INSTRUCTIONS FOR USE (IFU)

System for Selective Lung Lobe Recruitment, Lavage and Therapeutic Delivery

(Selective Lobar Ventilation and Targeted Pulmonary Delivery System)

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Table of Contents

1. Device Overview

The System for Selective Lung Lobe Recruitment, Lavage and Therapeutic Delivery (the "System") is a subglottic multi-lumen airway system that enables temporary, selective isolation of one or more pulmonary lobes, selective recruitment or differential ventilation, and targeted intrapulmonary delivery of therapeutics to the isolated lobe(s) while maintaining ventilation of the remaining lobes.

1.1 Intended Use / Indications for Use

The System is indicated for use in adult patients (≥18 years) requiring invasive mechanical ventilation who exhibit regionally heterogeneous lung mechanics. The device enables temporary isolation and differential ventilation of one or more lung lobes and facilitates targeted intrapulmonary delivery of therapeutic agents to the isolated lobe(s) while maintaining ventilation of non-isolated lobes.

Clinical scenarios where the device in indicated.

- Selective recruitment of lobar atelectasis (including during ex vivo lung perfusion (EVLP) / lung graft optimization; facilitation of liberation from ECMO; and management of regional lung dysfunction associated with prolonged mechanical ventilation and failure to wean).
- Targeted lobar therapeutic delivery, including delivery of solutions (e.g., saline) for selective lobar lavage (e.g., pulmonary alveolar proteinosis; localized infectious processes such as lobar pneumonia, pulmonary abscesses, and cavitary lesions) and targeted delivery of therapeutics when systemic treatment is refractory or limited by systemic toxicity.

1.2 Intended Users and Use Environment

Intended users: Clinicians trained and credentialed in airway management and flexible bronchoscopy (e.g., anesthesiology, critical care, interventional pulmonology, cardiothoracic surgery).

Use environment: ICU, operating room, bronchoscopy suite, and ex vivo lung perfusion (EVLP) settings where invasive ventilation and physiologic monitoring are available.

1.3 Contraindications

- Patients <18 years of age.
- Inability to perform or maintain invasive mechanical ventilation and continuous monitoring (SpO_2, $ETCO_2$, hemodynamics).
- Known or suspected tracheobronchial injury, active major airway bleeding, or airway pathology that precludes safe bronchoscopy (e.g., critical tracheal stenosis).
- Anatomy or obstruction that prevents safe advancement and stable placement of the lobar tube in the intended lobar bronchus.

2. Safety Information

2.1 Warnings

1. Only clinicians trained in bronchoscopy and advanced airway management should use this System; improper use may cause serious injury.
2. Continuous ventilation of non-isolated lobes must be maintained at all times unless a deliberate clinical decision is made otherwise.
3. Placement and cuff inflation of the lobar tube must be performed under direct bronchoscopic visualization to avoid malposition, cuff herniation into the mainstem bronchus, obstruction, or ineffective seal.
4. Use a cuff manometer (cuffometer) to measure lobar cuff pressure and maintain cuff pressure ideally between 20–30 cmH_2O and for a limited period of time.
5. During lobar recruitment, differential ventilation, CPAP, lavage, or therapeutic delivery, monitor delivered pressure and avoid excessive pressures to reduce the risk of barotrauma (e.g., pneumothorax, pneumomediastinum).
6. Immediately stop the procedure and return to conventional ventilation if there is unexplained hypoxemia, hypercapnia, hemodynamic instability, suspected barotrauma, or loss of airway control.
7. Single-patient, single-use device. Do not reprocess, resterilize, or reuse.

2.2 Precautions

- Confirm appropriate ventilation via the endotracheal tube before starting lobar instrumentation.
- Ensure unconsciousness (general anesthesia or deep sedation) before, neuromuscular blockade to minimize coughing, tube displacement, and airway trauma during tube-through-tube placement.
- Test the lobar cuff for integrity prior to insertion and fully deflate before advancement.
- Lubricate the bronchoscope and lobar tube to facilitate atraumatic placement.
- After lobar isolation and prior to delivery of lavage/therapeutics, assess gas exchange for 15–20 minutes and optimize ventilator settings.
- During delivery, confirm no spillage to unintended lung zones.
- After delivery, perform lobar recruitment as needed and reassess ventilation/gas exchange before removing the lobar tube.

2.3 Potential Adverse Events

Potential adverse events include (not exhaustive):

- Barotrauma (pneumothorax, pneumomediastinum, subcutaneous emphysema).
- Hypoxemia, hypercapnia, respiratory acidosis, worsening respiratory failure.
- Airway trauma (mucosal injury, bleeding), bronchospasm.
- Atelectasis of non-target lobes due to malposition or obstruction.
- Aspiration or unintended flooding/spillage of instilled fluid into non-target lung zones.

3. Device Description

Major components described in the Breakthrough submission include: (1) tracheal tube/endotracheal tube; (2) one or two flexible lobar tubes advanced under bronchoscopic guidance; (3) multi-port modular proximal connector allowing continuous ventilation while passing instruments/lobar tubes; (4) standard ventilator circuit and capnography connections; and (5) optional split ventilation connector for two lobar tubes.

3.1 Components and Accessories

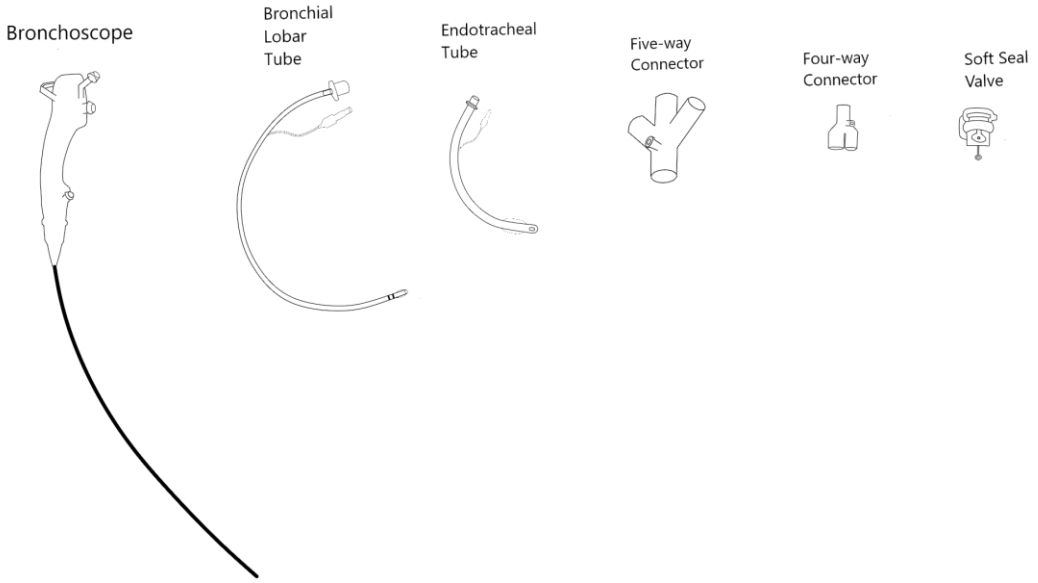

Figure: System components overview

Bronchoscope

Slim Bronchoscope

Bronchial
Lobar
Tube

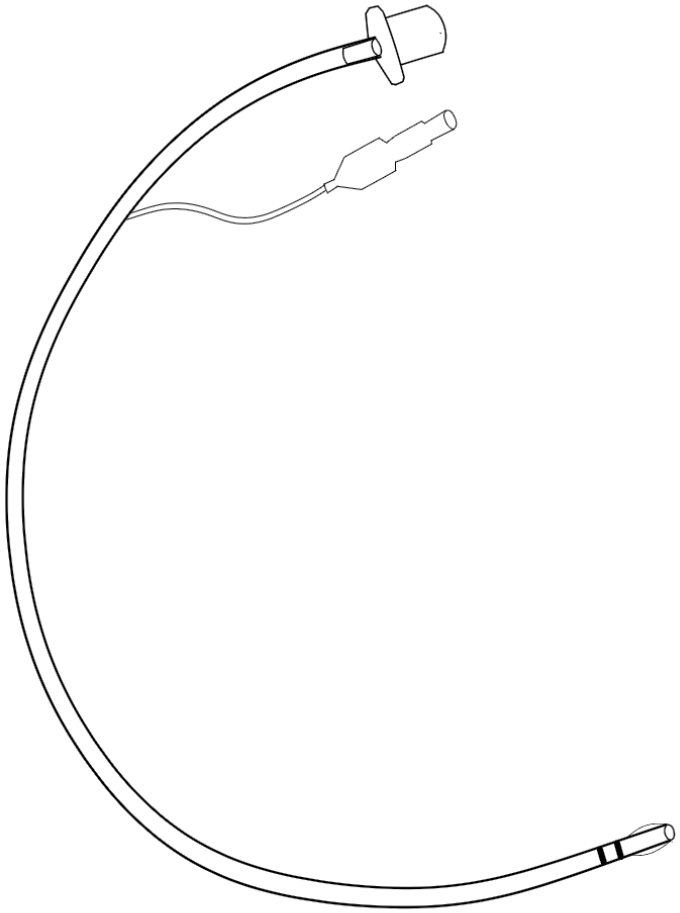

Figure: Bronchial Lobar Tube- two sizes ID 3.5 and 4.0mm

Endotracheal Tube

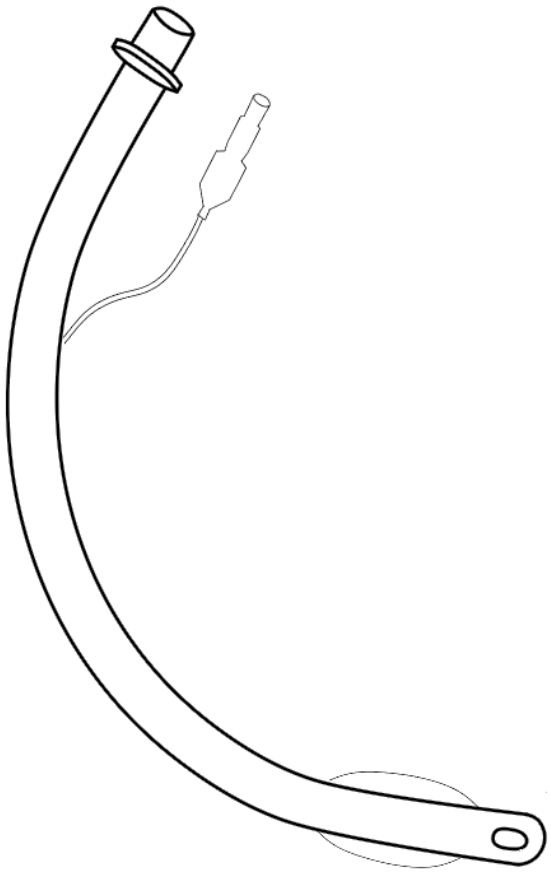

Figure: Endotracheal Tube (standard)

Five-way Connector

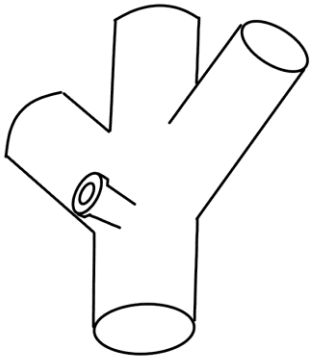

Figure: Five-way modular Connector

Soft Seal Valve

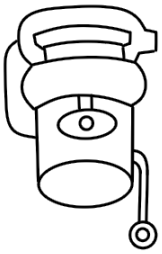

Figure: Soft Seal Valve

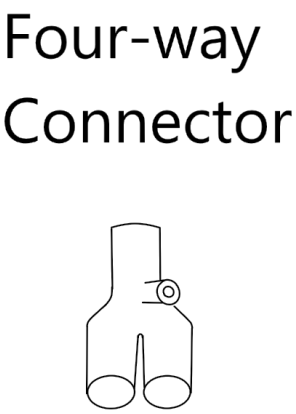

Figure: Four-way (split ventilation) Connector.

3.2 Sizes and Compatibility

Adult configurations described include tracheal tube compatibility with 8.0–10.0 mm internal diameter endotracheal tubes and lobar tubes with 3.5 mm and 4.0 mm internal diameter (cuffed tips sized for segmental/lobar bronchi).

The device interfaces with standard 15 mm connectors for ventilator circuits and standard capnography adapters.

3.3 Sterility and Single-Use

The Breakthrough submission describes EO sterilization, sterile packaging, and single-use / single-patient use. Verify package integrity prior to use and do not use if the sterile barrier is compromised.

4. Preparation for Use

4.1 Required Equipment (Not Supplied Unless Specified)

- Standard ventilator and respiratory circuit; capnography line.
- Standard endotracheal tube (appropriate size).
- Slim flexible bronchoscope compatible with lobar tube ID (e.g., 2.2–2.8 mm bronchoscope per device configuration).
- Cuff manometer (cuffometer).
- Pressure monitoring device for lobar ventilation/delivery (manometer or pressure transducer).
- Suction equipment.

- If performing lavage/therapeutic delivery: delivery system/reservoir and solution/therapeutic agent per institutional protocol.

4.2 Patient Selection and Pre-Procedure Checklist

- Confirm indication and target lobe(s) using clinical assessment and imaging (e.g., CXR/CT) and/or bronchoscopy.
- Confirm invasive ventilation is established with appropriate sedation (and muscle relaxation when appropriate).
- Establish continuous monitoring: ECG, SpO_2, noninvasive/invasive BP, $ETCO_2$; obtain baseline ABG when clinically indicated.
- Confirm availability of rescue equipment and readiness to revert to conventional ventilation immediately.
- Verify device packaging integrity and ensure all ports/valves/connectors are present and functional.

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5. Step-by-Step Instructions for Use

5.1 Assemble the Ventilation Connector

8. Before intubation, have the five-way connector attached or immediately available for ventilation.
9. After endotracheal intubation, attach the five-way connector with soft seal valves to the endotracheal tube, ventilator circuit, and capnography line.
10. Confirm appropriate ventilation has been achieved prior to proceeding.

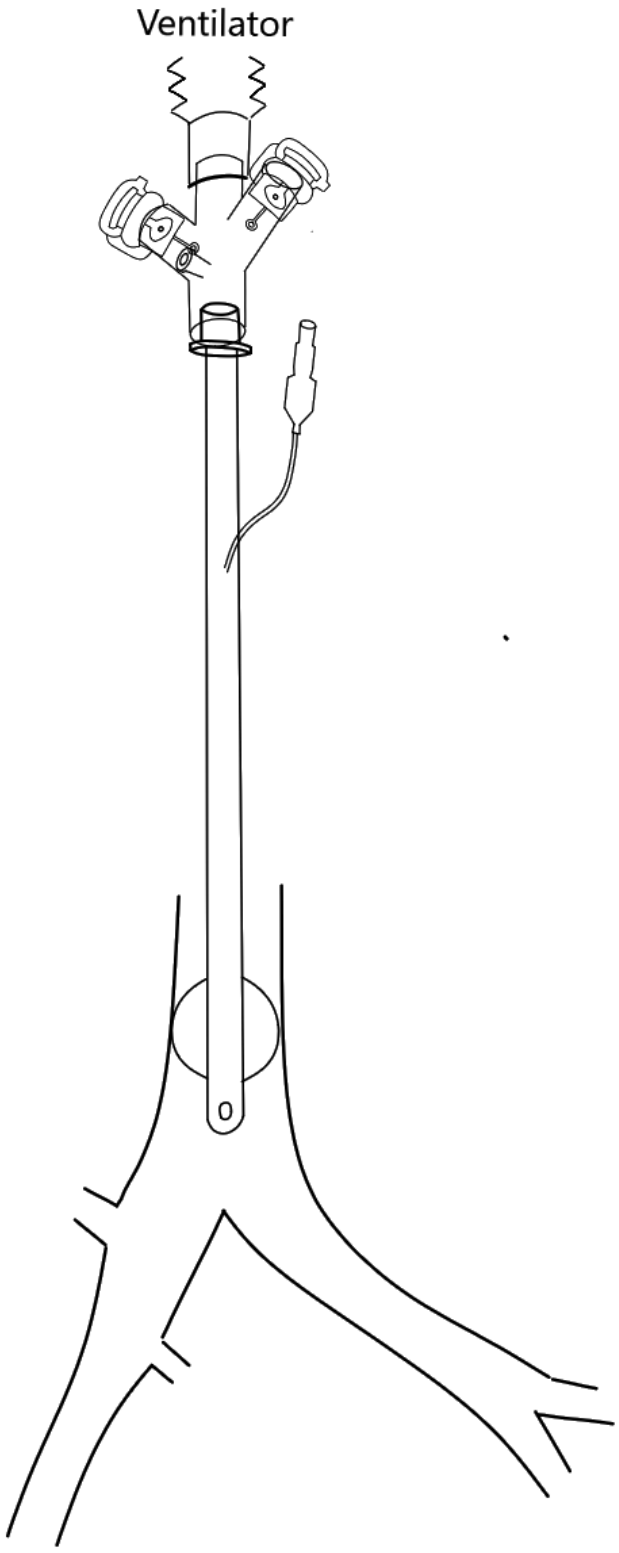

Figure: Five-way connector in-line between ventilator and endotracheal tube (schematic).

5.2 Prepare and Load the Lobar Tube

11. Test the distal cuff for leaks and fully deflate the cuff.
12. Load the lobar tube over the slim bronchoscope.
13. Lubricate the bronchoscope and lobar tube to facilitate placement.

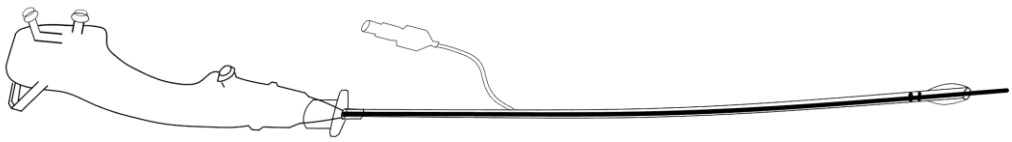

Figure: Lobar tube loaded over bronchoscope (schematic).

5.3 Place the Lobar Tube into the Target Lobe

14. Define the lobe requiring selective treatment.
15. Select the soft seal valve opposite to the desired lobe to facilitate ergonomics.
16. Open the selected soft seal valve and insert the bronchoscope with loaded lobar tube through the connector and endotracheal tube to the desired lobar bronchus.
17. Deploy the lobar tube at the target location, remove the bronchoscope, and hold the lobar tube in place.

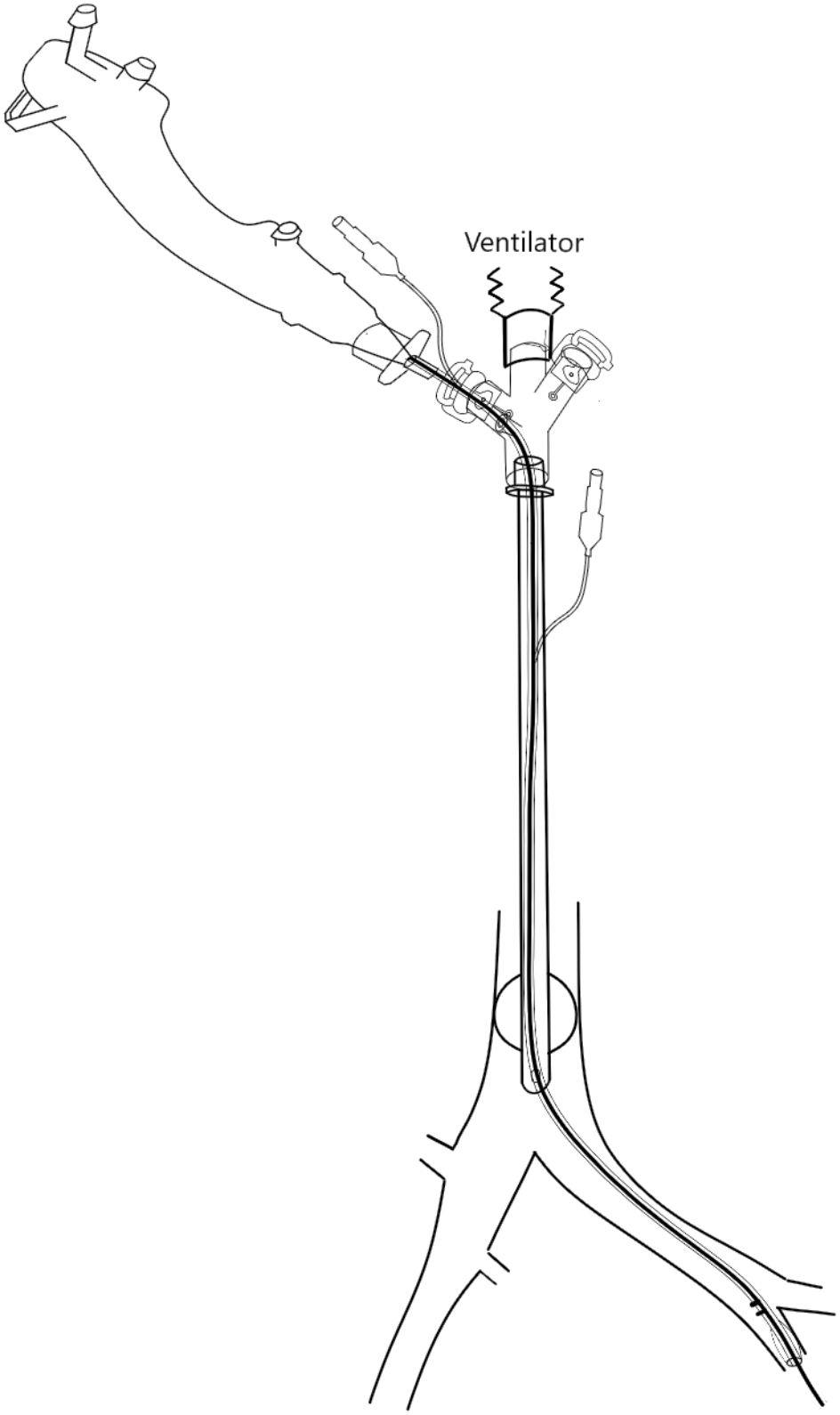

Figure: Placement of lobar tube into target lobar bronchus (schematic).

5.4 Confirm Position and Inflate the Lobar Cuff

18. Insert the bronchoscope through the contralateral soft seal valve to visualize the cuff of the lobar tube.
19. Inflate the lobar cuff under direct vision to confirm seal and avoid dislodgement or herniation into the mainstem bronchus.
20. Inflate with 8–12 mL of air as needed to achieve seal; measure and maintain cuff pressure ideally 20–30 cmH_2O using a cuff manometer.
21. Remove the bronchoscope after confirming correct position and adequate seal.

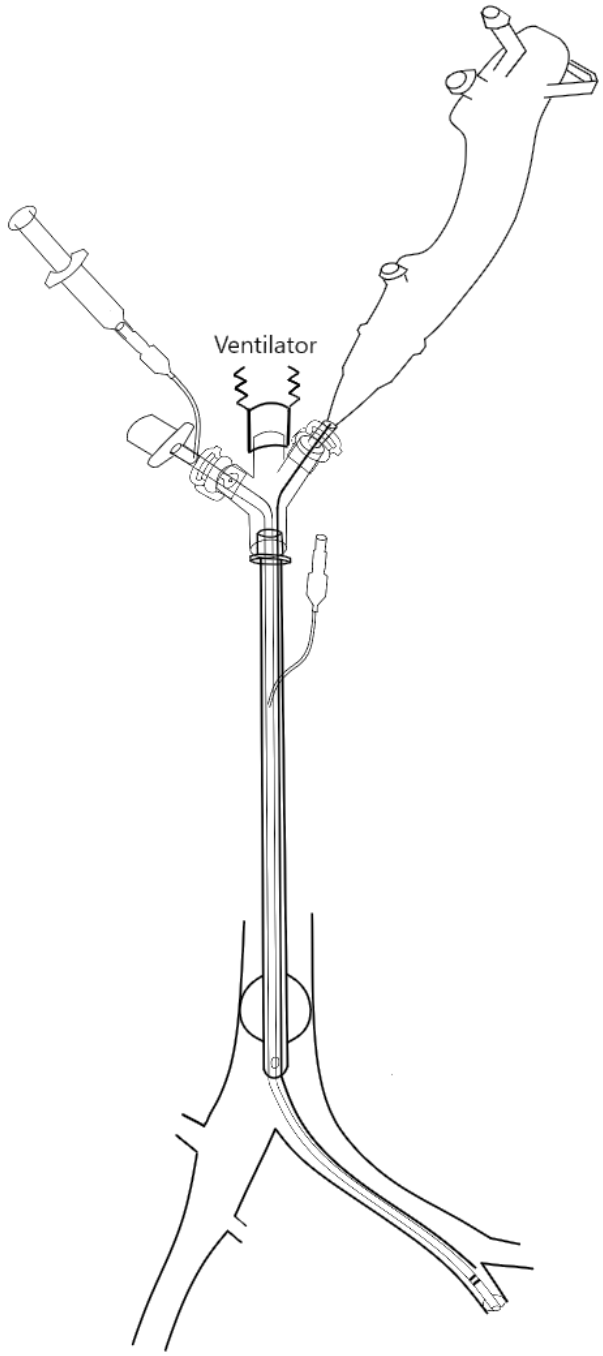

Figure: Bronchoscopic visualization and cuff inflation confirmation (schematic).

5.5 Perform Selective Lobar Ventilation / Recruitment / Delivery

Once the cuff is inflated, the target lobe is isolated from the rest of the lungs.

Connect a separate device to the lobar tube as clinically indicated (e.g., CPAP, bag ventilation, separate ventilator, or delivery system for lobar lavage and drug administration). Pressure monitoring is recommended to avoid barotrauma.

Recommended monitoring and workflow:

- Monitor vital signs, hemodynamics, and gas exchange (SpO_2, $ETCO_2$; ABG as indicated).
- After lobar isolation and prior to delivery, evaluate gas exchange for 15–20 minutes and optimize ventilatory parameters.
- During delivery, confirm no spillage to unintended lung zones.
- After delivery, perform recruitment of the treated lobe as clinically indicated and reassess oxygenation/ventilation.

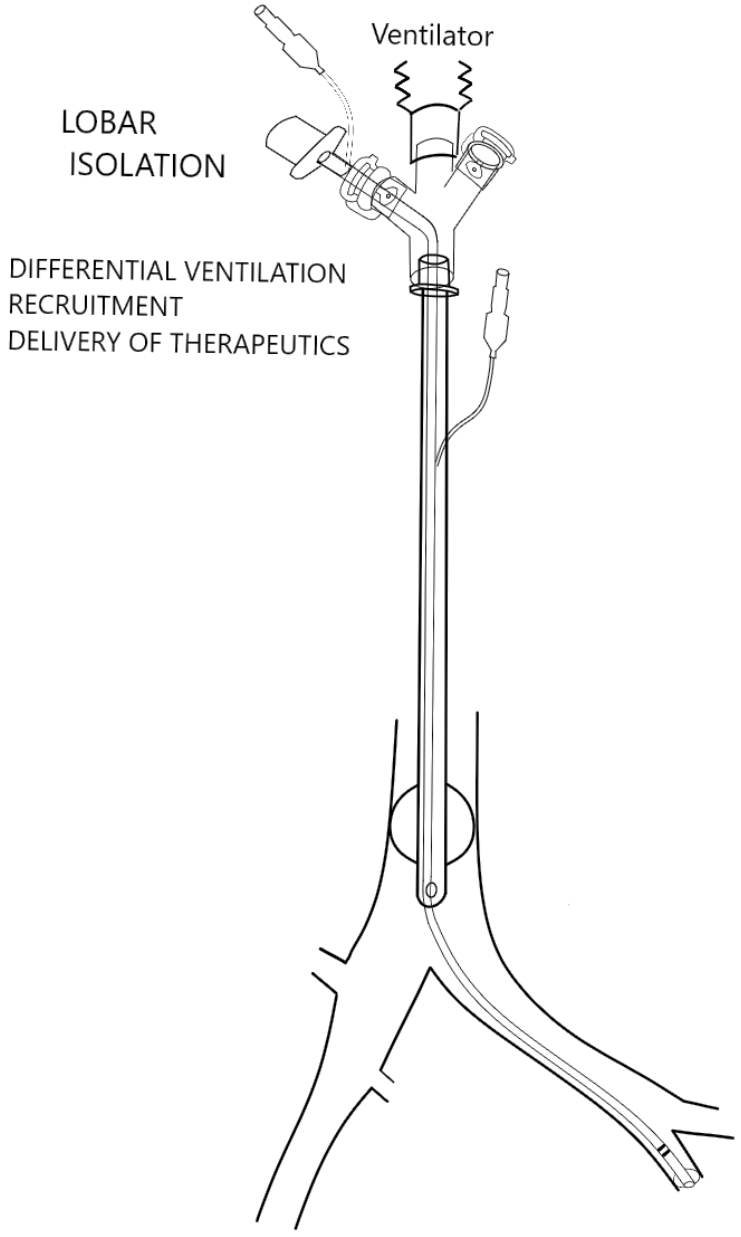

Figure: System configuration for lobar isolation, differential ventilation/recruitment, and therapeutic delivery (schematic).

5.6 Removal and Post-Procedure Care

22. Return the patient to conventional ventilation strategy via the endotracheal tube as clinically indicated.
23. Fully deflate the lobar cuff under bronchoscopic visualization when feasible.
24. Remove the lobar tube while maintaining endotracheal tube position.
25. Reassess ventilation and gas exchange; obtain ABG if clinically indicated.
26. Reevaluate pulmonary function and readiness for extubation per institutional protocol.

6. Troubleshooting

Problem	Possible Cause	Corrective Action
Air leak / inability to maintain ventilation	Soft seal valve not seated; connector leak; cuff underinflated; malposition	Check all connections and valves; confirm cuff position bronchoscopically; adjust cuff inflation and verify 20–30 cmH_2O; if persistent, deflate and reposition or remove.
Worsening hypoxemia	Loss of ventilation to non-isolated lobes; malposition; fluid spillage; barotrauma	Immediately return to conventional ventilation; suction as needed; confirm tube positions; evaluate for pneumothorax and treat per protocol.
High lobar pressure / poor compliance	Over-recruitment; obstruction; cuff herniation; bronchoscope wedged	Stop lobar ventilation/delivery; confirm position bronchoscopically; reduce pressures; ensure unobstructed exhalation; treat suspected barotrauma.
Cuff herniation into mainstem	Overinflation; malposition	Deflate cuff, reposition under visualization, reinflate to seal with pressure monitoring.

7. Storage and Handling

Store the sterile, single-use device in its original packaging until use. Protect from physical damage. Do not use after expiration date. Keep it in, dry, clean, and cool environment.

8. Disposal

Dispose of the used device and accessories as regulated medical waste per hospital and local requirements. Do not reuse.

9. Manufacturer and Contact Information

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