

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

# STERITALC®



The only talcum pleurodesis product  
available in the US.



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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<sup>1,2</sup>.

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)<sup>3,4</sup>. 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 ones<sup>5</sup>.

- 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

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 µm<sup>6</sup>.

STERITALC®, produced by Novatech SA, France, is specifically calibrated in order to avoid systemic dissemination. Animal<sup>7</sup> and clinical studies<sup>8</sup> 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 ARDS<sup>9</sup>. The authors recommend to use no other talcum.

Another cause of ARDS may be a sepsis due to unsterile talcum, or talcum containing endotoxines<sup>10</sup>. STERITALC® is free of endotoxines and comes sterile.

- 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

„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

*“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

STERITALC® comes in different forms allowing different methods of application:

### 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.

### STERITALC® 3 grams

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



# STERITALC®

Controlled particle size talc for use in the pleural cavity



## 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.



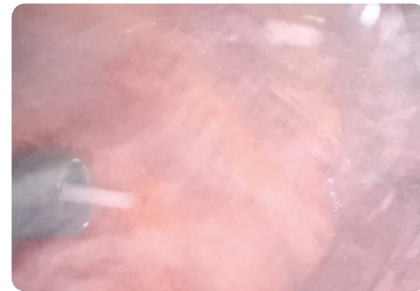
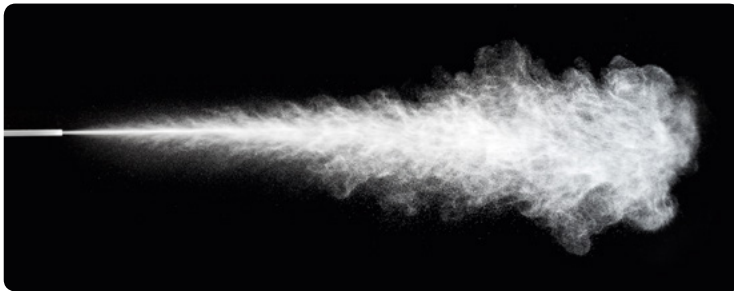
NOVATECH® TALCAIR™ is used in combination with STERITALC® 3 grams.



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.



Picture kindly provided by Dr. Bauer, Dortmund, Germany

REF	STERITALC®	
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

REF	NOVATECH® TALCAIR™	
109001T	Powder Blower for STERITALC® 3 grams (REF NDC-62327-333-43)	2 items per carton

Manufactured by



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Exclusive U.S. Distributor



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

### 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 two-day delivery.
- Express orders are accepted until 3:00 p.m. (EST) for next business day delivery nationwide.
- Most orders are shipped the same day.
- Saturday delivery is available in many areas.

### 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.

### Return Policy

All sales of STERITALC® are final. Boston Medical Products, Inc. will not accept any returns of STERITALC® products.



Prescribing Information:  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/205555s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205555s000lbl.pdf)



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