VVT MEDICAL

ScleroSafe™ INSTRUCTIONS FOR USE

READ CAREFULLY BEFORE USE!

SCLEROSAFE DESCRIPTION

ScleroSafe is a sterile, single use device designed to provide transient access to the peripheral venous system. Catheter is packaged in a tray (Figure 1) which includes all the accessories required for percutaneous introduction using the micropuncture technique. The catheter is a 5F dual lumen peripherally inserted percutaneous catheter made from biocompatible medical grade materials, with tapered - tip and two sets of Luer nozzles below the tip. (Figure 2). The ScleroSafe is available in two lengths indicated on the package and the TYVEK pouch - ScleroSafe 150mm, ScleroSafe 350 mm, and consists of the following components:
Micro puncture needle, Nitinol guidewire and plastic torque tool, Dual Lumen Catheter, and Dual procedure syringes to allow simultaneous withdrawal of blood and administration of fluids (Figure 3).

DEVICE CONTENTS (KIT MODEL ScleroSafe 150 AND ScleroSafe 350):
Each ScleroSafe includes the following components:

- Micropuncture needle - 21 G; 1.5 inch (A)
- Guidewire -0.018 inch (B)

Guidewire Length
ScleroSafe 150 - 500 mm
ScleroSafe 350 - 950 mm

- Plastic torque tool for guidewire (C)
- ScleroSafe Catheter :
  O. D of 1.67 mm (D)
  Distance between each depth marking is 10 mm

Catheter Working Length
ScleroSafe 150 - 150 mm
ScleroSafe 350 - 350 mm

- Dual Procedure Syringe 5cc/10cc (E)
- Instruction For Use

Figure 1 **ScleroSafe**

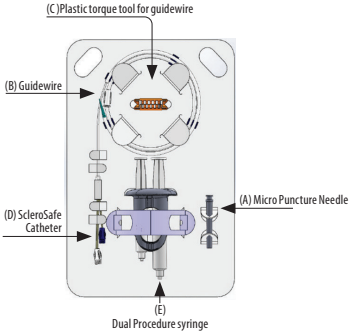

Figure 2 **The ScleroSafe Catheter**

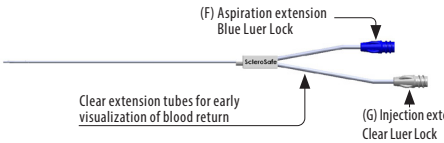

Figure 3 **The ScleroSafe**

INDICATIONS FOR USE

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.

CONTRAINDICATIONS

1. Vessel diameter> 3 and <2mm
2. Impaired renal function
3. Coagulopathy
4. Concurrent use of anti-coagulant therapy
5. Presence of skin abnormalities in vicinity of insertion site, (infection, phlebitis, ulcerations, scars, etc.)
6. History of prior episodes of deep venous thrombosis (DVT) or vascular surgical procedures at the prospective insertion site
7. Fever of unknown origin
8. Patient body size insufficient to accommodate the size of the inserted device
9. Post radiation at prospective insertion site
10. The patient is known to have brittle blood vessels
11. Obstruction in the venous system

WARNINGS

- This product should be used by physicians that have a thorough understanding of intravascular ultrasound, angiography, peripheral vascular procedures and anatomy.
- The physician should determine which patients are candidates for procedure that use this device.
- The ScleroSafe is for single use only. and should not be reprocessed or used after reprocessing' before period.
- Do not re-sterilize the catheter or accessories by any method.
- Re-use may lead to infection or illness/injury.
- The manufacturer will not be liable for any damages caused by re-sterilization of this catheter or accessories.
- Do not use catheter or accessories if package is opened or damaged.
- Do not use catheter or accessories if any sign of product damage is visible.
- To be used only with supplied DPS (E). Excessive pressure from syringe can lead to catheter damage.
- The safety and effectiveness of the device has not been established or is unknown in vascular region not specifically indicated.

Flow Rate [ml/min]	ScleroSafe 150 mm		ScleroSafe 350 mm	
	Injection	Aspiration	Injection	Aspiration
Max. Flow Rate	6.20	19.60	5.80	14.0
Average Flow Rate	5.56	17.96	5.14	13.59
Flow Rate Range	6 ± 3	19 ± 3	6 ± 3	13 ± 3

GUIDEWIRE PRECAUTIONS

- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire forcibly from any component, as this may result in fracture or unravelling of the wire. If the guidewire becomes damaged during the procedure, the introducer needle or sheath and guidewire must be removed together.

CATHETER PRECAUTIONS

- Do not use sharp instruments near the extension lines or catheter lumen.
- Examine catheter lumen and extensions before and after each infusion for damage.
- To prevent accidents, assure the security of all caps and connections prior to and between treatments.
- Use only the Luer lock connectors of the supplied catheter (F, G).
- Over tightening of Luer Lock connections (F, G) will reduce connector life and could lead to potential connector failure.

DUAL PROCEDURE SYRINGE PRECAUTIONS

- Prior to using the Dual Procedure Syringe, make sure that the Luer Lock connectors are hermetically closed. In case of incomplete hermetic seal between the syringe connectors, discontinue use immediately and stop the procedure until hermetic connection verified. If not successful, disconnect unit, discard and use a new product.
- Perform air degassing before use.

ADVERSE EVENTS

Potential adverse events that might be encountered during a peripheral vasculature infusion procedure using the ScleroSafe® are similar to those associated with any interventional procedure and include, but are not limited to, the following:

1. Abrupt thrombosis and occlusion of the treated vessel **2**. Bleeding from the site of access **3.** Vascular rupture and perforation **4.** Vascular dissection **5.** Hemolysis **6.** Hematoma **7.** Neurological deficits including stroke **8.** Embolization **9.** Reaction to infused substances **10.** Pain **11.** Pseudoaneurysm **12.** Hypotension, Hypertension **13.** Infection at the access site **14.** Death

CLINICAL PROCEDURE

(I) Before performing any procedure with the ScleroSafe:

1. Fill a syringe with normal saline or heparinized saline.
2. Attach syringe to Luer Lock of the injection extension and flush catheter.
3. Repeat section 2 on the aspiration extension. Flush all parts of the system using saline or heparinized saline.

DISPOSAL INSTRUCTIONS:
After use, dispose of the products used in the procedure per institutional protocol.

(II) ScleroSafe procedure using the micropuncture vascular access technique:

1. Locate vessel and prepare the skin at the intended puncture site in standard fashion.
2. Perform vein puncture (under US guidance if needed) with a 21 G (micro puncture) Introducer needle (A) and observe for flashback.
3. Insert guidewire (B) through the needle into the vessel lumen and gently advance it to the desired/required treatment length (under US guidance, if needed). Successful advancement may require rotation of the guidewire tip using the plastic torque tool (C).
4. Once the guidewire tip is at the desired location, hold the guidewire firmly in place and carefully remove needle.
5. Insert catheter (D) from its TIP over the guidewire, and carefully push it into vessel with slight rotary motion, while maintaining guidewire position and tautness.
6. Remove the guidewire leaving catheter in vessel.
7. Confirm catheter tip position visually or using ultrasound.

(III) Recommended Procedure for Dual Procedure Syringe - one hand simultaneous aspiration and injection of liquids.

1. Remove vented caps (protecting the luer locks) and discard.
2. Push plunger of the injection (5 cc syringe) side all the way down.
3. Aspirate injection liquid by pressing the other side plunger.
4. Perform de-bubbling to eliminate air bubbles.

(IV) Sclerotherapy and Obliteration of superficial veins using the Dual Procedure Syringe (E)

1. Connect the clear injection extension (G) to the 5cc syringe (containing Asclera® sclerosing agent. Note: Concentration limited to 1%, which is consistent with Asclera® labeling) of the Dual Procedure Syringe.
2. Connect the blue aspiration extension (F) to the 10cc syringe of the Dual Procedure Syringe.
3. Slowly withdraw catheter and Dual Procedure Syringe outside the body as a single unit (Figure 3) while pressing (one hand operation) the 5cc (Asclera®) plunger. Aspiration will be done simultaneously. Extreme caution should be taken to avoid extravascular injection or passage of the Asclera®. Recommended speed of catheter withdrawal from initial position while pressing the DPS 5cc plunger should be 1cm. per 1sec.
4. Withdraw catheter, apply manual hemostasis, and place a steristrip.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

There is no expressed or implied warranty, including, without limitation, any implied warranty of merchantability or fitness for a particular purpose, on the VVT Medical Ltd. Product and\or components as described in this publication. Under no circumstances shall VVT Medical Ltd. be liable for any direct, incidental or consequential damages other than as expressly provided by specific law. No person and/or entity has the right/authorization to bind VVT Medical Ltd. to any representation or warranty except as specifically set forth herein. Descriptions or specifications in this publication are meant solely for general description of the product and/or components and are valid for the date of product manufacturing (as appear on package), and do not constitute any express warranties. VVT Medical Ltd. will NOT be responsible for any direct or indirect incidental or consequential damages resulting from REUSE of this product.

VVT Medical Ltd.
6 Hasadna st. Kfar-Saba, 4442405 Israel
Tel.+972-9-7660480

Keep dry | Do not use if package is damaged | Keep away from sunlight | Do not re-sterilize | STERILE EO Sterilized utilizing EO | HANDLE WITH CARE
Use-by date | Consult instructions for use | Do not re-use | Rx Only Prescription Use Only | MD Medical Device | The device meets pyrogen limit specifications