Patient Information Document

NO0108PI-3 — 2021-11

EN

NOVATECH® GSS™

Tracheo-bronchial stent made of silicone

MR CE 0297

NOVATECH SA

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160.000€
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1 Dear Patient,

You have been given an implant of the type NOVATECH GSS. 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 conditional
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Manufacturer
	Patient name
	Implantation date
	Name of facility through which the implantation was performed
	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.

3 What you must look out for

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.

ATTENTION: Your NOVATECH GSS 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 NOVATECH GSS has been reached ([▸Expected Lifetime, page 3]).

4 Product Description

4.1 General

- Tracheo-bronchial stent made of silicone
- Transparent
- 2, 3 or 4 rows of studs on the outside of the stent (depending on specification)
  - Of these, 1 row of studs filled with barium sulfate
  - At least 2 studs with gold inlay (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
Stent	100% implant-grade silicone	Patient	With every use
Stud filling	100% gold	Patient	In the event of product damage
Stud filling	100% 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 use in the following patient groups:

- Adults
- Patients of all genders

5.3 Expected Lifetime

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

6 Expected Clinical Benefit

According to the clinical evaluation, the product can be used easily and safely for treatment according to the indications mentioned.

7 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

Special caution recommended in the following cases:

- Tracheostome (increased risk of obstruction)
- Tracheomalacia
- Compression by aneurysm

8 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.
- The product is MRI conditional. Use the product in MRI fields only as per specification.
  Possible consequences of using the product in MRI fields outside the specifications include: Heating of the product, electromagnetic discharges, consequential damages caused by the application of force to the product, errors in the imaging (also in the surrounding tissue)

For important information about MRI see:
http://www.novatech.fr/gss
Any method for reducing tissue, such as chemotherapy or radiation therapy, can lead to stent migration.

9 Other Residual Risks

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

10 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.

11 Additional Information

Download link for the Patient Information Document:[1)]	www.novatech.fr/pi/no108pi
Summary of Safety and Clinical Performance (SSCP): [1) 2)]	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.

[2)] Is only available with the entry into force of the EUDAMED database.

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

For Australia:

ATTENTION: In case that any serious incident has occurred in relation to the device the incident should be reported to the manufacturer and to the competent authority of the Member State in which you live.

https://www.tga.gov.au/