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Classic Silicone Stents

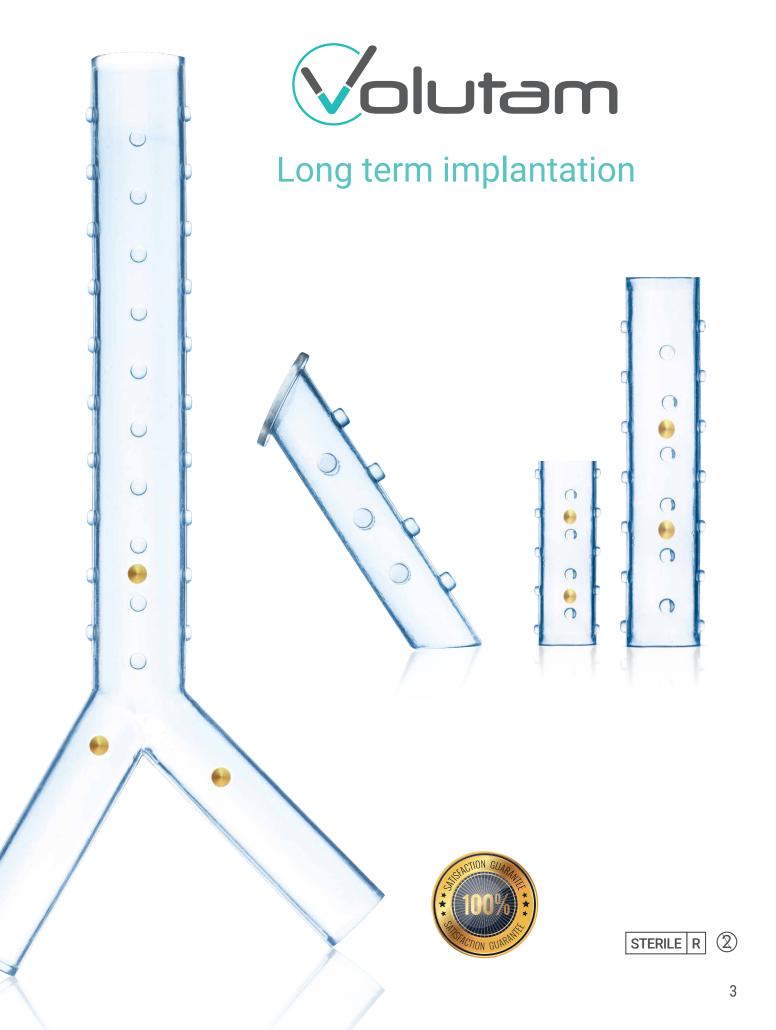














Classic Silicone Stents

Description

The VOLUTAM® Stens are Long-Term implantable products; more than 29 days. Made of Long-Term (unrestricted) implant grade silicone. The VOLUTAM® Stents can be easyly removed after Long-Term implantation. VOLUTAM® Stents produced with ultra high pressures have an improved non-stick surface that does not allow tissue epithelialization. The tracheo-bronchial stent has only 1 mm of wall thickness to provide better mucociliary clearance. 1 mm stent wall thickness facilitates the internal movements of the trachea. Inner surfaces are covered with a special hydrophilic coating to minimize biofilm formation and maximize secretion flow. The VOLUTAM® Tracheo-Bronchial Stents is the classic and anatomic stents for tracheal and bronchial use. It has foots or anatomic straps on its outer wall to prevent stent migration. Distal and Proximal tips are specially designed to minimize granulation tissue formation and facilitate fluid flow. Golden Radio-Opaque markers placed in the stent body, which will be displayed in any case Easy insertion with a hard bronchoscope or disposable bronchoscope introducer set. VOLUTAM® Stents have various length and diameter options, responds to the needs on treatment for special clinical situations. The User Manual supplied with each product provides detailed information on the placement technique and post-operative care of the products. Custom lengths and diameters are available on request.

Features

- · Long-Term more than 29 days (Unrestricted) implant grade silicone,
- · Can be easily removed after Long-term implantation
- · Transparency with Gold Marker and radio-opacity,
- · Non-adherent smooth surface.
- · Interior surfaces are covered with a special hydrophilic coating.
- · Anti-migration food system,
- · Atraumatic ends,



Volutam Y Stent Applied by: Prof. Dr. Hasan F. BATIREL Marmara University Hospital Thoracic Surgery Department



Volutam Y Stent Applied by:
Prof. Dr. Erdoğan ÇETİNKAYA
Yedikule Chest Diseases and Thoracic Surgery
Training and Research Hospital
Interventional Pulmonology Clinic



Indications

- VOLUTAM® Stent is especially suitable for the extrinsic and/or intinsic compresed tracheo-bronchial stenosis and treatment of tracheal-esophgeal fistul.
- Used to maintain the airway opened after argon plasma or laser resection, cryotherapy or electrocautery
- Post-Op Lung transplantation (anastomosis) bronchial stenosis,
- · Post-Op surgical resection (anastomosis) stenosis,
- Stenosis combined with minimal malacia or compression,
- · Post-traumatic stenosis.
- Primary or secondary tracheal neoplasm.
- Tracheo-Bronchial stenosis, tumours.
- Complex and long tracheal stenosis.
- Trachea-Broncho-Malacia: occur following tracheostomy or radiation therapy.
- Common trachea-broncho-malacia: idiopathic, polychondritis or Mounier-Kuhn syndrome.
- Tracheo-esophageal fistula.
- · Tracheal rupture.

- Stenosis after total laryngectomy.
- Carina and/or bronchial invasion caused by esophageal carcinoma.
- Extrinsic compression or compromise of the submucosa.
- Esophageal carcinoma with tracheal invasion.
- After infectious stenosis (endobronchial tuberculosis, histoplasmosis mediastinal fibrosis, herpes virus, diphtheria).
- · After endoscopic resection of bronchial metastasis.
- · After endoscopic resection of bronchial metastasis.
- Airway patency has been achieved after laser resection, cryotherapy or electrocautery resection.
- VOLUTAM® provides detailed instructions for each device, including insertion and removal techniques, precautions and postoperative maintenance. Please refer to the user manual.



VOLUTAM ANATOMIC Y STENT **ERDO Design by: Prof. Dr. Erdoğan ÇETİNKAYA**

University of Health Sciences (Dean) (Sağlık Bilimleri Üniversitesi (Dekan))



VOLUTAM TOTAL LARYNGECTOMY

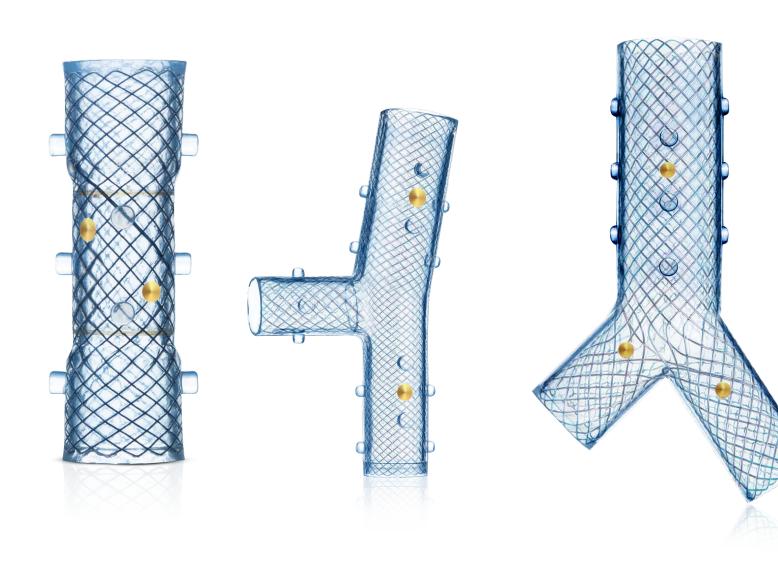
Y-STENT ADAPTED FOR TRACHEOSTOMIZED PATIENTS

Design by: Prof. Dr. Hasan F. BATIREL

Marmara University Thoracic Surgery Department



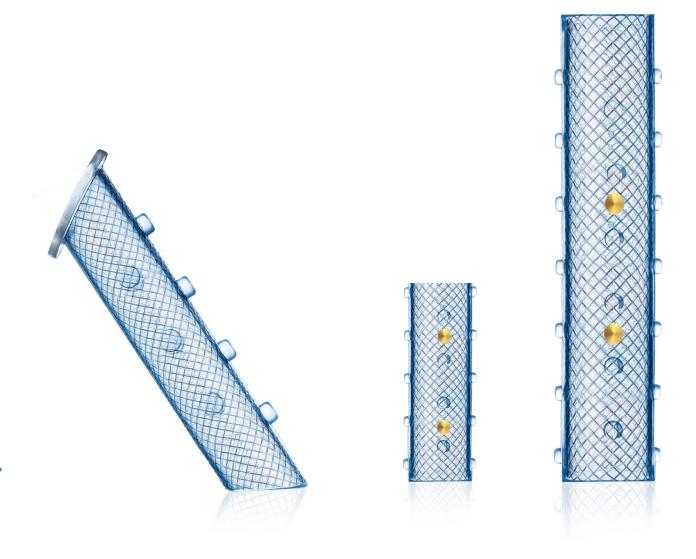
Custom Made Silicone Stents







Long term implantation







Custom Made Silicone Stents

Description

VOLUTAM® Stents produced with ultra high pressures have an improved non-stick surface that does not allow tissue epithelialization. VOLUTAM® Stent is especially used for the extrinsic and/or intinsic compresed tracheal stenosis and treatment of tracheal-esophgeal fistul. The tracheo-bronchial stent has only 1 mm of wall thickness to provide better mucociliary clearance. 1 mm stent wall thickness facilitates the internal movements of the trachea. The VOLUTAM® Stens are Long-Term implantable products; more than 29 days. Made of Long-Term (unrestricted) implant grade silicone. The VOLUTAM® Stents can be easyly removed after Long-Term implantation. VOLUTAM® Stents produced with ultra high pressures have an improved non-stick surface that does not allow tissue epithelialization. Easy insertion with a hard bronchoscope or disposable bronchoscope introducer set. Distal and Proximal tips are specially designed to minimize granulation tissue formation and facilitate fluid flow. Golden Radio-Opaque markers placed in the stent body, which will be displayed in any case VOLUTAM® Stents have various length and diameter options, responds to the needs on treatment for special clinical situations.



AFTER





Volutam Stenotic Stent Applied by: Prof. Dr. Cemal Asım KUTLU Medical Park Göztepe Hospital Thoracic Surgery Department

Volutam Regular Stent Applied by: Prof. Dr. Cengiz GEBİTEKİN Bursa Uludağ University Thoracic Surgery Department





Custom Made Silicone Stents

Features

- Long-Term more than 29 days (Unrestricted) implant grade silicone,
- Can be easily removed after Long-term implantation
- · Transparency with Gold Marker and radio-opacity,
- · Non-adherent smooth surface.
- Interior surfaces are covered with a special hydrophilic coating.
- · Anti-migration food system,
- · Atraumatic ends,

Indications

- · Tracheo-Bronchial stenosis.
- Surgical resection (anastomosis) stenosis after surgery,
- Bronchial stenosis developing after lung transplant surgery (anastomosis),
- · Stenosis combined with malacia or compression,
- · Extrinsic and/or intrinsic tracheal stenosis,
- Tracheal-esophgeal fistul.
- Used to maintain the airway opened after laser resection, cryotherapy or electrocautery











Thoracic Surgery Department

AFTER





Y Stent

Description

VOLUTAM Tracheal Y Stent is designed to support the trachea, carina, and mainstem bronchi to treatment of airway complications such as anastomosis stenosis, fistul and stenosis. The stent may also be used to minimize chronic bronchial strictures due to tuberculosis and malignancies. Treatment for Post-Op tracheal resection anastomosis fistul and Post-Op lung transplant anastomosis fistule and tracheo-esophageal fistuls. VOLUTAM® Stents produced with ultra high pressures have an improved non-stick surface that does not allow tissue epithelialization. Produced flexible, biocompatible, long-term implant-grade silicone, the VOLUTAM Tracheal Y Stent with foots and 1mm wall thickness allow humidification and phonation. Implantable with 14 mm rigid or disposable broncoscope and 12mm introducer set. The specially designed VOLUTM Y- bifurcated tracheobronchial stent fits snugly into the distal trachea, the carina, and the proximal bronchi. The VOLUTAM® provides detailed instructions for each device, including insertion and removal techniques, precautions and postoperative maintenance. Custom lengths and diameters are available on request.

Features

- VOLUTAM® Tracheo-Bronchial Y-Stent; is especially suitable for trachea, carina and on main bronchial the extrinsic and/or intrinsic tracheo-bronchial stenosis and treatment of tracheal-esophgeal fistul.
- Post-Op surgical resection (anastomosis) stenosis.
- Including Benign; Simple, Complex or Long tracheal stenosis.
- Long tracheobronchial neoplasm in the carina and/or its main bronchi.

- Esophageal carcinoma with an airway invasion.
- Tracheoesophageal or tracheocutaneous fistula.
- After laser resection, cryotherapy or electrocautery, to keep the airway opened.
- · Tracheal stenosis.
- · Tracheobronchial stenosis.
- Stenosis accompanying tracheobronchomalacia and / or tracheobronchomalacia.
- Excessive dynamic compression of the airway.





Stenotic Stent Applied by: Assoc. Prof. Dr. Levent ALPAY Süreyyapaşa Chest Diseases and Thoracic Surgery Training and Research Hospital



Volutam Y Stent Applied by: Assoc. Prof. Dr. Tunç LAÇİN Marmara University Thoracic Surgery Department

VOLUTAM CLASSIC TRACHEAL Y - STENT					
Ref. No.	Tracheal O.D.	Bronchial O.D.	Tracheal Length	Bronchial Length	Wall Thickness
Classic 15 Y-Stent	15	12 x 12	100	50 x 50	1 mm
Classic 16 Y-Stent	16	13 x 13	110	50 x 50	1 mm
Classic 17 Y-Stent	17	13,5 x 13,5	110	50 x 50	1 mm
Classic 18 Y-Stent	18	14 x 14	110	50 x 50	1 mm



Y Stent

Features

- · Long-Term more than 29 days (Unrestricted) implant grade silicone,
- · Can be easily removed after Long-term implantation
- VOLUTAM Tracheal Y stents have 3 rows of foots.
- No foots on the posterior side of tracheo-esophageal wall in order to avoid trauma
- Membranous surface's softer structure applies reduced pressure to the posterior tracheal mucosa.
- · Transparency and radio-opacity
- · Non-adherent smooth surface
- Y-angle anatomically designed to fit carina.
- The branches are angled according to anatomy.
- · Enables normal breathing and speech.
- · Permits healing and prevents desiccation.
- Custom lengths and diameters are available on request.
- Easy placement with introducer set for Rigid Bronchoscope and stent application.
- · Transparency with Gold Marker and radio-opacity,

BEFORE

- · Non-adherent smooth surface,.
- · Anti-migration food system,
- · Atraumatic ends,







Volutam Y Stent Applied by: Assoc. Prof. Dr. Tunç LAÇİN Marmara University Thoracic Surgery Department



Stenotic

Description

VOLUTAM® Stenotic Stent is especially suitable for the benign stenosis treatment The VOLUTAM® Stens are Long-Term implantable products; more than 29 days. Made of Long-Term (unrestricted) implant grade silicone. The VOLUTAM® Stents can be easyly removed after Long-Term implantation. VOLUTAM® Stents produced with ultra high pressures have an improved non-stick surface that does not allow tissue epithelialization. Easy insertion with a hard bronchoscope or disposable bronchoscope introducer set. Golden Radio-Opaque markers placed in the stent body, which will be displayed in any case VOLUTAM® Stents have various length and diameter options,responds to the needs on treatment for special clinical situations. Distal and Proximal tips are specially designed to minimize granulation tissue formation and facilitate fluid flow. The central part is narrower and maintains a sufficient lumen for air flow, while reducing the risk of trauma to the stenotic part of the trachea, thereby reducing the risk of restenosis. The VOLUTAM® stent is designed to avoid the risk of migration due to compression reduction. Where appropriate, this stent can prevent a tracheostomy. VOLUTAM® Stents have various length and diameter options,responds to the needs on treatment for special clinical situations.

Features

- Long-Term more than 29 days (Unrestricted) implant grade silicone,
- · Can be easily removed after Long-term implantation
- · Transparency with Gold Marker and radio-opacity,
- · Non-adherent smooth surface..
- · Anti-migration food system,
- · Atraumatic ends.

Indication

- Including benign; Simple, Complex or Long tracheal stenosis.
- Post-Op surgical resection (anastomosis) stenosis.
- · Stenosis combined with malacia or compression,
- Stenosis after intubation,
- · Stenosis after tracheostomy,
- · Subglottic stenosis,
- After laser resection, cryotherapy or electrocautery, to keep the airway opened.

VOLUTAM CLASSIC STENESTOP STENT				
Ref. No.	O.D.	Length	Wall Thickness	
Classic 15 Stenostop	15x13x15	15x20x15	1,5 mm	
Classic 16 Stenostop	16x14x16	15x20x15	1,5 mm	
Classic 17 Stenostop	17x15x17	15x20x15	1,5 mm	
Classic 18 Stenostop	18x16x18	15x20x15	1,5 mm	



VOLUTAM CLASSIC STENESTOP STENT				
Ref. No.	O.D.	Length	Wall Thickness	
Classic 15 Stenostop	15x13x15	7,5x20x7,5	1,5 mm	
Classic 16 Stenostop	16x14x16	7,5x20x7,5	1,5 mm	
Classic 17 Stenostop	17x15x17	7,5x20x7,5	1,5 mm	
Classic 18 Stenostop	18x16x18	7,5x20x7,5	1,5 mm	



Regular

Description

VOLUTAM® Stent is especially suitable for the extrinsic and/or intinsic compresed tracheal stenosis and treatment of tracheal-esophgeal fistul. Tracheo-Bronchial stent have a only 1 mm wall thickness for allows better mucociliary clearance. 1 mm stent wall thickness facilitate the internal movements of the trachea. For more than 29 days; Long-Term implantable. Made of Long-Term (unrestricted) implant grade silicone. VOLUTAM® Stenotic Stent is easy removal. Produced with ultra high pressures VOLUTAM® Stents has an improved non-stick surface that does not allow tissue epithelialization. Easy placement with Rigid Bronchoscope or disposable introducer set. Distal and Proximal tips are specially designed to minimize granulation tissue formation and facilitate fluid flow.

Gold Radio-Opaque markers placed insided the Stent body, so that every on positions is surely one displayed.

VOLUTAM® have various length and diameter options, responds to the needs on treatment for special clinical situations.

Features

- Long-Term more than 29 days (Unrestricted) implant grade silicone.
- Transparency and with Gold Marker; radio-opacity,
- · Non-adherent smooth surface.
- Interior surfaces are covered with a special hydrophilic coating.
- · Anti-migration stud system,
- · Atraumatic ends,
- After long-term implantation easy Removability.

Indication

- · Tracheo-Bronchial stenosis,
- Post-Op surgical resection (anastomosis) stenosis,
- Post-Op Lung transplantation (anastomosis) bronchial stenosis,
- Stenosis combined with malacia or compression,
- Extrinsic and/or intrinsic tracheal stenosis,
- Tracheal-esophgeal fistul.
- After laser resection, cryotherapy or electrocautery, to maintain the airway opened.





VOLUTAM REGULAR STENT 1 mm				
Ref. No.	0.D.	Length	Wall Thickness	
Regular Stent 10	10	80	1 mm	
Regular Stent 11	11	80	1 mm	
Regular Stent 12	12	80	1 mm	
Regular Stent 13	13	100	1 mm	
Regular Stent 14	14	100	1 mm	
Regular Stent 15	15	110	1 mm	
Regular Stent 16	16	110	1 mm	
Regular Stent 18	18	110	1 mm	
Regular Stent 16	16	110	1,5 mm	
Regular Stent 18	18	110	1,5 mm	



Anatomic Main Bronchi Upper Lobe Stent

Description;

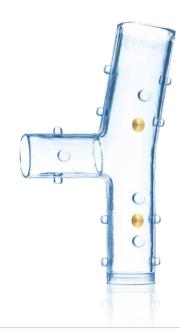
VOLUTAM Main Bronchus Upper Lobe Y-Stent is designed to support the main bronchi and upper lobes in the treatment of airway complications stenosis.VOLUTAM® Stents produced with ultra high pressures have an improved non-stick surface that does not allow tissue epithelialization. Produced flexible, biocompatible, long-term implant-grade silicone. The VOLUTAM Main Bronchi Upper Lob Y-Stent have foots and 1mm wall thickness. It can be implanted with a hard or disposable bronchoscope and introducer set. VOLUTAM® provides detailed instructions for each device, including insertion and removal techniques, precautions and postoperative maintenance. Custom lengths and diameters are available on request. Custom lengths and diameters are available on request.

Features

- Long-Term more than 29 days (Unrestricted) implant grade silicone,
- Can be easily removed after Long-term implantation
- VOLUTAM Main Bronchi upper lob Y-stent have 3 rows of foots.
- The posterior side has no foots in order to avoid trauma of the tracheo-esophageal wall.
- Membranous surface's softer structure, applies reduced pressure to the posterior tracheal mucosa.
- Transparency and with gold marker radio-opacity
- · Non-adherent smooth surface
- Y-angle anatomically designed to fit upper lob.
- The branches are angled according to anatomy.
- · Permits healing and prevents desiccation.
- Custom lengths and diameters are available on request.
- Easy placement with introducer set for Rigid Bronchoscope and stent application.

Indication

- VOLUTAM® Main Bronchus Upper Lobe Y-Stent; especially suitable for extrinsic and / or intrinsic stenosis treatment for the main bronchus and upper lobe
- Esophageal carcinoma with an airway invasion.
- · Bronchoesophageal or bronchocutaneous fistula.
- After laser resection, cryotherapy or electrocautery, to keep the airway opened.



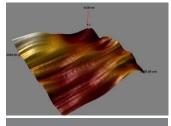
ANATOMIC MAIN BRONCHI UPPER LOBE STENT				
Ref. No.	O.D.	Length	Wall Thickness	
LD-Anatomik 12 Y-Stent	12 x 9 x 10	40 x 15 x 30	1 mm	
LD-Anatomik 13 Y-Stent	13 x 9 x 10	40 x 17 x 35	1 mm	
LD-Anatomik 13 Y-Stent	13 x 11 x 10	20 x 15 x 30	1 mm	



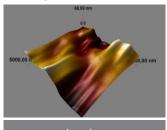
Surface Analysis

Atomic Force Microscope (AFM) Analysis (Tapping Mode)

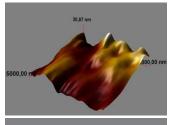
Generally accepted standard sample inner surface



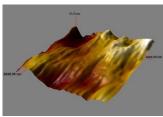




RMS(nm) 12.69



RMS(nm) 5.56



RMS(nm) 6.42

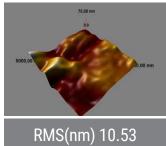
Average values: 8.73

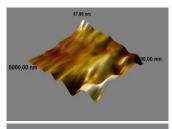
STD: 3.33

Analyzes on the generally accepted sample show different roughness in different regions and accordingly, the standard deviation is high.

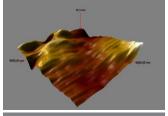
Atomic Force Microscope (AFM) Analysis (Tapping Mode)

Enbio standard sample inner surface

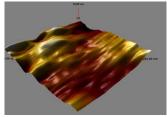




RMS(nm) 11.51



RMS(nm) 11.27



RMS(nm) 11.89

Average values: 11.3

STD: 0.6

The analysis on Enbio standard sample shows very close roughness in different regions and accordingly, the standard deviation is lower and homogeneity is much better than the generally accepted sample.

Contact Angle Measurement Analysis (Sessile drops & inner surface with serum)

Enbio standard sample

	. с. с ср.с	
Sample Measurement No	Contact Angle Value	
1	86.015	1
2	87.32	/
3	95.195	7
4	110.85	/
5	117.04	

Generally accepted standard sample

Sample Measurement No	Contact Angle Value	
1	101.99	1
2	72.43	/
3	91.69	1
4	92.365	/
5	110.855	7



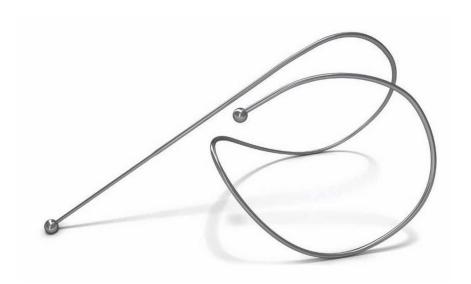


	Average Values	STD
Enbio standard sample	101.99	101.99
Generally accepted standard sample	72.43	72.43

Contact angle measurements are similar between the two samples, and the Enbio product tends to be more hydrophobic.



ENDOBRONCHIAL HELIX (COIL)



Technical Specifications



100 mm Helix (Coil)



125 mm Helix (Coil)



150 mm Helix (Coil)

Application System

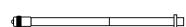




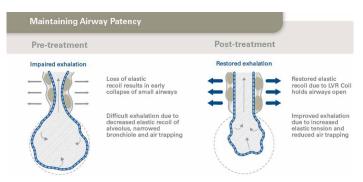
1 Cartridge



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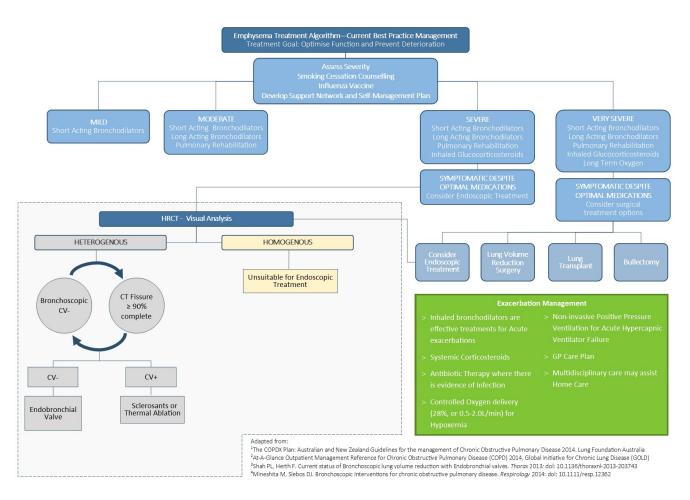


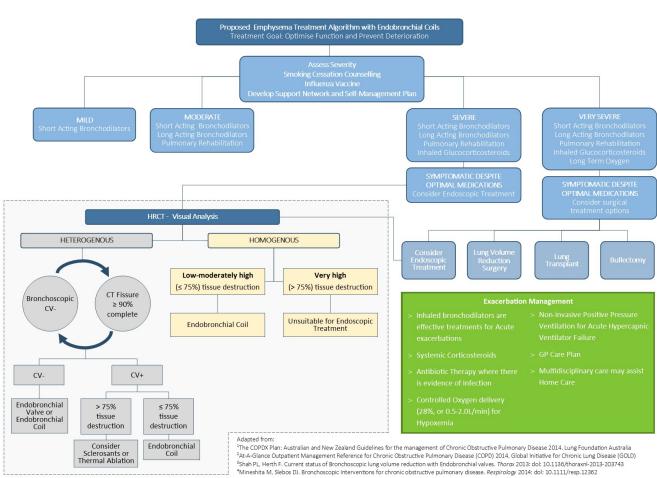




The coil is designed to maintain airway patency, preserving distal access while reducing airway collapse during exhalation and exercise.

Compressing diseased tissue and adjusting lung compliance Pre-treatment Post-treatment diseased parenchyma Untreated lung Treated upper lobe







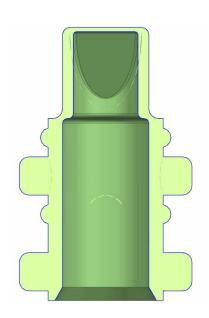
PleuraTalc



PT2: Content 2 g sterile Talc (in a 50 cc vial)
PT3: Content 3 g sterile Talc (in a 50 cc vial)
PT4: Content 4 g sterile Talc (in a 50 cc vial)

- · It is used for pleural effusion (pleurisy) treatment
- · It can be used for all pleuridic indications
- Asbestos free
- · Endotoxin free
- · Particle size has been standardized
- The average particle size is 25 μm
- Sterile
- * In the certification process.





VOLUTAM Endobronchial One Way Valve





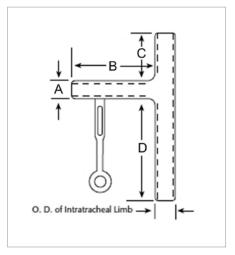
Disposable Ebus Balloon



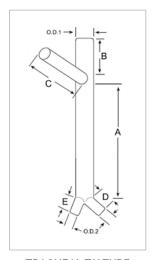
Disposable Bronchoscop and Stent Implantation Introducer Set



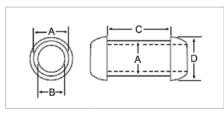
Custom Made Stents



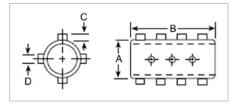




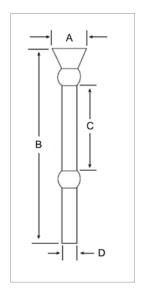
TRACHEAL T-Y TUBE



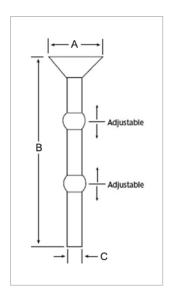
BRONCHIAL STENT DOUBLE FLANGED



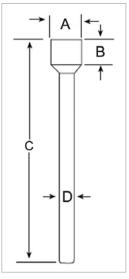
BRONCHIAL STENT



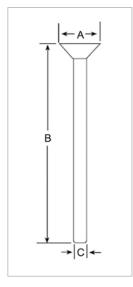
ESOPHAGEAL RECONSTRUCTION TUBE



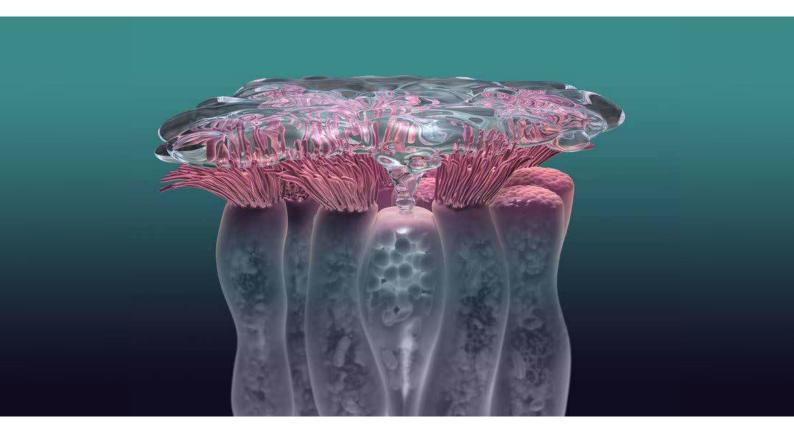
ADJUSTABLE RECONSTRUCTION TUBE



ESOPHAGEAL STENT



SALIVARY BYPASS TUBES





ENBIO ENDO BIOMEDIKAL SILIKON IMPLANT SAN. TIC. LTD. ŞTİ

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