STERITALC®

Novatech
new biotechnology for life
a bess group company

for Talc
Pleurodesis

NOVATECH

Because Life is Precious.

Founded in 1986, we have been producing silicone stents developed by Dr. Dumon for over 30 years. In order to improve patient care, we have added many developments over the years, such as STERITALC® and various instruments for bronchoscopy.

Office, production and warehouse in La Ciotat, South of France

Quality made in Europe

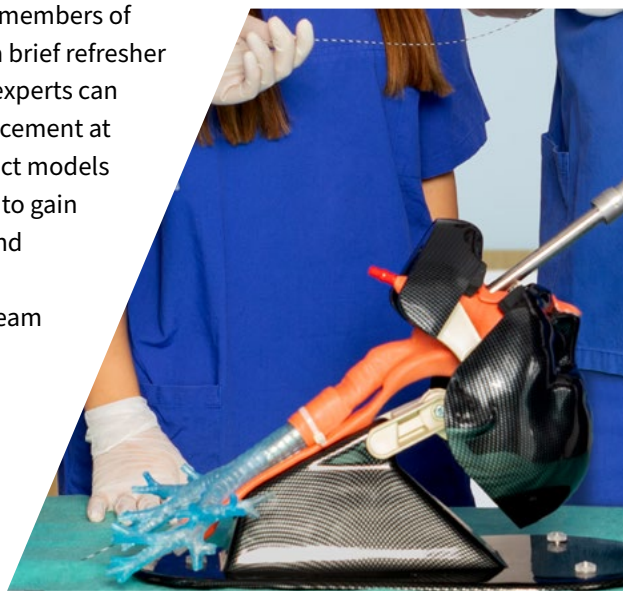
Our commitment to quality, function and cost-effectiveness along with the ability to respond quickly to individual needs, has earned us the trust of physicians worldwide.

The full package. Expert advice on demand.

Do your require training for new members of staff or an entire team? Perhaps a brief refresher in stent placement? Our qualified experts can deliver training sessions in stent placement at your location. Our anatomically correct models provide your staff with an opportunity to gain hands-on experience, handling stents and instruments in a relaxed atmoshphere.

Training is crucial — only a finely-tuned team will achieve optimal results.

Each year, we organize **rigid bronchoscopy workshops** in France – a valuable opportunity for experienced physicians and for beginners. A highly-esteemed faculty, small groups and extensive hands-on practice guarantee a high level of participant satisfaction.



Our extensive experience and strict quality standards serve one goal:

Providing products which improve patient quality of life.

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NOVATECH SA has been part of the bess group since 2003. Located in Berlin, Germany, bess group is a family-owned and owner-managed medical device company with more than 30 years of expertise in medical device technology.

STERITALC®

Indication

- Malignant pleural effusion
- Pneumothorax

Medical talc for instillation in the case of malignant pleural effusion or pneumothorax

- **Granulometrically modified talc**
- **Sterile**
- **Asbestos-free**
- **Endotoxin-free**

Recommended dose

- 2 to 5 g for pleural effusion and
- 2 g for pneumothorax.

STERITALC® is suitable for all indications for pleurodesis. It is insoluble and induces permanent pleurodesis.
Talc pleurodesis is more effective and less painful than tetracyclines.

STERITALC® has been the standard of care for decades. Thousands of patients worldwide have been successfully treated with STERITALC®.

21

16

It is the only talc-based pleurodesis product with a well-documented and proven track record of safety and efficacy.

2486

25

„The most important clinical implication of our study is that large-particle talc can safely be used for pleurodesis. Other talc preparations should not be used for this indication.“

Janssen et al.: Safety of pleurodesis with talc poudrage in malignant pleural effusion: a prospective cohort study. Lancet 2007; 369: 1535-1539

„Es gilt als gesichert, dass es beim französischen Luzenac-Talk (… Steritalc®, Novatech) zu keiner systemischen Talkumdissemination kommt.“

“It is accepted as certain that the French Luzenac talc (… STERITALC®, NOVATECH) does not result in a systemic talc dissemination.”

Schnyder/Tschopp: Behandlung des Pneumothorax mittels internistisch-thorakoskopischer Talkumpleurodese. Der Pneumologe 2010. 7: 357-363

A summary of selected papers on STERITALC® is available.
Please contact us!

clinical studies

from

countries

involving

patients

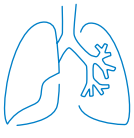
over a period of

years

✓ Meeting the particularly stringent requirements of the US Food and Drug Administration (FDA), STERITALC® is approved in the USA.

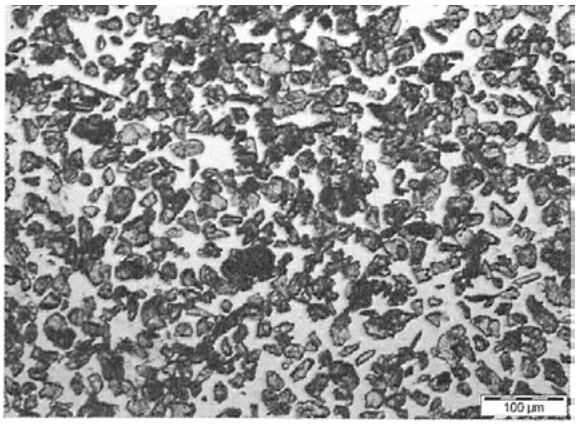
Excerpt from the US Prescribing Information for STERITALC®:

> *There are published reports of two large, prospective trials conducted to evaluate the safety of STERITALC® administered intrapleurally. One trial evaluated 558 patients treated with STERITALC® 4 g by poudrage for MPE. The second trial evaluated 418 patients with recurrent primary spontaneous pneumothorax treated with STERITALC® 2 g by poudrage.*
> ***No cases of ARDS or talc-related lung injury were reported.***

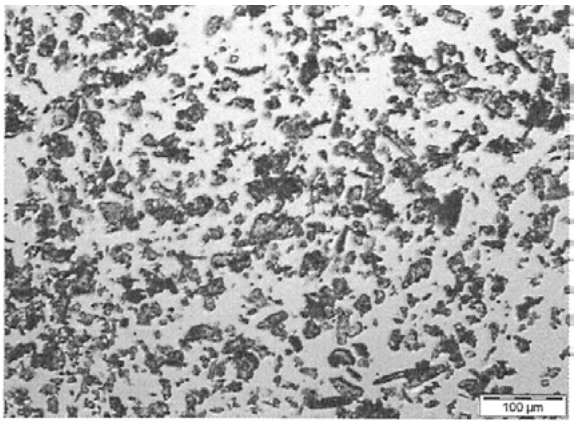


Modifying particle size – eliminating risks.

The reason why STERITALC® outperforms other talc products on safety can be found in additional, sophisticated production steps which actively eliminate small, high-risk particles and pyrogens.



STERITALC®

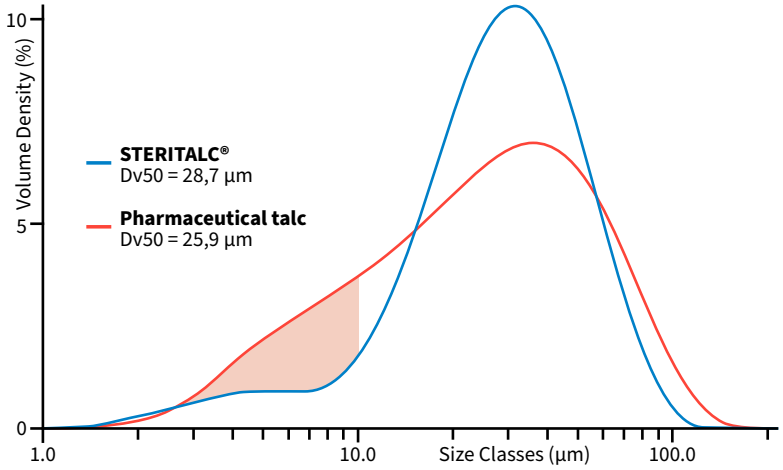


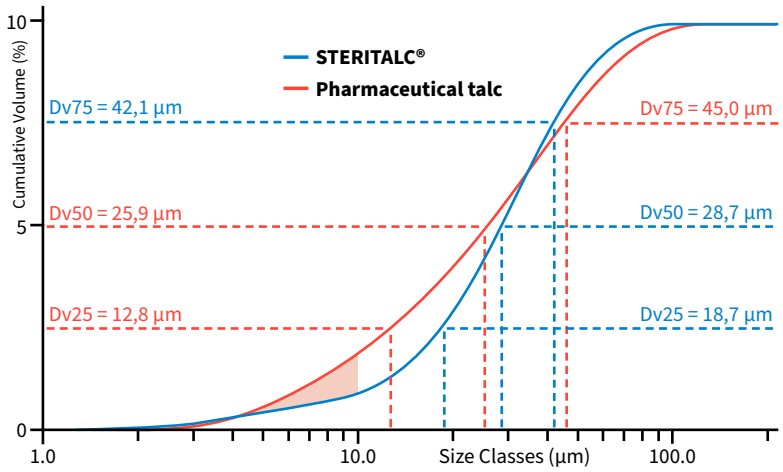
Pharmaceutical talc

Microscopy images from an independent testing laboratory show STERITALC® to have comparatively large particles and a homogeneous particle size distribution.

Small, high-risk particles – a possible cause of ARDS – have been eliminated.

Comparison of particle size distribution between STERITALC® and pharmaceutical talc





Parameter	**Unit**	**STERITALC®** nominal particle size: **28 µm**	**Pharmaceutical talc** nominal particle size: **25 µm**
Specific surface area	m²/kg	119.7	142.0
Particles below 15 µm	% Vol	16.78	29.72
Particles below 10 µm	% Vol	8.87	18.53

Even with similar nominal particle size, tests clearly show the difference:
Pharmaceutical USP talc contains significantly more small, high-risk particles.

Preventing systemic spread – preventing ARDS.

The systemic dissemination of talc following talc pleurodesis may be a cause of ARDS (Acute Respiratory Distress Syndrome). Published studies suggest that there is a correlation with talc particle size: smaller talc particles were associated with a higher systemic spread than larger particles.[1]

Particle size is also linked to severity of inflammatory response. Talc with an average particle size below 15µm has been shown to induce more severe systemic inflammation and more inflammation in the lungs.[2]

In order to prevent systemic spread, small, high-risk particles (≤ 10 µm) are actively eliminated during the STERITALC® production process. This ensures a high proportion of larger particles and a mean diameter of 28µm.
STERITALC® undergoes routine granulometry monitoring as part of its production process, safeguardiang the product's consistently high quality, which has been proven in numerous clinical studies.

Both animal studies[3] as well as clinical studies[2] have confirmed a lower systemic dissemination. A multicenter study has shown that STERITALC® with its calibrated particle size can be safely used for the pleurodesis of malignant pleural effusions. Not one case of ARDS occured in more than 550 patients. The authors recommended that no other form of talc be used.[4]

Another cause of ARDS may be sepsis from non-sterile talc or talc containing endotoxins.[5] This can also be ruled out when STERITALC® is used, since STERITALC® is endotoxin-free and sterile.

1 Ferrer, CHEST 2002; 122: 1018-1027
2 Maskell, Am .J. Respir. Crit. Care Med. 2004; 170: 377-382
3 Fraticelli, CHEST 2002; 122:1737-1741
4 Janssen, Lancet 2007; 369: 1535-1539
5 Antony, Eur. Respir. J. 2001; 18: 402-419

Completely sterile

STERITALC® is supplied in a sterile blister for maximum safety

STERITALC® PF3
sterile, in a blister pack

STERITALC® F2, F4
sterile, in a blister pack

Slurry or Poudrage

Video available

STERITALC® **vial F2, F4**

For instillation in the pleural space

- as **slurry** (suspension with NaCl); xylocaine can also be added
- via **poudrage** using a thoracoscope atomiser

STERITALC® can be administered via an IPC (Indwelling pleural catheter).
Combining talc poudrage and IPC has been shown to be beneficial[1,2],
as it enables treatment on an outpatient basis and eliminates the discomfort of additional injections.

STERITALC® **PF3**

- For direct instillation via thoracoscopy using air as a blowing agent.
- **Ready-to-use for poudrage** – supplied as a set comprising 3g STERITALC®, a cannula, and an insufflation bulb.

Poudrage with STERITALC® PF3

Set comprising 3g STERITALC®, a cannula, and an insufflation bulb. Perfectly adjusted for a safe and even distribution of the talc.

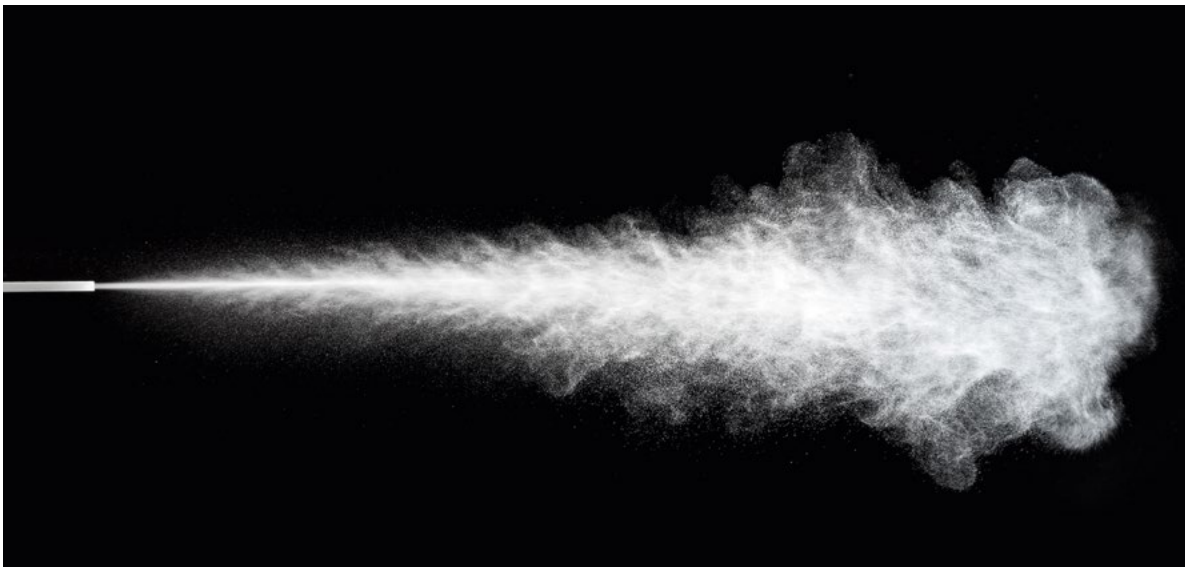
Ready to use in 3 steps

Remove the cap.

Place the atomiser cover on the vial.

Connect the bulb.

Poudrage: creating a “mist”



The goal when using STERITALC® PF3 for poudrage is to create a “mist” in the pleural cavity. This ensures an even distribution throughout the pleural cavity.

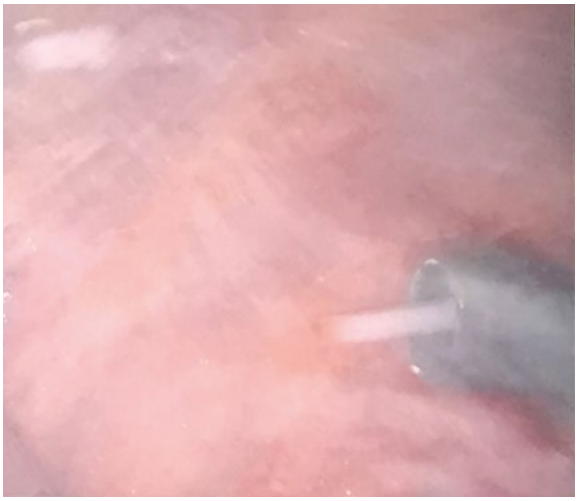


Image courtesy of Dr. Bauer (Dortmund, Germany)

REF	Description	Quantity of medical talc	items per box
16903	STERITALC® F2 Vial, 50 ml	2 g	4
16913	STERITALC® F4 Vial, 50 ml	4 g	4
16863	STERITALC® PF3 (Poudrage Kit) Vial 10 ml, with bulb and cannula, L: 420 mm, OD: 3.0 mm	3 g	2 kits
16983	Supplement for 16863: Vial, 10 ml	3 g	4
STERILE			

16903

16913

16863
Poudrage kit

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Silicone Airway Stents

Instruments
for Bronchoscopy

NOVATECH EWS™
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Nitinol Stents

The products in this catalog are CE-marked.

Novatech SA — La Ciotat, France

Please note that only the current instructions for use apply. Details in this catalog about the use of products serve as a guide only and reflect the information available at the time of print. If necessary, please request a current version!

The instructions for use for some of our products are available only in electronic form (in pdf format) on our website. Please see the product label for the required access information.

Please note that product availability may vary by country. Please contact us for details.

STERITALC®

for Talc Pleurodesis

NOV-MR-PCA-STE Steritalc_EN Rev. 8

Novatech
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Novatech SA
capital stock: 160.000 € • 398 941 260 RCS Marseilles
TVA CEE FR59398941260 • certified according to EN ISO 13485
Jurisdictional venue / seat of the company:
Z.I. Athélia III — 1058, Voie Antiope
F—13705 La Ciotat Cedex, France
Tel. +33 (0) 442 98 15 60
info@novatech.fr • www.novatech.fr