

Product Catalog



NOVATECH

NEW BIOTECHNOLOGY FOR LIFE

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TRACHEOBRONXANE® DUMON®

The TRACHEOBRONXANE® Dumon® Silicone Stent is the original design, patented worldwide and used successfully to treat tracheal and bronchial obstructions and stenoses. The stents are made from implant-grade silicone suitable for long-term placement and are considered the "golden standard to which all others should be compared".¹⁾

The material is flexible enough to allow for atraumatic insertion and placement, yet will seek its original shape following placement, providing the force necessary to correct extrinsic compression of the trachea or bronchus.

A study²⁾ covering 1,500 cases observed no case of secondary compression, not even in cases of the most serious tumors such as osteosarcoma. In all cases of extreme compression, the prosthesis recovered its round shape within two days after placement.

Indications

- Tracheobronchial tumors
- Tracheal stenoses with scarring
- Bronchial stenoses following surgical resection and anastomosis
- Bronchial stenoses following pulmonary transplantation

Application

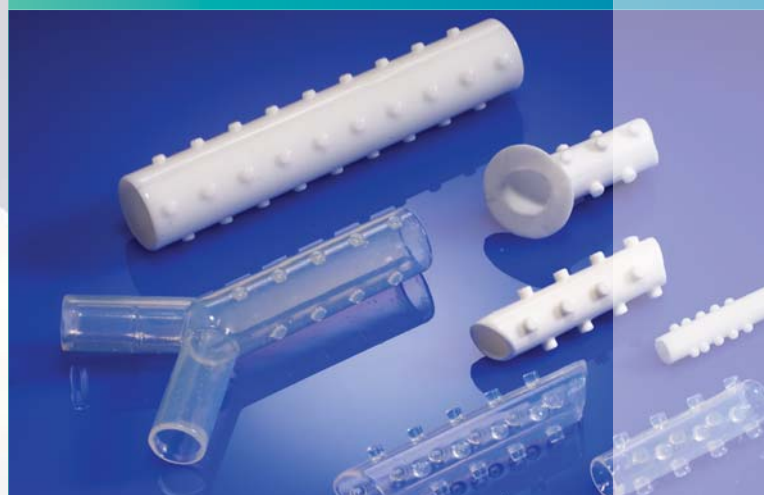
Placement and removal with a rigid bronchoscope

NOVATECH advises the use of the TONN Applicator to safely place Dumon® Stents.

Features

- Anti-migration stud system
- The ends of the stents are specially beveled to ensure mucociliary clearance while helping to prevent crusting and granulation tissue from forming.
- Non-adherent smooth surface
- Easily removable in case of necessity
- Implant grade silicone

The TRACHEOBRONXANE® Dumon® Silicone Stent is sold sterile. Non sterile stents are available upon request.



TRACHEOBRONXANE® DUMON®

• The different types of prostheses

Abbreviation	Type	wall thickness
TD	Tracheal Stent	1.5 mm
TF	Thin Tracheal Stent	1.0 mm
BD/BO	Bronchial Stent	1.0 mm
CB	Carina Stent for the main stem bronchi close to the carina	1.0 mm
Y	Total Carina Stent	1.0/1.3 mm
ST	Hourglass Stent particularly for post-intubation stenoses	1.5 mm
BB	Ultra thin Stent for pediatric and adult indications	0.5 mm

Other types of stents
and custom makes available.

¹⁾ Pr Bolliger, *Pulmonary Reviews*, Oct. 1997

²⁾ Cavaliere, Diaz, Dumon et Vergnon, *Journal of Bronchology* 3:6-10, 1996

TRACHEOBRONXANE® DUMON®

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, it is essential to have an entire basic line of different stent types, diameters and lengths available to be prepared for any situation.

The stents must not be cut in order to avoid the risk of granulation and to ensure mucocilar clearance (please refer to user manual).

Anti-migration stud system

A well adapted TRACHEOBRONXANE® Dumon® silicone stent does not migrate. The patented stud design aids in preventing migration by naturally fixing the stent between the cartilaginous rings of the trachea. Cough reflexes are inhibited by reflex centre saturation. The studs limit 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 perfectly tolerated by the mucosa. It allows mucocilar clearance. In vitro tests have shown that TRACHEOBRONXANE® DUMON® silicone stents are highly efficient compared to other stents available on the market.

Beveled ends

The ends of the stents are specially beveled to improve mucocilar clearance while helping to prevent crusting and granulation tissue from forming.

Stent removal

If necessary, TRACHEOBRONXANE® DUMON® stents can easily be removed, even after long-term implantation (results are available of removal after 11 years).

AT YOUR SERVICE



NOVATECH *New Biotechnology for Life* is a manufacturer of top quality medical products used successfully worldwide in interventional pulmonology. Our core product line, silicone TRACHEOBRONXANE® DUMON® stents, have been produced since 1989.

Our sophisticated quality management system together with medical technology expertise have lead to EN ISO 13485:2003 and ISO 9001:2000 certification and FDA clearance. Our products are manufactured using highest quality, long term implantable medical grade materials under strict quality control procedures.

The focal point of our work is to develop tailored medical devices in order to give patients a better quality of life. To this end we are in constant discussion with physicians, customers, and other specialists, striving to improve our existing products and to develop new ones. We are aware of the need for individual solutions, so please contact us for custom makes and innovations.

Please visit NOVATECH *New Biotechnology for Life* at our web site www.novatech.fr for additional information or contact our customer service at info@novatech.fr.

TRACHEOBRONXANE® DUMON® TD / TF

Endotracheal TRACHEOBRONXANE® DUMON® stents are available with two wall thicknesses. The TD stents have a wall thickness of 1.5 mm. Additionally, endotracheal stents of 13, 14, 16, 18 and 20 mm are available with a wall thickness of only 1.0 mm (TF stents).

Clinical results obtained with Y stents and other bronchial stents¹⁾ show that no secondary compression has been observed with TRACHEOBRONXANE® DUMON® silicone stents.

Due to the special material and shape of TRACHEOBRONXANE® DUMON® stents, the centripetal force is not altered, even with a wall thickness of only 1.0 mm, allowing increased airflow and better mucociliary clearance.

Features of the TF stents

- enhanced respiratory flow**
 The larger inner diameter significantly enhances respiratory flow. [For a standard tracheal stent of 50 mm in length and 16 mm in external diameter the luminal volume increase is 16% while the inner diameter increases by approx. 6%.]
- improved mucocilar clearance**
 The thinner walls facilitate the internal movements of the trachea (respiration and swallowing). This dynamic stent concept allows better mucocilar clearance (depending on mucous viscosity).



**TD Endotracheal Stent,
wall thickness 1.5 mm**

**TF Endotracheal Stent,
wall thickness 1.0 mm**

Diameters:	TD: 11, 12, 13, 14, 15, 16, 18, 20 mm
	TF: 13, 14, 16, 18, 20 mm
lengths:	20 to 110 mm in increments of 10 mm.
Please add „R“ for radiopaque and „S“ for a sterile stent.	
Please contact us for other diameters and lengths.	

Features

- Anti-migration stud system
- The ends of the stents are specially beveled to ensure mucocilar clearance while helping to prevent crusting and granulation tissue from forming.
- Non-adherent smooth surface
- Easily removable in case of necessity
- Implant grade silicone

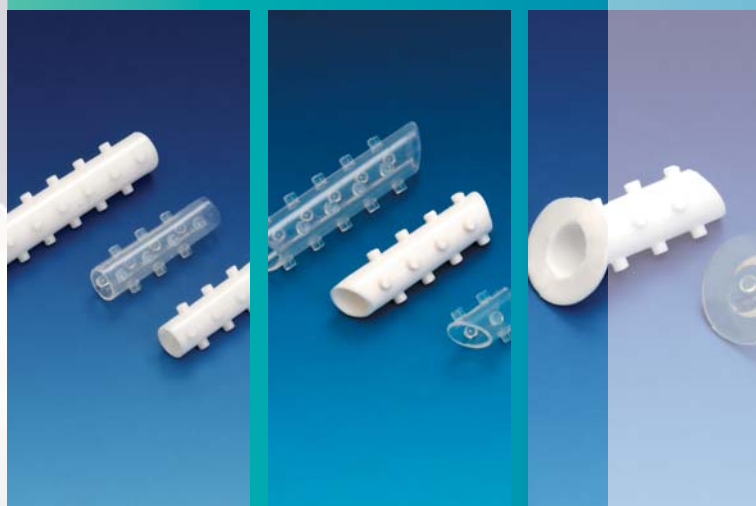
¹⁾ Seven years experience with Dumon stent, Journal of Bronchology 3:6-10, 1996

TRACHEOBRONXANE® DUMON® BD/BO and CB

The TRACHEOBRONXANE® DUMON® BD/BO and CB stents are perfectly adapted to bronchial indications (main bronchus and bronchus intermedius) and can, in certain cases, be placed in the lobar bronchus.

They facilitate mucociliary clearance while allowing optimal ventilation of the bronchi.

Due to its special material, the Tracheobronxane® Dumon® stent maintains its shape and resists external compression¹⁾ despite its wall thickness of only 1 mm.



Dumon BD

Dumon® BD stents have been developed for bronchial indications. The stent sizes correspond to the smaller bronchi diameters and ensure optimal ventilation of the patient.



Dumon BO

Dumon® BO stents have bevelled ends in order to facilitate ventilation of the upper lobar bronchus. They are used to reinforce the endobronchial walls ensuring collateral ventilation.



Dumon CB

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 they may be used instead of Y-stents.

BD/BO bronchial stent, straight
wall thickness 1.0 mm

CB carina-bronchus stent,
used for stenoses in the main
bronchus, close to the carina
wall thickness 1.0 mm

TRACHEOBRONXANE® DUMON® BD/BO and CB feature the same advantages of all NOVATECH silicone stents:

- anti-migration stud system
- The ends of the stents are specially bevelled to ensure mucociliary clearance while helping to prevent crusting and granulation tissue from forming
- non-adherent smooth surface
- Easily removable in case of necessity
- Medical grade silicone (implantable beyond 29 days)

Features of the BD/BO and CB stents

- enhanced respiratory flow
- improved mucociliary clearance

¹⁾ Seven years experience with Dumon stent, Journal of Bronchology 3:6-10, 1996

Diameters:	BD / BO / CB : 9, 10, 11, 12 mm
Lengths:	20 to 60 mm.
Please add „R” for a radio-opaque stent and „S” for a sterile stent.	
For other diameters and lengths, please contact us.	

TRACHEOBRONXANE® DUMON® Y

In 1994, NOVATECH New Biotechnology For Life started to produce the TRACHEOBRONXANE® DUMON® Y Stent, a prosthesis for the bifurcation, and has meanwhile broadened the choice of diameters and lengths in order to offer solutions for difficult cases of carina compression.

Customization

Custom lengths and diameters may be ordered.

The Y Stents may be modified by NOVATECH in order to allow airflow through the right upper lobe departure.

Also available on a custom basis is a closed right branch stem for pneumonectomized patients with a fistula.



Features

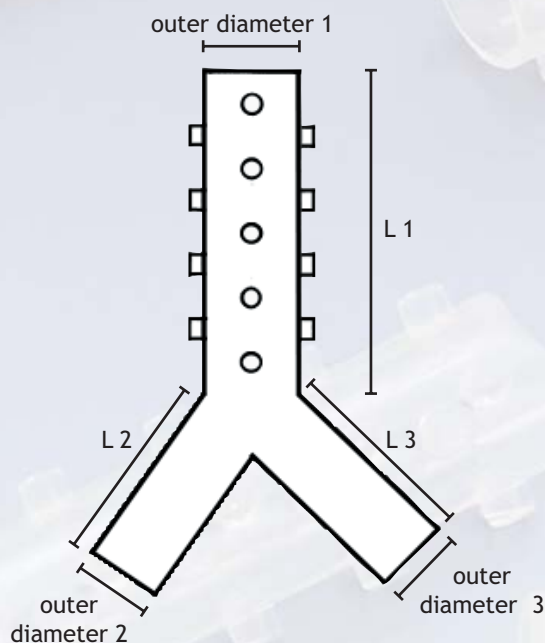
- Anti-migration stud system
- The ends of the stents are specially beveled to ensure mucocilar clearance while helping to prevent crusting and granulation tissue from forming.
- Non-adherent smooth surface
- Easily removable in case of necessity
- Implant grade silicone

REF	dimensions (mm)						wall thickness
	outer diameters			lengths			
	1	2	3	L1	L2	L3	
09101*	14	10	10	specify			1.0
091011				110	50	50	
09201*	15	12	12	specify			1.0
092011				110	50	50	
09301*	16	13	13	specify			1.0
093011				110	50	50	
090021*	15	12	12	50	30	30	1.3
09001*	16	13	13	20	15	20	1.3
09401*	18	14	14	specify			1.3
094011	18	14	14	110	50	50	1.3

* Please contact us for custom made stents.

Please add the dimensions (outer diameters and lengths) after the desired REF.

Please add „R” for radiopaque and „S” for a sterile prosthesis.



The LOT-number is engraved on the stent allowing traceability up to the patient.

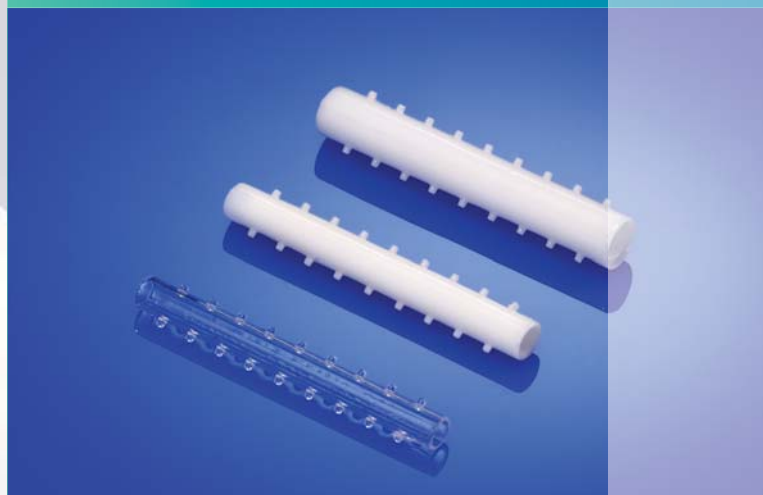
TRACHEOBRONXANE® DUMON® BB

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

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

Excellent results have been obtained in indications of lobar bronchi¹⁾. The placement method is very simple under direct view or X-ray control.

Placing a silicone stent with a flexible bronchoscope is a kind of revolution as it is now possible to place a stent distally and to remove it if necessary. For such indications it is no longer necessary to place a self-expandable stent, unless collateral ventilation is required.



Features

- Anti-migration stud system
- The ends of the stents are specially beveled to ensure mucocilar clearance while helping to prevent crusting and granulation tissue from forming.
- Non-adherent smooth surface
- Easily removable in case of necessity
- Implant grade silicone

REF	dimensions (mm)			
	internal diameter	external diameter	length	rows of studs
025301	4	5	10 to 50 specify	2
026201	5	6		
026501	6	7		
026701	7	8	20 to 80 specify	4 (available also with 2 rows; pls. specify)
026751	8	9		
026801	9	10		
Please add „R” for radiopaque and „S” for a sterile prosthesis.				
Please add the desired length after the REF.				
Please contact us for other diameters or lengths.				

¹⁾ Dr. Miyazawa, Hiroshima. Video available.
Please visit our website www.novatech.fr

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.

Like all TRACHEOBRONXANE® DUMON® stents, the BB stent is made of implant grade silicone. It is perfectly biocompatible and removal of the stent is possible without any problem even after more than 15 months¹⁾.

In infants a lumen reduction due to cardiopathy or malacia can be silicone stented endoscopically without suturing the stent to the mucosa or performing a tracheotomy.

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

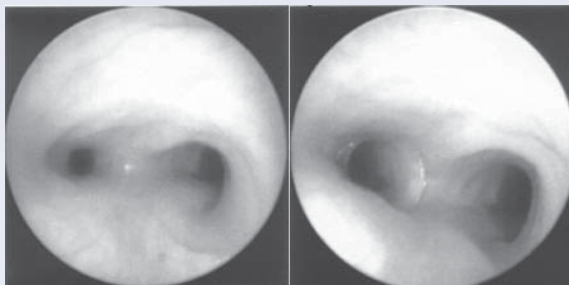
Adult indications, placement by flexible bronchoscope

Adult indications are rare and must be considered an exception.

Stenting must secure lobar ventilation. Patient quality of life is a key issue to determine the necessity of stenting.

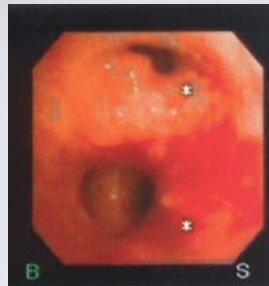
It may be indicated for a patient who has undergone right side pneumonectomy to secure ventilation of the left lower lobe.

In some cases TRACHEOBRONXANE® DUMON® BB can be placed instead of a self-expandable stent which are presently the preferred stents for such distal stenoses. The necessity of collateral ventilation does not make the latter obsolete but TRACHEOBRONXANE® DUMON® BB can be used when self-expandable stents are useless or even dangerous.



before

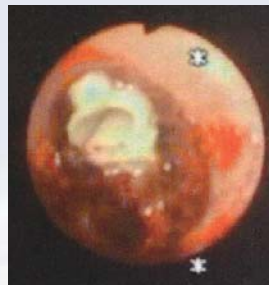
after



Left upper lobe indication



BB 10 L 20 grasped by a forceps



Just released



After balloon dilatation

¹⁾ Dr Donato, Service Pédiatrie, CHU Strasbourg

TRACHEOBRONXANE® DUMON® ST

TRACHEOBRONXANE® DUMON® ST was created in collaboration with Prof. Vergnon (Saint Etienne University Hospital, France). It is perfectly adapted to

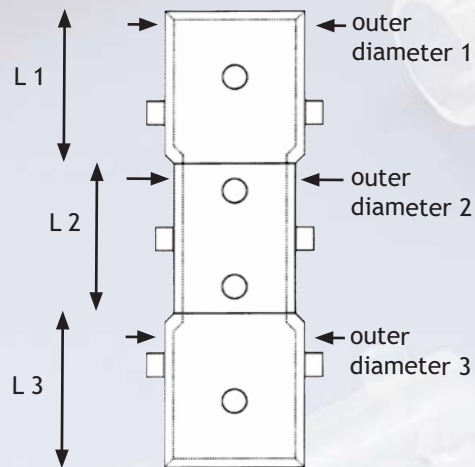
- complex benign stenoses
- post intubation stenoses
- post tracheostomy stenoses
- subglottic stenoses (custom made)

Easy to place after laser resection or dilatation, this stent is designed to avoid the risk of migration inherent to compression development. No migration was observed in a study covering a follow-up period of two years.¹⁾

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

With a mean duration of 19,6 months a curative effect has been observed in 4 from 13 patients.¹⁾

In some cases, this stent can prevent a tracheostomy.



Features

- Anti-migration stud system
- The ends of the stents are specially beveled to improve mucocilar clearance while helping to prevent crusting and granulation tissue from forming.
- Non-adherent smooth surface
- Easily removable in case of necessity
- Implant grade silicone

REF	outer diameter (mm)			L1	L2	L3
	1	2	3			
09011	16	14	16	15	20	15
09031	14	12	14			
09041	12	10	12			
09051	15	13	15			
Please add „R” for a radiopaque and „S” for a sterile prosthesis.						
The lengths and diameters can be modified in any manner, even to obtain a completely asymmetric prosthesis. Please contact us for custom orders.						

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

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 NOVATECH's TRACHEOBRONXANE® Dumon® tracheobronchial stents through a rigid bronchoscope.

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 preventing stent damage.



TONN/NOVATECH Stent Applicator	Introducer length (cm)	Introducer OD (mm)	to be used for the original Dumon® Stents...		REF
BLUE	32	12.75	∅ 14 - 20 mm	max. length 110 mm	02 BRS B 120
RED	42	12.75	∅ 14 - 20 mm	max. length 110 mm	02 BRS R 130
GREEN	42	10.25	∅ 11 - 13 mm	max. length 110 mm	02 BRS G 140
WHITE	42	8.2	∅ 9 - 12 mm	max. length 60 mm	02 BRS W 150

Individual components available as spare parts. Please contact us for a quotation.

TONN/NOVATECH TRACHEAL AND BRONCHIAL STENT APPLICATOR



1



2



3



4



5



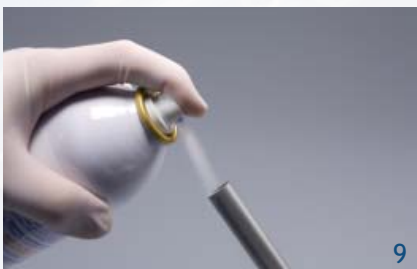
6



7



8



9



10



11



12



13



14



15

Place the basic block onto the folding system and lubricate generously (1) with NOVATECH's Silik'on4. **Lubrication is essential in order to facilitate placement and to avoid stent damage.** Lubricate the stent, too (2).

Position the stent centrally on the folding system (3). Insert the clamping rod by inserting its end into the provided hole in the basic block (on the side with the NOVATECH logo). Fold the stent by pushing down the clamping rod (4). Block the clamping rod in the basic block by rotating the rod one quarter.

Close the folding system ensuring that the stent is pushed inside completely (5). Lock the folding system, pushing the slider with the coloured button first to the right side, then to the left. The folding system must be closed completely (6).

Remove the clamping rod together with the folding system by rotating the rod one quarter. Pull the clamping rod out of the folding system (8). Note: In case of a lack of lubrication the stent might come out along with the clamping rod. In this case, simply start the procedure from the beginning.

Lubricate the inside of the introducer tube generously (9). Insert the introducer tube into the folding system (see mark on the folding system, 10).

By assuring that the NOVATECH logo is on top of the introducer tube (11), you can identify the position of the stent at any time. This is especially beneficial when Y-stents are placed (see „Placement of Y-stents“). Insert the loading rod into the folding system (see mark on the folding system, 12). Hold the folding system with the inserted introducer tube and loading rod in a vertical position.

Apply light pressure to the loading rod, carefully pushing the stent inside the tube (13). The loading rod cannot be pushed beyond the security point (14). Withdraw the introducer tube from the folding system. The stent is positioned inside the introducer tube (15).



16



17



18

Introduce the pusher into the proximal end of the introducer tube (Y-stents and stents with diameters 18 and 20 mm). The graduation on the pusher indicates the exact length of the stent inside the introducer tube (16). By applying pressure onto the pusher, the stent is easily released (17, 18) through a STORZ bronchoscope.

PLACEMENT OF Y-STENTS



19



20



21



22



23



24

The position of the main branches can be checked before placement and the risk of damaging such a stent is minimised. Lubricate the applicator system as described above. Place the Y-stent in the folding system with its right branch on the upper side of the folding system (19). Fold the stent with the help of the clamping rod (20) as described above. Close the folding system locking the stent inside (21). Important: Ensure that the NOVATECH logo is on top when inserting the introducer tube (22). This ensures that the right branch of the stent will be placed on the right hand side of the logo and will therefore be inserted in the main right bronchus (23, 24). Keeping the NOVATECH logo on top assures correct placement of the stent within the trachea before placing it in the main carina. This result is obtained with all Y-stents and tracheal stents with diameters of 18 and 20 as those stents have no studs on the posterior part. The red TONN/NOVATECH system enables the user to place large Y-stents.

CLEANING, STERILIZATION

Remove contaminants with a sponge or a soft brush. Following this, rinse out thoroughly with completely demineralized water and dry with sterile compressed air.

The instruments can be steam, gas or plasma sterilized, or immersed in solution at temperatures of up to 134°C. The instructions for use provided by the sterilization device manufacturer must be followed exactly.

CONTRAINDICATIONS

For **contraindications** as regards use of the original Dumon® stents, refer to the instructions for use. There are currently no known contraindications which relate directly to the use of the stent applicator sets. Use of the instrument is contraindicated if, in the opinion of an experienced physician, such use would put the patient at risk.

For safety reasons, modification of the device is NOT permitted. Novatech declines any responsibility for modified devices.

This applicator system can only be used for placement of original Dumon® stents.

APPLICATION, STORAGE CONDITIONS

	temperature	rel. humidity
storage	-20°C ... +60°C	10% ... 90%
application	+10°C ... +40°C	30% ... 70%



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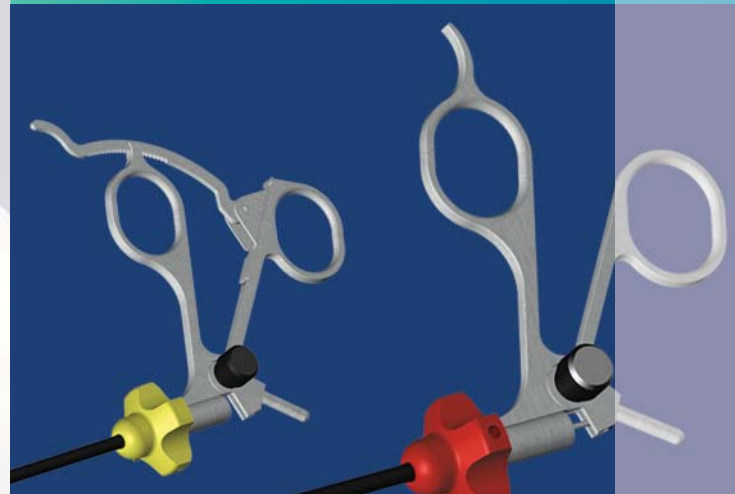
DUMON® FORCEPS FOR BRONCHOSCOPY

NOVATECH presents the new and innovative product line of forceps for bronchoscopy, developed in cooperation with Dr. Dumon and DB2C. The forceps can be disassembled completely and thus be cleaned safely and easily.

The handles have been ergonomically redesigned in order to facilitate handling. The ratchet is easy to manipulate with the little finger.

The forceps are color coded (i.e. yellow for open works forceps).

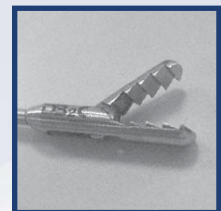
Complementing this line, the innovative stent dilator provides safe means of opening not fully deployed Tracheobronxane® Dumon® silicone stents.



Description	Color	Dimensions	RD*1	with ratchet	HF*2	extra-features	REF
Open work forceps	yellow	Head 3 mm, L 60 cm	X				02 BRO 01010
		Head 2 mm, L 40 cm				paediatric	02 BRO 01011
		Head 3 mm, L 60 cm	X	X			02 BRO 01012
Crocodile jaws grasping forceps	blue	Head 3 mm, L 60 cm					02 BRO 01050
		Head 2 mm, L 40 cm				paediatric	02 BRO 01051
Foreign body forceps	blue	Head 3 mm, L 60 cm	X	X			02 BRO 01052
		Head 3 mm, L 60 cm	X			2 mobile jaws	02 BRO 01060
		Head 3 mm, L 60 cm	X	X			2 mobile jaws
Blade hook scissors	red	Head 3 mm, L 60 cm	X		X		02 BRO 01100C
		Head 2 mm, L 40 cm				paediatric	02 BRO 01101
		Head 3 mm, L 40 cm	X		X	1 mobile smooth jaw	02 BRO 01103C
Biopsy forceps	red	Head 3 mm, L 60 cm	X		X	2 mobile smooth jaws	02 BRO 01150C
	grey	Head 2 mm, L 40 cm				1 mobile jaw, paediatric	02 BRO 01151
Extra strong crocodile forceps to remove Dumon® stents	green	Head 5 mm	X			1 mobile prehensile jaw	02 BRO 02050
		Head 5 mm	X	X		1 mobile prehensile jaw	02 BRO 02052
Y stent placement forceps	green	Head 4.5 mm, L 60 cm		X		2 mobile jaws	02 BRO 02252
		Head 4.5 mm, L 40 cm		X		2 mobile jaws	02 BRO 02254
ACCESSORIES							
Dumon® Bronchoscopy resectoscope	blue						02 BRO 01030
Scythe blade knife		3 mm - L 60 cm				red handle	02 BRO 01020
Suction canula		2.5 mm					02 BRO 01040
Angular tip Laser fibre guide							02 BRO 02040
NEW							
Stent dilator							02 BRO 02020
*1RD = rotatory and dismantable							
*2HF = High Frequency, coagulant forceps, with electrode							



open works forceps



crocodile jaws grasping forceps



stent placement forceps



blade hook scissors

TRACHEOBRONXANE® SILMET®

NOVATECH *New Biotechnology for Life*, manufacturer of TRACHEOBRONXANE® DUMON® silicone stents, which are considered the standard stents for treating tracheo-bronchial stenoses, introduces TRACHEOBRONXANE® SILMET®, a new stent concept, ideally complementing the Dumon® Stents for cases in which silicone stents are not indicated.

Silmet® is a self-expandable stent made of nitinol. Due to the special mesh structure together with the silicone covered nitinol wire, the stent is highly resistant to compression.

For improved intraoperative visualization, Silmet® has radiopaque gold markers.

Two versions are available: covered and non-covered.

Silmet® comes sterile in a large variety of sizes. Custom stents are available.



THE DIFFERENT TYPES OF STENTS

Silmet® MCS - Metallic Covered Symmetric
Silmet® MNC - Metallic Non-Covered
Silmet® SM - Metallic Customized Stent

FEATURES

- self-expandable
- highly resistant to compression
- covered or non-covered
- sterile
- large variety of sizes available
- custom stents available

CUSTOM STENTS (SILMET® SM)

Size

- individual stent length
- tapered and hourglass shape stents available

Cover

- individual length and place of cover (asymmetric cover available)
- stents with two different covers
- fully covered stents

Mesh

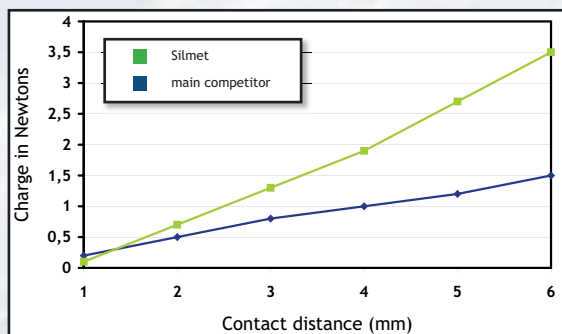
- mesh length extendable (normal length = 5mm, extendable up to 10mm), for example for improved collateral ventilation

Laboratoire National d'Essais (France)

Report No B0900838/CQPE/1 of 26 October 2001

Contact distance (mm)	N° LNE	
	B090838/1 main competitor	B090838/2 Silmet
	Force (N)	
1	0.2	0.1
2	0.5	0.7
3	0.8	1.3
4	1.0	1.9
5	1.2	2.7
6	1.5	3.5

The results obtained depending on the distance between the two compression plates show a better resistance of the NOVATECH product (Silmet®) than the other evaluated product (main competitor).¹⁾



¹⁾ LNE, Laboratoire National d'Essais, Rapport n° B0900838/CQPE/1 du 26 octobre 2001

TRACHEOBRONXANE® Silmet® inside its placement system. The blue ring facilitates proximal location during placement.

MCS - METALLIC COVERED STENT



Silmet® MCS is the standard stent if a silicone stent cannot be used.

The Polyester cover prevents tumor ingrowth. Even in case of benign stenoses NOVATECH strongly recommends placing Silmet® MCS which is easy to remove due to its cover.

NOVATECH offers a large choice of diameters and cover lengths. TRACHEOBRONXANE® Silmet® MCS is available with diameters between 6 and 26 mm in 1 mm increments. The standard mesh length is 5 mm and the cover leaves 5 mm of mesh at each end of the stent uncovered.

MNC - METALLIC NON-COVERED



Like Silmet® MCS, the standard mesh length is 5 mm.

TRACHEOBRONXANE® Silmet® MNC is available in diameters between 6 and 26 mm in 1 mm increments, and in lengths of 10 to 140 mm in 5 mm increments.

SM - METALLIC CUSTOMIZED STENT*

Specific indications may require custom made stents. Tracheobronxane® Silmet® SM can be customized in various manners: Size, Cover and Mesh may be adapted.

This can be an advantage in cases when previously two different stents (one covered, one uncovered) were necessary. Now, one single Silmet® SM can be placed, which could have one or several covers according to physicians specifications.

All customized Silmet® stents may be uncovered, or have one or more covers or may even be covered completely (ILL. 1 and 2). A complete cover minimizes as much as possible the risk of tumor ingrowth.



ILL. 1

Customization: A straight stent, completely covered

Silmet® SM may also come with several different diameters in order to give the stent a tapered (ILL. 3) or hourglass shape.

Seeking the best possible collateral ventilation, Silmet SM can come with a mesh size of 5 mm (standard) or 10mm for increased ventilation and a reduced risk of mucous accumulation.



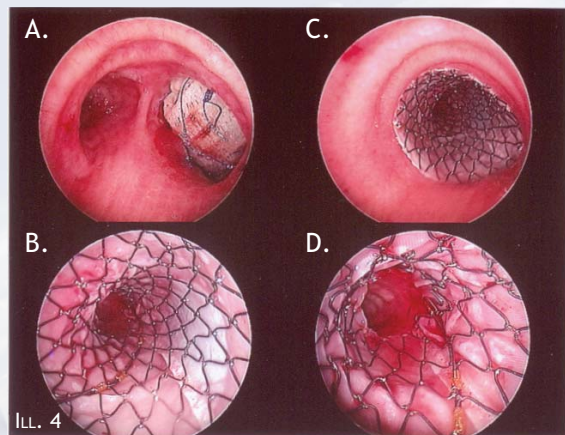
ILL. 2

Customization: A tapered stent, completely covered

Please contact us for a special order form for Tracheobronxane® Silmet® SM.



ILL. 3: Tapered Silmet® SM with three different diameters, covered



by courtesy of Dr. DUTAU, Ste. Marguerite, Marseilles
The stent from ILL. 2 in situ.

A.: Before stent placement. A hole created by suture release after pneumonectomy (speleotomy). In the hole, compresses are visible.
- B. to D.: After stent placement. The hole is sealed. The white spot on the right side of B. shows where the compresses are.

STERITALC®

Large Particle Size Talc for internal use

Indications

- chronic pleuritis, principally malignant
- spontaneous pneumothorax

According to the literature, talc is more efficient than Bleomycine and cyclines¹⁾. It appears that talc is the best sclerosis product available and can be used even after the application of other agents has failed.

Features

- produced for medical purposes only (talcum pleurodesis)
- guaranteed asbestos free
- sterile
- free of endotoxines
- graded talc perfectly controlled granulometry avoiding any migration as shown by Pr ASTOUL et al.²⁾, Marseilles, France
- suitable for all pleurodesis indications, it is non-soluble and induces permanent pleurodesis
- compared with Cyclines, STERITALC® is more effective and less painful. Any pain occurring can be reduced according to doctor's decision, for example by using Xylocaine 1% in the pleura or in the slurry.
- complies with the regulations of the European Pharmacopoeia (3rd edition): STERITALC® is a pharmaceutical talc of a lamellar structure which is stable and inert physically, chemically and biologically.

REF	Description
16833	STERITALC® sterile, 3g of STERITALC® per spray 1 spray/pouch, 2 pouches/box Including one canula per pouch
16843	Extra-long canula (24/box) <i>fits only with 16833</i>
16903	STERITALC® F2 sterile, 2g of STERITALC® in a vial 1 vial / pouch, 24 pouches / carton
16913	STERITALC® F4 sterile, 4 g of STERITALC® in a vial 1 vial / pouch, 24 pouches / carton
16853	STERITALC® PF4, 4g, including Luer-Lock-Connector (4/box)



The dose varies from 3 to 6 grams for malignant pleural effusion and generally does not exceed 2g for spontaneous pneumothorax. Individual doses according to physician's decision. STERITALC® comes in three pharmaceutical forms allowing different ways of application:

• Vial F2, F4

For physicians preferring to use talc in bulk, a line of talc in vials is available, which can be used for slurry as well as talc poudrage.

• Spray (Aerosol)

One box contains two pouches each containing one ready to use 3g STERITALC® aerosol and one canula. To be used for talc poudrage procedures.

• Spray PF4

Safe handling and storage. Unlike the Spray (Aerosol), STERITALC® PF4's propellant is air. For this reason it is not considered an IATA dangerous good.

Pulverisation at room temperature: No risk of hypothermia or local necrosis due to extremely low gas release temperature.

Can be used for talc poudrage or slurry.

¹⁾ Cf. reverse page for a bibliography.

²⁾ Fraticelli, CHEST 2002; 122:1737-1741

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PLEURA CONCEPT SINGLE USE TROCARTS

For pleura biopsies and pleural punctions

NOVATECH has launched a Pleura Concept with Professor C. Boutin (Marseilles, France) in 1998. He redesigned the existing Trocart to improve the quality of sampling. The three-sided mandrel and the improved shape of the hook of the 3 mm Trocart give this device a sampling quality higher than with the Abrams needle¹⁾.

The single use Boutin Trocarts have a working length of 78 mm. They come sterile and are available in two diameters (2 and 3 mm).

- 3 mm: for biopsies and pleural puncture
- 2 mm: for pleural puncture only

trocart material: stainless steel
stopcock material: PEHD and polycarbonate



Boutin Trocart 3 mm: for biopsies and pleural punctions, with lateral hook and two mandrels: blunt and sharp.



Boutin Trocart 2 mm: for pleural puncture only, with lateral orifice and two mandrels: blunt and sharp.

Features

- single use, minimizing risk of contamination
- sterile (gamma-rays)
- less traumatic due to diameters adapted to intended use
- comes with both sharp and blunt mandrel in order to avoid damage to the pulmonary parenchyma
- equipped with a three-way stopcock eliminating the risk of air entering the pleura

REF	Description	items per box
58023	Disposable Boutin Trocart for pleural puncture 2 mm, with two mandrels	12
58033	Disposable Boutin Trocart for pleura biopsy 3 mm, with two mandrels	12

* Study by Pr. Boutin - H. La Conception de Marseille - presentation : CHEST/Toronto/1998

Single Use Product. Do not resterilize.

EWS

Endobronchial Watanabe Spigots

TRACHEOBRONXANE® Endobronchial Watanabe Spigots (EWS) were developed by NOVATECH in close cooperation with Dr. Y. WATANABE, Okayama, Japan. They are made of implant-grade, radiopaque silicone.

Indications

for re-expansion of the lung in case of

- inoperable pneumothorax
- bronchio-pleural fistula

with a continuous loss of air and collapse of the lung despite thoracic suction drain, when surgical intervention is not indicated.

A study¹⁾ performed in Japan with 63 patients including 40 cases of intractable pneumothorax, 12 cases of pyothorax with fistula and 7 cases of pulmonary fistula has shown that using EWS is safer and has more permanent results than conventional methods. After determination of the affected bronchi with a balloon catheter (alternatively X-ray etc.), the EWS are placed with a flexible bronchoscope and forceps guided by the working tube of the bronchoscope. The use of EWS was successful in 96.7% of the cases. The loss of air was stopped or significantly reduced in 77.6% of the cases. No severe complications occurred.

Aftercare

- If the use of EWS alone does not improve the patients' condition, pleurodesis (for example using Steritalc®) or other therapy can follow after the collapsed lung has reexpanded and the loss of air is stopped.
- The spigots can be removed after the clinical condition has improved and the thoracic drain is removed.




Three Sizes available

- S = Ø 5 mm
- M = Ø 6 mm
- L = Ø 7 mm

REF	Endobronchial Watanabe Spigots, unsterile
165661	EWS, 12 pcs. sizes: 3xS / 6xM / 3xL
165671 [size]	EWS, 6 pcs, same size
165681	EWS, 12 pcs., sizes according to customers' specification

¹⁾ Dr. Y. Watanabe, *Journal of Bronchology*, 2003

 Read instructions prior to use of the product.

SILIK'ON 4®

SILICONE AEROSOL

NOVATECH is a specialist manufacturer of various types of silicone products.

SILIK'ON 4 lubricates and protects medical devices.

It facilitates instrument insertion and cleaning of aspiration bottles.

SILIK'ON 4 is a medical grade silicone oil which is chemically pure and inert. It contains an environmentally non-hazardous propellant¹. SILIK'ON 4 is perfectly suited for the lubrication of TRACHEOBRONXANE® DUMON® silicone stents and the TONN/NOVATECH placement kit.

SILIK'ON 4 is not sterile but the oil is protected from contamination due to its package. It is necessary to control storage conditions of the product and to keep the cap in order to prevent nozzle contamination.

- latex-free
- non-sterile
- shelf life: 3 years

Operating Instructions:

- Shake before use
- Briefly spray, approx. 25 cm away from the surface to be lubricated.
- Do not push on the nozzle continuously.
- Read carefully the security instructions written on the package.

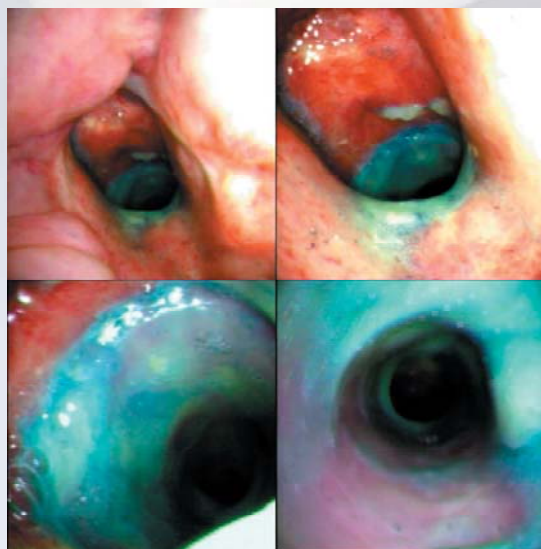


REF	Description	items per box
682010	Silik'on 4 bottle of 400 ml	12

¹ Silik'on 4 is made of a propellant protecting the ozone layer, in compliance with the 1989 Copenhagen Agreement.

HYDROSALINE®

NOVATECH New Biotechnology for Life has created HYDROSALINE® to enhance the mucociliary clearance of the bronchial tree. This product is particularly adapted to patients for whom it is advisable to regularly moisturise the mucous after a stent placement. The physician has to make a prescription to the patient and determine how many times the product must be used. The dose usually advised is one to two sprayings two times a day during one month (see notice). This can be adapted according to the production of secretions. HYDROSALINE® is equipped with a special nozzle which delivers 5 to 6 µm drops, allowing a very good moisturisation of the bronchial tree.



HYDROSALINE® is ideal to complete the traditional spray sessions where a big equipment is necessary and cannot be easily carried. HYDROSALINE® can also be efficiently used for all cases where the upper respiratory tract has to be moisturised. HYDROSALINE® is available as an aerosol and can be easily carried even when travelling. The use of HYDROSALINE® after a stent placement limits the risks of obstruction. Methylene blue tests have been performed on patients with stent. After a flexible bronchoscopy it has been shown that the drops of HYDROSALINE® were sprayed even in the main stem bronchi.

Reference	Designation	Packing
17003	HYDROSALINE® - Moisturiser for the upper respiratory tract	12

DERMOTRACE® SKIN MARKER

DERMOTRACE® is a sterile skin marker with two nylon points, fine and medium, for surgical use.

Facilitating the surgeon's work, the DERMOTRACE® skin marker comes in a set with a ruler.

Apply the marker to dry skin only.

Ink can be easily erased with alcoholic solution (ethylic and isopropyl alcohol), for example Hibitane®, Hibiscrub®, Betadine®.

Ink composition:

- Methyl violet
- Cremophor RH 40
- Transcutol CG
- Osmotic water



DERMOTRACE® has specific advantages :

- Perfect ink resistance against soap and water
- Good visibility with most skin types
- Easy drawing even in angles and wrinkles thanks to the fine tip
- Medical grade ink, nontoxic
- Sterile (gamma-rays)

Reference	Description	Items per box
18996	Dermotrace® Marker comes sterile together with a ruler	36

bess DENTAL PROTECTION

Protects the teeth against excessive instrument pressure

Features

- anatomic design offering the dental arch maximum protection against excessive instrument pressure
- made of medical grade silicone
- multiple use product (comes unsterile)
- highly resistant to heat
- hygienically sound cleaning by gas, plasma or steam sterilization (134°C)
- can be sterilized together with instruments on the instrument tray and will thus be directly available as part of the tray



REF	Description	items per box
bess ZS-1/10	bess Dental Protection	10
bess ZS-1/50	bess Dental Protection	50



Manufacturer:



bess pro gmbh
14167 Berlin, Germany

Distributor:



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