pulmonX®

aeriseal®
system

Endobronchial Polymer Implant

Instructions for Use

1.0 USE REQUIREMENTS

Completion of the 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.

If patient is being treated under a Pulmonx clinical trial protocol, eligibility criteria outlined in the Investigational Plan must be adhered to.

2.0 DEVICE DESCRIPTION

The AeriSeal System is comprised of the following:

AeriSeal® Foam Components: The Foam Components are provided sterile and are mixed together to create a single use device, the AeriSeal Foam, that is administered through the AeriSeal Catheter. The Foam 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 in phosphate buffer at pH 6.5. Solution B consists of 1.25% glutaraldehyde in phosphate buffer at pH 4.0.

AeriSeal® Balloon Catheter Preparation Kit (AER-BC-KIT): The Preparation Kit contains the AeriSeal Balloon Catheter and the AeriSeal Balloon Catheter Accessories Kit intended for use with this catheter and the foam components. The Catheter and Accessories are provided sterile and are labeled as a single use device used for bronchoscopic administration of the AeriSeal Foam to targeted regions of the lung. The Accessories Kit includes commercially available syringes, needles, stopcocks and other items used in the preparation and administration of the AeriSeal Foam.

3.0 INTENDED USE / INDICATIONS FOR 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 by physically occluding 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.

4.0 CONTRAINDICATIONS

The AeriSeal System is contraindicated for patients:

- with heterogeneous non-upper lobe predominant emphysema;
- with evidence of active respiratory infection or major bleeding diathesis;
- with an ongoing COPD exacerbation or bronchospasm;
- who cannot tolerate bronchoscopic procedures or the required anesthesia;
- who have a known allergy to the device components:
  - Pebax
  - Polyvinyl Alcohol
  - Glutaraldehyde
  - Who have not quit smoking.

5.0 EQUIPMENT REQUIREMENTS

The AeriSeal System is designed to be used with a flexible bronchoscope that has a minimum working channel diameter of 2.8 mm for the AeriSeal Balloon Catheter.

6.0 WARNINGS

The AeriSeal System should only be used in a fully equipped bronchoscopy suite or operating room 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.

The AeriSeal System is not recommended for patients who:

- have a primary diagnosis of asthma, chronic bronchitis or bronchiectasis;
- have giant bullous disease;
- have had more than two COPD exacerbations within the past 12 months;
- require mechanical ventilatory support;
- have a pre-treatment FEV_1 < 20%
- have a 6MWT < 150 m
- cannot tolerate corticosteroids or antibiotics;
- cannot tolerate the stress of post-treatment inflammatory response;
- are pregnant or breast-feeding.

Patients should undergo cardiac risk assessment in accordance with published guidelines*:

- AeriSeal System treatment should be considered higher risk than standard bronchoscopy due to the post-treatment inflammatory response;
- patients with 1 or more risk factors (ischemic heart disease, congestive heart failure, renal failure or cerebrovascular disease) and low exercise tolerance (6MWT< 350 m) are at higher cardiovascular risk and should be considered for additional screening;
- all patients should have a baseline EKG to screen for arrhythmias or conduction abnormalities. Significant abnormalities should be evaluated appropriately prior to AeriSeal System treatment.

*Fleisher LA, et al. ACC/AHA 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery. J Am Coll Cardiol. 2007 50(17):1707-32.

When selecting lung airways for treatment:

- No more than two lobes should be targeted during a treatment.
- Do not treat regions with pre-existing radiologic abnormalities that require follow-up.
- Do not treat airways that are scarred or have granulation tissue due to prior pathology or valve therapy.

Device introduced into the human body:
The AeriSeal Foam is comprised of an aminated polyvinyl alcohol (aPVA) (CAS # 9002-89-5) matrix crosslinked by an optimized low concentration glutaraldehyde (GA) (CAS # 6346-09-4) in the presence of phosphate buffer. A patient receives one or more AeriSeal Foam implants, which results in a total implanted volume of 10 mL to 80 mL, depending on the number of treatment sites and delivered volume. This corresponds to an implanted mass of 0.05 g to 0.40 g of aPVA-GA matrix.

7.0 PRECAUTIONS

7.1 GENERAL PRECAUTIONS

- Do not use if Foam Components, Catheter, or Accessories packaging is opened, damaged, or past the expiry date.
- Do not use the Foam Components if frozen or if not stored at temperatures between 2 ˚C and 8 ˚C.
- Do not mix vials from different packages of Foam Components.
- All preparation and administration procedures should be performed with gloves and eye protection.
- The AeriSeal Balloon 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.
- Only the AeriSeal Balloon Catheter Preparation Kit should be used to prepare and deliver the Foam.
- Preparation of the Foam 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 Stopcocks. Do not use excessive force.
- The targeted airway should be sealed during and after the foam administration. These measures help ensure peripheral distribution of the Foam and minimize the risk of spillage into the non-targeted airways.
- The Foam should be administered as quickly as possible after preparation to prevent polymerization before delivery.
- Repositioning of the bronchoscope while the balloon catheter is inflated may result in compromised sealing or inaccurate delivery of foam.

AeriSeal Balloon Catheter:

- Balloon inflation in an improper location may lead to patient injury.
- Do not exceed a maximum inflation volume of 3 mL (cc) as over inflation of balloon may lead to balloon burst.
- If the balloon bursts during inflation, remove the catheter immediately and discard.
- If the balloon bursts during foam delivery, maintain catheter position, stop delivery of foam and wait 1 minute to allow polymerization of foam. Remove catheter and bronchoscope as one unit.
- The balloon catheter should not be advanced out of the visual range of the bronchoscope.
- Avoid disengaging the catheter strain relief from the bronchoscope valve while the obturator is removed from the catheter to prevent kinking.

8.0 PERFORMANCE CHARACTERISTICS

Component	Characteristics
AeriSeal Foam	
AeriSeal Foam (Solution A)	2.1% aminated polyvinyl alcohol in phosphate buffer at pH 6.5
AeriSeal Foam (Solution B)	1.25% glutaraldehyde in phosphate buffer at pH 4.0
AeriSeal Balloon Catheter	
Inner Diameter	1.75 mm
Outer Diameter	2.74mm (8.23F)
Working (Usable) Length	72 cm
Overall Catheter Length	107 cm
Balloon Material	Pellethane
Inflation Diameter	12 mm
Inflation Air Volume	3 cc
Working Channel Through Bronchoscopes	2.8 mm

9.0 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Link to SSCP to be included when EUDAMED is available.

10.0 TREATMENT

10.1 PATIENT SELECTION

The AeriSeal System has not been extensively studied in patients who:

- have homogeneous emphysema, in upper lobes with >17% perfusion on quantitative lung perfusion scan;
- have undergone lung transplantation, lung volume reduction surgery, or lobectomy;
- have a pre-treatment DLC_O < 20% predicted or > 60% predicted;
- have alpha-1 antitrypsin deficiency.

10.2 TREATMENT

Do not proceed with AeriSeal System treatment in patients who are vigorously coughing or otherwise not tolerating bronchoscopy.

- patients should be adequately anesthetized or sedated to safely tolerate bronchoscopy and AeriSeal System treatment;
- topical anesthesia should be used appropriately to minimize coughing;
- pre-procedure treatment with an inhaled bronchodilator is recommended to minimize possible bronchospasm

When selecting airways for treatment.

- No more than 3 segments or 4 subsegments should be targeted for a treatment in a patient.
- This treatment can be performed in one or two sessions based

upon clinical judgement.

- Treating adjacent lung regions can be associated with increased incidence and/or severity of post-treatment inflammatory responses and COPD exacerbations.

10.3 POST TREATMENT

AeriSeal System treatment is associated with a transient, post-treatment inflammatory response. Prophylaxis with corticosteroids, antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs) and anti-acids is recommended as described in section 12.1.2.

Patients should not undergo additional treatment sessions until any post-treatment inflammatory response has resolved.

11.0 POTENTIAL COMPLICATIONS/ADVERSE EVENTS

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

• Loss of appetite	• Dyspnea	• Hypoxemia
• Chest pain	• Elevated serum markers of inflammation (CRP, ESR, fibrinogen, procalcitonin)	• Leukocytosis
• Cough	• Fever/chills	• 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:

• Acute kidney Injury	• Hemoptysis	• Pulmonary embolism
• Acute respiratory distress syndrome, respiratory failure	• Hypercapnea	• Pulmonary shunting
• Airway stenosis	• Hypokalemia	• Respiratory infection/pneumonia/ bronchitis/ empyema
• Allergic reaction	• Hypotension	• Sepsis
• Bronchospasm	• Iatrogenic injuries	• Sore throat
• Cavities at the site of treatment	• Increased mucus secretions	• Stroke/CVA/TIA
• COPD exacerbation	• Insomnia	• Systemic inflammatory response
• Death	• Irritation at balloon site (Balloon Catheter Only)	• Urinary tract Infection
• Disorientation/anxiety	• Lung abscess	• Venous thromboembolism
• Expectoration	• Musculoskeletal event	• Vertigo
• Flu-like symptoms	• Nausea/vomiting	• Vocal cord injury
• Granulation tissue / ulceration formation	• Pleural effusion	• Worsened lung function
• Heart arrhythmia/heart failure/myocardial infarction/cardiac arrest	• Pneumonitis/Pulmonary infiltrate	
• Hematoma	• Pneumothorax	

12.0 PROCEDURAL INSTRUCTIONS FOR USE

12.1 PERI-PROCEDURE PATIENT MANAGEMENT

12.1.1 PRE-PROCEDURE

Follow institutional guidelines for preparing patient for bronchoscopy and anesthesia.

- Administer corticosteroids and antibiotics (at least 2 hours before procedure)
- Administer inhaled bronchodilator (15–20 minutes before procedure)

12.1.2 POST-PROCEDURE

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. Patients who are not taking adequate fluids by mouth in the post treatment period should receive IV fluids (75-100 mL/hr, up to 15 mL/kg) until resumption of oral intake. Patients should have standard deep venous thrombosis (DVT) prophylaxis as appropriate.

Prophylactic corticosteroids and antibiotics should be continued for 6 additional days. Non-steroidal anti-inflammatory drugs (NSAIDs) are recommended for 3 days beginning on the day of treatment to reduce pleuritic chest pain symptoms. Anti-acids are recommended for 7 days beginning on the day of treatment as prophylaxis for gastrointestinal ulcers.

DAY	0	1	2	3	4	5	6
Corticosteroids[1]	100	75	75	50	50	25	25
Antibiotics[2]	✓	✓	✓	✓	✓	✓	✓
NSAIDs[3]	✓	✓	✓				
Anti-acids[4]	✓	✓	✓	✓	✓	✓	✓

1. Prednisolone specified mg QD or equivalent
2. Recommended antibiotics include: ampicillin/sulbactam, ciprofloxacin, extended spectrum penicillin or cephalosporin
3. Naproxen 500 mg BID or equivalent
4. Omeprazole 40 mg QD or equivalent

It is recommended that patients who have not returned to baseline dyspnea, exercise tolerance, and supplemental oxygen use by post-treatment day 7 should continue a low dose extended corticosteroid taper for an additional 2 weeks:

DAY	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Corticosteroids[1]	20	20	20	20	20	20	20	10	10	10	10	10	10	10

AeriSeal System therapy causes a focal infiltrate and atelectasis at and adjacent to the site of treatment, detectable by conventional 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.

Dose Equivalents for Corticosteroids (mg)				
Prednisolone	100	75	50	25
Betamethasone	12	9	6	3
Cortisone	500	375	250	125
Dexamethasone	15	11.25	7.5	3.75
Hydrocortisone	400	300	200	100
Methylprednisolone	80	60	40	20
Prednisone	100	75	50	25
Triamcinolone	80	60	40	20

12.2 MATERIALS, EQUIPMENT AND SUPPLIES REQUIRED

REF **AER-FO-100** Each Box Contains:	**Pulmonx® AeriSeal Foam Components** (1) Vial, Solution A (1) Vial, Solution B	CE 2797
REF **AER-FO-200** Each Box Contains:	**Pulmonx® AeriSeal® Foam Components** (2) Vials, Solution A (2) Vials, Solution B	CE 2797
REF **AER-FO-400** Each Box Contains:	**Pulmonx® AeriSeal® Foam Components** (4) Vials, Solution A (4) Vials, Solution B	CE 2797

REF AER-BC-KIT	Pulmonx® AeriSeal® Balloon Catheter Preparation Kit*
Each Kit Contains:	(1) Pulmonx® AeriSeal Balloon Catheter
	(2) Needle, 20 G x 4 cm
	(1) Stopcock, 3-way
*Regulated according to Article	(1) Stopcock, 1-way
12 of the Council Directive 93/42/	(1) Syringe, 1 mL
EEC (amended by 2007/47/EC) for	(1) Syringe, 3 mL
medical devices.	(1) Syringe, 6 mL
	(1) Syringe, 20 mL
	(1) Syringe, 30 mL
	(1) Syringe, 60 mL
	Patient Card
	Instructions for Use

Equipment and Materials also required but not supplied include:

- For use with the AeriSeal Balloon Catheter: Standard Flexible Bronchoscope (working channel diameter ≥ 2.8 mm)
- Sterile field, disposable

12.3 PATIENT PREPARATION

Step	Action
1	Verify that the patient is a good candidate for bronchoscopy and AeriSeal System treatment (See Section 6.0 Warnings, Section 7.0 Precautions and Section 12.1 Peri-Procedure Patient Management).
2	Select treatment site as instructed in Section 10.1 and 10.2.
3	Administer prophylactic corticosteroids and antibiotics (1st dose to be given at least 2 hours prior to treatment).
4	Administer inhaled bronchodilator 15-20 minutes before the procedure.

12.4 PRE-TREATMENT PREPARATION

Step	Action
⚠	**CAUTION:** All procedures should be performed with gloves and eye protection.
Note:	Remove the Foam 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 the bronchoscope and sterile field.

12.5 AERISEAL BALLOON CATHETER PREPARATION

Step	Action
1	Lubricate the distal tip of the Balloon Catheter with a viscous sterile lubricant for ease in passing the Catheter through the working channel of the bronchoscope.
2	Attach the 1-way Stopcock to balloon inflation port of the catheter.
3	Depress plunger of sterile 3 mL syringe and attach to opposite end of the 1-way Stopcock. Ensure the 1-way Stopcock is in open position.
4	Apply a vacuum to the balloon lumen by retracting the plunger of the inflation syringe and closing the 1-way Stopcock prior to inserting the catheter into the bronchoscope.

12.6 ACCESSORIES 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 syringe and connect to 3-way Stopcock.
3	Position “OFF” handle of the 3-way Stopcock to point opposite the 20 mL syringe.
⚠	**CAUTION:** Ensure that the Stopcock is positioned so that the “OFF” handle points opposite the 20 mL syringe to prevent accidental spillage of treatment material.

12.7 SOLUTION A PREPARATION

Step	Action
1	Using a new 20 G needle and a 6 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 3-way Stopcock and connect the 6 mL syringe containing Solution A to the port.
3	Deliver all of Solution A to the 20 mL syringe. Remove the empty 6 mL syringe.

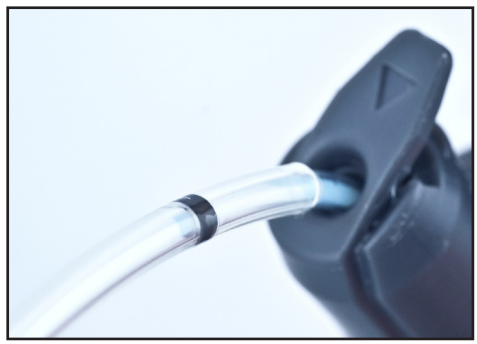
12.8 SOLUTION B PREPARATION

Step	Action
1	Using a new 20 G needle and 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.

12.9 TREATMENT

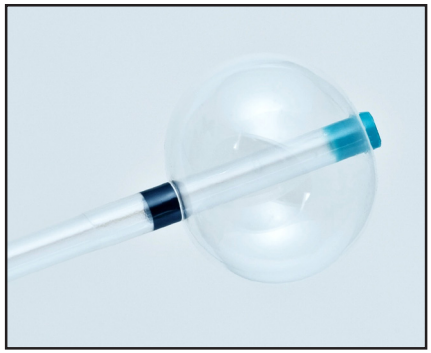
12.9.1 BRONCHOSCOPE POSITIONING AND BALLOON CATHETER PLACEMENT

Step	Action
1	Carefully insert the Balloon Catheter with the obturator into the working channel of the bronchoscope.
2	Advance the Balloon Catheter approximately 2 cm beyond the distal tip of the bronchoscope until the catheter's distal balloon tip is visualized and the strain relief is engaged in the bronchoscope valve. **NOTE:** Use caution to avoid kinking the catheter when the strain relief marker is visible outside the bronchoscope valve.
3	Guide the flexible bronchoscope to the subsegment that has been selected for treatment.
4	Position the distal tip of catheter into the target airway. The black proximal balloon marker identifies the proximal edge of the balloon.
5	Remove the obturator from the catheter.



The Visible Strain Relief Marker indicates the catheter is not fully inserted

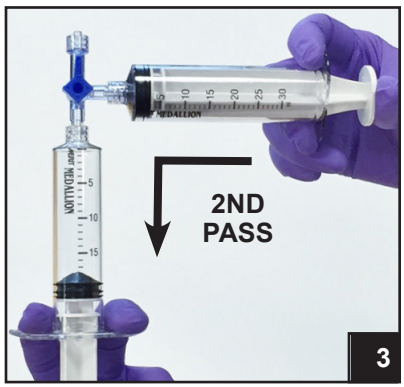
Step	Action
6	Using the 3 mL syringe, inject up to 3 mL (cc) of air as needed for balloon expansion to create a seal in the airway under constant visualization, and close the 1-way Stopcock to secure the inflated balloon. Do not over-inflate balloon in smaller airways. **CAUTION:** To prevent balloon rupture, do not inject more than 3 mL (cc) of air.
7	Confirm via visual inspection that the target airway is occluded. Air bubbles at the balloon should not be visible during respiration.



The Black proximal balloon marker identifies the proximal edge of the balloon.

12.9.2 FOAM PREPARATION

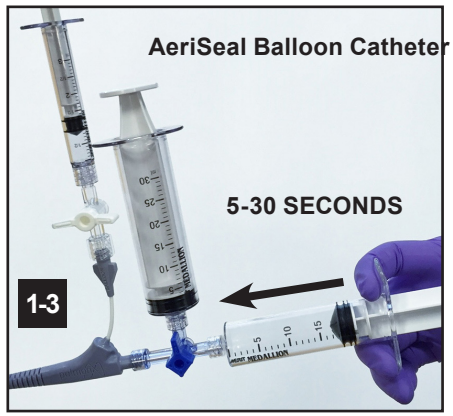
Step	Action
⚠	**Caution:** Do not begin mixing the Foam Components until the catheter is correctly positioned with the balloon inflated. Work quickly to complete prepare the foam in order to prevent the material from polymerizing before delivery.
1	Connect the 1 mL syringe containing Solution B to the 3-way Stopcock at the middle port. Deliver Solution B from the 1 mL syringe to the 20 mL 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 3-way Stopcock at the middle port.
3	Generate a uniform white foam by alternately pushing the plungers of the 20 mL and 30 mL syringes so that the mixture passes through the 3-way Stopcock a total of 10 cycles. Two passes through the 3-way Stopcock make up one cycle. This should take between 7 and 15 seconds.
4	Following foam generation, ensure that the desired volume of Foam is contained in the 20 mL syringe. Transfer any excess foam to the 30 mL syringe.
⚠	**Caution:** Ensure the 3-way Stopcock valve is positioned correctly so that material is not wasted.

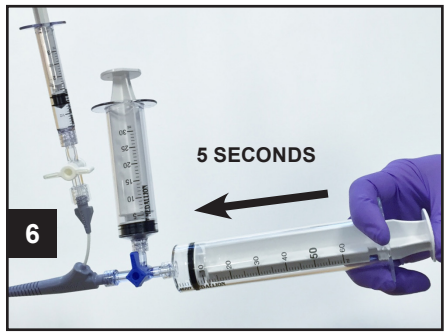


12.9.3 FOAM ADMINISTRATION

Step	Action
⚠	**Caution:** It is extremely important to maintain balloon seal during Foam administration.
1	Immediately connect the Catheter to the port on the 3-way Stopcock opposite the 20 mL syringe. Maintain balloon seal and do not pull the Catheter out of position.
2	Position the “OFF” handle of the 3-way Stopcock so that it points towards the middle port.
3	Inject the desired volume of Foam through the Catheter applying steady firm pressure to the plunger of the 20 mL syringe. Complete injection of the Foam should take between 5 and 30 seconds.
4	Keep the plunger of the 20 mL syringe depressed for at least 5 seconds after completion of injection to ensure that all of the Foam is delivered.
5	Remove the 20 mL syringe from the 3-way Stopcock.
6	• Over 5 seconds inject up to 30 mL of air through the 3-way Stopcock using a 60 mL syringe to promote distal distribution of the Foam. • Position the “OFF” handle of the 3-way Stopcock so that it points towards the catheter. Maintain balloon seal for at least 1 minute without applying suction to prevent spillage of material. • When foam delivery is complete open the 1-way Stopcock and retract the plunger on the 3 mL syringe to deflate the balloon on the Balloon Catheter. Remove the Balloon Catheter by retracting it through the working channel of the bronchoscope.
7	Dispose of the Balloon Catheter and Solution vials per institutional standard for biohazardous materials.

Note: Repeat Treatment Steps for each airway to be treated.





13.0 BRONCHOSCOPE CLEANING

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

14.0 HOW SUPPLIED

Instructions for Use are supplied and packaged with the AeriSeal Balloon Catheter Preparation Kit.

AeriSeal® Foam Components
The AeriSeal Foam Components are aseptically processed and supplied sterile. The product is intended for SINGLE USE ONLY. Do not reuse or re-sterilize.

AeriSeal® Balloon Catheter Preparation Kit

The AeriSeal Balloon Catheter Preparation Kit contains the AeriSeal Balloon Catheter and various commercially available accessories. The AeriSeal Balloon Catheter is sterilized by ethylene oxide and supplied sterile. The provided accessories are also provided sterile. The product provided is intended for SINGLE USE ONLY. Do not reuse or re-sterilize. The kit contains sufficient material for a single treatment.

15.0 STORAGE

AeriSeal Foam Components

Product should be stored in refrigerated conditions (2 - 8 °C).

AeriSeal Balloon Catheter Preparation Kit

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

16.0 DISPOSAL

AeriSeal Foam Components

- Solution A is composed of a 2.1% Aminated Polyvinyl Alcohol in a phosphate buffered solution. Unused material should be disposed of following standard institutional practices. Safety Data Sheets for the material are available upon request.
- Solution B is composed of 1.25% Glutaraldehyde in a phosphate buffered solution. Unused material should be disposed of following standard institutional practices. Safety Data Sheets for the material are available upon request.

17.0 EXPLANATION OF SYMBOLS AND SIGNAL WORDS

LOT	Batch code	2 STERILE	Do not re-sterilize
REF	Catalog number		Do not reuse
CONT	Contents		Date of manufacture
STERILE EO	Sterilized using Ethylene Oxide		Manufacturer
STERILE A	Sterilized using Aseptic Processing Techniques		Consult instructions for use
STERILE	Sterile. Indicates a medical device that has been subjected to a sterilization process.		Use by
	Keep dry		Do not use if package is damaged or opened
EC REP	Authorized representative in the European Community		Temperature limit, store between
Ø	Minimum Bronchoscope Working Channel Diameter	**Note**	Indicates essential information.
⚠	Caution, consult accompanying documents. 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.		

MAX INFLATION VOLUME	Maximum Inflation Volume

AeriSeal Foam Treatment: the therapeutic composition, the delivery catheter, and/or its use are covered by the following United States patents and applications: 8198365; 8445589; and 8911750; 6,610,043; 6,682,520; 7,654,999; 7,300,428; 13/898,624; and 14/571,873. Other U.S. patents pending. The therapeutic composition, the delivery catheter, and/or its use are covered by the following international patents and applications: CN2008823717; EP2008755145; EP20080745018; and KR1020100019488A. Other international patents pending.

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UK REP

Pulmonx GmbH
6 Wilmslow Road,
Rusholme
Manchester M14 5TP
United Kingdom

Pulmonx® Corporation
700 Chesapeake Drive
Redwood City, CA 94063
United States of America
Tel: +1 (650) 364-0400

EC REP

Pulmonx GmbH
Fürstenrieder Straße 263
81377 München
Germany

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