AeriSeal®

EMPHYSEMATOUS LUNG SEALANT SYSTEM

Instructions For Use

CE 0050

Deutsch (DE)

English (EN)

Français (FR)

Nederlands (NL)

Aeris Therapeutics

LB1168-01 REV 00 12/10

EN

Instructions For Use

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AeriSeal® System

COMPLETION OF THE AERISEAL EMPHYSEMATOUS LUNG SEALANT SYSTEM ("AERISEAL SYSTEM") TRAINING PROGRAM AND A THOROUGH UNDERSTANDING OF THE TECHNICAL PRINCIPLES, CLINICAL APPLICATIONS AND RISKS ASSOCIATED WITH LUNG VOLUME REDUCTION FOR THE TREATMENT OF PATIENTS WITH EMPHYSEMA ARE NECESSARY BEFORE USING THIS PRODUCT. READ THIS ENTIRE BOOKLET, THE AERISEAL SYSTEM INSTRUCTIONS FOR USE, PRIOR TO ATTEMPTING USE OF THE AERISEAL SYSTEM.

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1.0 DEVICE DESCRIPTION

The AeriSeal System consists of the AeriSeal Foam Sealant Components, AeriSeal Catheter and AeriSeal Accessories Kit:

AeriSeal Foam Sealant Components: The Foam Sealant Components are provided sterile and are mixed together to create a single use device, the AeriSeal Foam Sealant, that is administered through the AeriSeal Catheter. The Foam Sealant is created by mixing and foaming Solution A (4.5 mL) and Solution B (0.5 mL) with 15 mL room air. Solution A consists of 2.1% aminated polyvinyl alcohol dissolved in phosphate buffer at pH 6.5. Solution B consists of 1.25% glutaraldehyde in phosphate buffer at pH 4.0.

AeriSeal Catheter: The Catheter is provided sterile and is a single use device used for bronchoscopic administration of the AeriSeal Foam Sealant to targeted regions of the lung.

AeriSeal Accessories Kit: The Accessories Kit includes commercially available syringes, needles, stopcock and other items used in the preparation and administration of the AeriSeal Foam Sealant.

2.0 INTENDED USE

The AeriSeal System is intended to reduce lung volume in order to improve lung function and quality of life in patients with advanced emphysema. It functions as a tissue sealant, physically blocking both small airways and collateral air channels, causing the treated area to collapse via absorption atelectasis. It is a single use device intended to be used by pulmonologists and thoracic surgeons in a bronchoscopy suite or operating room.

3.0 BRONCHOSCOPE REQUIREMENTS

The AeriSeal Catheter is designed to be used with a flexible bronchoscope that has a working channel with a minimum diameter of 2.0 mm.

4.0 CONTRAINDICATIONS

The AeriSeal System is contraindicated for patients:

- with evidence of active respiratory infection
- with an ongoing COPD exacerbation or bronchospasm
- who cannot tolerate bronchoscopic procedures
- who have a known allergy to the device components

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5.0 WARNINGS

The AeriSeal System is not recommended for patients who:

- have a primary diagnosis of asthma, chronic bronchitis or bronchiectasis;
- have had frequent COPD exacerbations within the past year;
- require mechanical ventilatory support;
- have a pretreatment FEV1 < 20% predicted AND a DLCO < 20% predicted;
- have a pretreatment FEV1 < 20% predicted AND homogeneous emphysema;
- have giant bullae;
- have heterogeneous non-upper lobe predominant emphysema;
- have undergone lung transplantation, lung volume reduction surgery, or lobectomy;
- are intolerant of corticosteroids or antibiotics;
- are pregnant or breast-feeding.

When selecting lung subsegments for treatment:

- no more than 3 subsegments should be targeted for treatment in a single treatment session;
- adjacent pulmonary subsegments should not be selected for treatment during the same session. Treatment of adjacent subsegments in a single treatment session can be associated with increased incidence and/or severity of post-treatment inflammatory responses and COPD exacerbations.

The AeriSeal System should only be used in a fully equipped bronchoscopy suite by clinicians who are experienced in bronchoscopy and in managing potential bronchoscopic or anesthesia related emergencies. The treating clinician and assistant should have completed the AeriSeal System training program.

AeriSeal System treatment is associated with a transient, post-treatment inflammatory response. Prophylaxis with corticosteroids and antibiotics is recommended for at least 1 week beginning on the day of treatment.

There have been no studies of patients with alpha-1 antitrypsin deficiency.

Patients should not undergo more than 1 treatment session in any 12 week period.

6.0 PRECAUTIONS

Do not use if Foam Sealant Components, Catheter or Accessories packaging is opened, damaged, or past the expiry date.

Do not use the Foam Sealant Components if frozen or not stored at (2 - 8˚ C).

All preparation and administration procedures should be performed with gloves and eye protection.

The AeriSeal Catheter and the AeriSeal Accessories are designated for SINGLE USE ONLY and must not be reused. The reuse of such devices can affect their safety, performance and effectiveness and expose patients and staff to unnecessary risks.

6.0 PRECAUTIONS continued

Only the AeriSeal Catheter and the AeriSeal Accessories should be used to prepare and deliver the Foam Sealant.

Preparation of the Foam Sealant is dependent upon the precise ratios and amounts of Solution A, Solution B and air. Ensure that the correct volumes of Solution A, Solution B, and air are drawn into the syringes.

Hand tighten the Catheter Luer hub and syringes onto the Stopcock. Do not use excessive force.

The Catheter should be advanced 4 cm beyond the tip of the bronchoscope. The bronchoscope should be maintained in good wedge position during and after Foam Sealant administration. These measures help ensure peripheral distribution of the Foam Sealant and minimize the risk of spillage into the airways.

The Foam Sealant should be administered as quickly as possible after preparation to prevent polymerization before delivery.

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7.0 POTENTIAL COMPLICATIONS/ADVERSE EVENTS

Twelve to twenty-four hours after treatment, the majority of patients experience a transient post-treatment inflammatory response characterized by some or all of the following:

- Elevated serum markers of inflammation (CRP, ESR, fibrinogen, procalcitonin)
- Fever/chills
- Chest pain
- Anorexia
- Dyspnea
- Cough
- Hypoxemia
- Leukocytosis
- Malaise

Potential complications related to the procedure or device include but are not limited to (i) those listed above, (ii) known complications of anesthesia, bronchoscopy, and peri-procedure medications, and (iii) the following (in alphabetical order):

- Acute respiratory distress syndrome
- Airway stenosis
- Allergic reaction
- Bronchospasm
- Cavities at the site of treatment
- COPD exacerbation
- Death
- Flu-like symptoms
- Heart arrhythmia/heart failure/myocardial infarction/cardiac arrest
- Hemoptysis
- Hypercapnea
- Pleural effusion/Empyema
- Pneumonitis
- Pneumothorax
- Respiratory failure
- Respiratory infection/Pneumonia/Bronchitis
- Sepsis
- Stroke/CVA/TIA
- Systemic inflammatory response
- Venous thromboembolism
- Vocal chord injury
- Worsened lung function

8.0 CLINICAL EXPERIENCE

AeriSeal System therapy has been shown to reduce lung volume and improve lung function and quality of life in patients with advanced homogeneous and heterogeneous upper-lobe predominant emphysema.

Treatments have been performed safely using either conscious sedation or general anesthesia.

Clinical testing has shown no evidence of sensitization to the components of the AeriSeal System.

9.0 PROCEDURAL INSTRUCTIONS FOR USE

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9.1 Materials, Equipment and Supplies Required

REF 30300 AeriSeal® Foam Sealant Components

Each Box Contains: (1) Vial, Solution A
(1) Vial, Solution B

REF 30200 AeriSeal® Catheter

Each Box Contains: (1) Catheter

REF 30100 AeriSeal® Accessories Kit

Each Kit Contains: (2) Needle, 20 G x 1 ½
(1) Stopcock
(1) Syringe, 1 mL
(1) Syringe, 5 mL
(1) Syringe, 30 mL
(1) Syringe, 60 mL
(1) Administration Syringe, 20 mL
(1) Steri-Strip™ Package
Instructions For Use and Patient Card

Equipment and Materials also required but not supplied include:

- Standard Flexible Bronchoscope (>2 mm ID)
- Sterile field, disposable

9.2 Patient Preparation

Step	Action
1	Verify that the patient is a good candidate for bronchoscopy and AeriSeal System treatment.
2	Select non-adjacent target lung subsegments based on CT and Perfusion Scan findings.
3	Administer prophylactic corticosteroids and antibiotics (1st doses to be given on the day of treatment).

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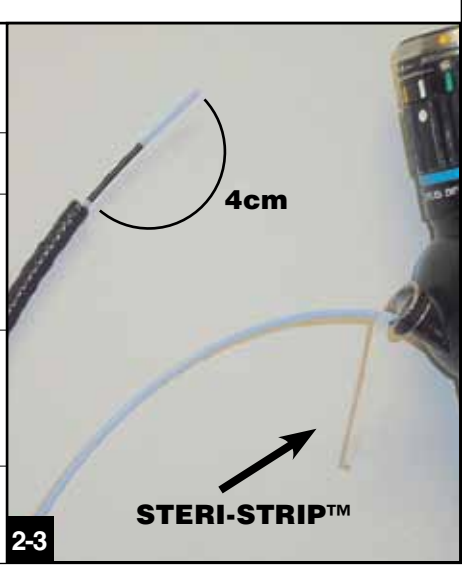
9.3 Pre-treatment Preparation

Step	Action
⚠	**CAUTION:** All procedures should be performed with gloves and eye protection.
NOTE:	Remove the Foam Sealant Components Box from the refrigerator approximately 15 minutes prior to the procedure.
1	Inspect all packaging and components for signs of defects or damage.
2	Prepare bronchoscope and sterile field.

9.3.1 Catheter Preparation

Step	Action
⚠	**CAUTION:** The AeriSeal Catheter should be measured and marked prior to starting the procedure.
1	Insert the Catheter into the working channel of the bronchoscope.
2	Advance Catheter until its tip extends 4 cm beyond the end of bronchoscope. A black band begins 2 cm and ends 4 cm from the distal tip of the Catheter.
3	Secure a Steri-Strip™ around the Catheter where it enters the working channel to mark the furthest point the Catheter should be advanced during treatment.
4	Remove the Catheter from the bronchoscope and place it on the sterile field.



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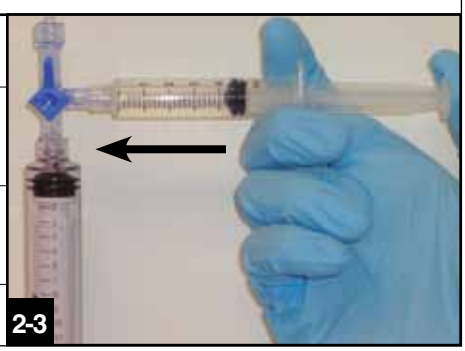
9.3.2 Administration Syringe Preparation

Step	Action
1	Fill a 30 mL syringe with 15 mL of air and set aside.
2	Push air out of the 20 mL Administration Syringe and connect to Stopcock.
3	Position “OFF” handle of the Stopcock to point opposite the Administration Syringe.
⚠	**CAUTION:** Ensure that the Stopcock is positioned so that the “OFF” handle points opposite the Administration Syringe to prevent accidental spillage of treatment material.

9.3.3 Solution A Preparation

Step	Action
1	Using a 5 mL syringe, draw up **4.5 mL** of Solution A.
⚠	**CAUTION:** It is important that the volume of Solution A is exactly 4.5 mL and that no air bubbles are present.
2	Remove the white cap from the middle port of the Stopcock and connect the 5 mL syringe containing Solution A to the port.
3	Deliver all of Solution A to the Administration Syringe.



9.3.4 Solution B Preparation

Step	Action	
1	Using a 1 mL syringe, draw up **0.5 mL** of Solution B.	
⚠	**CAUTION:** It is important that the volume of Solution B is exactly 0.5 mL and that no air bubbles are present.	
2	Remove the empty 5 mL syringe and connect the 1 mL syringe containing Solution B to the Stopcock at the middle port and place on the sterile field.	
⚠	**CAUTION:** In order to prevent premature polymerization of the materials, **DO NOT DEPRESS THE PLUNGER** of the 1 mL syringe.	

NOTE: Repeat Pre-treatment Preparation Steps (9.3.1 – 9.3.4) for each subsegment to be treated.

9.4 Treatment

9.4.1 Placement of Bronchoscope

Step	Action
1	Guide the flexible bronchoscope to the sub-segment that has been selected for treatment.
2	Advance the bronchoscope into “wedge” position such that it fits snugly against the airway wall. Verify wedge position by applying suction and confirming airway collapse.
3	Advance the Catheter through the working channel of the bronchoscope until the Steri-Strip™ abuts the opening of the working channel of the bronchoscope.
⚠	**CAUTION:** It is important that the tip of the Catheter be positioned 4 cm beyond the tip of the scope to ensure peripheral distribution of the Foam Sealant. If resistance is encountered before the Catheter is extended 4 cm, the Catheter and/or scope should be repositioned.

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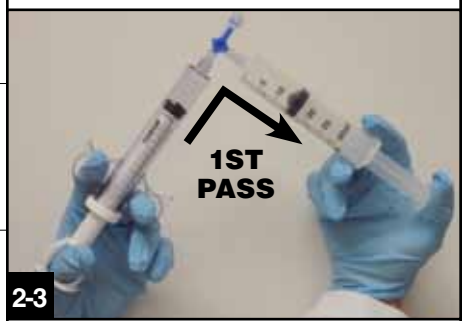
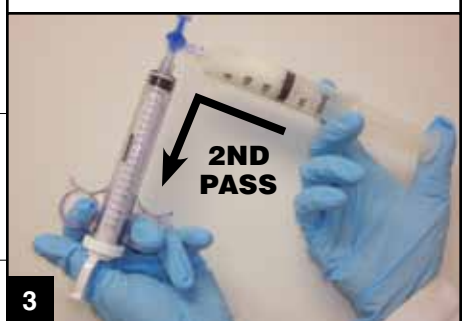
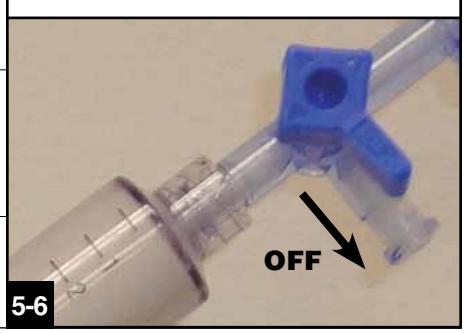
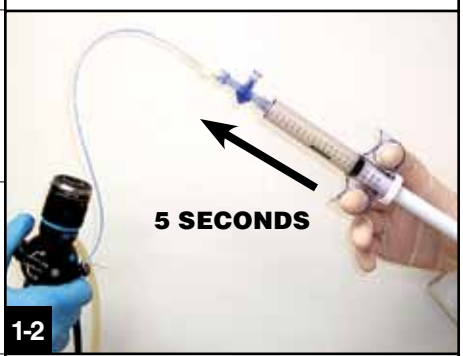
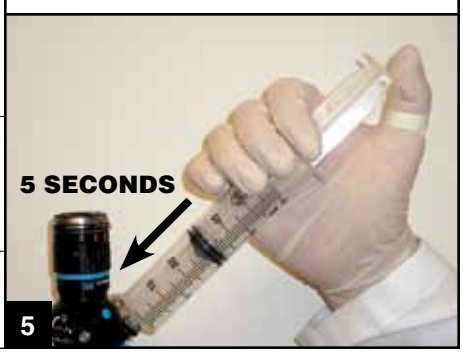
9.4.2 Foam Sealant Preparation

Step	Action	
⚠	**CAUTION:** Do not begin mixing the Foam Sealant Components until the Catheter is correctly positioned with the bronchoscope in wedge position. Work quickly to complete the remaining steps (9.4.2 – 9.4.3) in order to prevent the material from polymerizing before delivery.	 1
1	Deliver Solution B from the 1 mL syringe to the Administration syringe that contains Solution A. THIS INITIATES POLYMERIZATION.	
2	Remove the empty 1 mL syringe and connect the 30 mL syringe containing 15 mL of air to the Stopcock at the middle port.	 2-3
3	Generate a uniform white foam by alternately pushing the plungers of the 20 mL (Administration) and 30 mL syringes so that the mixture **passes through the Stopcock a total of 10 times**. This should take between 7 and 15 seconds.	
4	Following foam generation, ensure that all the Foam Sealant is contained in the 20 mL Administration Syringe.	 3
5	Position the “OFF” handle of the Stopcock so that it points towards the middle port.	
6	Remove the 30 mL syringe from the Stopcock leaving the 20 mL Administration Syringe attached to the Stopcock.	 5-6
⚠	**CAUTION:** Ensure the Stopcock valve is positioned correctly so that material is not wasted.	

9.4.3 Foam Sealant Administration

Step	Action	
⚠	**CAUTION: It is extremely important to maintain wedge position during Foam Sealant Administration.**	
1	Immediately connect the Catheter to the port on the Stopcock opposite the Administration Syringe. Maintain wedge with the bronchoscope. Do not pull the Catheter out of position.	
2	Inject the Foam Sealant into the Catheter over 5 seconds, applying steady firm pressure to the plunger of the Administration Syringe.	
3	Keep the plunger of the Administration Syringe depressed for 5 more seconds after completion of injection to ensure that all of the Foam Sealant is delivered.	
4	Remove the Catheter and attached Administration Syringe from the bronchoscope.	
5	Over 5 seconds inject 30 mL of air through the working channel using a 60 mL syringe to promote distal distribution of the Foam Sealant.	
6	Keep the bronchoscope in wedge position for 1 minute **without applying suction** to prevent spillage of material.	
7	Remove the bronchoscope from wedge position.	

NOTE: Repeat Treatment Steps (9.4.1 – 9.4.3) for each subsegment to be treated.

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9.5 Bronchoscope Cleaning

The bronchoscope should be cleaned after each patient use in accordance with the manufacturer's instructions. No special cleaning techniques are required.

10.0 PATIENT MANAGEMENT

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Standard institutional post-bronchoscopy procedures should be followed.

Once patients have fully recovered from anesthesia or conscious sedation and are stable, they can be transferred to an appropriate medical setting for additional follow-up. It is recommended that patients be observed for 24 hours to ensure clinical stability before discharge. Prophylactic corticosteroids and antibiotics should be continued for 7 days.

AeriSeal System therapy causes a focal infiltrate and atelectasis at and adjacent to the site of treatment, detectable by conventional chest X-ray or chest CT scan. The diagnosis of pneumonia should not be based upon this radiographic finding alone.

Treatment may be associated with formation of cavities in the lung parenchyma at the site of administration. Lesions of this type are generally asymptomatic, do not require intervention, and regress over time.

In some cases, mild leukocytosis and elevation of inflammatory markers may persist beyond 1 week in the absence of apparent infection. This may represent a delayed resolution of the post-treatment inflammatory response and has not been observed to be of any clinical consequence.

11.0 HOW SUPPLIED

AeriSeal Foam Sealant Components

The AeriSeal Foam Sealant Components are aseptically processed and supplied sterile. The product is intended for SINGLE USE ONLY. Do not reuse or re-sterilize. The box contains sufficient material for treatment of 1 subsegment.

AeriSeal Catheter

The AeriSeal Catheter is sterilized by ethylene oxide and supplied sterile. The product is intended for SINGLE USE ONLY. Do not reuse or re-sterilize. The box contains 1 Catheter.

AeriSeal Accessories Kit

The AeriSeal Accessories Kit contains various commercially available accessories that are sterile. Each accessory is intended for SINGLE USE ONLY. Do not reuse or re-sterilize. The kit contains sufficient material for treatment of 1 subsegment.

12.0 STORAGE AND DISPOSAL

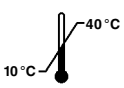
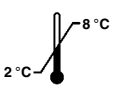
AeriSeal Foam Sealant Components

Product should be stored in refrigerated conditions (2 - 8 °C). Unused product should be disposed of following standard institutional practices.

AeriSeal Catheter and AeriSeal Accessories Kit

Product should be stored between 10 and 40 °C. Unused product should be disposed of following standard institutional practices.

13.0 EXPLANATION OF SYMBOLS AND SIGNAL WORDS

REF	Catalog number
LOT	Batch code
	Manufacturer
EC REP	Authorized Representative in the European Community
	Consult Instructions for Use
	Do not re-use
	Do not resterilize
	Use by
STERILE	Sterile
STERILE A	Sterile using aseptic processing techniques
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
	Store between 10 to 40 ˚C
	Store between 2 to 8 ˚C
	Do not use if package is opened or damaged

WARNING:	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION: 	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practice or potential equipment damage.
NOTE:	Indicates essential information.

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14.0 DISCLAIMER OF WARRANTY AND LIMITATION OF LIABILITY

Aeris Therapeutics, LLC (Aeris) warrants the AeriSeal® System against defects in construction and workmanship to the original purchaser for a period of one year from the original date of purchase. Aeris is not responsible for and will have no liability for any items or services provided by any persons other than Aeris.

THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES WHETHER EXPRESSED, IMPLIED, WRITTEN OR ORAL, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

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Handling and storage of the AeriSeal System components as well as factors relating to patient diagnosis, treatment, and patient management, and other matters beyond Aeris' control directly affect the product and the results obtained from its use; Aeris shall have no liability for damages due to any of the foregoing factors. Aeris shall not be liable for any incidental or consequential loss, damage, or expense arising directly or indirectly from the use of this product. Aeris will replace any product that has defects in construction and workmanship within the one-year warranty period. Replacement of the product shall be the sole and exclusive remedy of any kind against Aeris. No person has the authority to bind Aeris to any representation or warranty except as specifically set forth herein.

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15.0 CUSTOMER SERVICE

All questions and concerns related to the device should be directed to Aeris Therapeutics' Customer Service or an authorized Aeris Therapeutics representative. No product should be returned without prior authorization.

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European Service Center

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