Patient Information Document

NO136PI-2 — 2026-05

EN

TRACHEOBRONXANE DUMON

Tracheo-bronchial Silicone Stent

MR

NOVATECH SA

Société anonyme au capital de
160.000€
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TVA CEE FR59398941260
Certifiée selon EN ISO 13485

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1 Dear Patient,

You have been given an implant of the type TRACHEOBRONXANE DUMON. For your own safety, please read this Patient Information Document carefully and keep it somewhere safe. If you have any questions about your implant, please contact the physician who treats you.

2 About this Document

2.1 Symbols Glossary

Symbol	Description
MR	MR safe
REF	Catalog number
LOT	Batch code
UDI	Unique Device Identification (UDI)
	Manufacturer
	Patient name
31	Date of implantation
	Name of the implanting healthcare institution / provider
	Patient information website

Table 1: Symbols Glossary

2.2 Safety Information Marking

WARNING

Non-compliance may result in serious injuries, serious deterioration of your general condition or your death.

2.3 Additional Information

Download link for the Patient Information Document:[1]	www.novatech.fr/pi/no136pi
This patient information is based on the following instructions for use:	NO136-3 (2026-05)
Disclaimer for the availability of the SSCP	As a general rule: The SSCP will only be made available after the product has been authorised in accordance with REGULATION (EU) 2017/745 (MDR). The implementation described here does not apply until the corresponding module of the Eudamed database comes into force. Until then, the SSCP is available at the following download link: www.novatech.fr/sscp/sscp136
Summary of Safety and Clinical Performance (SSCP): [1]	https://ec.europa.eu/tools/eudamed To search for the product-specific SSCP, enter the basic UDI-DI of the product.
Basic UDI-DI (device identifier):	4063108SSTC9

[1] Updated on an ongoing basis. Other language versions are also available there.

For the complete UDI (UDI-PI) please refer to the product label.

The catalog number and batch code for your implant can be found on your implant card.

3 What you need to pay attention to

1. Always carry your implant card with you. Show your implant card and this Patient Information Document to your treating physician before undergoing diagnostic or therapeutic procedures.
2. To prevent any encrustation, perform regular damp inhalations with saline.
3. Contact your doctor if you experience one or more of the following symptoms: Foreign body sensation, halitosis (bad breath), bleeding, coughing
4. Stick to the appointments you make with your treating physician for follow-up examinations and observe their instructions for any necessary follow-up measures.

ATTENTION: Your TRACHEOBRONXANE DUMON must be monitored regularly by your attending physician. Be sure to keep your appointments for these follow-up examinations and follow your physician's advice on the necessary aftercare measures. This is especially true when the intended lifetime of your TRACHEOBRONXANE DUMON has been reached ([Expected Lifetime, page 3]).

4 Product Description

4.1 General

- Tracheo-bronchial stent made of silicone
- Clear / radiopaque (depending on specifications)
- 2, 3 or 4 rows of studs made of clear or radiopaque silicone (depending on specification)

For specifications please refer to the implant card.

4.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
TRACHEOBRONXANE DUMON (clear)	100% implant-grade silicone	Patient	With every use
TRACHEOBRONXANE DUMON (radiopaque)	100% blend of implant-grade silicone and barium sulphate	Patient	With every use

5 Intended Use

5.1 Intended Purpose

The product is intended for use in the trachea and /or bronchus to keep the airway open.
The product is for long-term use.

5.2 Patient Target Group

The product is suitable for use in the following patient groups:

- Infants and young children
- Children and youth
- Adults
- Patients of any gender

5.3 Expected Lifetime

Expected lifetime of the product: 12 months
Unless an earlier replacement is needed, it is recommended to replace the product after 12 months as a precautionary measure.

6 Possible Complications and Side Effects

- Perforations
- Stent migration
- Foreign body sensation
- Bleeding
- Ingrowth of / overgrowth with tissue
- Secretion obstruction
- Formation of granulation tissue
- Ulceration of the tracheal or bronchial wall
- Restenosis due to progressive tumor growth

- Infection
- Halitosis
- Coughing

7 Combining with Other Procedures

⚠ WARNING

- Laser therapy, argon plasma coagulation, high-frequency surgery, and other procedures, the effect of which is due to heat: Do not use those methods directly on the product.
  Otherwise, injury to the tissue and product damage are possible.
- Do not use an endotracheal tube with a cuff to ventilate patients wearing a product of type TRACHEOBRONXANE DUMON.
  Otherwise, there is a risk of stent dislocation. This could pose a risk of suffocation for your patient.

Any method for reducing tissue, such as chemotherapy or radiation therapy, can lead to stent migration.
The product is MRI safe.

8 Other Residual Risks

Beyond the listed safety instructions, possible complications and side effects, no further significant residual risks are known.

9 Follow-up measures after removal of the product

An endoscopic check-up is required 7 days after stent removal.
In addition, the following applies:
The follow-up measures after removal of the product will depend on your underlying disease as well as your general health and shall be at the discretion of your treating physician.

10 Specifications

Not all products are available in all markets.

	REF	Ø [mm]	Length [mm]	REF	Ø [mm]	Length [mm]
	025301S20	5	20	026501S20	7	20
	025301S30	5	30	026501S30	7	30
	025301S40	5	40	026501S40	7	40
	025301S50	5	50	026501S50	7	50
	026201S20	6	20	026701S20	8	20
	026201S30	6	30	026701S30	8	30
	026201S40	6	40	026701S40	8	40
	026201S50	6	50	026701S50	8	50

Table 2: TRACHEOBRONXANE DUMON BB (radiopaque *)*

	REF		Ø [mm]	Length [mm]	REF		Ø [mm]	Length [mm]
	Clear	Radiopaque			Clear	Radiopaque		
	03001S	03001RS	11	20	03531S	03531RS	15	30
	03021S	03021RS	11	30	03541S	03541RS	15	40
	03041S	03041RS	11	40	03551S	03551RS	15	50
	03061S	03061RS	11	50	03561S	03561RS	15	60
	03081S	03081RS	11	60	03571S	03571RS	15	70
	03101S	03101RS	11	70	03581S	03581RS	15	80
	03121S	03121RS	12	20	03591S	03591RS	15	90
	03141S	03141RS	12	30	03491S	03491RS	15	100
	03161S	03161RS	12	40	03501S	03501RS	15	110
	03181S	03181RS	12	50	03621S	03621RS	16	30
	03201S	03201RS	12	60	03641S	03641RS	16	40
	03221S	03221RS	12	70	03661S	03661RS	16	50
	03231S	03231RS	12	80	03681S	03681RS	16	60
	03261S	03261RS	13	30	03701S	03701RS	16	70
	03281S	03281RS	13	40	04281S	04281RS	16	80
	03301S	03301RS	13	50	04291S	04291RS	16	90
	03321S	03321RS	13	60	04301S	04301RS	16	100
	03341S	03341RS	13	70	04311S	04311RS	16	110
	03381S	03381RS	14	30	04141S	04141RS	18	40
	03401S	03401RS	14	40	04151S	04151RS	18	50
	03421S	03421RS	14	50				
	03441S	03441RS	14	60				
	03461S	03461RS	14	70				

Table 3: TRACHEOBRONXANE DUMON TD

	REF		Ø [mm]	Length [mm]	REF		Ø [mm]	Length [mm]
	Clear	Radiopaque			Clear	Radiopaque		
	03141FS	n.a.	12	30	04141FS	n.a.	18	40
	03161FS	n.a.	12	40	04151FS	n.a.	18	50
	03221FS	n.a.	12	70	04161FS	n.a.	18	60

	REF		Ø [mm]	Length [mm]	REF		Ø [mm]	Length [mm]
	Clear	Radiopaque			Clear	Radiopaque		
	03261FS	03261RFS	13	30	04171FS	n.a.	18	70
	03281FS	03281RFS	13	40	04181FS	n.a.	18	80
	03301FS	03301RFS	13	50	04191FS	n.a.	18	90
	03321FS	03321RFS	13	60	04201FS	n.a.	18	100
	03341FS	03341RFS	13	70	04231FS	n.a.	20	40
	03381FS	03381RFS	14	30	04241FS	n.a.	20	50
	03401FS	03401RFS	14	40	04251FS	n.a.	20	60
	03421FS	03421RFS	14	50	04261FS	n.a.	20	70
	03441FS	03441RFS	14	60	04271FS	n.a.	20	80
	03461FS	03461RFS	14	70	04431FS	n.a.	20	90
	03641FS	03641RFS	16	40	04441FS	n.a.	20	100
	03661FS	03661RFS	16	50	04451FS	n.a.	20	110
	03681FS	03681RFS	16	60				
	03701FS	03701RFS	16	70				
	04281FS	04281RFS	16	80				
	04291FS	04291RFS	16	90				
	04301FS	04301RFS	16	100				

Table 4: TRACHEOBRONXANE DUMON TF

	REF		Ø [mm]	Length [mm]	REF		Ø [mm]	Length [mm]
	Clear	Radiopaque			Clear	Radiopaque		
	02841S	02841RS	9	20	03841S	03841RS	11	20
	04341S	04341RS	9	30	03861S	03861RS	11	30
	04371S	04371RS	9	40	03881S	03881RS	11	40
	04391S	04391RS	9	50	03901S	03901RS	11	50
	04411S	04411RS	9	60	03921S	03921RS	11	60
	04421S	04421RS	9	70	03961S	03961RS	12	20
	03721S	03721RS	10	20	03981S	03981RS	12	30
	03741S	03741RS	10	30	04001S	04001RS	12	40
	03761S	03761RS	10	40	04021S	04021RS	12	50
	03781S	03781RS	10	50	04041S	04041RS	12	60
	03801S	03801RS	10	60	04051S	04051RS	12	70
	03821S	03821RS	10	70				

Table 5: TRACHEOBRONXANE DUMON BD

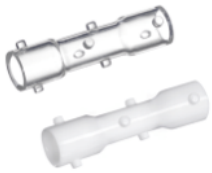
	REF		Ø [mm]	Length [mm]
	Clear	Radiopaque		
	09041S	09041RS	12 – 10 - 12	15 – 20 - 15
	09031S	09031RS	14 -12 - 14	15 – 20 - 15
	09051S	09051RS	15 – 13 - 15	15 – 20 - 15
	09011S	09011RS	16 – 14 - 16	15 – 20 - 15
	09061S	09061RS	18 – 16 - 18	15 – 20 - 15

Table 6: TRACHEOBRONXANE DUMON ST

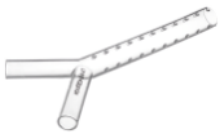
	REF Clear	Ø [mm]	Length [mm]
	091011S	14 – 10 - 10	110 – 50 - 50
	092011S	15 – 12 - 12	110 – 50 - 50
	093011S	16 – 13 - 13	110 – 50 - 50
	094011S	18 – 14 - 14	110 – 50 - 50

Table 7: TRACHEOBRONXANE DUMON Y