

STERITALC®



a bess group company

for Talcum
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 high demand on quality, function and cost-effectiveness along with the ability to react quickly to individual needs, has earned us the trust of physicians worldwide

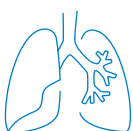
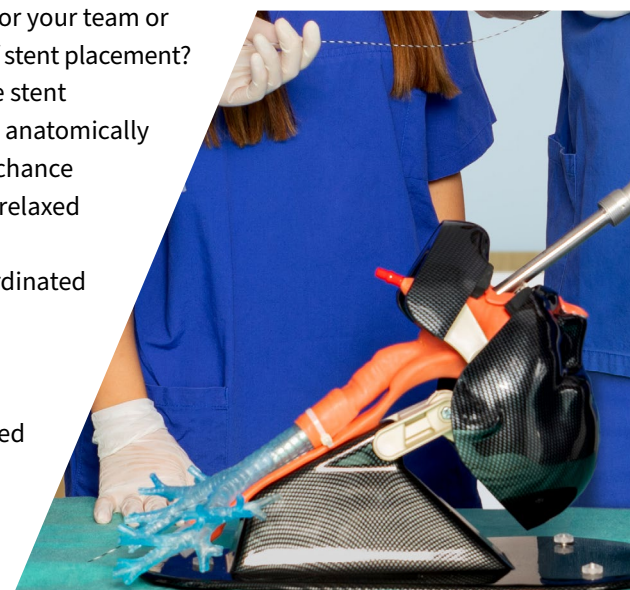
The full package. Expert advice on demand.



You wish to train new members or your team or refresh your team's knowledge of stent placement? Our qualified experts demonstrate stent placement at your location. We use anatomically correct models and give your staff a chance to handle stents and instruments in a relaxed atmosphere.

Training is important — only a well-coordinated team will achieve perfect results.

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





Our extensive experience and our strict quality standards serve one goal:

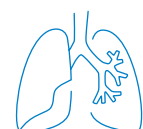
To provide products that give patients a better quality of life.



Since 2003 **Novatech SA** has been part of bess group in Berlin, Germany – a family-owned and managed medical device company with more than 30 years of expertise in medical device technology.



NOVATECH
Finest Products for Interventional Pulmonology



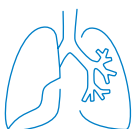
STERITALC®

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

- Controlled particle size
- Sterile
- Asbestos-free
- Endotoxin-free

Indication

- Malignant pleural effusion
- Pneumothorax



Effective and safe

Standard of care for decades



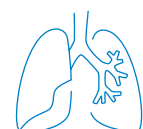
„The most important clinical implication of our study is that large-particle talc can safely be used for pleurodesis. Other talc preparations should not be used for this indication.“

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

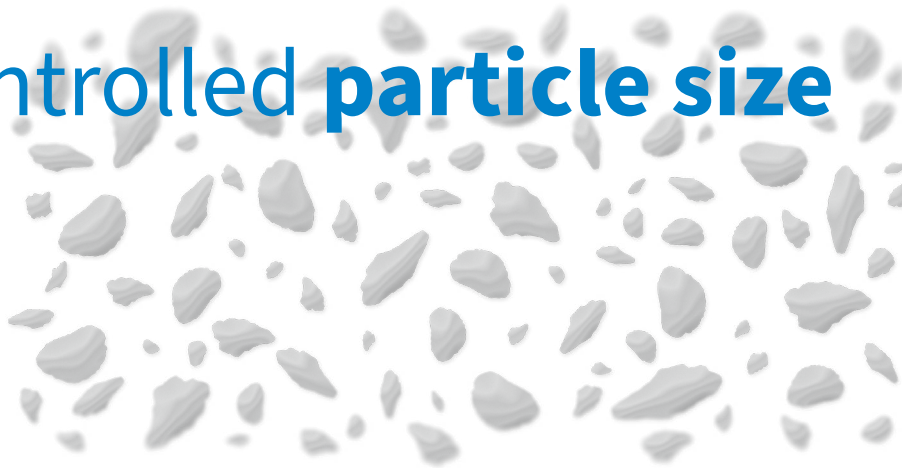
„Es gilt als gesichert, dass es beim französischen Luzenac-Talc (... Steritalc®, Novatech) zu keiner systemischen Talkumdissemination kommt.“

“It is regarded secure that the French Luzenac talcum (... STERITALC®, NOVATECH) does not lead to a systemic talcum dissemination.”

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



Controlled particle size



STERITALC® consists of talcum, which is mined in France before being further processed specifically for medical purposes (talcum pleurodesis).

STERITALC® is suitable for all indications of pleurodesis. It is insoluble and induces a permanent pleurodesis. Talcum is more effective and pain-free compared with tetracyclines.

The recommended dose is 2 to 5 g for pleural effusion and 2 g for pneumothorax.

The development of ARDS (Acute Respiratory Distress Syndrome) is considered to be a critical side effect of talcum pleurodesis. One possible cause of ARDS may be a systemic dissemination of talcum. In some cases, talcum has also been found in other organs (kidney, spleen, liver) after use in the pleural cavity.

Published studies assume that there is a correlation with talcum particle size: smaller talcum particles revealed a higher systemic spread than larger particles.¹

The clinical presentation also shows the effect of different particle sizes: Talcum with an average particle size below 15 µm induced stronger systemic and pulmonary inflammatory reactions than talcum with an average particle size of 25 µm.²

In order to prevent systemic spread, small risk particles ($\leq 10 \mu\text{m}$) are actively eliminated during the STERITALC® production process.

A high proportion of particles $\geq 25 \mu\text{m}$ in size (mean: 28 µm) is achieved. The high quality is permanently ensured by granulometric control measurements during production and has been clinically proven in numerous studies only for STERITALC®.

Both animal studies³ as well as clinical studies² have confirmed a lower systemic dissemination. A multi-centre 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 occurred in more than 550 patients. The authors recommended that no other form of talcum be used.⁴

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

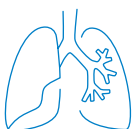
1 Ferrer, CHEST 2002; 122: 1018-1027

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® vial F2, F4

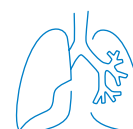
For instillation in the pleural space

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



STERITALC® PF3

- For direct instillation via thoracoscope using air as a blowing agent
- Ready-to-use - supplied in a set with 3 g STERITALC®, a cannula, as well as a balloon atomiser

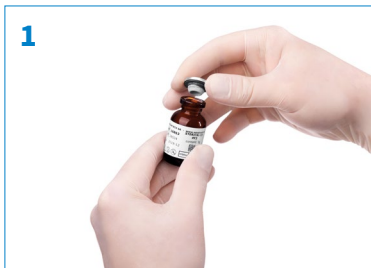


Poudrage with STERITALC® PF3

Set with 3g STERITALC®, a cannula and a balloon atomiser. Perfectly adjusted for a safe and even distribution of the talcum.



Ready to use in 3 steps



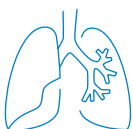
1 Remove the cap.



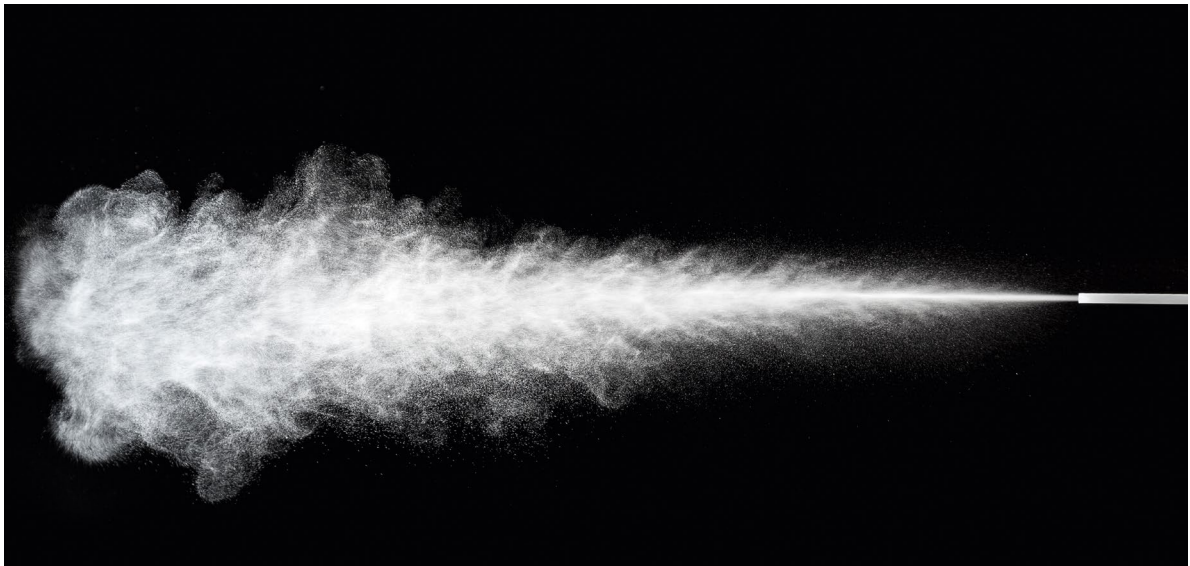
2 Place the atomiser cover.



3 Connect the balloon.



Poudrage creating a “mist”



The goal when using STERITALC® PF3 for the poudrage is to create a “mist” in the pleural cavity. In this way, the talcum becomes evenly distributed over the pleural layers.



Image courtesy of Dr. Bauer (Dortmund, Germany)



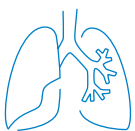
REF	Description	Quantity of medical talcum	items per box
16903	STERITALC® F2 Vial, 50 ml	2 g	4
16913	STERITALC® F4 Vial, 50 ml	4 g	4
16863	STERITALC® PF3 (Poudrage Kit) Vial 10 ml, with balloon and cannula, L: 420 mm, OD: 3.0 mm	3 g	2 kits
16983	Supplement for 16863: Vial, 10 ml	3 g	4
STERILE			



16903

16913

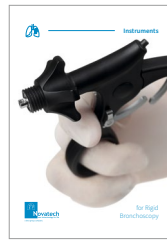
16863
Poudrage kit



Request information about more pulmonology products:



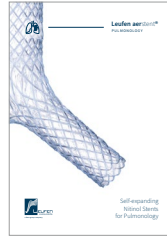
NOVATECH® GSS™
Silicone Airway Stents



Instruments
for Bronchoscopy



NOVATECH EWS™
Endobronchial
Watanabe Spigots



Leufen aerstent®
self-expanding
Nitinol Stents

The products in this catalog are **CE**-marked.



Novatech SA — La Ciotat, France

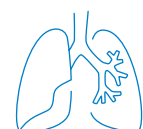


Please note that only the current instructions for use apply. Details in this catalog about the use of products serve as a guide only and reflect the information available at the time of print. If necessary, please request a current version!



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.



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Pleurodesis

