Enbio
ADVANCED ENDOBRONCHIAL SOLUTIONS

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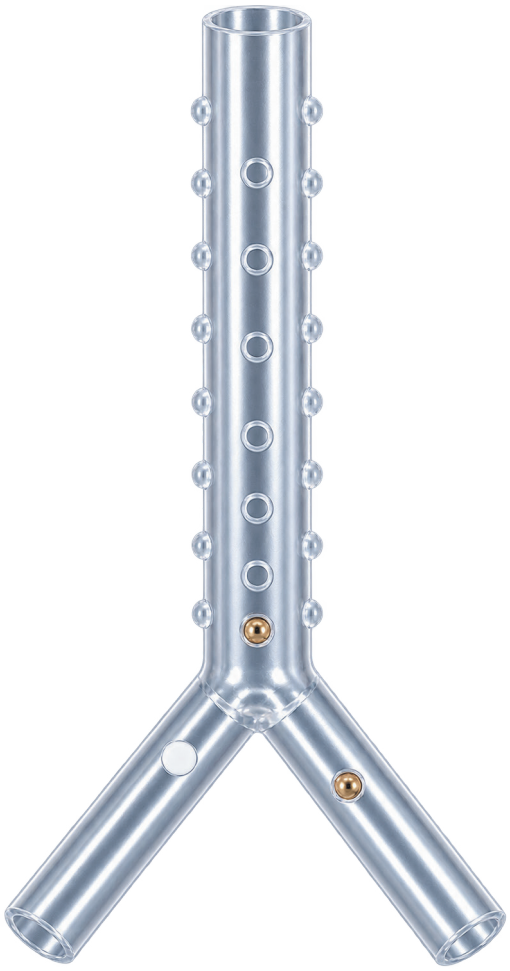
VOLUTAM™ Tracheobronchial Silicone Stent System



ANATOMY-DRIVEN AIRWAY SUPPORT

Clinical product overview for healthcare professionals

Central airway obstruction

Stent therapy is one component of multimodality therapeutic bronchoscopy - selected according to etiology, anatomy, symptoms and treatment goals.

TREATMENT STRATEGIES FOR AIRWAY OBSTRUCTION

INTRINSIC

Endoluminal disease may first require debulking or ablative therapy. A stent is not automatically required if durable airway patency is achieved.

EXTRINSIC

External compression may require mechanical airway support when there is no endoluminal tissue to remove.

MIXED

Combined endoluminal disease and external compression often require a multimodality strategy.

WHEN STENTING BECOMES RELEVANT

- Clinically justified benign or malignant tracheobronchial stenosis/obstruction where mechanical airway support is required.
- Airway support after recanalization when patency cannot otherwise be maintained.
- Tracheal, bronchial or tracheobronchial fistula when stenting is clinically justified.
- Selected central-airway collapse conditions and complex tracheal/carinal/bronchial anatomy requiring individualized geometry and sizing.
- • Final indication, patient selection and procedure must follow the current approved IFU.

CLINICAL PRINCIPLE

The 2024 CHEST guideline emphasizes multimodality therapeutic bronchoscopy and multidisciplinary decision-making. Evidence certainty for stent placement recommendations remains very low; selection therefore matters.

Source: CHEST Clinical Practice Guideline, 2024; WABIP MCAO 2024; WABIP BCAO 2025.

Why silicone airway stents?

A removable mechanical support platform with multiple geometries for central airway management.

ANATOMY & CONFIGURATION

Straight and bifurcated geometries allow the implant concept to be adapted to different central-airway locations.

VISIBLE DESIGN FEATURES

Transparent silicone construction with radiopaque markers and external anti-migration features on selected configurations.

REVISION CAPABILITY

Silicone stents are removable and can be revised or exchanged when clinically required.

CLAIM-DISCIPLINED COMMUNICATION

This catalog focuses on observable design features, anatomy, selection logic and clinical use context. Product-specific performance claims should be interpreted together with the current approved labeling and Instructions for Use.

CONTROLLED DEVICE FAMILY

Single-use, long-term implantable (>29 days) tracheobronchial silicone stents. The family includes sterile and non-sterile configurations; supply status and pre-use processing requirements are controlled by the label and current IFU.

Appropriate stent selection

Data-driven. Anatomy-focused. The final device choice must follow the approved IFU and specialist assessment.

CLINICAL ASSESSMENT

Define etiology (benign/malignant), symptoms, prior therapy, expected treatment course, surgical options and overall patient condition.

AIRWAY ASSESSMENT

Define location, length, healthy-airway diameter, fixed versus dynamic narrowing, distal airway viability and relationship to the carina/lobar branches.

SIZING LOGIC

1 LOCATION

- Trachea
- Carina
- Main bronchi
- Bronchial segments

2 GEOMETRY

- Straight
- Stenotic / hourglass
- Y / bifurcated
- T-stent
- Anatomy-specific

3 DIAMETER

Reference adjacent healthy airway; avoid undersizing or excessive wall pressure

4 LENGTH

Cover the target segment while minimizing unnecessary airway coverage

IMPORTANT

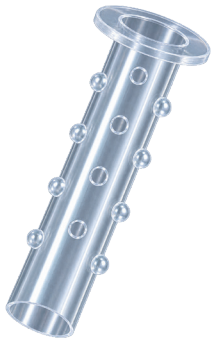
A stent that is too small may increase the risk of migration, whereas excessive diameter or length may increase airway-wall pressure or result in unnecessary mucosal coverage. Bronchoscopic and CT assessments should be integrated to optimize stent selection and positioning.

Controlled product configurations

A coordinated silicone stent portfolio for tracheal, carinal, bronchial and lobar anatomy.

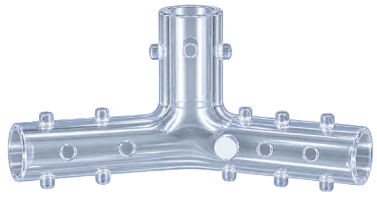
J STENT

Angled configuration for directional tracheobronchial support where airway anatomy requires a non-linear geometry. Select orientation and size from the target anatomy.



CARINA STENT

Flanged proximal geometry with a straight silicone body for selected carinal or proximal main-bronchus support.

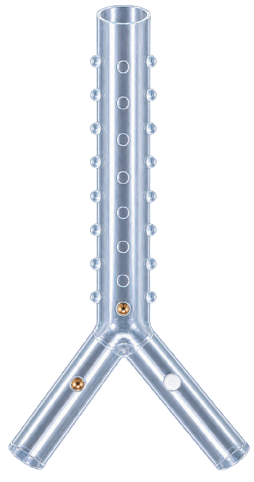


UPPER LOBE

Anatomy-specific configuration designed around right-upper-lobe bronchial branching while maintaining support of the adjacent bronchial segment.

STENOTIC STENT

Tapered / hourglass geometry with a narrowed central segment for focal stenotic anatomy. Diameter transition and length should be selected according to the target segment.

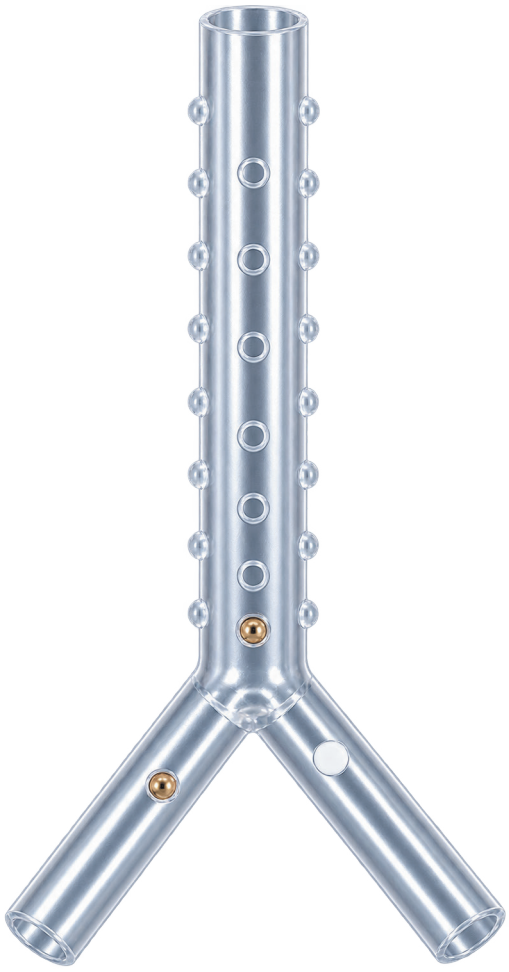


Y STENT

Distal trachea, carina and both main bronchi

Y stent

Designed around distal tracheal, carinal and main-bronchial anatomy.



ANATOMICAL ROLE

Bifurcated support spanning the distal trachea and proximal main bronchi.

DESIGN FEATURES

Transparent silicone body, bifurcated geometry, radiopaque markers and external anti-migration features.

PLACEMENT LOGIC

Orientation and branch geometry should be selected from bronchoscopic and imaging assessment.

CLINICAL USE

Device selection, sizing and placement technique must follow specialist assessment and the current IFU.

ANATOMY

Distal trachea, carina and proximal main bronchi.

GEOMETRY

Bifurcated support. Branch orientation and lengths are anatomy-dependent.

SIZING

Select tracheal and bronchial diameters and lengths from healthy reference airway measurements.

Ordering: For ordering information, please refer to the Instructions for Use (IFU) or the Ordering Information section of this catalog.”

Straight & stenotic configurations

Two complementary geometries for straight airway support and focal stenotic segments.

STRAIGHT / REGULAR

Cylindrical silicone configuration for tracheal or bronchial segments where a straight support geometry is appropriate.

GEOMETRY

Tapered / hourglass profile with a narrower central segment.

CLINICAL FIT

For focal stenotic anatomy where a diameter transition is required.

SELECTION

Choose diameter profile and length from bronchoscopic and imaging measurements.

TECHNICAL SELECTION PRINCIPLE

Use the smallest geometry that provides the intended mechanical support without unnecessary mucosal coverage or excessive wall pressure. Final device selection and placement technique must follow the current approved Instructions for Use.

Bronchoscopic Procedure Workflow

A disciplined workflow is more valuable than a “simple placement” marketing claim.

1

ASSESS

Bronchoscopy + CT; define lesion mechanism, location, distal patency and treatment goal.

2

SIZE

Select geometry, diameter and length based on healthy reference airway and target segment.

3

PREPARE

Confirm model, size, accessories, orientation and supply configuration. For sterile products verify sterile-barrier integrity. For non-sterile products confirm completion of the validated pre-use steam sterilization instruction: 121 °C for 15 minutes in accordance with ISO 17665 and the current IFU.

4

DEPLOY

Placement technique and bronchoscope/introducer compatibility must follow the current IFU.

5

VERIFY

Confirm position, airway patency, branch ventilation and immediate complications.

HCP USE ONLY

This catalog is a clinical product overview, not a substitute for the IFU, institutional protocol, specialist training or patient-specific clinical judgment.

Clinical Risks and Follow-up

Airway stents are foreign-body implants. Benefit depends on appropriate indication, sizing, placement and structured follow-up.

MIGRATION

Recognized complication; risk varies with anatomy, indication, stent type and sizing.

MUCUS PLUGGING / MUCOSTASIS

Secretions can accumulate and obstruct the stent or distal airway.

GRANULATION TISSUE

Tissue reaction can develop, particularly near stent edges.

INFECTION

Lower respiratory tract infection is a recognized post-stent complication.

TUMOR OVERGROWTH

In malignant disease, progression can occur at stent margins.

BLEEDING / AIRWAY INJURY

Procedure- and device-related airway injury must be considered.

FOLLOW-UP

CHEST 2024 suggests either routine surveillance bronchoscopy or bronchoscopy when patients become symptomatic after stent placement. The 2025 WABIP benign-CAO guideline also addresses surveillance and post-stent management; local practice should follow current guidance and the device IFU.

THERMAL / ABLATIVE PROCEDURES

Silicone is flammable. Laser, electrocautery and argon plasma coagulation near the stent require specific fire/device-damage risk controls and may require stent removal. Follow the current IFU.

General Airway-stenting Clinical Evidence

The catalog separates general airway-stenting evidence from ENBIO device-specific claims.

CHEST 2024

Mahmood K, et al. Management of Central Airway Obstruction: An American College of Chest Physicians Clinical Practice Guideline. Chest. 2025;167(1):283-295. Published online July 17, 2024. DOI: 10.1016/j.chest.2024.06.3804.

WABIP - Malignant CAO 2024

Chaddha U, et al. WABIP guidelines on airway stenting for malignant central airway obstruction. Respirology. 2024;29(7):563-573. DOI: 10.1111/resp.14764.

WABIP - Benign CAO 2025

Chaddha U, et al. WABIP Guidelines on Airway Stenting for Benign Central Airway Obstruction. Respirology. 2025;30(7):587-604. DOI: 10.1111/resp.70068.

Review

Sabath BF, Casal RF. Airway stenting for central airway obstruction: a review. Mediastinum. 2023;7:18. Contemporary review of indications, stent types and complications.

The references above provide the general clinical context for airway stenting. They should not be interpreted as evidence of product-specific clinical outcomes for VOLUTAM? Silicone Airway Stents.

Y-Stent families

Models and dimensions reproduced from the supplied F-131 Product Description - STENT.

FAMILY	MODEL	DIAMETER	LENGTH
Classic Tracheal Y	Classic 15 Y-Stent	15×12×12 mm	110×50×50 mm
Classic Tracheal Y	Classic 16 Y-Stent	16×13×13 mm	110×50×50 mm
Classic Tracheal Y	Classic 17 Y-Stent	17×13.5×13.5 mm	110×50×50 mm
Classic Tracheal Y	Classic 18 Y-Stent	18×14×14 mm	110×50×50 mm
Classic Tracheal Y	Classic 14 Y-Stent	14×10×10 mm	110×50×50 mm
Bronchial Y	Classic 13 Y-Stent	13×9×10 mm	40×17×35 mm
LD-Bronchial Y	Classic 12 Y-Stent	12×9×10 mm	40×17×35 mm
EC-Anatomic Y	EC-Anatomik14Y-Stent	14×10×10 mm	110×50×50 mm
EC-Anatomic Y	EC-Anatomik15Y-Stent	15×12×12 mm	110×50×50 mm
EC-Anatomic Y	EC-Anatomik16Y-Stent	16×13×13 mm	110×50×50 mm
EC-Anatomic Y	EC-Anatomik17Y-Stent	17×13×13 mm	110×50×50 mm

All stents are long-term implantable (>29 days), single-use tracheobronchial silicone stents. Sterile/non-sterile supply status is controlled by the specific label and IFU.

Stenotic / hourglass stent family

Approved model names and dimensions according to F-131.

FAMILY	MODEL	DIAMETER	LENGTH
Classic	Classic-15 StenoStop	15×13×15 mm	15×20×15 mm
Classic	Classic-16 StenoStop	16×14×16 mm	15×20×15 mm
Classic	Classic-17 StenoStop	17×15×17 mm	15×20×15 mm
Classic	Classic-18 StenoStop	18×16×18 mm	15×20×15 mm
Classic	Classic-14 StenoStop	14×12×14 mm	15×20×15 mm
Classic	Classic-12 StenoStop	12×10×12 mm	10×20×10 mm
StenoStop	StenoStop 06-Stent	6×4×6 mm	6×10×6 mm
StenoStop	StenoStop 08-Stent	8×6×8 mm	8×15×8 mm
StenoStop	StenoStop 10-Stent	10×8×10 mm	8×15 mm
StenoStop	StenoStop 15-Stent	15×13×15 mm	10×20×25 mm
StenoStop	StenoStop 16-Stent	16×14×16 mm	10×20×25 mm
StenoStop	StenoStop 18-Stent	18×16×18 mm	10×20×25 mm

Sterile and non-sterile configurations

Final ordering must be based on the current controlled F-131 product list, label/UDI information and approved IFU.

STERILE CONFIGURATIONS

Supplied terminally sterilized in an approved sterile barrier system. Do not use if the sterile barrier is opened or damaged. The product is single-use and shall not be reused, reprocessed or resterilized after clinical use. Sterile stents are sterilized using the gamma sterilization method.

NON-STERILE CONFIGURATIONS

Supplied non-sterile. Before clinical use, the user shall follow the validated manufacturer instruction for steam sterilization: 121 °C for 15 minutes in accordance with ISO 17665 and the current IFU. After clinical use, the device remains single-use and shall not be reprocessed or resterilized.

ORDERING / PRODUCT-LIST RULE

Only models present in the current controlled F-131 Product Description and corresponding approved label/UDI/order records may be offered commercially. The previous catalogue draft contained J-Stent, Carina-Stent, Right/Left Upper-Lobe families and VHY/VHJ/VHK/VHUL/VHSTR/VHS codes that were not present in the supplied F-131 product list; these have been removed from this aligned version.

Where a model name or dimension is changed, the catalogue shall be revised only after the controlled technical documentation and ordering information have been updated.

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For healthcare professionals. Product availability, approved indications and labeling vary by market.
Refer to the current Instructions for Use.

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