



STERITALC®

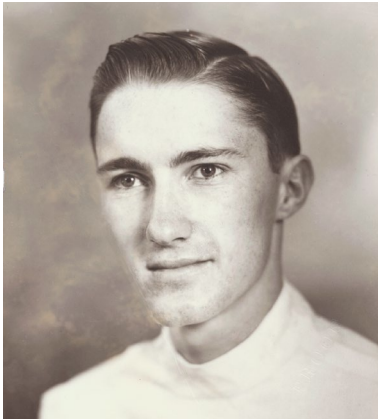


a bess group company

for Talcum Pleurodesis

Groundbreaking solutions. From physicians for physicians.

Though much has changed at Boston Medical Products over the past 40 years, one thing remains constant: our commitment to deliver the world's finest specialty surgical products — products that physicians can rely on and patients can trust.



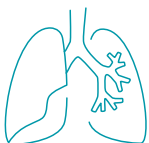
Boston Medical Products was founded in 1980 by three physicians - including world-renowned surgeon **William W. Montgomery, M.D.** as a way to make Dr. Montgomery's original innovations widely available to fellow physicians.

Today, Boston Medical Products continues to be driven by his life-long commitment to superior patient care.

William W. Montgomery, M.D. 1923–2003



Office, production and warehouse in Shrewsbury, Massachusetts



NOVATECH®

Because Life is Precious.

Novatech has been producing silicone stents developed by Dr. Jean-François Dumon for over 30 years. In order to improve patient care, many developments have been added over the years, such as STERITALC® and various instruments for bronchoscopy.

Novatech's extensive experience and strict quality standards serve one goal:

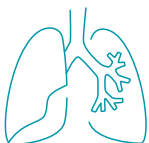
To provide products that give patients a better quality of life.



Both Boston Medical Products and Novatech are 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.



STERITALC®



(talc) powder, for intrapleural use, indicated to decrease recurrence of malignant pleural effusions and pneumothorax

- Granulometrically controlled talc
- Sterile
- Asbestos-free
- Endotoxin-free



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

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

21

16

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-Talc (... 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 Talkumpleurodesse. 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

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.



Preventing systemic spread

– preventing ARDS.

STERITALC® consists of talcum which is mined in France and is specifically processed for medical use (talcum pleurodesis).

STERITALC® is intended for treatment of malignant pleural effusion by insufflation of medical grade talc following drainage of pleural effusion. It is non-soluble and induces permanent pleurodesis. Compared with tetracyclines, talcum is more effective^{1,2}.

For malignant indications 2 to 5 g are used, for treatment of pneumothorax 1 to 2 g are used.

A critical side effect of talcum pleurodesis can be ARDS (Acute Respiratory Distress Syndrome). A possible cause of ARDS may be the systemic dissemination of talcum. In some cases, after application in the pleural cavity, talcum was found even in other organs (kidneys, spleen, liver)^{3,4}.

The literature assumes that there is a relation between the talcum particle size and the systemic dissemination of talcum: smaller talcum particles appear to disseminate more than larger ones⁵.

The clinical picture also shows the effect of different particle sizes: talcum with a mean particle size below 15 µm induced stronger systemic and pulmonary inflammation reactions than talcum with a mean particle size of 25 µm⁶.

STERITALC®, produced by Novatech SA, France, is specifically calibrated in order to avoid systemic dissemination. Animal⁷ and clinical studies⁸ show the lesser systemic dissemination.

A multi-center study showed that STERITALC® with its calibrated particle size can be safely used for pleurodesis of malignant pleural effusions. None of more than 550 patients developed ARDS⁹. The authors recommend to use no other talcum.

Another cause of ARDS may be a sepsis due to unsterile talcum, or talcum containing endotoxines¹⁰. STERITALC® is free of endotoxines and comes sterile.

1 Noppen et al 1997, Acta Clin Belg. 1997; 52(5): 258-62

2 Hamed et al 1989, Br. J. Surg. 1989; Vol. 76, December 1266-1267

3 Fraticelli et al 2002, Chest 2002; 122: 1737-1741

4 Ferrer et al 2002, Chest 2002; 122: 1018-1027

5 Ferrer et al 2002, Chest 2002; 122: 1018-1027

6 Maskell, Am. J. Respir. Crit. Care Med. 2004; 170: 377-382

7 Fraticelli et al 2002, Chest 2002; 122: 1737-1741

8 Maskell, Am. J. Respir. Crit. Care Med. 2004; 170: 377-382

9 Janssen, Lancet 2007; 369: 1535-1539

10 Antony, Eur. Respir. J. 2001; 18: 402-419



STERITALC®

dosage forms



NDC-62327-222-42



NDC-62327-444-44

STERITALC® 2 grams and 4 grams

- For use as a **slurry** (to be mixed with physiological saline solution; Xylocain may be added).
- For **poudrage** application via a thoracoscope/trocar.



NDC-62327-333-43

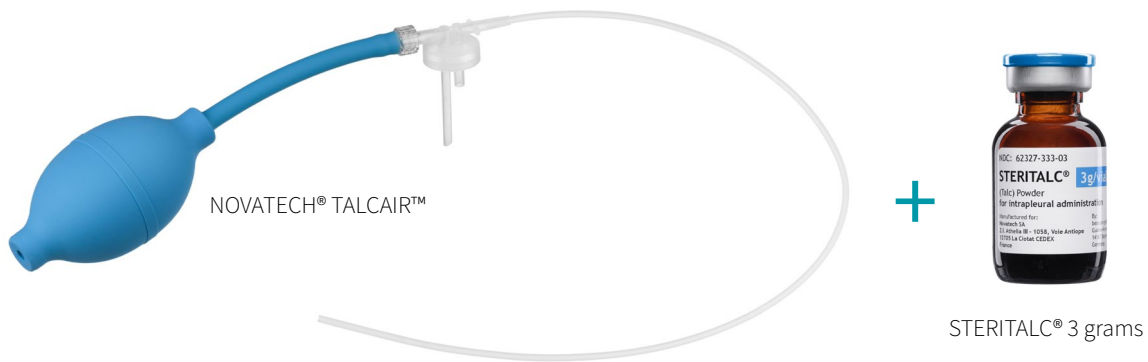
STERITALC® 3 grams

- For **poudrage** application via a thoracoscope/trocar (nebulization by air) **in combination with powder blower NOVATECH® TALCAIR™**.

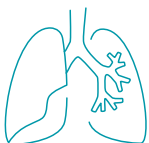


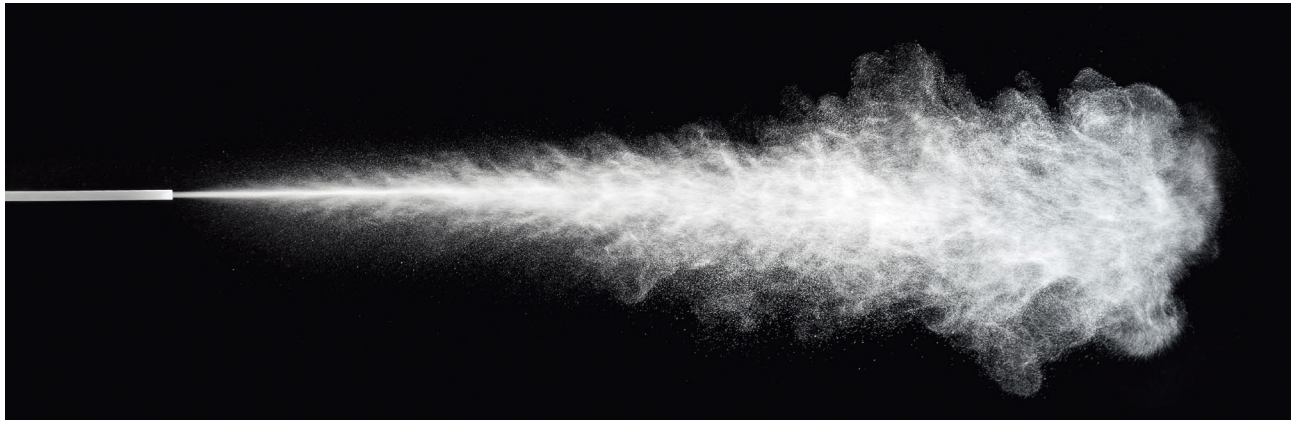
NOVATECH® TALCAIR™

NOVATECH® TALCAIR™ is a powder blower, consisting of an insufflation cannula with attached coupling for the **STERITALC® 3 grams** vial and a separate insufflation bulb.



NOVATECH® TALCAIR™ has been especially designed for use with STERITALC® from Novatech, medical talcum intended for treatment of malignant pleural effusion by insufflation of medical grade talc following drainage of pleural effusion. The talcum is applied by poudrage through a thoracoscope.

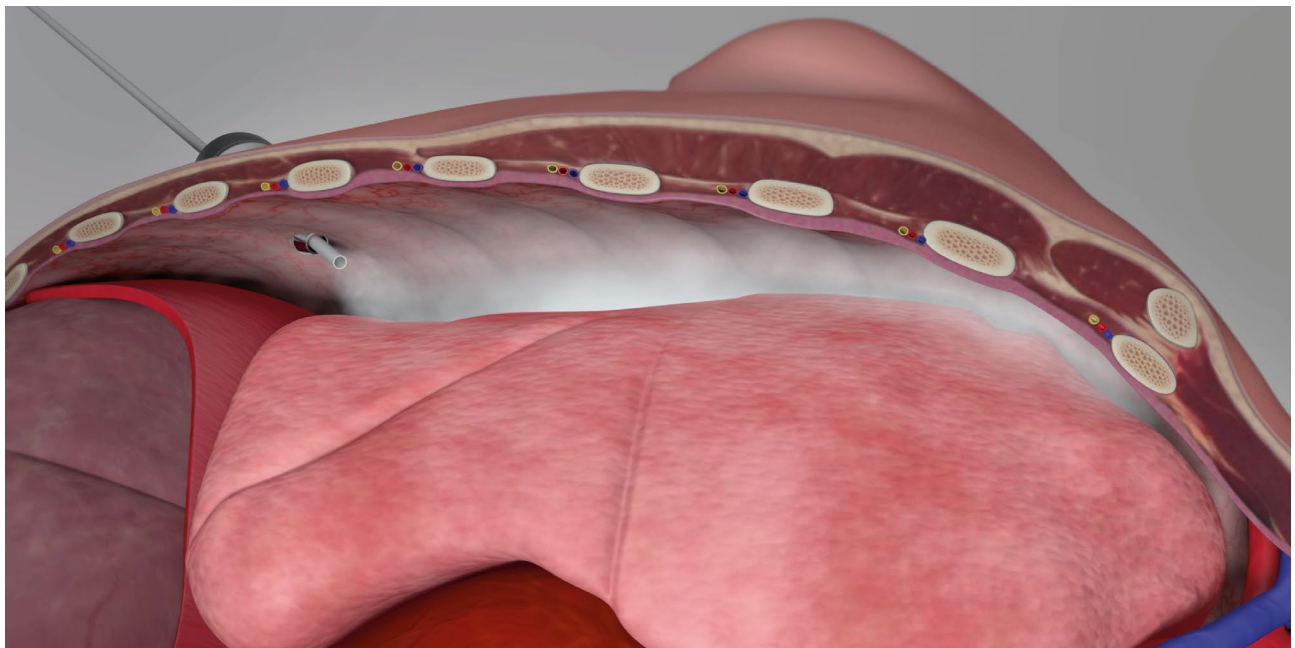




Poudrage – creating a “mist”

NOVATECH® TALCAIR™ allows the talcum to take full effect, spreading it homogeneously inside the pleural cavity.

The aim is to create a “mist” in the pleural cavity, evenly distributing the talcum onto the parietal and visceral pleura.



STERITALC®

| REF | | |
|------------------|---------|--------------------|
| NDC-62327-222-42 | 2 grams | 4 vials per carton |
| NDC-62327-333-43 | 3 grams | 4 vials per carton |
| NDC-62327-444-44 | 4 grams | 4 vials per carton |

— 3 grams for use with NOVATECH® TALCAIR™

sterile, in blister pack



NDC-62327-222-42



NDC-62327-444-44

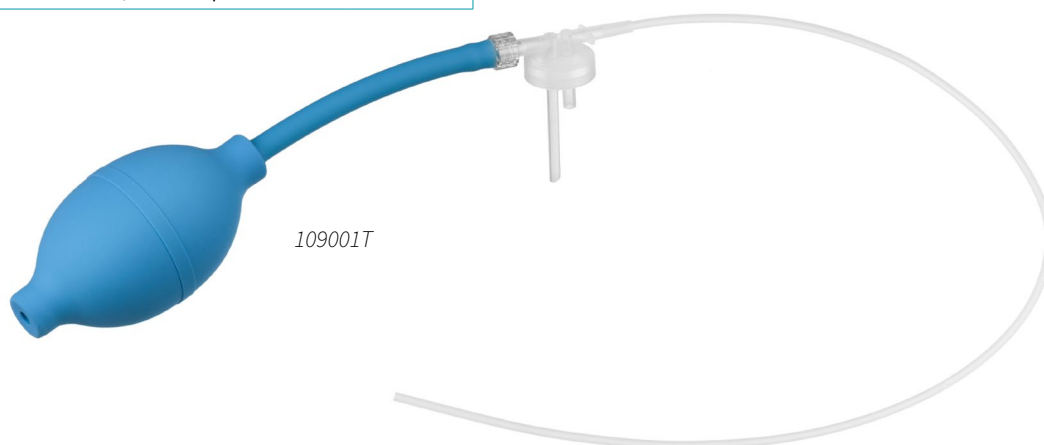


NDC-62327-333-43

NOVATECH® TALCAIR™

| REF | | |
|---------|--|-----------------------|
| 109001T | Powder Blower for use in combination only with STERITALC® 3 grams (REF NDC-62327-333-43) | 2 items per carton |

sterile, in blister pack



109001T



Prescribing Information



https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205555s000lbl.pdf



Manufactured by

Exclusive U.S. Distributor



To Place an Order

Our Customer Service Representatives are available from 8:30 a.m. to 5:00 p.m. (EST) Monday through Friday. Orders can also be placed through our 24-hour fax line or by e-mail.

- Customer Service: 800-433-2674 (toll-free in the U.S.)
- Main Telephone: 508-898-9300
- 24-hour-Fax: 508-898-2373
- customerservice@bosmed.com

Prescription Policy

U.S. federal law restricts these products to sale by or on the order of a physician.

Shipment

Standard shipping within the U.S. is FedEx Ground delivery. Express orders are accepted until 4:00 p.m. (EST) for next business day delivery nationwide.

Return Policy

All sales final, no returns or exchanges will be accepted.

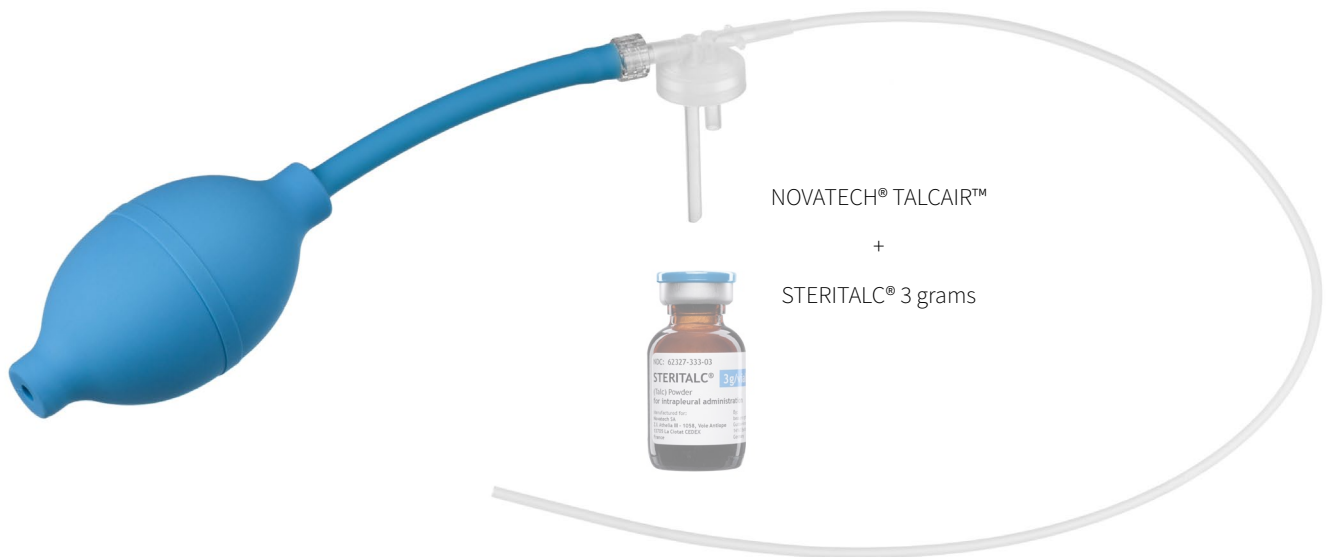
Warranty

Boston Medical Products, Inc. warrants that reasonable care has been used in the manufacturing of all products. All products are warranted to be free of defects at the time of shipment. For specific product warranties, please refer to individual product Instructions for Use.



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