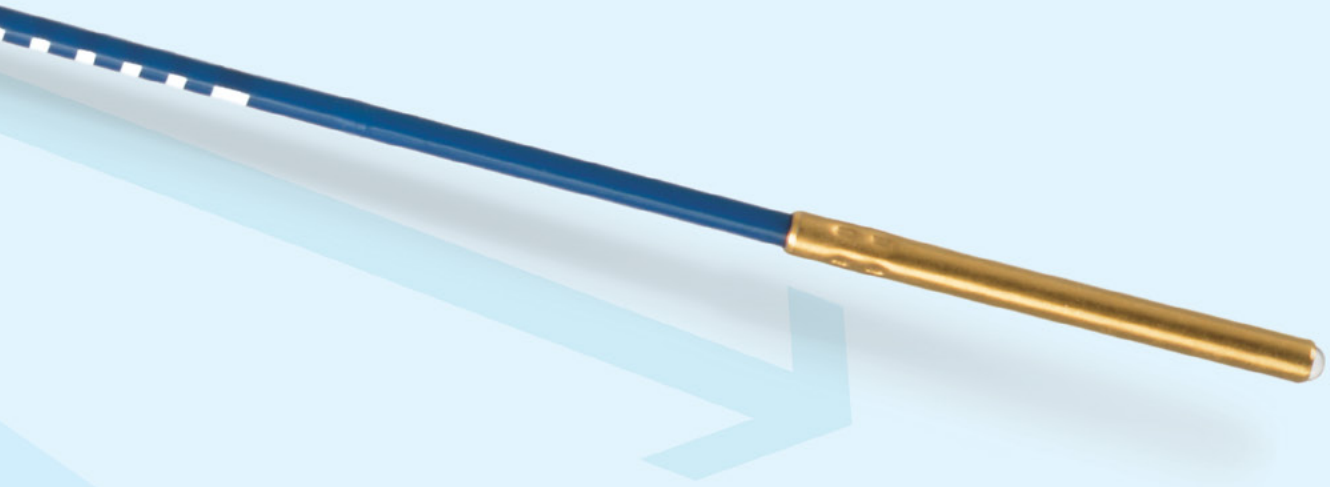


VenaCure *Direct*
NeverTouch Direct Fiber



NeverTouch Direct
PROCEDURE KIT

cardiva®

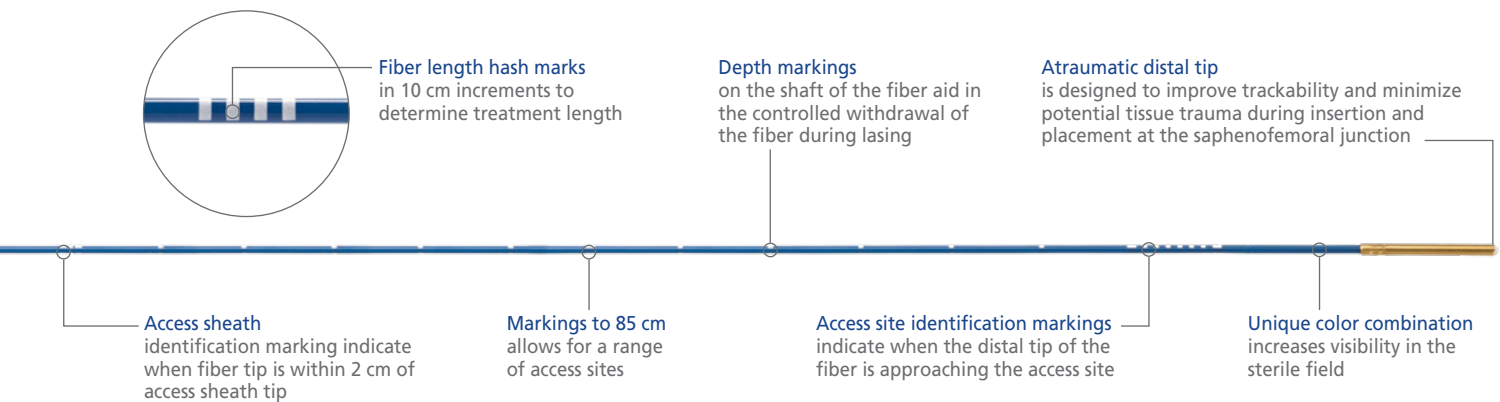
 **angiodynamics**

GO DIRECT: Less steps. Less time.

All the benefits of the NeverTouch fiber with a potentially shorter procedure time

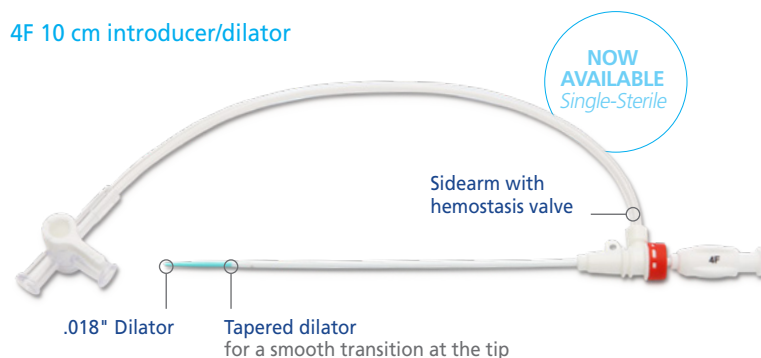
NeverTouch Direct Fiber

- Provides same benefits as the NeverTouch fiber, now with an atraumatic tip for sheathless placement
- Allows physicians to advance to the saphenofemoral junction without the use of a TRE-Sheath introducer in appropriate patients
- Allows physicians to gain access, advance the fiber and treat a diseased vein without the placement of a second guidewire
- Potentially results in faster procedures with fewer components



Enhanced Access Set

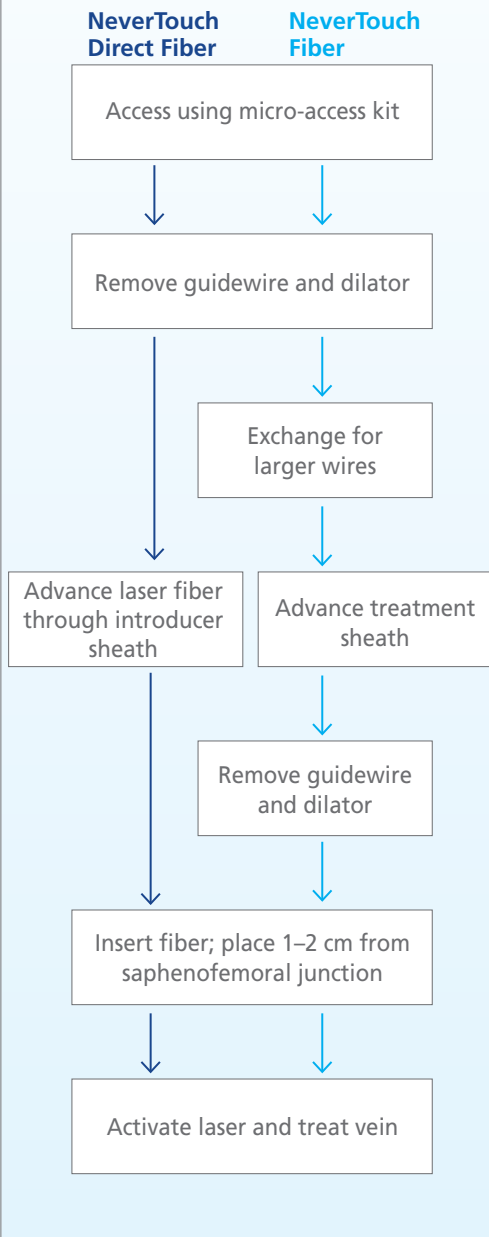
New access set components are designed for physician ease of use.



PROCEDURE STEPS

NeverTouch Direct Kit vs. NeverTouch Kits[†]

Fewer procedure steps result in a reduction of procedure time.

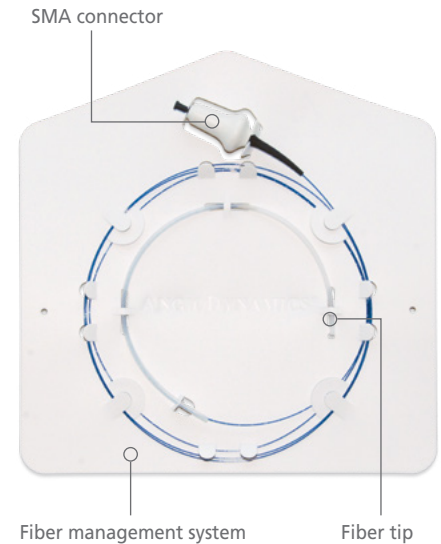


[†]The above is an abbreviated representation of the steps to treat a vein with the VenaCure EVLT system. All the steps necessary to successfully treat a varicose vein have not been included.

Procedure Kit Design

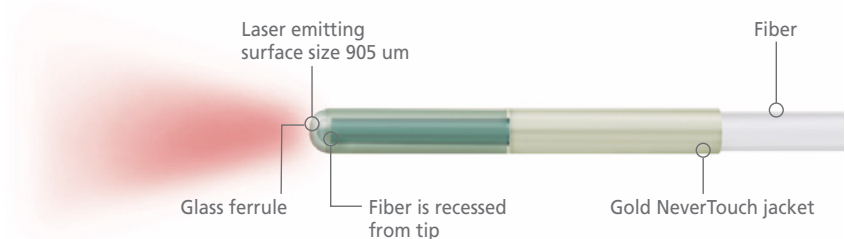
The package, designed with physician feedback, increases usability and functionality:

- The fiber management system allows for controlled removal of the fiber to increase ease of use and helps maintain a sterile field
- Access in the sterile field from either the SMA connector or fiber tip, or both
- Separate micro-access components packaging reduces waste
- Stackable boxes with a smaller package footprint makes storage more efficient



The Proprietary Science Behind NeverTouch Fibers

The innovation behind the NeverTouch fiber is a glass weld at the distal tip of a 600 μm fiber. The weld results in an effective fiber diameter of 905 μm and lowers the actual power density by 56 percent from that of a standard bare tip 600 μm fiber. The net effect is a homogeneous ablation with less focal charring of the vein wall than that which is seen with bare tip fibers. AngioDynamics' patent-pending technology is different from competitors with standard covered-tip fibers that have the same power density as a 600 μm fiber.



NEVERTOUCH DIRECT PROCEDURE KIT

Description	Part #	Sheath Length	Access Guidewire
NeverTouch Direct Procedure Kit	H787114031015	10 cm	45 cm

PROCEDURE KIT INCLUDES: (1) NeverTouch Direct fiber, (1) 21G echogenic access needle, (1) 4F 10 cm introducer/dilator, (1) 45 cm .018" nitinol/stainless steel wire

ACCESSORIES

Description	Part #	Size/Length	Qty/Box
NeverTouch Direct Introducer Sheath	H787165100011	4F/10 cm	10
TRE-Sheath Introducer Hydrophilic Coated	H787114033015	45 cm	5
TRE-Sheath Introducer Hydrophilic Coated	H787114033025	65 cm	5

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.

Consult your local AngioDynamics representative for country specific availability.

IMPORTANT RISK INFORMATION

INDICATION FOR USE: The AngioDynamics, Inc. VenaCure EVLT NeverTouch Direct Procedure Kits are indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremity. This product should be used only with lasers cleared for use in the treatment of varicose veins, varicosities with superficial reflux of the GSV, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limbs.

CONTRAINDICATIONS: Patients with thrombus in the vein segment to be treated. Patients with an aneurysmal section in the vein segment to be treated. Patients with peripheral artery disease as determined by an Ankle-Brachial Index <0.9. Patients with an inability to ambulate. Patients with deep vein thrombosis (DVT). Patients who are pregnant or breast feeding. Patients in general poor health. Other contraindications may be raised by the individual physician at the time of treatment.

PRECAUTION: Prior to and during use, avoid damaging the fiber by striking, stressing, or excessive bending. Do not coil the fiber tighter than a diameter of 20cm. Clinical safety and effectiveness data is not available for other fiber tip designs and diameters. Prior to and during use, avoid bending the introducer sheath and

dilator as this can cause kinks and damage. All persons in the treatment room must be wearing protective glasses with the proper rating for the wavelength being used.

WARNINGS: Treatment of a vein located close to the skin surface may result in skin burn. Paresthesia 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. Use appropriate eye and protective wear for both patient and operating personnel. Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your sales representative. Inspect prior to use to verify that no damage has occurred during shipping. Storage instructions: Keep away from sunlight; Keep dry; Upper limit of temperature: 27 degrees Celsius. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness, or death of the patient. Reprocessing may compromise the integrity of the device and/or lead to device failure, which, in turn, may result in patient injury, illness or death. VenaCure EVLT NeverTouch Procedure Kit is to be treated as contaminated biomedical waste subsequent to use. Additionally, the needle provided within the kit is a sharp device. The used or unused devices, as well as the sharps, should be disposed of in accordance with hospital, administrative and/or local government policy for such items. Uncontaminated device packaging should be recycled if

applicable, or disposed of as common waste in accordance with hospital, administrative and/or local government policy for such items. The fiber, guidewire and needle contain cobalt. Cobalt is classified as CMR 1B and is present in a concentration above 0.1% weight by weight.

CAUTION: This device is ethylene oxide sterilized and intended for single patient use only. Do not reuse or resterilize the fibers. Contents sterile in unopened, undamaged package. Do not use if opened or any sign of product damage is visible. Carefully read all directions and observe all Warnings and Precautions prior to performing the procedure.

POTENTIAL COMPLICATIONS: Adverse reactions may include, but are not limited to: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, skin pigmentation alteration, neovascularization, paresthesia due to thermal damage of adjacent sensory nerves, anesthetic tumescence, non-target irradiation, vasospasm, hemorrhage, necrosis, skin burns and pain.

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.

CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.



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International > Haaksbergweg 75 (Margrietoren), 1101 BR, Amsterdam Z-O > The Netherlands
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www.angiodynamics.com

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