

# ScleroFoam®

For the production of a high quality foam



Kreussler Pharma  
Chemische Fabrik Kreussler & Co. GmbH  
Postfach 12 04 54 • D-65082 Wiesbaden  
Tel.: +49 (0)611 9271-0 • Fax: +49 (0)611 9271-111  
E-Mail: [info@kreussler.com](mailto:info@kreussler.com)  
[www.kreussler-pharma.de](http://www.kreussler-pharma.de)

# ScleroFoam®



ScleroFoam® is a single-use medical device made up of two components:

- A female/female luer lock connector
- An 0.2µm air filter for sterilization of room air

For injection do not use needles with a diameter less than 25 G (0.5mm diameter), since it could reduce the quality of the foam.

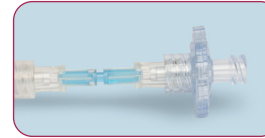
To increase the foam quality in respect to the half-life time, use non-siliconized syringes for drawing up Aethoxysklerol. This will reduce the contact time of Aethoxysklerol with the silicon inside the syringes.

## FEATURES

For production of a fine bubbled foam for sclerotherapy treatments of medium and larger varicose veins.

Please refer to the SmPC of Aethoxysklerol® 2% and 3% in your country.

**ScleroFoam®**  
Medical device of class IIa  
CE 0459



## PREPARATION

Take the connector + 0.2µm filter kit as well as two 2.5ml syringes (one of them should be non-siliconized) and a needle for drawing up the sclerosing agent.



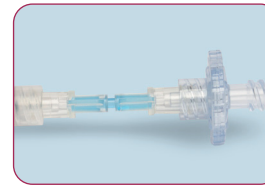
## PRODUCTION AND COLLECTION OF STERILE AIR

Take the siliconized syringe and attach the connector. Attach the 0.2µm filter on the free end of the connector. Check that all elements are firmly connected. Draw exactly 2.0ml of air into the syringe (in order to prepare 2.5ml of foam).

## COLLECTING THE SCLEROSING AGENT

Attach the needle/cannula to the tip of the second syringe (non-siliconized), collect exactly 0.5ml of sclerosing agent. Remove carefully all residual air bubbles from the syringe.

Caution: If the quantity of the collected sclerosing agent and air differs from the recommended volumes, the physical properties of the foam will be changed.

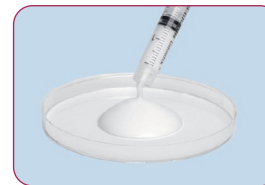


## FOAM PREPARATION

Disconnect the filter from the connector and immediately connect the syringe with the sclerosing agent. Hold the set in such a way that each syringe is in one hand and that the thumbs are on each syringe plunger. Pump the entire content from one syringe into the other 10 times without interruption and within approximately 10 seconds.

## DISASSEMBLING

Transfer all foam into the siliconized syringe and disconnect it from the connector.



## CONTROLLING THE QUALITY OF THE FOAM

By expelling a small amount of foam the quality of the foam should be checked before injection. The foam must be compact, homogeneous and without bubbles visible to the naked eye (diameter < 0.3mm), comparable to "whipped cream". In the case of any visible bubbles, the preparation must be repeated.

## MAXIMUM TIME FROM THE PREPARATION TO THE INJECTION

The foam should be injected within 60 seconds after preparation has started. After 60 seconds, the residual foam must be discarded. Prepare fresh foam again if necessary.