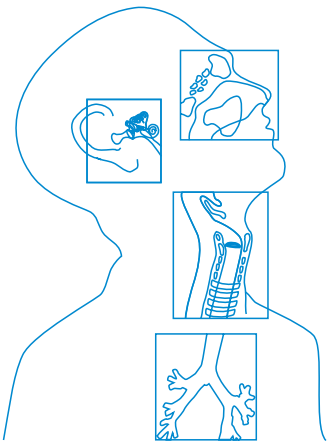
Novatech
new biotechnology for life
a bess group company

Products for Pulmonology



STERITALC®
LARGE 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 non-soluble and induces permanent pleurodesis. Compared with tetracyclines, talcum is more effective and less painful.

As a rule, for malignant indications 3 to 5 g are used, for treatment of spontaneous pneumothorax 2 g are sufficient in most cases.

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 ones[1]. 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[2].

STERITALC®, produced by NOVATECH, is specifically calibrated to a mean particle size of 25 µm in order to avoid systemic dissemination. Animal[3] and clinical studies[2] 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[4]. The authors recommend to use no other talcum.

Another cause of ARDS may be a sepsis due to unsterile talcum, or talcum containing endotoxines[5]. 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*
Please see page 6 for more professional references.

STERITALC®
LARGE PARTICLE SIZE TALC FOR USE IN THE PLEURAL CAVITY

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® PF3
- For direct poudrage application via a thoracoscope / trocar (nebulization by air)
- No limitations regarding storage and handling
- Self-contained system – comes in a set with 3 g STERITALC®, a 420 mm cannula as well as a balloon nebulizer.

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

REF	STERITALC® Description	Quantity of medical talc	Items/ box
16903	F2: Vial, 50 ml	2 g	4
16913	F4: Vial, 50 ml	4 g	4
16833	Spray, with cannula 440 mm	3 g	2
16863	PF3: Vial 10 ml with balloon and cannula 420 mm (Poudrage Kit)	3 g	2 kits
16983	*Accessory for 16863:* Vial, 10 ml	3 g	4
STERILE			

„Es gilt als gesichert, dass es beim französischen Luzenac-Talk (… 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

EWS®
SILICONE SPIGOTS FOR SEGMENTAL AND SUBSEGMENTAL BRONCHI

Endobronchial Watanabe Spigots (EWS®) were developed by NOVATECH in close cooperation with Dr. Y. Watanabe, Okayama, Japan. They are made of medical grade silicone (implantable for more than 29 days) dyed with barium-sulfate for excellent radiodiagnostic visibility. EWS® are tapered and have an anatomical design with studs on the outside avoiding migration. They come sterile, individually blister-packed. Three sizes are available.

Indications

- persistent (even after successful pleural drainage), inoperable pneumothorax,
- bronchopleural fistula (especially following thoracic surgery) with a continuous loss of air despite thoracic suction drain, in cases in which surgical intervention is not indicated,
- temporary treatment of haemoptysis of peripheral origin in expectation of a bronchial arterial embolisation or surgery.[1)]

A study[2)] performed in Japan with 63 patients including 40 cases of intractable pneumothorax, 12 cases of pyothorax with fistula and 7 cases of pulmonary fistula has shown that using EWS® is safer and has more permanent positive results than conventional methods. After determination of the affected bronchi with a balloon catheter (alternatively X-ray etc.), the EWS® are placed with a flexible bronchoscope and forceps guided by the working tube of the bronchoscope. EWS® were successfully placed in 96.7% of the cases. The loss of air was stopped or significantly reduced in 77.6% of the cases. No severe complications ocurred.

Three sizes are available:
S = Ø 5 mm
M = Ø 6 mm
L = Ø 7 mm

Subsequent therapy

- For certain patients bronchial occlusion with EWS® can be envisaged as the only treatment. When it fails or the result is imperfect, pleurodesis (for example using STERITALC®) or other surgery (if not contra-indicated) can be considered.
- The spigots can be removed after the patient's condition has improved and the thoracic drain is removed. If there are difficulties in removing EWS® for any reason, removal is not necessary.

REF	EWS® Endobronchial Watanabe Spigots, sterile	
01EWS12A	12 EWS®	3 x S, 6 x M, 3 x L
01EWS3S	6 EWS®	6 x S (Ø 5 mm)
01EWS3M	6 EWS®	6 x M (Ø 6 mm)
01EWS3L	6 EWS®	6 x L (Ø 7 mm)
STERILE		

1) H. Dutau et al. Endobronchial Embolization with a Silicone Spigot as a Temporary Treatment for Massive Hemoptysis. Respiration DOI:101159/000092954, published online April 21, 2006
2) Watanabe Y. et al. Bronchial Occlusion with Endobronchial Watanabe Spigot, J Bronchol., 10, 4, 2003

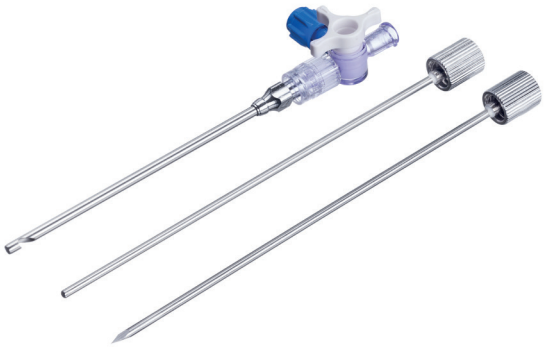
SINGLE USE BOUTIN TROCARS FOR THE PLEURA

For pleural biopsies and punctions

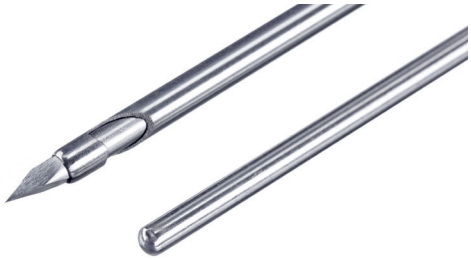
NOVATECH has launched trocars for the pleura in cooperation with Professor C. Boutin (Marseilles, France) in 1998. He redesigned the existing trocar to improve the quality of sampling.

The single use Boutin trocars have a working length of 78 mm. They come sterile and are available in two diameters (2 and 3 mm).
The three-sided mandrel and the improved shape of the hook of the 3 mm trocar give this device a sampling quality higher than with the Abrams needle[1)].

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



Boutin Trocar 2 mm: for pleural punction only, with a lateral orifice and two mandrels: sharp resp. blunt.



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

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

REF	Description	Items per box
58023	Disposable BOUTIN Trocar for pleural punction 2 mm, with two mandrels	12
58033	Disposable BOUTIN Trocar for pleural biopsy and punction, 3 mm, with two mandrels	12
STERILE		

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

STERITALC®
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