Patient Information Document

NO0121PI-1 — 2022-02

EN

STERITALC® PF3
STERITALC® F2/F4

Sterile Talc

MR CE 0297

NOVATECH SA

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472469259 —22.02.2022 14:14

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1 Dear Patient,

You have been given an implant of the type STERITALC. 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
	Unique Device Identification (UDI)
	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.

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. Contact your doctor if you experience one or more of the following symptoms: Chest pain, fever, increasing difficulty breathing, cardiovascular problems
3. 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 information

STERITALC is a sterile talc with a controlled particle size. STERITALC is either brought into the pleural cavity as a powder with the help of a flexible cannula and a powder blower or it is injected into the pleural cavity as a suspension.

4.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
Talc	100% Talc	Patient	With every use
Cannula (with STERITALC PF3 only)	100% Polyethylene	Patient	With every use (only during the procedure)

5 Intended use

5.1 Intended Purpose

STERITALC is an insoluble mineral powder, which is applied to the pleural cavity to cause permanent pleurodesis.

Application as slurry or poudrage.

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

The concept of product life time is not applicable here: The product triggers an inflammatory reaction which leads to the desired effect. The further presence of the product is not relevant for the persistence of the desired effect. The persistence of the effect depends on factors not related to the product, such as progress of the disease.
The product is intended to remain in the body.

6 Expected Clinical Benefit

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

7 Possible Complications and Side Effects

The following product-related complications are known:

- Fever
- Infection (empyema, wound infection)
- Respiratory complications (respiratory insufficiency, pulmonary oedema, pneumonia, dyspnoea)
- Cardiovascular complications (dysrhythmia, myocardial infarction, hypotension, hypovolaemia)
- Complications related to the intervention (local bleeding, subcutaneous emphysema)

STERITALC has controlled particle size to minimize the risk of acute pneumonitis or ARDS (Acute Respiratory Distress Syndrome).

8 Combining with Other Procedures

The product is MRI safe.
Talc administration induces an inflammatory reaction. The inflammatory reaction activates the coagulation cascade, which leads to permanent pleurodesis. Do not give any anti-inflammatory medication before or after administering talc, because this may hinder the success of the treatment. Interferences with laboratory tests are possible.
False positive diagnoses are possible in Positron Emission Tomography (PET) and Computer Tomography (CT) exams (long lasting effect).

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 product is intended to remain in the body.

11 Additional Information

Download link for the Patient Information Document:[1)]	www.novatech.fr/pi/no121pi
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):	4063108STEBE

[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.