

Spotlight One-Piece Sheath Procedure Kit

The Spotlight OPS* procedure kit makes treating veins easy and fast. Designed in collaboration with leading interventional physicians, the Spotlight* One-Piece Sheath has all the features physicians need to effectively treat the SSV, the full GSV, and other superficial veins of the lower extremity.

Easy

The tungsten-loaded sheath tip increases echogenicity allowing for bright and easy tip placement while the smooth, soft, atraumatic tip and low profile makes it easy to navigate

Fast

Unique self-dilation technology eliminates the need for a separate dilator, resulting in fewer components, fewer exchanges and potentially faster procedures

Small

Low-profile small 4F sheath with a 600 μm fiber



PROCEDURE KIT FEATURES AND BENEFITS

One-Piece Introducer Sheath

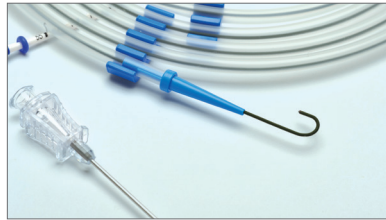
One-Piece self-dilating sheath allows for the insertion of the laser fiber directly after sheath placement, with no dilator removal

Clearly Numbered Sheath Markings

Clearly numbered sheath markings offer a clear indication to measure progress

Echogenic Atraumatic Tip

Smooth and soft atraumatic tip is designed for easy insertion, and is tungsten-loaded for visualization during venous navigation



Bare-tip Fiber with Site Marks

Site marks are designed for ease of positioning the laser fiber tip

Entry Point Marker

Easy marking of initial depth of sheath insertion for quick assessment of treated vein length

Simple Twist-and-Click Hub

Simple twist-and-click hub provides ease of use when securing fiber and creating hemostatic seal

Double-ended .035" Guidewire

Straight-tip and J-tip end allows for a choice when navigating tortuous veins

Gripper with RFID Chip

Designed for easy connection to laser, while embedded chip transfers key fiber data to most AngioDynamics' lasers

SPOTLIGHT ONE-PIECE SHEATH PROCEDURE KITS

Description	Part #	Kit Length
Procedure Kit with Spotlight OPS Sheath	H787EVL25OP55	25 cm
Procedure Kit with Spotlight OPS Sheath	H787EVL55OP55	55 cm
Procedure Kit with Spotlight OPS Sheath	H787EVL80OP55	80 cm

AngioDynamics' VenaCure EVLT endovenous laser vein treatment offers patients a minimally-invasive choice for treating the source of their varicose veins and provides them with quicker recovery and a return to normal daily routines, as compared to surgical stripping. The VenaCure EVLT System includes a 1470 nm laser, 600 um or 400 um laser fiber procedure kits including accessories, marketing materials, support and more. For more information on these products, including our proprietary NeverTouch* fiber technology, please visit www.VenaCure-EVLT.com.

IMPORTANT RISK INFORMATION

INDICATION FOR USE: AngioDynamics Laser and VenaCure EVLT Procedure Kits with Spotlight OPS Sheath are indicated for use in the treatment of varicose veins and varicosities associated with superficial vein reflux of the great saphenous vein, and with veins in the lower limbs with superficial reflux. The D15 Plus, D30 Plus, Delta-15 and Delta-30 lasers and VenaCure EVLT Kits are indicated for treatment of incompetent refluxing veins in the superficial venous system.

CONTRAINDICATIONS: Patients should not have their varicosities ablated who have the following conditions: thrombus in the vein segment to be treated; aneurysmal section in the vein segment to be treated; peripheral artery disease as determined by Ankle Brachial Pressure Index with a value of <0.9; an inability to ambulate; deep vein thrombosis; pregnant or breast-feeding; or patients in general poor health.

Other contraindications may be raised by the individual physician at the time of treatment.

WARNINGS AND PRECAUTIONS: Read the Instructions For Use and the Laser Operator's manual thoroughly prior to using the VenaCure EVLT Procedure Kits with Spotlight OPS Sheath. Observe all warnings, precautions and cautions noted. Failure to do so may result in patient complications. Laser protective eyewear must be worn by everyone in the treatment room, including the patient.

CAUTION: Intended for use only by fully trained physicians. Federal (USA) law restricts these devices to sale by or on the order of a physician. The VenaCure EVLT Procedure Kit is intended for single patient use only. Inspect the sealed packages before opening. If seals are broken or the packages are damaged, treat as non-sterile and discard. Ensure expiration dates are still

valid. Treatment of a vein located close to the skin surface may result in a skin burn. Parasthesia may occur from thermal damage to adjacent sensory nerves. Tissue not targeted for treatment must be protected from injury by direct and reflected laser energy with appropriate eye and protective wear for any person present in the operating room.

POTENTIAL COMPLICATIONS: Adverse reactions may include, but are not limited to: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, paresthesia due to thermal damage of adjacent sensory nerves, skin burns, and thrombophlebitis.

Indications, contraindications, warnings and instructions for use can be found in the instructions for use supplied with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.



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