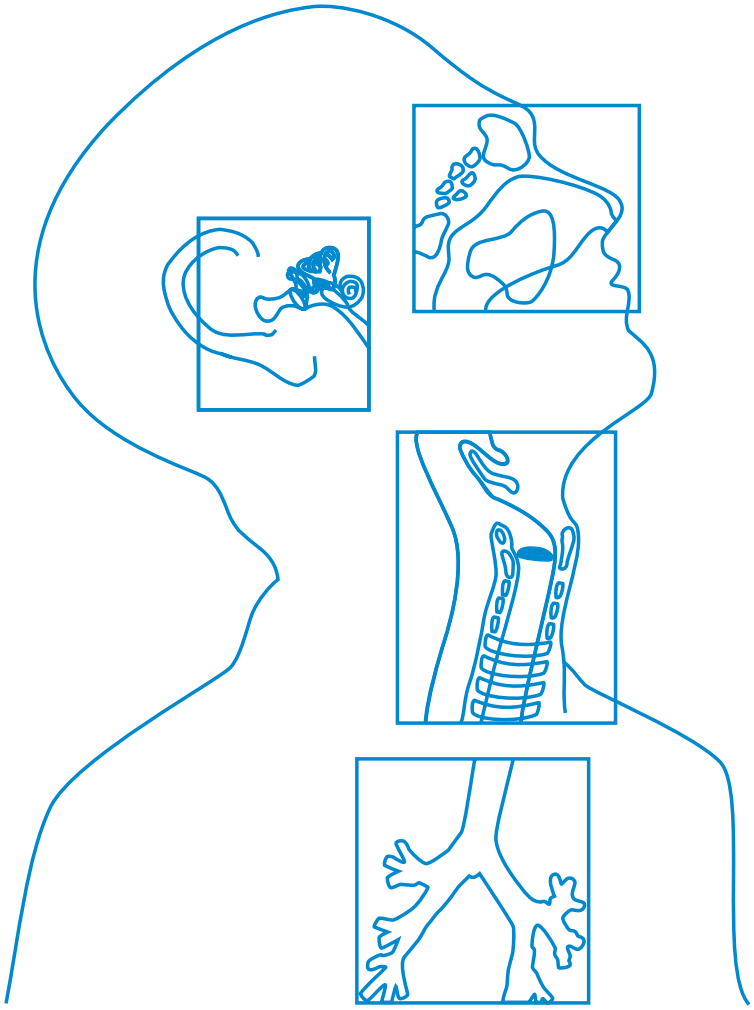
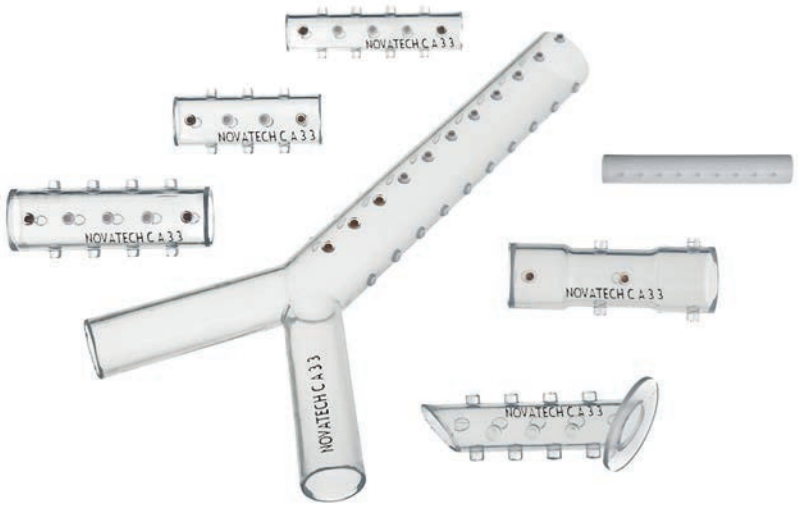


TRACHEOBRONCHIAL SILICONE STENTS
NOVATECH® GSS™ and DUMON®



Novatech
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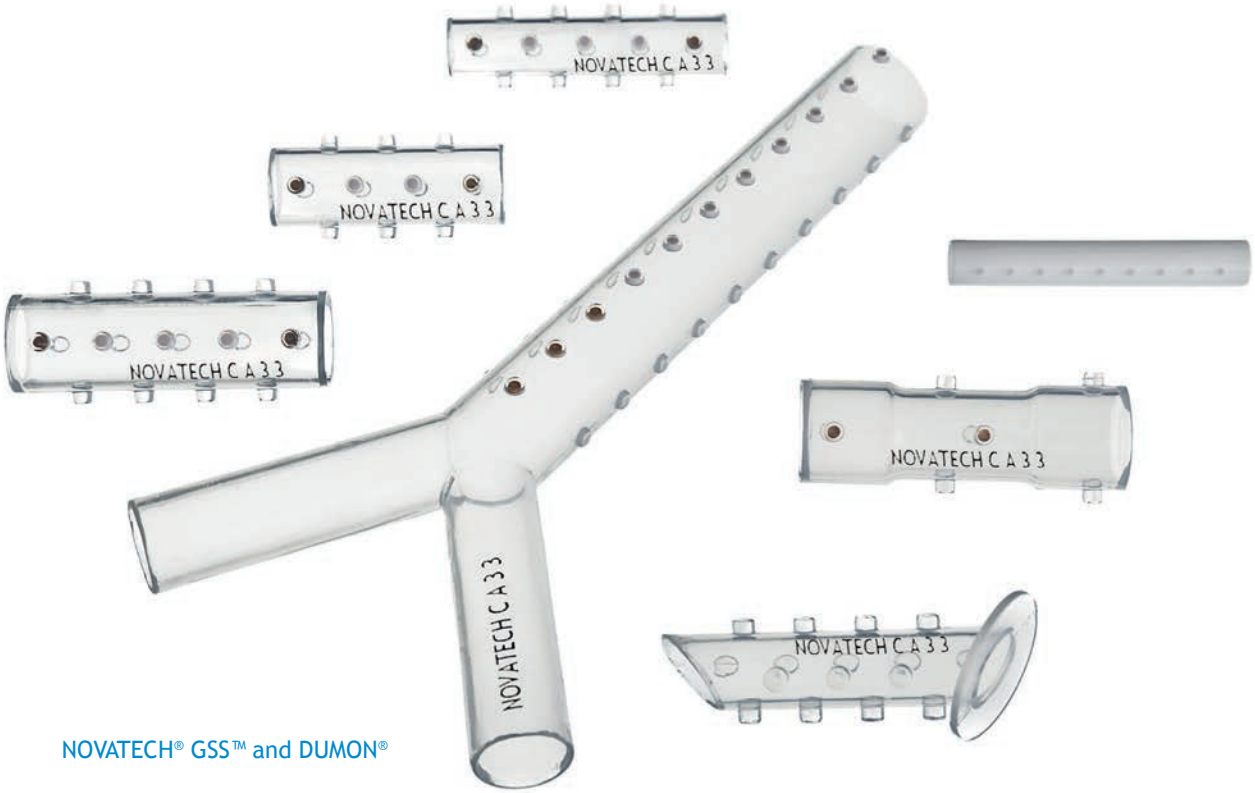
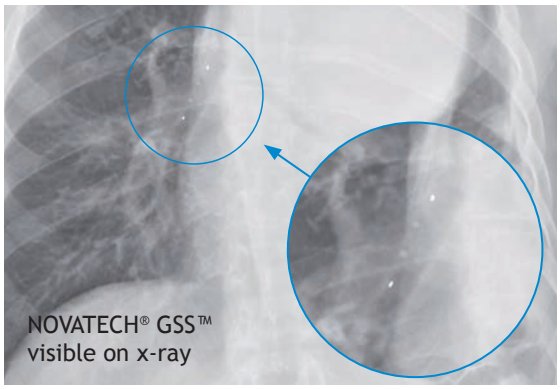
TRACHEOBRONCHIAL SILICONE STENTS NOVATECH® GSS™ and DUMON®



NOVATECH® GSS™ and DUMON®

NOVATECH® GSS™ Gold Studded Stents - a decisive innovation related to the famous DUMON® stents - are made of transparent implant grade silicone with studs filled with gold and barium sulfate, combining good x-ray visibility with optimized endoscopic tissue monitoring, i.e. **X-ray visibility plus tissue monitoring.**

Since 1989, Novatech has been manufacturing the patented **DUMON®** silicone stent – a stent system that has been tried-and-tested to improve patient comfort. TRACHEOBRONXANE™ DUMON® stents are made of specially treated medical grade transparent or radiopaque silicone (implantable for more than 29 days). They are considered the “golden standard to which all others should be compared”[1].



NOVATECH® GSS™
visible on x-ray

[1] *Prof. Bolliger, Pulmonary Reviews, Oct. 1997*

TRACHEOBRONCHIAL SILICONE STENTS NOVATECH® GSS™ and DUMON®

Depending on design, there are 2, 3 or 4 lines of studs on the stent outside. This stud system has proven its reliability for improved stent fixation between the cartilaginous rings of the trachea and the bronchial tree.

The stent inside is treated with a silicone-based layer which makes the surface anti-adherent, minimizing the risk of obstructions and improving mucociliary clearance.

For the various indications and their sites, a large variety of stent types is available as well as a large choice of lengths and diameters.

NOVATECH and the LOT are imprinted on each GSS™. This way, the stent can easily be traced back to its origin if necessary.

The GSS™ comes sterile in blister packaging with Instructions for Use, patient card and adhesive stickers for documentation.

INDICATIONS

Maintaining airway patency after desobstruction or dilatation of a stenosis, in particular in the following cases:

- **tracheobronchial tumors**
- **tracheal stenoses with scarring**
- **bronchial stenoses following surgical resection and anastomosis**
- **bronchial stenoses following pulmonary transplantation**
- **In general, in any case of reduction of airway diameter due to intrinsic or extrinsic compression**

TRACHEOBRONCHIAL SILICONE STENTS NOVATECH® GSS™ and DUMON®

FEATURES

• Transparency and radio-opacity (GSS™)
Studs filled with gold and barium sulfate, combining good x-ray visibility with optimized endoscopic tissue monitoring.

• Large collection for perfect adaption
The key condition for perfect tolerance of the stents is to use a stent which is perfectly adapted to the patient's needs. For this reason and in order to be prepared for any situation, it is essential to provide the physician with a basic line of different stent types, diameters and lengths.
The stents must not be cut in order to avoid the risk of granulation and to ensure mucociliary clearance (please refer to the Instructions for Use).

• Anti-migration stud system
The stud design minimizes the risk of migration of the stent by fixing it between the cartilaginous rings of the tracheo-bronchial tree. The stent design inhibits cough reflexes. The studs reduce direct contact between the stent surface and the mucosa and distribute compressive forces evenly among the small stud surfaces.

• Non-adherent smooth surface
The non-adherent stent surface is excellently tolerated by the mucosa. It allows mucociliary clearance. In vitro tests have shown that GSS™ and DUMON® silicone stent surfaces are highly efficient compared to other stents available on the market.

• Bevelled ends
The ends of the stents are designed to reduce the risk of mucus accumulation. They are specially bevelled to be atraumatic and to improve mucociliary clearance.

• Removability
If necessary, GSS™ and DUMON® stents can easily be removed, even after long-term implantation (positive results of removal even after 11 years are available).

• Unrestricted implant grade silicone
(over 29 days)

GSS™ and DUMON® — THE DIFFERENT TYPES OF STENTS

	type	wall thickness (mm)	rows of studs
GSS™ TD	Tracheal Stent	1.5	4 (Ø ≥ 20 mm: 3)
GSS™ TF	Thin Tracheal Stent	1.0	
GSS™ BD	Bronchial Stent	1.0	4
GSS™ Y	Total Carina Stent	1.0	3
GSS™ OKI	Right Upper Lobe Departure Stent for the right main stem bronchus around the right upper lobe departure and the bronchus intermedius	1.0	3
GSS™ ST	Hourglass Stent particularly for post-intubation stenoses	1.5	4
DUMON® BB	Ultra Thin Stent initially developped for pediatric indications	0.5	2
DUMON® CB	Carina Stent used for stenoses in the main bronchus, close to the carina	1.0	4

The above mentioned stents are available as standard stents, in a large variety of sizes (see chart on the following page). Other sizes and types are available as custom made stents (see form "Request for Customization" page 15.

TRACHEOBRONCHIAL SILICONE STENTS NOVATECH® GSS™ and DUMON®

STENT SIZE GUIDE (straight stents only*)

TD / TF / BD / BB / CB											
Length (mm) → / OD (mm) ↓	10	20	30	40	50	60	70	80	90	100	110
5	BB	BB	BB	BB	BB						
6	BB	BB	BB	BB	BB						
7	BB	BB	BB	BB	BB						
8	BB	BB	BB	BB	BB						
9	BB	BB CB	BB CB	BB CB	BB CB	BB					
10	BB	BD BB CB	BD BB CB	BD BB CB	BD BB CB	BD BB	BD				
11	BB	TD BD BB CB	TD BD BB CB	TD BD BB CB	TD BD BB CB	TD BD BB	TD BD	TD			
12	BB	TD BD BB CB	TD TF BD BB CB	TD TF BD BB CB	TD TF BD BB CB	TD TF BD BB CB	TD TF BD	TD TF BD			
13			TD TF	TD TF	TD TF	TD TF	TD TF	TD			
14			TD TF	TD TF	TD TF	TD TF	TD TF	TD			
15			TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF
16			TD	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD
18				TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF
20				TD TF	TD TF	TD TF	TD TF	TD TF	TF	TF	TF

* For sizes of GSS™ Y, GSS™ OKI and GSS™ ST, please refer to the respective catalog page.

TRACHEOBRONCHIAL SILICONE STENTS NOVATECH® GSS™ and DUMON®

GSS™ TD/TF — ENDOTRACHEAL STENTS

Endotracheal GSS™ stents are available with two wall thicknesses. GSS™ TD stents have a wall thickness of 1.5 mm. Additionally, endotracheal stents — with diameters of 12, 13, 14, 16, 18 and 20 mm — are available with a wall thickness of only 1.0 mm (GSS™ TF stents).

Features of the GSS™ TF stent

- **enhanced respiratory flow**

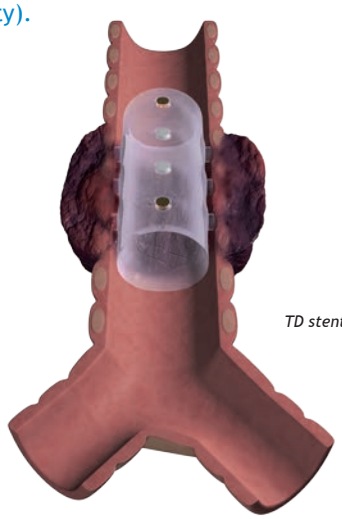
The larger inner diameter of a TF stent significantly enhances respiratory flow. For a standard tracheal stent of 50 mm in length and 16 mm in external diameter, the inner diameter increases by approx. 6%, resulting in an increase of the luminal volume of 16%.

- **improved mucociliary clearance**

The thinner walls of TF stents facilitate the internal movements of the trachea (respiration, ease of the peristaltic movements of the esophagus). This dynamic stent concept allows better mucociliary clearance (depending on mucous viscosity).

Features

- Transparency and radio-opacity
- Non-adherent smooth surface
- Anti-migration stud system
- Bevelled ends
- Removability
- Unrestricted implant grade silicone



TD stent in situ

Length (mm) → / OD (mm) ↓	20	30	40	50	60	70	80	90	100	110
11	TD	TD	TD	TD	TD	TD	TD			
12	TD	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF			
13		TD TF	TD TF	TD TF	TD TF	TD TF	TD			
14		TD TF	TD TF	TD TF	TD TF	TD TF	TD			
15		TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF
16		TD	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD
18			TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF	TD TF
20			TD TF	TD TF	TD TF	TD TF	TD TF	TF	TF	TF

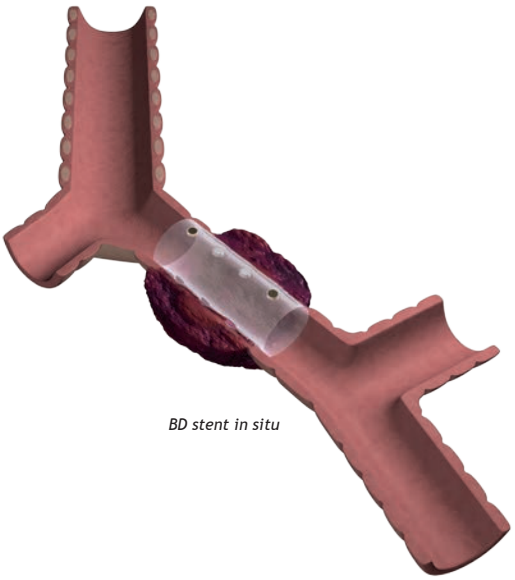
GSS™ BD — BRONCHIAL STENTS

GSS™ BD stents have been developed for bronchial indications. The stent design corresponds to the smaller bronchi diameters and ensures optimal ventilation of the patient.

Wall thickness: 1.0 mm

Features
- enhanced respiratory flow
- improved mucociliary clearance

Features
- Transparency and radio-opacity
- Non-adherent smooth surface
- Anti-migration stud system
- Bevelled ends
- Removability
- Unrestricted implant grade silicone



BD stent in situ

Length (mm) → / OD (mm) ↓	20	30	40	50	60	70	80
10	BD	BD	BD	BD	BD	BD	
11	BD	BD	BD	BD	BD	BD	
12	BD	BD	BD	BD	BD	BD	BD

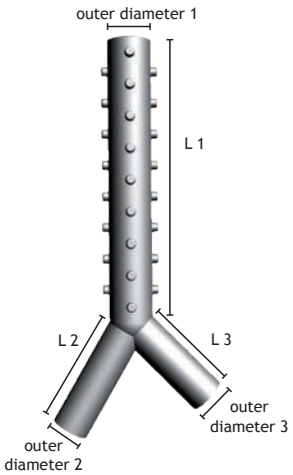
GSS™ Y-STENT — BIFURCATION STENT

GSS™ Y-Stents have 3 rows of studs. The posterior side has no studs in order to avoid trauma of the tracheo-esophageal wall. The branches are angled according to anatomy.
Custom lengths and diameters are available on request (see “BAF” in table below). The Y-Stents may be modified by Novatech in order to allow airflow to the right upper lobe.
A closed right branch stem for pneumonectomized patients with a fistula is available on a custom basis.

Features

- Safe fit
- Reduced pressure to the posterior tracheal mucosa
- Easy placement with ™/ NOVATECH stent applicator
- Anti-migration stud system
- Transparency and radio-opacity
- Non-adherent smooth surface
- Anti-migration stud system
- Bevelled ends
- Removability
- Unrestricted implant grade silicone

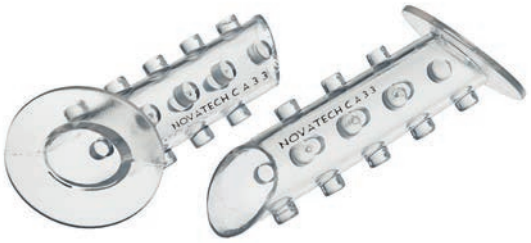
REF	dimensions (mm)						
	OD			lengths			wall thickness
	1	2	3	L1	L2	L3	
01Y141010	14	10	10	110	50	50	1.0
01Y141010V1				40	30	30	
01Y141010BAF*				specify			
01Y151212	15	12	12	110	50	50	1.0
01Y151212V1				40	30	30	
01Y151212V2				50	30	30	
01Y151212BAF*				specify			
01Y161313	16	13	13	110	50	50	1.0
01Y161313V1				40	30	30	
01Y161313V2				50	30	30	
01Y161313BAF*				specify			
01Y181414	18	14	14	110	50	50	1.0
01Y181414BAF*				specify			
01Yd1d2d3BAF	specify, please see form “Request for customization”, page 15						
*Please add the lengths after the desired REF.							



DUMON® CB — CARINA BRONCHUS STENT

DUMON® CB stents have a collar ring which permits placement in the bifurcation. CB stents allow treatment of indications of the main bronchus close to the carina and limit covering healthy mucosa. In certain cases, at the doctor's discretion, they may be used instead of Y-stents.

Wall thickness: 1.0 mm

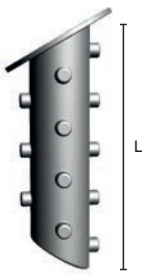


Features

- Easy placement
- Non-adherent smooth surface
- Anti-migration stud system
- Bevelled ends
- Removability
- Unrestricted implant grade silicone

Length (mm) → / OD (mm) ↓	20	30	40	50	60
9	CB	CB	CB	CB	
10	CB	CB	CB	CB	
11	CB	CB	CB	CB	
12	CB	CB	CB	CB	CB

Please indicate whether a transparent or radio-opaque stent is needed.



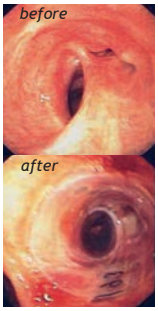
GSS™ OKI-STENT

Developped as a variation of a Y-Stent by Dr. Masahide Oki (Nagoya Medical Center, department Dr. Saka), the OKI-stent is designed for stenting the right main stem bronchus around the right upper lobe departure and the bronchus intermedius.

In most cases, the angle of the limb which is introduced into the upper lobe bronchus conforms with the anatomic situation and therefore facilitates stent placement.

The OKI-stent is available as a standard-stent with a specific combination of diameters and lengths. Custom made OKI-stents with different diameters and lengths are also available.

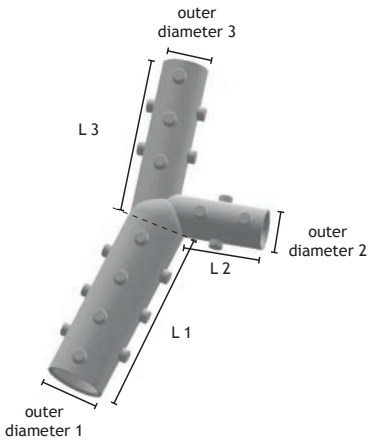
The OKI-stent complements the GSS™ range and features the same benefits as all GSS™ stents.



Features

- Safe fit
- Easy placement with TONN™/ NOVATECH stent applicator
- Anti-migration stud system
- Transparency and radio-opacity
- Non-adherent smooth surface
- Anti-migration stud system
- Bevelled ends
- Removability
- Unrestricted implant grade silicone

REF	dimensions (mm)						
	OD			lengths			wall thick-ness
	1	2	3	L1	L2	L3	
01OKI130910	13	9	10	40	17	35	1.0
01OKId1d2d3BAF	specify, please see form “Request for customization”, page 15						



GSS™ ST — HOURGLASS STENT

GSS™ ST was designed in collaboration with Prof. Vergnon (Saint Etienne University Hospital, France). It is especially adapted to

- complex benign stenoses
- post intubation stenoses
- post tracheostomy stenoses
- subglottic stenoses

Easy to place after laser resection or dilatation, this stent is designed to avoid the risk of migration inherent to compression reduction. No migration was observed in a study covering a follow-up period of two years. With a mean dwell time of 19,6 months even a curative effect has been observed in 4 from 13 patients.[1)]

The diameters of the distal and proximal ends correspond to the size of the healthy trachea. The central part is narrower, reducing the risk of traumatising the stenotic part of the trachea while maintaining a sufficient lumen for the airflow and thus reducing the risk of restenosis.

In some cases, this stent can prevent a tracheostomy.

[1)] Pr Jean-Michel Vergnon, CHEST 2000; 118:422-426

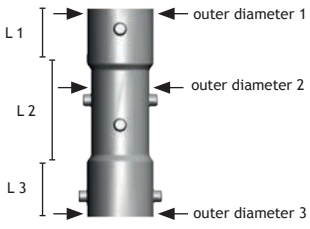
Features

- Special design for minimizing the risk of migration after compression reduction
- Transparency and radio-opacity
- Non-adherent smooth surface
- Anti-migration stud system
- Bevelled ends
- Removability
- Unrestricted implant grade silicone

REF	dimensions (mm)						
	OD			lengths			wall thick-ness
	1	2	3	L1	L2	L3	
01ST121012	12	10	12	15	20	15	1.5
01ST141214	14	12	14	15	20	15	
01DST141214*	14	12	14	7,5	20	7,5	
01ST151315	15	13	15	15	20	15	
01ST161416	16	14	16	15	20	15	
01DST161416*	16	14	16	7,5	20	7,5	
01ST161416BAF	16	14	16	specify			
01ST181618	18	16	18	15	20	15	
01DST181618*	18	16	18	7,5	20	7,5	
01STd1d2d3BAF	The lengths and diameters can be modified in any manner, even to obtain a completely asymmetric stent. Please see form “Request for customization”, page 15						

*** new design:**

- enhanced proportion of the narrower central part to the wider distal and proximal ends
- more rounded inner shape



DUMON® BB — PEDIATRIC STENT

Initially developed for pediatric indications, DUMON® BB have a wall thickness of only 0.5 mm.

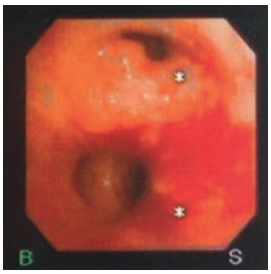
The ratio between inner and outer diameter offers an excellent compromise between reduced wall-thickness and resistance to compression. Stent placement is possible with either a rigid scope or, for distal stenoses in adults, with a flexible bronchoscope.

Pediatric Indications

For pediatric indications a rigid bronchoscopy must be performed for safety reasons. There is no debate between surgery and stenting as surgery must be the first choice to solve a problem. In some case stenting can be a good temporary alternative.[1)]

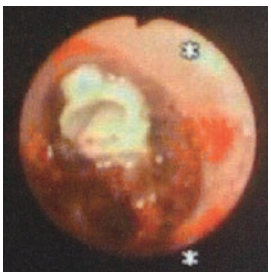
Like all DUMON® stents, the BB stent is made of implant grade silicone. It is highly biocompatible and removal of the stent is possible any time.

DUMON® BB are available in lengths of 10 to 50 mm in order to both cover the stenosis and anchor the stent. The controlled wall thickness aids in avoiding obstruction. In case of necessity, the stent can be removed with foreign body forceps.

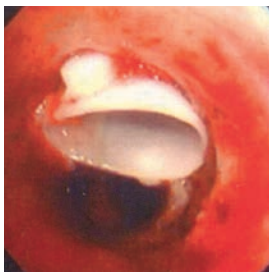


Left upper lobe indication

BB 10 L 20 grasped by a forceps



Just released



After balloon dilatation

Adult indications, placement by flexible bronchoscope

Adult indications are rare and must be considered as an exception, when stenting must secure lobar ventilation. Patient quality of life is a key issue to determine the necessity of stenting.

Length (mm) → / OD (mm) ↓	10	20	30	40	50	60
5	BB	BB	BB	BB	BB	
6	BB	BB	BB	BB	BB	
7	BB	BB	BB	BB	BB	
8	BB	BB	BB	BB	BB	
9	BB	BB	BB	BB	BB	BB
10	BB	BB	BB	BB	BB	BB
11	BB	BB	BB	BB	BB	BB
12	BB	BB	BB	BB	BB	BB

As a standard, BB stents have 2 rows of studs.
BB stents with 4 rows of studs are available as custom made stents (only with diameter ≥ 8 mm).

[1)] *FAYON, M. et al: French experience of silicone tracheo-bronchial stenting in children. Pediatr Pulmonol. 2005, 39: 21-27*

COMPLEMENTARY PRODUCTS

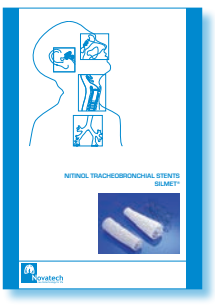
TONN™ / NOVATECH STENT APPLICATOR

Stent placement is done by a rigid bronchoscope together with the **TONN™ / NOVATECH Stent Applicator**.
Easy to handle, the TONN™ / NOVATECH Stent Applicator is available in four sizes (BLUE, RED, GREEN and WHITE) allowing the insertion of silicone stents in a wide range of sizes: Stents with an OD of up to 20 mm and a length of up to 160 mm (Y-Stents) can be placed.
Furthermore Y-Stent insertion is facilitated. The position of the main branch can be determined before insertion, minimising the risk of misplacement and stent damage.

SILMET®

SILMET® is a self-expandable stent made of nitinol, an alloy of nickel and titanium. Silmet® is entirely handcrafted and comes sterile (ethylene oxide) inside its placement system. Silmet® complements the line of DUMON® and GSS™ silicone stents, both considered as basic references, when Silmet® is more indicated.
SILMET® can be placed by flexible bronchoscopy, under direct vision or X-ray.

For further details about these products, please contact our customer service for the respective catalog.



REQUEST FOR CUSTOMIZATION
NOVATECH® GSS™ / DUMON®

Novatech SA
Z.I. Athélia III - 1058, Voie Antiope
F-13705 La Ciotat CEDEX
FRANCE

Tel: +33 (0) 442 98 15 60
Fax: +33 (0) 442 98 15 63
info@novatech.fr

.....

Unique patient identifier
(Patient name or number)

Please mark the adequate drawing and indicate:

Ø 1 .....mm

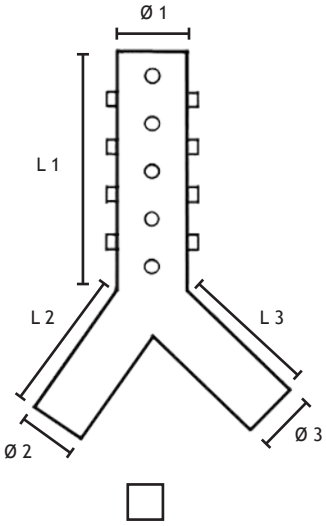
Ø 2 .....mm

Ø 3 .....mm

L 1 .....mm

L 2 .....mm

L 3 .....mm



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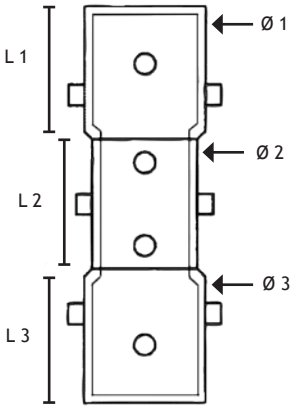

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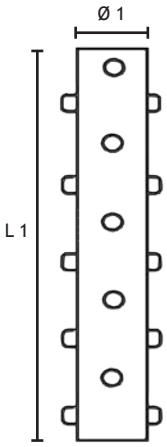

Wall thickness:

☐	TD	1.5 mm
☐	TF, BD	1.0 mm
☐	BB	0.5 mm

Customer

.....
doctor's name

.....
address

.....

.....
telephone

.....
e-mail

stamp and signature for approval

Distributor

.....
name

.....
address

stamp and signature

Novatech

.....
REF

.....
LOT

.....
official representative

.....
Date / Visa

Dimensioned drawing
For a stent that does not correspond to any of the above drawings, please provide a dimensioned drawing:

NOVATECH hereby confirms that the custom made stent described above is manufactured in strict compliance with the Council Directive 93/42/EEC annexe I.

It is in the prescribing doctor's responsibility to determine whether this custom made stent is suitable for the patient.

The products in this catalog are CE-marked.

NOVATECH SA, La Ciotat, France

⚠ Please note that only the instructions for use enclosed with the respective product apply. Details in this catalogue about the use of products serve as a guide only and reflect the information available at the time of print. If necessary, please request a current version!

Your local contact:

CA 001EN/03
03/2014

Novatech
new biotechnology for life
a bess group company

Novatech SA
capital stock: 160.000 € • 398 941 260 RCS Marseilles
TVA CEE FR59398941260 • EN ISO 13485
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