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ADVANCED ENDOBRONCHIAL SOLUTIONS

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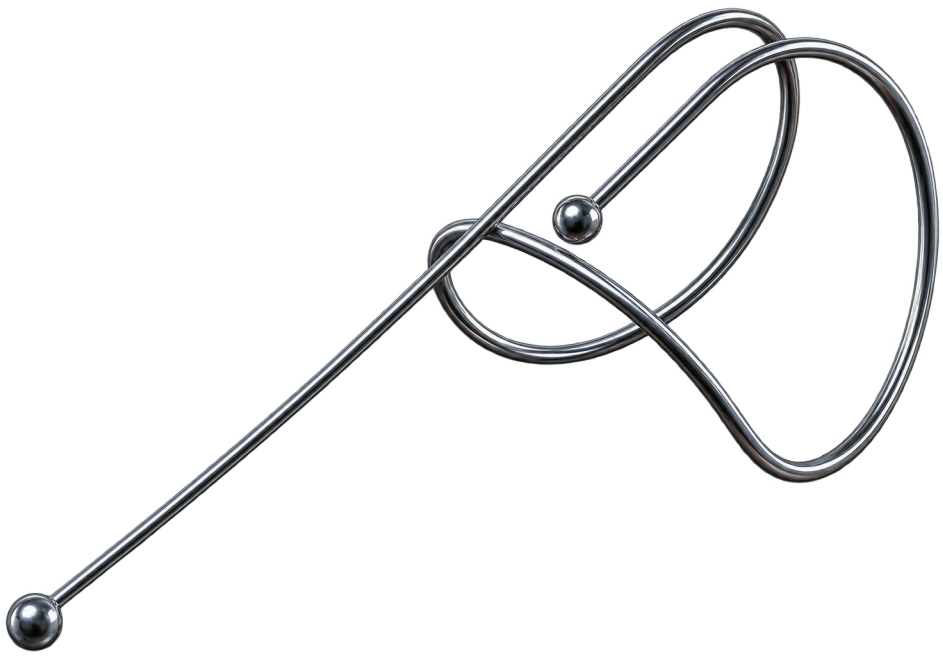
VOLUTAM™ Endobronchial Coil System



NON-BLOCKING BRONCHOSCOPIC LUNG VOLUME REDUCTION

Clinical product overview for healthcare professionals

Appropriate Patient Selection

Data-driven. Patient-focused.

Volutam coil therapy may be considered for carefully selected patients with severe emphysema and marked hyperinflation. Patient evaluation should integrate symptoms, pulmonary physiology, CT/QCT findings, comorbidities and multidisciplinary risk-benefit assessment. Treatment suitability and technique must follow the current Volutam IFU.

CLINICAL ASSESSMENT

Optimized pharmacologic therapy Pulmonary rehabilitation Persistent symptoms / exercise limitation FEV1, RV, TLC, RV/TLC Gas exchange / vascular status Cardiac and overall comorbidity

QCT-LED PLANNING

Lobar volume - anatomical burden LAA-950 / LAA-910 - emphysema burden Heterogeneity - target vs non-target Fissure map - context, not a coil gate Follow-up QCT - redistribution / safety

WHEN COIL CONSIDERATION BECOMES RELEVANT

Severe emphysema > **Marked hyperinflation** > **Symptoms despite optimized care** > **Suitable CT / QCT target** > **MDT confirms risk-benefit**

WARNING - USE CAUTION / AVOID

Large focal or giant bullae; paraseptal-predominant emphysema; airway-predominant disease; clinically significant pulmonary hypertension; major uncontrolled cardiac disease; active infection or unstable exacerbation. Exact criteria and thresholds must follow the current Volutam IFU.

DECISION PRINCIPLE

No single CT or physiologic variable should be used in isolation. Selection is a multidisciplinary clinical decision integrating symptoms, physiology, imaging, comorbidity and the current approved labeling.

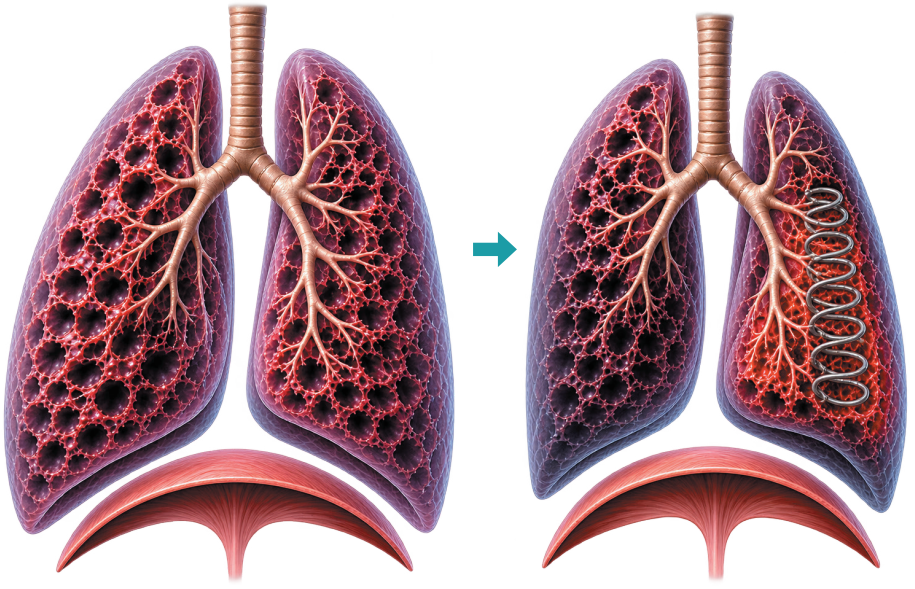
Hyperinflation

From air trapping to respiratory limitation

In emphysema, destruction of alveolar walls reduces elastic recoil. Expiratory flow limitation promotes air trapping, progressive hyperinflation and diaphragmatic flattening. The result is a rising mechanical burden on breathing and reduced exercise capacity.

HYPERINFLATED LUNG

TARGETED VOLUME REDUCTION



THE CYCLE OF OVERINFLATION

1 OVERDISTENSION
Alveoli lose elasticity and remain overdistended.

2 AIR TRAPPING
Expiratory flow limitation leaves air behind.

3 HYPERINFLATION
Lung volumes rise; the diaphragm flattens.

4 REDUCED FUNCTION
Mechanical efficiency and exercise capacity decline.

MECHANICAL CONSEQUENCE

Progressive air trapping increases lung volume, flattens the diaphragm and reduces mechanical efficiency. Targeted parenchymal gathering is intended to reduce the burden of hyperinflation in appropriately selected patients.

VOLUTAM™ CLINICAL OBJECTIVE

Mechanical gathering of targeted emphysematous parenchyma, with the aim of reducing hyperinflation and improving respiratory mechanics. Treatment suitability and technique must follow the current IFU.

Targeted volume reduction

Non-blocking. Mechanical. Image-guided.

Unlike one-way valves, coils do not aim to occlude an entire lobe. The deployed nitinol implant recovers its memorized form, gathers diseased parenchyma and increases local tissue tension. The mechanism therefore does not require complete lobar blockage.

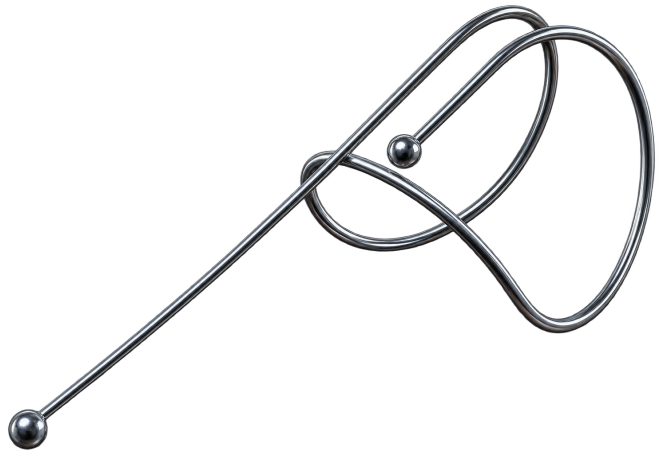
1 PLAN
Physiology + CT/QCT target selection

2 NAVIGATE
Bronchoscopy + fluoroscopy

3 DELIVER
Advance the straightened implant

4 DEPLOY
Release; coil recovers pre-set form

5 ASSESS
Confirm position and procedural safety



CLINICAL DISTINCTION

Collateral ventilation is central to valve eligibility; coil suitability still requires comprehensive imaging, physiology and multidisciplinary assessment. Treatment suitability and technique must follow the current Volutam IFU.

Published coil-system evidence

Benefits and risks shown together

INDIVIDUAL PARTICIPANT DATA META-ANALYSIS • 680 PATIENTS

+0.07 L
FEV 1
6 months

-0.36 L
RV
12 months

-9.8 pts
SGRQ
12 months

+38 m
6MWD
3 months

RENEW RCT • 315 PATIENTS • 12 MONTHS

+14.6 m
6MWD

-8.9 pts
SGRQ

+7.0%
FEV 1

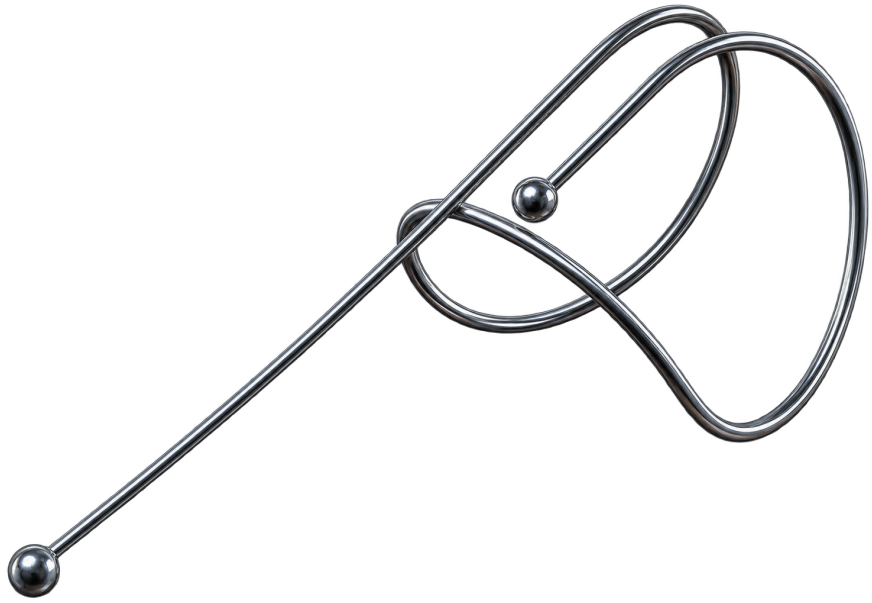
34.8% vs 19.1%
Major complications

INTERPRETATION

These values summarize published coil-system evidence and should not be presented as Volutam-specific efficacy data unless supported by an appropriate bridging rationale and regulatory review. Major complications were more frequent with coil treatment than usual care in RENEW.

The implant

Shape-memory nitinol for non-blocking bronchoscopic lung volume reduction.



SHAPE-MEMORY NITINOL

Delivered straightened; designed to recover its pre-set three-dimensional form after deployment.

NON-BLOCKING CONCEPT

Mechanical tissue gathering rather than complete lobar occlusion.

TARGETED PLACEMENT

Selected subsegmental airways under bronchoscopic and fluoroscopic guidance.

IMPLANT LENGTHS

100 mm	125 mm	150 mm

Product configurations and availability may vary by market. Refer to the current IFU and ordering information.

Precision delivery

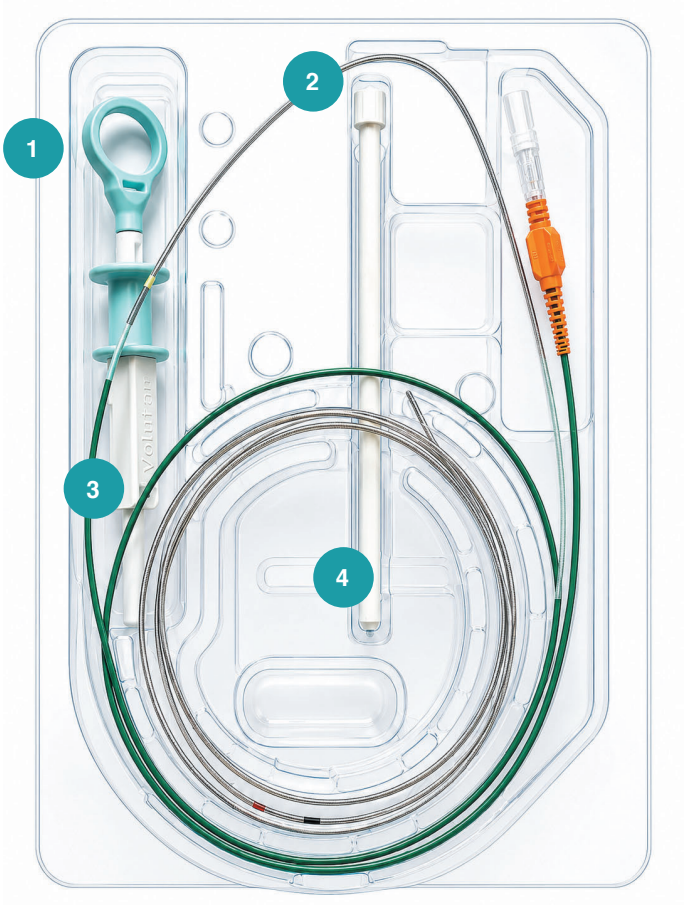
Dedicated system for controlled implantation.

1 **FORCEPS**
Purpose-designed for coil grasping and positioning

2 **GUIDE WIRE**
Specially designed, nitinol wire-supported

3 **APPLICATION CATHETER**
For coil delivery

4 **CARTRIDGE**
Sterile packaging and protection



FORCEPS
O.D. Ø 1.8 mm
Opening width 5.5 mm
Working length 1600 mm
Working channel >= Ø 2.0 mm

PURPOSE-DESIGNED
Specially formed jaw geometry is designed to grasp the Volutam coil during implantation,supporting controlled positioning and adjustment.

GUIDE WIRE
Overall length 1250 mm
Outer diameter 1.7 mm
Outer material 316LVM stainless steel
Inner support Nitinol wire

SPECIAL DESIGN
316LVM stainless-steel outer construction with internal nitinol wire support, engineered as a dedicated guide wire for the delivery system.

APPLICATION CATHETER
Shaft length 100 cm
Inner diameter
2.0 mm (0.081 in)

Technical specifications as provided for the delivery components.

SINGLE-USE COMPONENTS

Supplied sterile I For use in bronchoscopic procedures

Refer to the current IFU for final specifications, nomenclature and instructions for use.

Risk management

Safety belongs in the main clinical history.

Clinical Risks and Considerations

HEMOPTYSIS

Clinically significant bleeding can occur.

COPD EXACERBATION

May occur early post-procedure.

PNEUMONIA / LRTI

Prominent signal in randomized trials.

PNEUMOTHORAX

Recognized post-procedural risk.

COIL-ASSOCIATED OPACITY

Radiographic phenomenon that may mimic infection.

MR CONDITIONAL

1.5 T / 3 T

Field strength

≤ 2 W/kg

Whole Body SAR

Normal Mode

Operating mode

15 min

Maximum active scan

Refer to the current approved MRI labeling, implant card and IFU for complete MR Conditional conditions and safety information.

Clinical Evidence

Selected references supporting the clinical context presented in this catalog.

1. Sciurba FC, et al. RENEW. JAMA. 2016;315:2178-2189.
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3. Shah PL, et al. RESET. Lancet Respir Med. 2013.
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5. Slebos DJ, et al. Best Practice Recommendations. Respiration. 2018.
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7. SEPAR Clinical Protocol on Endoscopic Lung Volume Reduction for Severe Emphysema. Open Respir Arch. 2026.

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