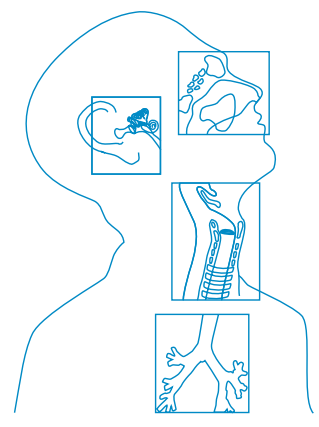


Novatech
new biotechnology for life

a bess group company

STERITALC®





STERITALC®

Controlled particle size talc for use in the pleural cavity

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

STERITALC® is suited for all indications of pleurodesis. It is insoluble and induces permanent pleurodesis. Compared with tetracyclines, talcum is more effective and less painful.

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

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 in other organs (kidneys, spleen, liver), too.

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 ones¹.

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 µm².

STERITALC®, produced by Novatech, is specifically calibrated to a mean particle size of 25 µm in order to avoid systemic dissemination. Animal³ and clinical studies² 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 ARDS⁴. The authors recommend to use no other talcum.

Another cause of ARDS may be a sepsis due to unsterile talcum, or talcum containing endotoxines⁵. This, too, can be excluded when STERITALC® is used, because STERITALC® is free of endotoxines and comes 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

„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 three dosage forms allowing different ways of application:



STERITALC® Vial F2, F4

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



STERITALC® Spray

- For direct poudrage application via a thoracoscope / trocar (nebulization by aerosol)

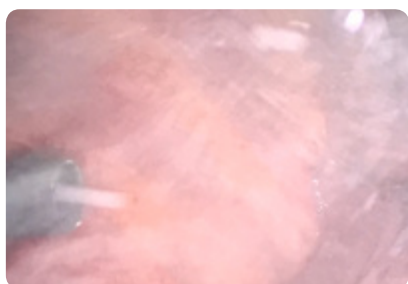


STERITALC® PF3

- For direct poudrage application via a thoracoscope / trocar (nebulization by air)
- Ready to use - comes in a set with 3 g STERITALC®, a cannula and a balloon nebulizer.

Poudrage – creating a “mist”

The aim of using STERITALC® PF3 for poudrage 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	Description	Quantity of medical talc	Items/box
16903	STERITALC® F2 Vial, 50 ml	2 g	4
16913	STERITALC® F4 Vial, 50 ml	4 g	4
16833	STERITALC® Spray with cannula, L: 440 mm, OD: 2.1 mm	3 g	2
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			

Professional References

- Antony VB; Loddenkemper R; Astoul P; Boutin C; Goldstraw P; Hott J; Rodriguez Panadero F; Sahn SA: Management of malignant pleural effusions. *European Respiratory Journal* 18 (2001): 402-419
- Bloom AI; Wilson MW; Kerlan RK Jr; Gordon RL; LaBerge JM: Talc pleurodesis through small-bore percutaneous tubes. *Cardiovascular and Interventional Radiology* 22 (1999): 433-436
- Bresticker MA; Oba J; LoCicero J; Greene R: Optimal pleurodesis: a comparison study. *The Annals of Thoracic Surgery* 55 (1993): 364-367
- Cardillo G; Facciolo F; Carbone L; Regal M; Corzani F; Ricci A; Di Martino M; Martelli M: Long-term follow-up of video-assisted talc pleurodesis in malignant recurrent pleural effusions. *European Journal of Cardio-Thoracic Surgery* 21 (2002): 302-305
- Diacon AH; Wyser C; Bolliger CT; Tamm M; Pless M; Perruchoud AP; Solér M: Prospective Randomized Comparison of Thoracoscopic Talc Poudrage under Local Anesthesia versus Bleomycin Instillation for Pleurodesis in Malignant Pleural Effusions. *Am. J. Respir. Crit. Care Med.* 162(4) (2000): 1445-1449
- Erickson KV; Yost M; Bynoe R; Almond C; Nottingham J: Primary treatment of malignant pleural effusions: video-assisted thoracoscopic surgery poudrage versus tube thoracostomy. *The American Surgeon* 68 (2002): 955-959
- Ferrer J; Montes JF; Villarino MA; Light RW; Garcia-Valero J: Influence of particle size on extrapleural talc dissemination after talc slurry pleurodesis. *Chest* 122 (2002): 1018-1027
- Ferrer J; Villarino MA; Tura JM; Traveria A; Light RW: Talc preparations used for pleurodesis vary markedly from one preparation to another. *Chest* 119 (2001): 1901-1905
- Fratelli A; Robaglia-Schlupp A; Riera H; Monjanel-Mouterde S; Cau P; Astoul P: Distribution of calibrated talc after intrapleural administration: an experimental study in rats. *Chest* 122 (2002): 1737-1741
- Gillissen A; Kellner S: Talkumpleurodesse mittels internistischer Thoraskopie beim malignen oder chronischen Pleuraerguss. *Der Pneumologe* 5 (2010): 336-342
- Glazer M; Berkman N; Lafair JS; Kramer MR: Successful talc slurry pleurodesis in patients with nonmalignant pleural effusion. *Chest* 117 (2000): 1404-1409
- Janssen JP; Collier G; Astoul P; Tassi GF; Noppen M; Rodriguez-Panadero F; Loddenkemper R; Herth FJF; Gasparini S; Marquette CH; Becke B; Froudarakis ME; Driesen P; Bolliger CT; Tschopp JM: Safety of pleurodesis with talc poudrage in malignant pleural effusion: a prospective cohort study. *Lancet* 369 (2007): 1535-1539
- Kennedy L; Harley RA; Sahn SA; Strange C: Talc Slurry Pleurodesis: Pleural Fluid and Histologic Analysis. *Chest* 107 (1995): 1707-1712
- Kennedy L; Sahn SA: Talc Pleurodesis for Treatment of Pneumothorax and Pleural Effusion. *Chest* 106 (1994): 1215-1222
- Keller SM: Current and future therapy for malignant pleural effusion. *Chest* 103 (1993): 635-675
- Mager HJ; Maesen B; Verzijlbergen F; Schramel F: Distribution of talc suspension during treatment of malignant pleural effusion with talc pleurodesis. *Lung Cancer* 36 (2002): 77-81
- Marom EM; Patz EF Jr; Erasmus JJ; McAdams HP; Goodman PC; Herndon JE: Malignant pleural effusions: treatment with small-bore-catheter thoracostomy and talc pleurodesis. *Radiology* 210 (1999): 277-281
- Maskell NA; Kee, YCG; Gleeson FV; Hedley EL; Pengelly G; Davies RJO: Randomized Trials Describing Lung Inflammation after Pleurodesis with Talc of Varying Particle Size. *American Journal of Respiratory and Critical Care Medicine* 170 (2004): 377-382
- Milanez de Campos JR; Filho LO; de Campos Werebe E; Sette H Jr; Fernandez A; Filomeno LT; Jatene FB: Thoracoscopy talc poudrage, a 15 Year experience. *Chest* 119 (2001): 801-806
- Mourad IA; Abdel Rahman AR; Aziz SA; Saber NM; Fouad FA: Pleurodesis as a Palliative Treatment of Advanced Lung Cancer with Malignant Pleural Effusion. *Journal of the Egyptian Nat. Cancer Inst.* 16(3) (2004): 188-194
- Nasreen N; Mohammed KA; Dowling PA; Ward MJ; Galffy G; Antony VB: Talc induces apoptosis in human malignant mesothelioma cells in vitro. *American Journal of Respiratory and Critical Care Medicine* 161 (2000): 595-600
- Sanchez-Armengol A; Rodriguez-Panadero F: Survival and talc pleurodesis in metastatic pleural carcinoma, revisited. *Chest* 104 (1993): 1482-1485
- Schnyder JM; Tschopp JM: Behandlung des Pneumothorax mittels internistisch-thorakoskopischer Talkumpleurodesse. *Der Pneumologe* 5 (2010): 357-363
- Schramel FM; Sutedja TG; Braber JC; van Mourik JC; Postmus PE: Cost effectiveness of video-assisted thoracoscopic surgery versus conservative treatment for first time or recurrent spontaneous Pneumothorax. *European Respiratory Journal* 9 (1996): 1821-1825
- Tschopp JM; Bolliger CT; Boutin C: Treatment of spontaneous pneumothorax: why not simple talc pleurodesis by medical thoracoscopy. *Respiration* 67 (2000): 108-111
- Tschopp JM; Boutin C; Astoul P; Janssen JP; Grandin S; Bolliger CT; Delaunoy L; Driesen P; Tassi G; Perruchoud AP: Talcage by medical thoracoscopy for primary spontaneous pneumothorax is more cost-effective than drainage: a randomised study. *European Respiratory Journal* 20 (2002): 1003-1009
- Viallat JR; Rey F; Astoul P; Boutin C: Thoracoscopic talc poudrage pleurodesis for malignant effusions. *Chest* 110 (1996): 1387-1393
- Weissberg D; Ben-Zeev I: Talc Pleurodesis. *Journal of Thoracic and Cardiovascular Surgery* 106 (1993): 689-695

Boutin Trocar

Single use Boutin Trocars for the pleura

For pleural punctions and biopsies

Trocars for the pleura were introduced by Novatech in 1998 in cooperation with Professor C. Boutin (Marseilles, France).

The single use Boutin trocars have a working length of 78 mm. They are available in two diameters (2 and 3 mm) and are equipped with both a sharp and a blunt stylet.

- 2 mm: for pleural punctation only
- 3 mm: for pleural punctation and biopsy

Both trocars can be used to drain biological fluids in case of pleural effusions.

The 3 mm trocar features a three-sided sharp stylet. The shape of the hook was improved in order to provide a sampling quality higher than that of the Abrams needle.¹

Features

- sterile, ready for use
- convenient dispenser box
- single use, minimizing risk of contamination
- less traumatic due to diameters adapted to intended use
- equipped with a three-way stopcock

¹ Study by Prof. C. Boutin - Hôpital La Conception, Marseilles
Presentation: CHEST/Toronto/1998


REF	Description	Items per box
58023	Disposable Boutin Trocar for pleural punctation 2 mm, with two stylets, ID: 2.4 mm	12
58033	Disposable Boutin Trocar for pleural punctation and biopsy, 3 mm, with two stylets, ID: 1.5 mm	12
Sterile		



Boutin Trocar 3 mm: for pleural punctation and biopsy, with lateral hook and two stylets: sharp resp. blunt.



Boutin Trocar 2 mm: for pleural punctation only, with two stylets: sharp resp. blunt.

The products in this catalog are -marked.



Novatech SA – La Ciotat, France



Please note that only the instructions for use enclosed with the respective product 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.

Your local contact:



Novatech
new biotechnology for life

a bess group company

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 • Fax +33 (0) 442 98 15 63
info@novatech.fr • www.novatech.fr