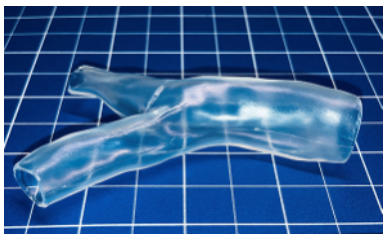
Patient Information Document

NO133PI-3 — 2024-03

EN



NOVATECH® 3D

Tracheo-bronchial silicone stent

Custom-made device

MR

NOVATECH SA

Société anonyme au capital de
160.000€
398 941 260 RCS Marseille
TVA CEE FR59398941260
Certifiée selon EN ISO 13485

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
www.novatech.fr

Novatech
new biotechnology for life

63050395255038091 —03.04.2024 10:25

1 Dear Patient,

You have been given an implant of the type NOVATECH 3D (custom-made device). 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 safe
	Catalog number
	Batch code
	Manufacturer
	Patient name
	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/NO133PI
This patient information is based on the following instructions for use:	NO133-4 (2024-03)

[1)] Updated on an ongoing basis.

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
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.

4 Product Description

4.1 General

- Tracheo-bronchial stent made of silicone
- Transparent
- Outer surface of the stent: (depending on specifications):
  - Without studs
  - Silicone studs (solid)
  - Studs filled with silicone and barium sulfate (x-ray markers)

4.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
Stent	100% implant-grade silicone	Patient	With every use
Filling of the studs	100% blend of implant-grade silicone and barium sulphate	Patient	In the event of product damage

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 the following patient groups:

- Children and youth
- Adults
- Patients of all genders

Custom-made device. The suitability of the product for the patient must be checked and confirmed by the prescribing physician/facility.

5.3 Expected Lifetime

Unless an earlier replacement is needed, it is recommended to replace the product after 12 months as a precautionary measure.
ATTENTION: The expected lifetime is the time that the manufacturer expects the product to be safe and perform its function. The actual application duration may deviate from this and is at the discretion of your attending physician.

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

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.

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

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.