Instructions for Use
NO123-4 — 2022-03
EN

STERITALC® F2/F4

Sterile talc (vial)

NOVATECH SA

Société anonyme au capital de
160.000€
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1 About these Instructions for Use

1.1 Symbols Glossary

Symbol	Description
	Caution: Consult Instructions for Use
	Do not use if package is damaged
	Keep away from direct sunlight
	Keep dry
	Use-by date
	Sterilized using irradiation
	Do not re-use
	Do not resterilize
	Single sterile barrier system with protective packaging inside
	MR safe
	Medical device
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Quantity per packaging unit
	Manufacturer
	Date of manufacture
	Consult Instructions for Use. The Instructions for Use are provided in electronic form (e-labelling).
	Patient name
	Date of implantation
	Name of the implanting healthcare institution / provider
	Patient information website

Table 1: Symbols Glossary

1.2 Safety Information Marking

⚠ WARNING

Non-compliance may result in serious injuries, serious deterioration of the general condition or the death of the patient, user, or a third party.

1.3 Additional Information

Download link for these Instructions for Use:[1)]	www.novatech.fr/ifu/no123
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
Disclaimer for the availability of the SSCP	The implementation described here applies only with the entry into force of the EUDAMED database.

[1] Updated on an ongoing basis.

2 Important Safety Information

⚠ WARNING

- Before using the product, read the Instructions for Use. Adhere to and save the Instructions for Use.
  Otherwise there are risks to the health of your patient.

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 the user and/or patient is established.

3 Product Codes / REF

[Scope of Delivery, page 4]

4 Scope of Delivery

Article number	Name	Quantity of talc per vial	Packaging unit
16903	STERITALC F2	2 g	4
16913	STERITALC F4	4 g	4

- 1 x implant card

Product sterile, individually packaged, in blister pack.

5 Product Description

5.1 General information

Sterile talc with controlled particle size.

5.2 Structure and Operation

The product is applied to the pleural cavity where it causes an inflammation which leads to a permanent pleurodesis, thus counteracting the collaps of the lung.

5.3 Materials with Potential Patient Contact

The following table lists all materials of the implant with which the user or the patient has contact during use, either for every application ("standard") or in case of a damage to the product ("potentially").

Product (part)	Material	Contact person	Type of contact
Talc	100% Talc	Patient	Standard

Not made with natural rubber (latex).

No products made with natural rubber (latex) are used in the production process.

5.4 Other Devices to be Used in Combination with the Device

Apart from the equipment and materials required for implantation, the product STERITALC F2/F4 is not intended to be used in conjunction with any other products.

6 Intended use

6.1 Intended Purpose

STERITALC is an insoluble mineral powder, which is applied to the pleural cavity to cause permanent pleurodesis.
Application as slurry or poudrage.

6.2 Indications

- Malignant pleural effusion
- Pneumothorax

6.3 Contraindications

- After mechanical abrasion of the pleura

If a patient cannot undergo thoracoscopy, poudrage is contraindicated.
The use of the product must be carefully considered in case of patients in poor general health condition.

6.4 Patient Target Group

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

- Adults
- Patients of all genders

6.5 Intended User

The intended user is a physician with experience in treating similar cases with this product or with comparable products or a physician with the following speciality:

- Thoracic surgery

6.6 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.

6.7 Intended place of use

- Operating theatre

It is the responsibility of the user to decide on a case-by-case basis which precautions must be taken for any complications that may arise.

7 Expected Clinical Benefit

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

8 Possible Complications and Side Effects

The following product-related complications are known:

- Pain
- 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).

9 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).

10 Shelf Life and Storage

For date of expiry, see the product label.

11 Processing

⚠ WARNING

- Single use product: Do not process (e.g., clean, disinfect, sterilize), resterilize or reuse the product.
  This is the only way to ensure the product is germ-free and functional. Due to the mechanical properties of the product, processing or resterilization could lead to material degradation.

12 Application Instructions

⚠ WARNING

- Do not use the product if the packaging or the product is damaged or expired.
  This is the only way to ensure the product is germ-free and functional.
- Do not use the product if no further expansion of the lungs can be achieved.
  Otherwise the risks related to the treatment outweigh its benefits.

The goal is to achieve an even and complete spraying / wetting of the pleural cavity with the talc.
Ensure the presence of hygienic / sterile conditions needed for the intervention.

12.1 Dosage

The recommended dose is:

- 2 g to 5 g for pleural effusion
- 1 g to 2 g for spontaneous pneumothorax

By decision of the treating doctor and in consideration of the patient's general health condition, other doses may be administered.
Do not exceed a total dose of 10 g.

12.2 Required Equipment and Materials

As normal for pleurodesis.
Additionally for application by poudrage:

- Applicator suitable for poudrage

ATTENTION: Observe the applicator manufacturer's instructions for poudrage.
Additionally for application as a slurry:

- Lavage syringe, at least 50 ml
- Saline solution
- Thoracic drain

All in sterile condition.

12.3 Use as Poudrage

Perform intervention by means of a thoracoscopy.
Normally some talc will remain in the vial.

12.3.1 Product Preparation

1. Fully remove the flap and the top from the vial.
2. Fill the content into the applicator for poudrage.

Normally some talc will remain in the vial.

12.3.2 Product Use

⚠ WARNING

- Ensure that the air introduced into the pleural cavity during talc application can escape.
  Otherwise there is a risk of barotrauma.

1. Introduce the cannula into the trocar.
2. Distribute the talc evenly in the pleural cavity. To do this, carefully spray several times.
3. After spraying a few times, change the cannula direction.

12.4 Use as a Slurry

Application through a thoracic drain.

12.4.1 Product Preparation

Do not prepare the slurry in advance. Use the slurry immediately after preparation.

1. Remove the blue cap from the vial.

2. Fully bend or remove the flap into the direction of the arrow. The top can now be punctured to mix the slurry.

3. Use 10 ml of saline solution per 1 g of talc. If needed, add 1% Xylocaine for pain relief.
4. Shake the mixture well to ensure equal distribution of the talc and to prevent sedimentation.

12.4.2 Product Use

1. Inject the slurry through the thoracic drain into the pleural cavity.
2. Clamp the thoracic drain. Keep the negative pressure in the pleural cavity.
3. While the slurry remains in the pleural cavity reposition the patient regularly to achieve even distribution of the slurry.
4. Aspirate the slurry through the thoracic drain.

13 Instructing the Patient

ATTENTION: Fill out the implant card and give it to the patient.
Before performing a CT / PET of the thorax, the patient must inform the radiologist about the pleurodesis. [Combining with Other Procedures, page 5]

14 Aftercare

- Follow-ups as indicated by the treating physician.

15 Follow-up measures after removal of the product

The product is intended to remain in the body.

16 Disposal

⚠ WARNING

- The product was in contact with potentially infectious substances of human origin. Clean/pack the product for disposal according to the specific contamination risk.
  Otherwise there is a risk of infection for the user and for third parties.

Disposal must be in accordance with national disposal regulations and pursuant to the corresponding risk class.

17 Warranty

The reliability of the product's material and design at the time of shipment is guaranteed. The manufacturer does not know either the diagnosis of the patient or the nature of the application and has no influence on the conditions under which the product is used. The storage conditions after delivery of the product are also beyond the manufacturer's area of responsibility.
Due to biological and individual differences, no product is 100% effective under all circumstances.
Therefore, the manufacturer cannot guarantee a positive effect or the absence of negative effects for product application. The medical staff must use the product on the basis of their medical training and experience, and they are responsible for correct application.
The warranty (repair or replacement) applies only if the product is used in accordance with these Instructions for Use (for instruments, particularly with regard to handling, cleaning, sterilization and maintenance); the warranty period starts on the delivery date.

If you have reason to believe that a new product is faulty, please contact the Customer Service in writing immediately and provide as detailed a description as possible of the fault, the REF (product code), and the LOT (batch code) and/or series number. All allegedly defective products must be returned to us for inspection. Instruments have to be completely cleaned and sterilized, appropriate documentation must be enclosed with the return.
If the manufacturer finds that despite all due care the product was defective at the time of delivery, he will repair the product or replace it promptly. If repair or replacement of the product is not possible, the buyer has the right to cancel the purchase or to reduce the payment, but by a maximum of the purchase price amount.
Additional claims or those not mentioned here due to defect, and other claims regardless of the legal reason, including those based on illegal acts and for compensation of immaterial damages against the manufacturer, his agents, dealers and suppliers, are excluded unless existing law is contrary to the liability exclusion, e.g. in cases of intent or gross negligence or in the event of physical injury.
All claims based on the consequences of non-compliance with the Instructions for Use, including specified indications, contraindications, warnings, instructions, application, storage and off-label use, as well as the consequences of a combination with third-party products are excluded.
Furthermore, all claims that result from the use of products that have expired, or were used despite the obvious damage to the packaging, or resterilized and/or recycled contrary to the Instructions for Use, are excluded.
No one is allowed to change the above conditions, make further warranty or liability declarations, or guarantee any properties that surpass those specified in the Instructions.
The General Terms and Conditions of the manufacturer, which can be accessed at http://www.novatech.fr/gtc apply in all remaining instances.