

ScleroSafe™

Your **Modern** Vein Treatment.



methapharm
Specialty Pharmaceuticals

ScleroSafe™

Revolutionizing Vein Closure Treatments

FDA cleared ScleroSafe is a groundbreaking advancement in venous therapy, featuring a proprietary Dual Procedure Syringe and an Advanced Double Lumen Catheter. This system integrates precise sclerosant delivery and efficient blood aspiration into a single device, offering unparalleled control, safety, and procedural efficiency.

How Each Component Contributes

Advanced Double Lumen Catheter

The catheter combines precise sclerosant delivery and blood aspiration in one device.

Over-the-Wire Design:

Allows accurate placement within the target vein for improved control.

Simultaneous Functions:

Injects Asclera® through side ports while aspirating blood through the distal tip, ensuring localized treatment and enhanced efficacy.

Dual Procedure Syringe

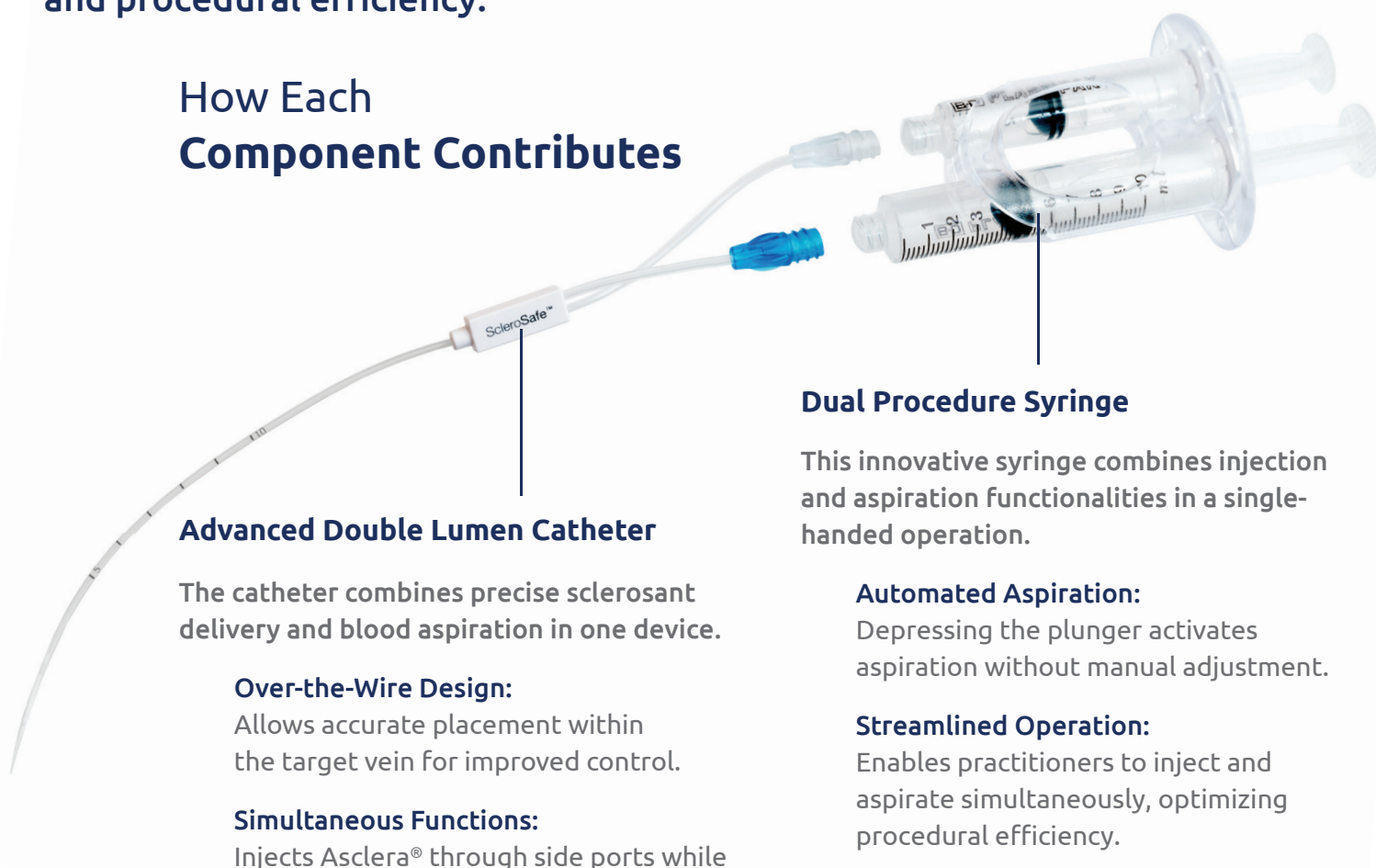
This innovative syringe combines injection and aspiration functionalities in a single-handed operation.

Automated Aspiration:

Depressing the plunger activates aspiration without manual adjustment.

Streamlined Operation:

Enables practitioners to inject and aspirate simultaneously, optimizing procedural efficiency.



ScleroSafe: Mode of Action

Synergistic Vein Closure

The ScleroSafe system combines Negative Pressure, Sclerosing Agent Delivery, and Aspiration for precise and effective vein closure.

Negative Pressure¹

Vein Collapse:

Controlled negative pressure collapses the vein lumen.

Intimal Disruption:

Induces micro-tears in the vein wall, enhancing sclerosant penetration.

Enhanced Sclerosing Agent Contact¹

Maximized Exposure:

Maintains effective contact of Asclera with the vein endothelium.

Irritation & Occlusion:

Asclera chemically irritates endothelial cells, initiating thrombosis and fibrosis to permanently seal the vein.



Aspiration^{1,2}

Evacuation & Venous Drainage:

Blood and residual sclerosant are efficiently aspirated, ensuring vessel clearance.

Prevents Complications:

Minimizes inflammation and trapped blood, thereby enhancing patient outcomes.

Packaging & Availability

Product Description	Order Number
ScleroSafe™ 150 (double lumen catheter length 150 mm)	5000041
ScleroSafe™ 350 (double lumen catheter length 350 mm)	5000042

Each ScleroSafe platform includes: ScleroSafe's 5cc/10cc dual procedure syringe, ScleroSafe 5Fr catheter, 21G micropuncture needle, Guidewire, plastic torque device for guidewire. Please consult IFU for more information, available on sclerosafeus.com.

ScleroSafe Peripheral Venous Aspiration & Infusion Kit with Dual Procedure Syringe (ScleroSafe) is intended for the delivery of Asclera, an FDA-approved sclerosant, in the treatment of varicosities in superficial veins with a diameter of 2 to 3mm. ScleroSafe is a sterile, single use device designed to provide transient access to the peripheral venous system. For complete ScleroSafe contraindications and warnings, please consult Package Instructions for Use.

References:

1. ScleroSafe™ Instructions for Use. Methapharm, Inc.

2. Ralf R. Kolvenbach et al. Retrospective Evaluation of Safety and Efficacy for ScleroSafe Device - Case Report Summary
Using the ScleroSafe Device in treating Superficial Peripheral incompetent Varicose Veins. 2020.

ScleroSafe™

Innovative. Precise. Effective. Your **Modern** Vein Treatment.

The ScleroSafe platform sets a new standard for vein treatment by combining precision, safety, and efficiency. Its Dual Procedure Syringe and Double Lumen Catheter deliver a seamless, controlled, and effective experience, benefiting both patients and practitioners.²

Enhanced Efficacy:

Prevents sclerosant dilution and inactivation, increasing therapeutic impact.

Facilitates uniform sclerosant distribution for consistent results.

Improved Patient Comfort:

Reduces procedural pain
non-thermal, non tumescent treatment

Eliminates risk of thermal heat transfer, pain, bruising, and damage to surrounding tissue and nerves

Visible Results:

Immediate improvements in treated vein appearance.

Reduced Risk of Complications:

Prevents matting, staining, and thrombophlebitis by aspirating blood and residual sclerosing agent.

Practitioner Convenience:

Single-hand operation simplifies procedure making it convenient and efficient for the practitioner.

Controlled catheter pullback (1 cm/sec) ensures optimal sclerosant infusion and vein aspiration.



Elevate Your Practice with ScleroSafe

Engineered for precision, efficiency, and safety, empowering vein specialists to deliver exceptional results while enhancing the patient experience.

Visit us online at sclerosafeus.com

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For product inquiries or questions related to ordering, please contact
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