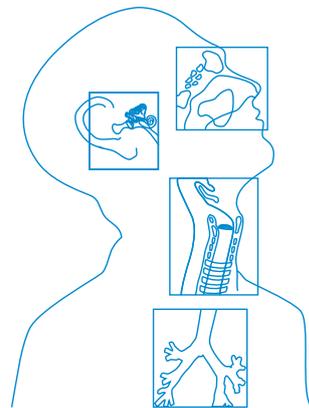
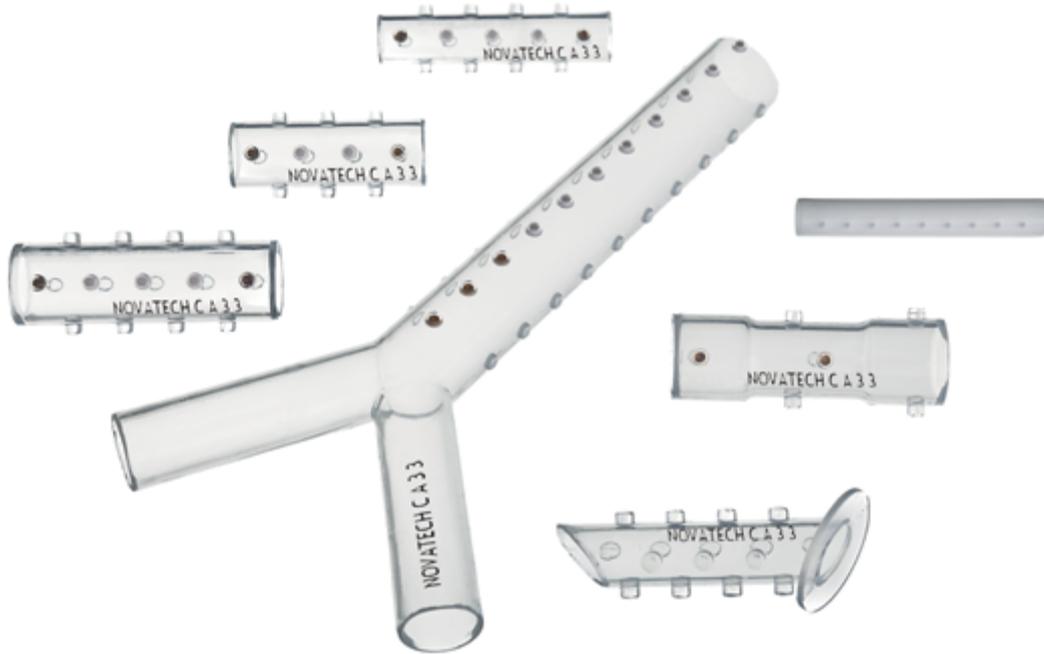


Novatech
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a bess group company

Tracheobronchial Silicone Stents NOVATECH® GSS™ and DUMON®





IFU e-labelling

The instructions for use for some of our products are available only in electronic form (in pdf format) on our website. Please see the product label for the required access information.

Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



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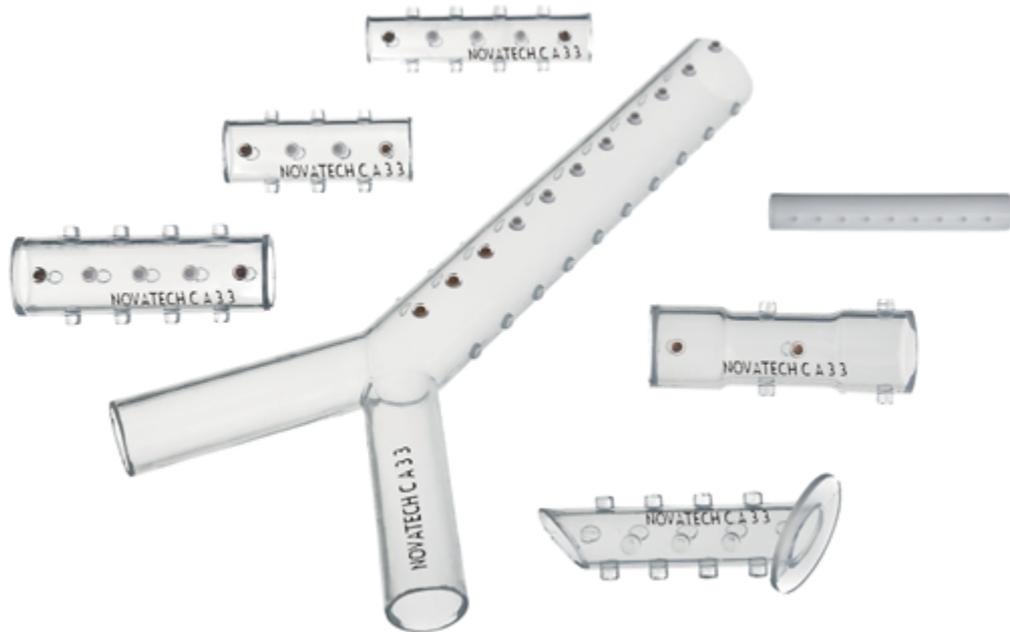
Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



Tracheobronchial silicone stents

NOVATECH® GSS™ and DUMON®



DUMON®

Renowned for decades

Since 1989, Novatech has been manufacturing the patented DUMON® silicone stent – a stent system that has been tried-and-tested to improve patient comfort. 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

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

NOVATECH® GSS™

State of the art

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.

Indications

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

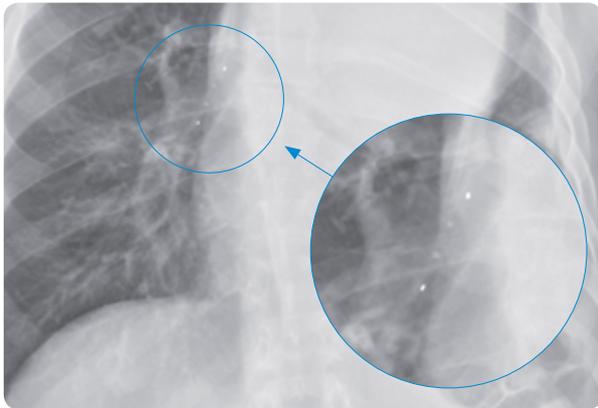
- tracheo-bronchial tumors
- scarred tracheal stenosis
- stenosis after anastomosis, resection or lung transplantation
- diameter reduction from intraluminal, extraluminal, and intramural changes

Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



NOVATECH® GSS™ combine good X-ray visibility with optimized endoscopic tissue monitoring



NOVATECH® GSS™ visible on X-ray



NOVATECH® GSS™: studs filled with gold and barium sulfate



"NOVATECH" and LOT imprinted, specially bevelled ends

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

Features

Transparency and radio-opacity (NOVATECH® 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

Depending on design, there are 2, 3 or 4 lines of studs on the stent outside. 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 stent inside is treated with a silicone-based layer which makes the surface anti-adherent, minimizing the risk of obstructions and improving mucociliary clearance. The stent surface is excellently tolerated by the mucosa. In vitro tests have shown that NOVATECH® 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, the 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)

Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



The different types of stents

	Designation	"short" name used in this catalog	Type	Wall Thickness (mm)	Rows of Studs
NOVATECH® GSS™	NOVATECH® GSS™ TD	GSS™ TD	Tracheal Stent	1.5	4
	NOVATECH® GSS™ TF	GSS™ TF	Thin Tracheal Stent	1.0	4 (∅ ≥ 20 mm: 3)
	NOVATECH® GSS™ ST NOVATECH® GSS™ DST	GSS™ ST GSS™ DST	Hourglass Stent <i>particularly for post-intubation stenoses</i>	1.5	4
	NOVATECH® GSS™ BD	GSS™ BD	Bronchial Stent	1.0	4
DUMON®	DUMON® BB	n.a.	Ultra Thin Stent <i>initially developed for pediatric indications</i>	0.5	2
	DUMON® CB	n.a.	Carina-Bronchus Stent <i>used for stenoses in the main bronchus, close to the carina</i>	1.0	4
NOVATECH® GSS™	NOVATECH® GSS™ Y	GSS™ Y	Bifurcation Stent	1.0	3
	NOVATECH® GSS™ OKI	GSS™ OKI	Right Upper Lobe Departure Stent <i>for the right main stem bronchus around the right upper lobe departure and the bronchus intermedius</i>	1.0	3

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.

Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



Stent size guide

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

This chart comprises only straight stents.

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

Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



NOVATECH® GSS™ TD

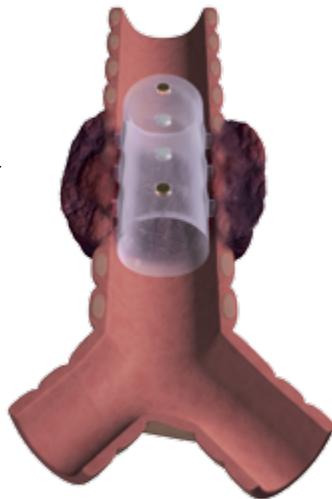
Endotracheal Stents

GSS™ TD are Novatech's standard endotracheal stents, coming with a wall thickness of 1.5 mm.



NOVATECH® GSS™ TD

GSS™TD stent
in situ



Features

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

GSS™ TD, sterile										
Length (mm) →	20	30	40	50	60	70	80	90	100	110
OD (mm) ↓										
11	01TD1120	01TD1130	01TD1140	01TD1150	01TD1160	01TD1170	01TD1180			
12	01TD1220	01TD1230	01TD1240	01TD1250	01TD1260	01TD1270	01TD1280			
13		01TD1330	01TD1340	01TD1350	01TD1360	01TD1370	01TD1380			
14		01TD1430	01TD1440	01TD1450	01TD1460	01TD1470	01TD1480			
15		01TD1530	01TD1540	01TD1550	01TD1560	01TD1570	01TD1580	01TD1590	01TD15100	01TD15110
16		01TD1630	01TD1640	01TD1650	01TD1660	01TD1670	01TD1680	01TD1690	01TD16100	01TD16110
18			01TD1840	01TD1850						

Custom made stents available. Please contact customer service.

Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



NOVATECH® GSS™ TF

Endotracheal Stents

Endotracheal GSS™ TF stents have a wall thickness of only 1 mm, which makes larger stent-diameters possible.

Enhanced respiratory flow

The larger inner diameter of a GSS™ 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 GSS™ 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).



NOVATECH® GSS™ TF

Features

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

GSS™ TF, sterile

Length (mm) →	30	40	50	60	70	80	90	100	110
OD (mm) ↓									
12	01TF1230	01TF1240	01TF1250	01TF1260	01TF1270	01TF1280			
13	01TF1330	01TF1340	01TF1350	01TF1360	01TF1370				
14	01TF1430	01TF1440	01TF1450	01TF1460	01TF1470				
15	01TF1530	01TF1540	01TF1550	01TF1560	01TF1570	01TF1580	01TF1590	01TF15100	01TF15110
16		01TF1640	01TF1650	01TF1660	01TF1670	01TF1680	01TF1690	01TF16100	
18		01TF1840	01TF1850	01TF1860	01TF1870	01TF1880	01TF1890	01TF18100	01TF18110
20		01TF2040	01TF2050	01TF2060	01TF2070	01TF2080	01TF2090	01TF20100	01TF20110

Custom made stents available. Please contact customer service.

Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



NOVATECH® GSS™ ST

Hourglass Stents

GSS™ ST were designed in collaboration with Prof. Vergnon (Saint Etienne University Hospital, France). They are especially adapted to

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



NOVATECH® GSS™ ST

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.

Features

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

NOVATECH® GSS™ DST

Hourglass Stent

GSS™ DST is a further development of the tried-and-tested GSS™ ST, featuring enhanced proportions of the narrower central part to the wider distal and proximal ends of the stent. Moreover, GSS™ DST have a more rounded inner shape.



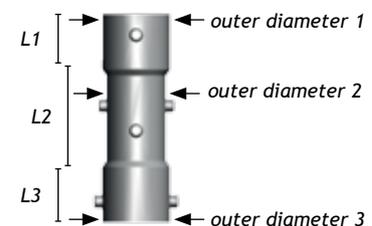
NOVATECH® GSS™ DST

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

GSS™ ST, sterile							
REF	Dimensions (mm)						Wall Thickness
	OD			Lengths			
	1	2	3	L1	L2	L3	
01ST121012	12	10	12	15	20	15	1.5
01ST141214	14	12	14	15	20	15	
01ST151315	15	13	15	15	20	15	
01ST161416	16	14	16	15	20	15	
01ST181618	18	16	18	15	20	15	

GSS™ DST, sterile							
REF	1	2	3	L1	L2	L3	Wall Thickness
01DST141214	14	12	14	7.5	20	7.5	1.5
01DST161416	16	14	16	7.5	20	7.5	
01DST181618	18	16	18	7.5	20	7.5	

Custom made stents available. Please contact customer service.



Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



NOVATECH® 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.

Improved mucociliary clearance

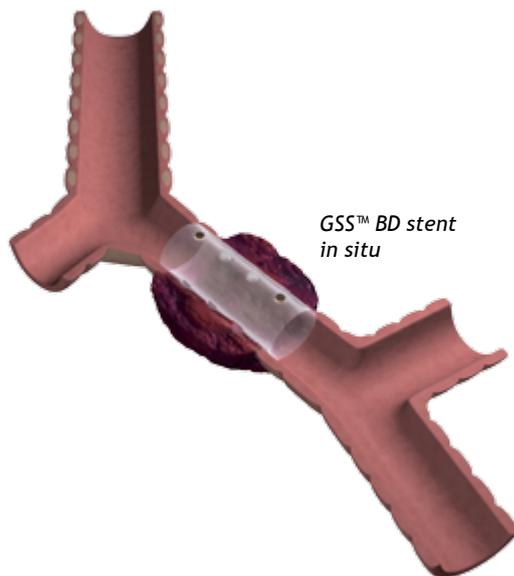
The 1.0 mm thin walls of GSS™ BD stents facilitate the internal movements of the trachea (respiration, ease of the peristaltic movements of the esophagus). This dynamic stent concept allows better mucociliary clearance (depending on mucous viscosity).



NOVATECH® GSS™ BD

Features

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



GSS™ BD stent
in situ

GSS™ BD, sterile							
Length (mm) →	20	30	40	50	60	70	80
OD (mm) ↓							
10	01BD1020	01BD1030	01BD1040	01BD1050	01BD1060	01BD1070	
11	01BD1120	01BD1130	01BD1140	01BD1150	01BD1160	01BD1170	
12	01BD1220	01BD1230	01BD1240	01BD1250	01BD1260	01BD1270	01BD1280

Custom made stents available. Please contact customer service.

Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



DUMON® BB

Pediatric Stents

DUMON® BB stents are fully radiopaque (white) and have a wall thickness of only 0.5 mm. They are particularly suitable for pediatric indications and were developed for specific anatomical requirements in infants. DUMON® BB stents have very thin walls and only two rows of studs, facilitating introduction through the vocal cords.

The ratio between inner and outer diameter is very favorable, wall-thickness is only 0.5 mm. Stent placement is possible with either a rigid scope or, for distal stenoses in adults, e.g. in the upper lobe, with a flexible bronchoscope under X-ray control (Dr. T. Miyazwa, St. Marianna Hospital, Kawasaki, Japan).



DUMON® BB



before stent placement



after stent placement

Features

- Available radiopaque only
- Non-adherent smooth surface
- Anti-migration stud system
- Bevelled ends
- Removability
- Unrestricted implant grade silicone

DUMON® BB, sterile, radiopaque

Length (mm) →	20	30	40	50
OD (mm) ↓				
5	025301S20	025301S30	025301S40	025301S50
6	026201S20	026201S30	026201S40	026201S50
7	026501S20	026501S30	026501S40	026501S50
8	026701S20	026701S30	026701S40	026701S50
9	026751S20	026751S30	026751S40	026751S50
10	026801S20	026801S30	026801S40	026801S50
11	026901S20	026901S30	026901S40	026901S50
12	026951S20	026951S30	026951S40	026951S50

Custom made stents available. Please contact customer service.

Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®

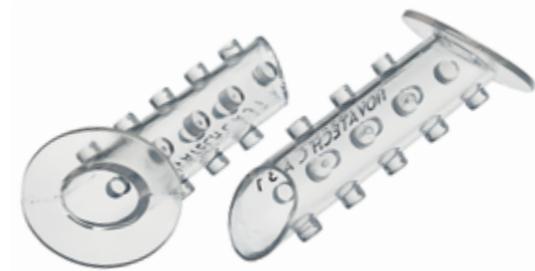


DUMON® CB

Carina-Bronchus Stents

DUMON® CB stents are available either transparent or radiopaque. They have a collar ring which permits placement in the bifurcation. DUMON® 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 GSS™ Y stents.

Wall thickness: 1.0 mm



DUMON® CB

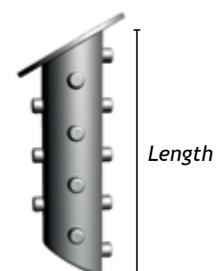
Features

- Available either transparent or radiopaque
- Easy placement
- Non-adherent smooth surface
- Anti-migration stud system
- Bevelled ends
- Removability
- Unrestricted implant grade silicone

DUMON® CB, sterile, transparent					
Length (mm) →	20	30	40	50	60
OD (mm) ↓					
9	05881S	05901S	05921S	05941S	
10	06001S	06021S	06041S	06061S	
11	06121S	06141S	06161S	06181S	
12	06241S	06261S	06281S	06301S	06311S

DUMON® CB, sterile, radiopaque					
Length (mm) →	20	30	40	50	60
OD (mm) ↓					
9	05881RS	05901RS	05921RS	05941RS	
10	06001RS	06021RS	06041RS	06061RS	
11	06121RS	06141RS	06161RS	06181RS	
12	06241RS	06261RS	06281RS	06301RS	06311RS

Custom made stents available. Please contact customer service.



Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®

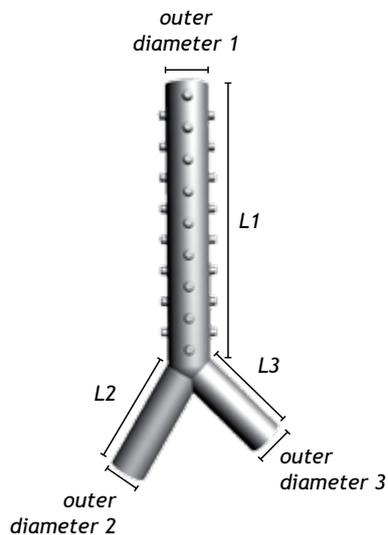


NOVATECH® GSS™ Y

Bifurcation Stents

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. GSS™ 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 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

GSS™ Y, sterile							
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	
01Y151212	15	12	12	110	50	50	1.0
01Y151212V1				40	30	30	
01Y151212V2				50	30	30	
01Y161313	16	13	13	110	50	50	1.0
01Y161313V1				40	30	30	
01Y161313V2				50	30	30	
01Y181414	18	14	14	110	50	50	1.0

Custom made stents available. Please contact customer service.

Tracheobronchial Silicone Stents

NOVATECH® GSS™ and DUMON®



NOVATECH® GSS™ OKI

Right Upper Lobe Departure Stents

Developed as a variation of Y-shaped stents by Dr. Masahide Oki (Nagoya Medical Center, department Dr. Saka), the GSS™ OKI stents are 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.

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

GSS™ OKI stents complement the NOVATECH® GSS™ range and feature the same benefits as all NOVATECH® GSS™ stents.



NOVATECH® GSS™ OKI



before stent placement



after stent placement

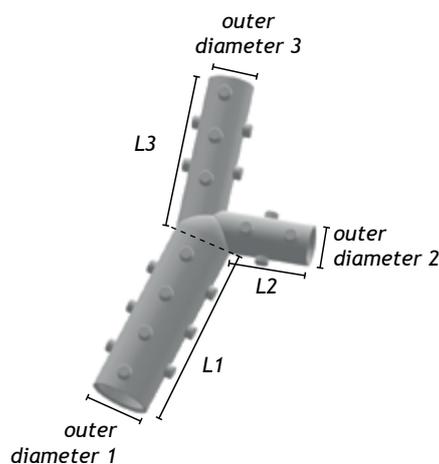
Features

- 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

GSS™ OKI, sterile

REF	Dimensions (mm)						Wall Thickness
	OD			Lengths			
	1	2	3	L1	L2	L3	
01OKI130910	13	9	10	40	17	35	1.0

Custom made stents available. Please contact customer service.



Complementary Products

TONN™ NOVATECH® Tracheal and Bronchial Stent Applicator



Developed by Dr. Tonn (Hanover, Germany), the TONN™ NOVATECH® tracheal and bronchial Stent Applicator facilitates the placement of tracheobronchial stents NOVATECH® GSS™ and DUMON® through a rigid bronchoscope.

DUTAU® NOVATECH® Rigid Bronchoscope



The modular DUTAU® NOVATECH® Rigid Bronchoscope is designed for use in interventional bronchoscopy. It combines innovative features for easier handling and a wide compatibility with essential bronchoscopy instruments.

ROTEPS® Rotatable Forceps for Bronchoscopy



ROTEPS® are an innovative line of Bronchoscopy Forceps, rotatable for ease of use and fully dismountable for efficient cleaning. Seven different forceps heads are broadly combinable with two shafts (2 mm and 4 mm) and three types of handles. Adapted cleaning accessories complement this product line.

The products in this catalog are -marked.



Novatech SA – La Ciotat, France



Please note that only the instructions for use enclosed with the respective product apply. Details in this catalog 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!



The instructions for use for some of our products are available only in electronic form (in pdf format) on our website. Please see the product label for the required access information.



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