MANN CT
MONMOUTH BCH, NJ 07750-1052
(732) 222-1758

SIC Codes:

83510000 Child day care services
DUNS Number: 15-228-0616
Sales Volume: \$1000 - \$50,000

[Record S1.33--Dun & Bradstreet #805367]

ALLAIRE BUSINESS DEVELOPMENT
CEO: THOMAS V SOLLAS JR, PRESIDENT
P O BOX 105
SPRING LAKE, NJ 07762-0105
(732) 449-6300

SIC Codes:

80599906 Rest home, with health care
DUNS Number: 62-064-0714
Sales Volume: \$500,00 - \$999,000

[Record S1.34--Dun & Bradstreet #932826]

ALLAIRE AUTOMOTIVE INC
ALLAIRE RADIATOR
CEO: TOM VAN HARTE, PRESIDENT
P O BOX 71
ALLENWOOD, NJ 08720-0071
(732) 449-4141

SIC Codes:

75390000 Automotive repair shops, nec
DUNS Number: 10-823-8007
Sales Volume: \$99,000 - \$249,000

ALAIR

[Record S1.35--Dun & Bradstreet #932828]

ALLAIRE ELECTRICAL CONTRACTORS

CEO: CHARLES WOLF, PRESIDENT

P O BOX 84

ALLENWOOD, NJ 08729-0084

(732) 528-5010

SIC Codes:

17319903 General electrical contractor

DUNS Number: 15-541-6357

Sales Volume: \$250,000 - \$500,000

[Record S1.36--Dun & Bradstreet #935385]

ALLAIRE GYNECOLOGY & OBSTETRIC

CEO: N TCHILINGUIRIAN, BRANCH MANAGER

RUR RTE 88

BRICK, NJ 08724

(732) 840-9779

SIC Codes:

80110524 Fertility specialist, physician

DUNS Number: 79-686-8073

Sales Volume: Not reported to Dun & Bradstreet

[Record S1.37--Dun & Bradstreet #938521]

ALLAIRE GYMNASTICS

CEO: KIM SOLOVIKOS, PARTNER

23 STATE HWY NO 71

MANASQUAN, NJ 08736

(732) 223-4060

SIC Codes:

79991109 Gymnastic instruction, non-membership

79110202 Dance instructor

DUNS Number: S2-970-3685

Sales Volume: \$99,000 - \$249,000

ALAIR

[Record S1.38--Dun & Bradstreet #938939]

KENNETH INDAHL DPM
ALLAIRE FOOT & ANKLE CENTER
CEO: KENNETH INDAHL DPM, OWNER
2517 HIGHWAY 35 STE 102
MANASQUAN, NJ 08736-1918
(732) 528-8223

SIC Codes:

80430000 Offices and clinics of podiatrists
DUNS Number: 78-073-0263
Sales Volume: \$99,000 - \$249,000

[Record S1.39--Dun & Bradstreet #939042]

ALLAIRE GYNECOLOGY & OBSTETRIC
CEO: NUBAR TCHILINGUIRIAN MD, PRESIDENT
2640 HIGHWAY 70 STE 2
MANASQUAN, NJ 08736-2609
(732) 223-8181

SIC Codes:

80110000 Offices and clinics of medical doctors
DUNS Number: 10-951-5783
Sales Volume: \$99,000 - \$249,000

[Record S1.40--Dun & Bradstreet #939199]

ALLAIR AWARDS INC
CEO: JOHN RENA, PRESIDENT
125 MAIN ST
MANASQUAN, NJ 08736-3037
(732) 223-3928

SIC Codes:

59999927 Trophies and plaques
50859915 Textile printers' supplies
DUNS Number: 10-823-9583
Sales Volume: \$99,000 - \$249,000

ALAIR

[Record S1.41--Dun & Bradstreet #939294]

ALLAIRE COMMUNITY BANK
CEO: ANNE MISCH, PRINCIPAL
155 MAIN ST
MANASQUAN, NJ 08736-3544
(732) 292-1577

SIC Codes:
60210000 National commercial banks
DUNS Number: 00-315-4148
Sales Volume: Not reported to Dun & Bradstreet

[Record S1.42--Dun & Bradstreet #941182]

ALLAIRE COMMUNITY BANK
CEO: CARL CHRICO, PRESIDENT
P O BOX 440
SEA GIRT, NJ 08750-0440
(732) 974-7070

SIC Codes:
60210000 National commercial banks
DUNS Number: 96-123-7781
Sales Volume: \$1,000,000 - \$4,999,000

[Record S1.43--Dun & Bradstreet #1123173]

ALAIR HOLDINGS INC
CEO: HARVEY GOLUB, MANAGER
AMERICAN EXPRESS TWR WFC
NEW YORK, NY 10285-0001
(212) 640-2000

SIC Codes:
62110000 Security brokers and dealers
62210000 Commodity contracts brokers, dealers
DUNS Number: 62-199-8830
Sales Volume: \$250,000 - \$500,000

ALAIR

[Record S1.44--Dun & Bradstreet #1249421]

ALAIRE TRANSPORT SERVICE
CEO: ALHAJI ODUNSI, PARTNER
122 ASHLAND PL APT 10K
BROOKLYN, NY 11201-3908
(718) 625-3633

SIC Codes:
41420000 Bus charter service, except local
DUNS Number: 96-313-3269
Sales Volume: \$500,00 - \$999,000

[Record S1.45--Dun & Bradstreet #1301215]

ALAIRES CLG SVC & THEN SOME
CEO: ALAIRE CHAPPELL, OWNER
546 E 88TH ST
BROOKLYN, NY 11236-3202
(718) 346-6533

SIC Codes:
73499903 Maid services, contract or fee basis
DUNS Number: 82-995-2837
Sales Volume: \$1000 - \$50,000

[Record S1.46--Dun & Bradstreet #1482575]

ALLAIRE GROUP
CEO: JOAN V COMPAGE, OWNER
105 JANSEN AVE
JOHNSTOWN, NY 12095-1916
(518) 762-3137

SIC Codes:
73380102 Resume writing service
DUNS Number: 00-358-2806
Sales Volume: \$1000 - \$50,000

ALAIR

[Record S1.47--Dun & Bradstreet #1670143]

SANDRA ALLAIRE
70 N MAIN ST
CANANDAIGUA, NY 14424-1465
(716) 396-0490

SIC Codes:

87480000 Business consulting, nec
DUNS Number: 96-178-8304
Sales Volume: \$99,000 - \$249,000

[Record S1.48--Dun & Bradstreet #3597112]

ALLAIRE COMMUNITY MGT SVCS
CEO: RONALD ALLAIRE, PRESIDENT
P O BOX 1960
FT WALTON BCH, FL 32549-1960
(850) 244-5510

SIC Codes:

65319901 Appraiser, real estate
DUNS Number: 80-700-6887
Sales Volume: \$99,000 - \$249,000

[Record S1.49--Dun & Bradstreet #3750379]

ALLAIRE FLOWERS
CEO: ANTHONY KING, OWNER
7167 NW 62ND TER
CORAL SPRINGS, FL 33067-1458
(954) 346-0902

SIC Codes:

59929901 Flowers, fresh
DUNS Number: 96-814-9096
Sales Volume: \$50,000 - \$99,000

ALAIR

[Record S1.50--Dun & Bradstreet #6289732]

HEARTLAND DATAWORKS
ALLAIRE JAMES
CEO: JAMES ALLAIRE, OWNER
251 E WABASHA ST
WINONA, MN 55987-3850
(507) 454-4778

SIC Codes:
50459903 Computer software
DUNS Number: 62-311-3883
Sales Volume: \$99,000 - \$249,000

[Record S1.51--Dun & Bradstreet #7792686]

ALLAIR FILTERS INC
CEO: DON JAX, PRESIDENT
521 SHEPHERD DR
GARLAND, TX 75042-6830
(972) 276-0178

SIC Codes:
35640105 Filters, air; furnaces, air conditioning equipment, etc.
DUNS Number: 93-931-3458
Sales Volume: \$500,00 - \$999,000

[Record S1.52--Dun & Bradstreet #8504398]

ALAIR & ASSOCIATE
CEO: TOM ALAIR, OWNER
P O BOX 156
SPRINGLAKE, TX 79082-0156
(806) 986-4267

SIC Codes:
51699907 Industrial chemicals
DUNS Number: 06-213-1123
Sales Volume: \$99,000 - \$249,000

ALAIR

[Record S1.53--Dun & Bradstreet #8504399]

THOMAS E ALAIR ASSOCIATES
CEO: THOMAS E ALAIR, OWNER
P O BOX 156
SPRINGLAKE, TX 79082-0156
(806) 986-4267

SIC Codes:

51910102 Fertilizer and fertilizer materials
51720204 Lubricating oils and greases
DUNS Number: 05-633-5243
Sales Volume: \$99,000 - \$249,000

[Record S1.54--Dun & Bradstreet #8687387]

ALLAIRE TIMBERS INN LTD
ALLAIRE TIMBERS INN
CEO: KATHLEEN GUMPH, PRESIDENT
P O BOX 4653
BRECKENRIDGE, CO 80424-4653
(970) 453-7530

SIC Codes:

70110401 Bed and breakfast inn
DUNS Number: 55-690-2666
Sales Volume: \$99,000 - \$249,000

[Record S1.55--Dun & Bradstreet #8960755]

GREGORY J ALLARE
NORTHWESTERN MUTUAL
CEO: GREGORY J ALLARE, OWNER
2701 E CAMELBACK RD
PHOENIX, AZ 85016-4305
(602) 955-7370

SIC Codes:

64110000 Insurance agents, brokers, and service
DUNS Number: 94-819-1275
Sales Volume: \$250,000 - \$500,000

ALAIR

[Record S1.56--Dun & Bradstreet #8970780]

ALLAIRE JOHN
ALL TECH MEDICAL EQUIPMENT
CEO: JOHN ALLAIRE, OWNER
1764 W BELL RD
PHOENIX, AZ 85023-3414
(602) 993-4415

SIC Codes:
50470000 Medical and hospital equipment
DUNS Number: 02-449-7625
Sales Volume: \$99,000 - \$249,000

[Record S1.57--Dun & Bradstreet #9003724]

ALLAIRE BROTHERS INC
CEO: DANIEL ALLAIRE, PRESIDENT
2418 W ORCHID LN
CHANDLER, AZ 85224-4022
(602) 963-6995

SIC Codes:
57120000 Furniture stores
DUNS Number: 95-767-1787
Sales Volume: \$99,000 - \$249,000

[Record S1.58--Dun & Bradstreet #9018678]

ALLAIRE BROTHERS INC
CEO: DAVID ALLAIRE, PRINCIPAL
1201 N 85TH PL
SCOTTSDALE, AZ 85257-4196
(602) 423-8881

SIC Codes:
57120000 Furniture stores
DUNS Number: 15-038-7033
Sales Volume: \$99,000 - \$249,000

ALAIR

[Record S1.59--Dun & Bradstreet #96096S2]

KESSLER ALAIR INSURANCE SVC
CEO: LEON R LOTT, PRESIDENT
P O BOX 353
ONTARIO, CA 91762-8353
(909) 931-1500

SIC Codes:

64110301 Insurance agents, nec
DUNS Number: 08-968-6067
Sales Volume: \$1,000,000 - \$4,999,000

[Record S1.60--Dun & Bradstreet #96776S8]

ALLAIRES DRAIN SVC
CEO: DOUGLAS ALLAIRE, PRINCIPAL
14056 HALPER RD
POWAY, CA 92064-2836
(619) 486-5480

SIC Codes:

76990000 Repair services, nec
DUNS Number: 03-255-4763
Sales Volume: \$50,000 - \$99,000

[Record S1.61--Dun & Bradstreet #10055574]

ALLAIRE INSURANCE
CEO: MATT ALLAIRE, OWNER
P O BOX 263
CARMEL VALLEY, CA 93924-0263
(831) 622-8305

SIC Codes:

64110301 Insurance agents, nec
DUNS Number: 16-994-2265
Sales Volume: \$99,000 - \$249,000

ALAIR

[Record S1.62--Dun & Bradstreet #10061271]

STOCKER ALLAIRE INC
CEO: DAVID STOCKER, PRESIDENT
P O BOX 51879
PACIFIC GROVE, CA 93950-6879
(831) 375-1890

SIC Codes:

15210101 General remodeling, single-family houses
15420103 Commercial and office buildings, renovation and repair
DUNS Number: 15-509-0236
Sales Volume: \$1,000,000 - \$4,999,000

[Record S1.63--Dun & Bradstreet #10135271]

WAN ALAIRE KIA-KWONG
ATTIC CARPET & DRAPERY CO
CEO: ALAIRE KIA-KWONG WAN, OWNER
2742 JUDAH ST
SAN FRANCISCO, CA 94122-1434
(415) 665-2088

SIC Codes:

57130000 Floor covering stores
57140000 Drapery and upholstery stores
DUNS Number: 84-975-3397
Sales Volume: \$250,000 - \$500,000

[Record S1.64--Dun & Bradstreet #10268696]

ALLAIRE SCHOOL
CEO: MARY ALLAIRE, DIRECTOR
50 EL CAMINO DR
CORTE MADERA, CA 94925-2057
(415) 927-2640

SIC Codes:

S2110206 Private elementary school
DUNS Number: 94-051-8962
Sales Volume: \$50,000 - \$99,000

CORSEARCH.



**NO RELEVANT COMPANY NAMES,
TRADE NAMES, PRODUCT NAMES, OR
BRAND NAMES WERE FOUND IN OUR
HARDBOUND SOURCES.**

ALAIR

56. ALAIR.COM

Owner: Global C&S Inc
Suite 1/87 Niran Condominium B,
Songprapa Rd, Don
Bangkok, na 10210

Administrative Contact: Carpenter, Allen, (501) 835 8919
(FAX) (501) 835 7206

History: Registered by InterNIC: July 6, 1999
Updated by InterNIC: July 6, 1999

57. ALEIR.COM

Owner: Automated Police Systems
808 Whispering Windsong
O'Fallon, MO 63366

Administrative Contact: Wilkinson, Ian, 314-652-2787

History: Registered by InterNIC: February 21, 1997
Updated by InterNIC: February 13, 1999

58. ALAYRE.COM

Owner: First Financial Services
P.O. Box 1701
Chicago, IL 60690-1701
US

Administrative Contact: Dabbs, Wanda, 312-808-0232

History: Registered by InterNIC: February 17, 1999
Updated by InterNIC: February 17, 1999

59. ELAIR.COM

Owner:
Administrative Contact:
History: Registered by InterNIC:
Updated by InterNIC:

ALAIR

60. ALARE.COM

Owner: Alare Systems Corporation
PO Box 347
Sparta, NJ 07871
US
Administrative Contact: Nardozzi, Thomas, 6262965561
History: Registered by InterNIC: August 6, 1998
Updated by InterNIC: August 6, 1998

61. ALARE.NET

Owner: alaRE.NET Alabama Real Estate Network
35-31 Talcottville Rd., #234
Vernon, CT 06066
US
Administrative Contact: Sys Admin, 860-456-6006
History: Registered by InterNIC: February 21, 1999
Updated by InterNIC: March 1, 1999

62. ALARES.COM

Owner: ALARES IT
roslagsgatan 23
stockholm, se, 11355,
SE
Administrative Contact: Alares, Carlos, 0708154232 (FAX)
0708154233
History: Registered by InterNIC: March 2, 1998
Updated by InterNIC: May 28, 1998

63. ALARES.NET

Owner: Sand Man Internacional S.A. de C.V.
Avenida Diego Rivera #2532 6 Piso Zona
Rio
Tijuana, B.C. CP 22320
Administrative Contact: Cohen, Stephen Michael, 0115266
343480 (FAX) 0115266 343480
History: Registered by InterNIC: April 7, 1999
Updated by InterNIC: April 7, 1999

ALAIR

64. ALLAER.COM

Owner: Internet Proline
Boterdaal 31
Nimove, 9400
BE

Administrative Contact: Andy, Allaer, +32.54.324100
(FAX) +32.54.326171

History: Registered by InterNIC: May 26, 1999
Updated by InterNIC: May 26, 1999

65. ALLAIR.COM

Owner: All AIR Incorporated
175 Clearbrook Road
Elmsford, NY 10523
US

Administrative Contact: Steinkamp, Cliff, (914) 347-2445
(FAX) (914) 347-3975

History: Registered by InterNIC: January 29, 1996
Updated by InterNIC: March 19, 1998

66. ALLAIRE.COM

Owner: Allaire Corporation
One Alewife Center
Cambridge, MA 02140
US

Administrative Contact: Master, Web, 617-761-2000

History: Registered by InterNIC: August 11, 1994
Updated by InterNIC: August 9, 1999

67. ALLAIRE.NET

Owner: MailBank
800 - 555 West Georgia Street
Vancouver, BC V6B 1Z6
CA

Administrative Contact: Sumpton, Jerry, 604 687 0288

History: Registered by InterNIC: November 2, 1998
Updated by InterNIC: August 10, 1999

68. ALLAIRE.ORG

Owner: EcoSystems, Inc.
P O Box 7080
Santa Cruz, CA 95061
US
Administrative Contact: Swenson, Ron, 831.425.8523
(FAX) 831.425.8533
History: Registered by InterNIC: January 30, 1998
Updated by InterNIC: April 1, 1999

69. ALLARE.COM

Owner: VisNet Internet Services
3210 SE Mile Hill Dr.
Port Orchard, WA 98366
US
Administrative Contact: Webmaster, (360)871-9455
History: Registered by InterNIC: April 30, 1999
Updated by InterNIC: August 16, 1999

70. ALLARE.NET

Owner: VisNet Internet Services
3210 SE Mile Hill Dr.
Port Orchard, WA 98366
US
Administrative Contact: Webmaster, (360)871-9455
History: Registered by InterNIC: April 30, 1999
Updated by InterNIC: April 30, 1999

71. ALLEAR.COM

Owner: CHANG, YOUNG-FONG
Shin-Fu 1st Street
PING-JEN CITY, TAO-YUAN 324
TW
Administrative Contact: CHANG, YOUNG-FONG, 886 3
4681452 (FAX) 886 3 4681453
History: Registered by InterNIC: July 26, 1999
Updated by InterNIC: July 26, 1999

72. ALLEARS.COM

Owner: All Ears Hearing Center and Tinnitus and
Hyperacusis Center of Ithaca
200 Pleasant Grove Rd.
Ithaca, NY 14850
US
Administrative Contact: Lalley, Joe, 607 257-8268
History: Registered by InterNIC: June 24, 1997
Updated by InterNIC: June 24, 1997

73. ALLEARS.NET

Owner: All Ears Productions
14038 Drexel Drive
Magalia, CA 95954
US
Administrative Contact: Ank, Tom, (530) 873-6928
History: Registered by InterNIC: December 18, 1997
Updated by InterNIC: December 18, 1997

74. ELLAIRE.COM

Owner: Ellaire peintre et poete
255, chemin des Cerisiers
St-Cergues, France F-74140
FR
Administrative Contact: Ravion, Lihane, (33) 0450435914
(FAX) (33) 0450435203
History: Registered by InterNIC: May 11, 1999
Updated by InterNIC: May 11, 1999

75. ALLAREA.COM

Owner: All Area Taxi & Limo
P.O. Box 1686
Boston, MA 02205
Administrative Contact: Jones, James, 617-536-2208
History: Registered by InterNIC: September 5, 1995
Updated by InterNIC: October 23, 1996

ALAIR

INDEX BY OWNER

Owner Trademark(s)	Status	Classes	Section*	Page
AIR-SHIELDS, INC. SOLAIR	Cancelled	Intl 10	FED	40
ALAIR LABORATORIES LTD. ALAIR	Cancelled	Intl 3	FED	9
ALARE SYSTEMS CORPORATION ALARE ALARE.COM	Pending N/A	Intl 9 N/A	FED DOM	4 81
ALARE.NET ALABAMA REAL ESTATE NETWORK ALARE.NET	N/A	N/A	DOM	81
ALARES IT ALARES.COM	N/A	N/A	DOM	81
ALBERT EDWARD KEEN TARZANA CA ALAIRCO	Renewed	Intl 35, ...	ST	46
ALL AIR INCORPORATED ALLAIR.COM	N/A	N/A	DOM	82
ALL AREA TAXI & LIMO ALLAREA.COM	N/A	N/A	DOM	84
ALL EARS HEARING CENTER AND TINNITUS AND HYPERACUS ... ALLEARS.COM	N/A	N/A	DOM	84
ALL EARS PRODUCTIONS ALLEARS.NET	N/A	N/A	DOM	84
ALLAIRE CORPORATION ALLAIRE ALLAIRE ALLAIRE.COM	Pending Pending N/A	Intl 9 Intl 42 N/A	FED FED DOM	5 5 82
ALLAIRE VILLAGE INC FARMINGDALE NJ ALLAIRE VILLAGE INC ALLAIRE VILLAGE INC	Registered Registered	Intl 16, ... Intl 35, ...	ST ST	46 47
AUTOMATED POLICE SYSTEMS ALEIR.COM	N/A	N/A	DOM	80
BAUSCH & LOMB PHARMACEUTICALS, INC. PENTOLAIR	Cancelled	Intl 5	FED	39
BURDICK, INC. ALTAIR	Registered	Intl 10	FED	16

* FED=US Federal ST=US State CL=US Common Law DOM=Domain Names
 CFED=Canadian Federal CCL=Canadian Common Law CORP=CORcorp INT=CORGlobe

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Owner Trademark(s)	Status	Classes	Section*	Page
CHANG, YOUNG-FONG ALLEAR.COM	N/A	N/A	DOM	83
CLUETT, PEABODY & CO., INC. THERMALAIRE	Expired	Intl 25	FED	13
CNS, INC. NARE FLARE	Abandoned	Intl 10	FED	41
COOPERS ANIMAL HEALTH INC. FLAIR	Cancelled	Intl 5	FED	45
DENTSPLY RSEARCH AND DEVELOPMENT CORP. FLAIR	Registered	Intl 10	FED	30
DURA PHARMACEUTICALS, INC. ALLAIRE	Pending	Intl 5,10	FED	2
ALLAIRE SPIROS	Pending	Intl 5,10	FED	3
ECOSYSTEMS, INC. ALLAIRE.ORG	N/A	N/A	DOM	83
ELLAIRE PEINTRE ET POETE ELLAIRE.COM	N/A	N/A	DOM	84
ERGOVISION, INC. GLARE DROPS	Registered	Intl 5	FED	34
EV-JEN MEDICAL THOMPSON-BLAIR	Abandoned	Intl 10, ...	FED	43
FETTO, JOSEPH F. LATERAL FLARE	Pending	Intl 10	FED	34
FIRST FINANCIAL SERVICES ALAYRE.COM	N/A	N/A	DOM	80
FLARE COMPANY LIMITED FLARE	Abandoned	Intl 10	FED	36
FLARE PRODUCTS, INC. FLARE	Cancelled	Intl 10	FED	36
FRAASS SURVIVAL SYSTEMS, INC. ANTI-SHEAR LAYER	Abandoned	Intl 5	FED	44
GLAXO GROUP LIMITED ADVAIR	Pending	Intl 5	FED	23

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Owner Trademark(s)	Status	Classes	Section*	Page
GLAXO INC. AMILAIR	Abandoned	Intl 5	FED	15
GLOBAL C&S INC ALAIR.COM	N/A	N/A	DOM	80
HAMILTON MEDICAL, INC. VENTILAIR	Registered	Intl 10	FED	29
INTERNET PROLINE ALLAER.COM	N/A	N/A	DOM	82
INTERVENTIONAL INNOVATIONS CORP. FLAIR	Abandoned	Intl 10	FED	42
JOHNSON & JOHNSON ELARE	Pending	Intl 5	FED	4
LEFKOVITS, ALBERT M. ALAIR	Registered	Intl 5	FED	14
LOUIS M. GERSON CO., INC. ISOLAIR	Registered	Intl 10	FED	28
MAILBANK ALLAIRE.NET	N/A	N/A	DOM	82
MARKS & SPENCER CANADA INC. D'ALLAIRD'S	Cancelled	Intl 25	FED	12
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MAYNARD, MICHAEL WILLIAM FLAIR DENTAL ARTS	Abandoned	Intl 10	FED	44
MERCK & CO., INC. SINGULAIR	Registered	Intl 5	FED	31
MILES LABORATORIES, INC. ALPARE	Expired	Intl 5	FED	22
MONMOUTH AIRCRAFT SERVICE INC FARMINGDALE NJ ALLAIRE AIRCRAFT SERVICES	Registered	Intl 35, ...	ST	47
MUL ACQUISITION CORP. II ALTAIR	Registered	Intl 10	FED	18

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Owner Trademark(s)	Status	Classes	Section*	Page
NEW ZEALAND DAIRY BOARD ALAREN	Cancelled	Intl 29	FED	10
NEW ZEALAND MILK PRODUCTS, INC. ALAREN	Abandoned	Intl 29	FED	7
NEXT NUTRITION, INC. RHEO BLAIR	Pending	Intl 5	FED	33
NOVARTIS AG ZOLAIR XOLAIR	Pending Pending	Intl 5 Intl 5	FED FED	27 31
ORMCO CORPORATION QUANTEC FLARE SERIES	Pending	Intl 10	FED	35
PURDUE FREDERICK COMPANY BELAIR	Cancelled	Intl 5	FED	37
RIKER LABORATORIES, INC. ALVAIR CARBOLAIR	Abandoned Cancelled	Intl 5 Intl 5	FED FED	19 35
SAND MAN INTERNACIONAL S.A. DE C.V. ALARES.NET	N/A	N/A	DOM	81
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STANFORD SEED CO., THE ALLAIRE	Cancelled	Intl 31	FED	8
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TREND MEDIA, INC. BLAIR	Registered	Intl 5	FED	24
TURF MERCHANTS, INC. ALLAIRE	Abandoned	Intl 31	FED	7
VISNET INTERNET SERVICES ALLARE.COM ALLARE.NET	N/A N/A	N/A N/A	DOM DOM	83 83
VITAL SIGNS, INC. NASALFLAIR	Abandoned	Intl 10	FED	42

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Owner Trademark(s)	Status	Classes	Section*	Page
WEST DISINFECTING COMPANY DUSTALAYR	Expired	Intl 3	FED	11
WINEASE, LLC FLAIR	Pending	Intl 10	FED	32
WINTHROP-STEARNES INC. ALEVAIRE	Expired	Intl 5	FED	20