Description
The InvisiGrip® Disposable Vein Stripper (Model # 1500-01, 1500-05) is designed for the removal of the long saphenous vein (LSV) by inversion stripping from the knee to the groin, without a distal incision.

The InvisiGrip® Disposable Vein Stripper Kit consists of the following components:
1. InvisiGrip Disposable Vein Stripper – an effective length of 60 cm. The nosepiece/sheath comes in a 5 mm diameter, connected to a 7 Fr. catheter.

Warning
Do not strip through a tourniquet or other restriction. Cable may break.

Sterility
This product is for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. LeMaitre Vascular will not be responsible for any product that has been re-sterilized.

Contents sterile unless package has been opened or damaged.

Contraindications/Precautions
• Immunocompromised patients and others with poor expectations for healing
• Infections
• Patients with active Deep Vein Thrombosis

Instruction For Use
1. Perform a skin incision at the groin area, above the saphenofemoral junction. Ligate the long saphenous vein and all the side branches at this junction including the subfascial branches.
2. After ligation of the long saphenous vein, lock the vein stripper closed, as shown in Figure 1, then insert the nosepiece of the vein stripper into the saphenous vein. Pass the vein stripper nosepiece through the long saphenous vein to the level of the knee joint.
   • To close: While maintaining traction on the T-handle, slide the T-handle body distally. Turn T-handle body towards the closed icon until markings align. FIGURE 1: Handle and Nosepiece LOCKED
3. Insert nosepiece of InvisiGrip into the saphenous vein at the saphenofemoral junction, and track it in the closed position to the knee. The location of the vein stripper's nosepiece/sheath should be evident by the lump formed under the skin. If there is no lump, the nosepiece and sheath can be found by palpating at the knee to locate head of device.
4. Once the vein stripper is in position, open the InvisiGrip to separate the nosepiece from the sheath, exposing the gripper blades as shown in Figure 2.
   • To open: While holding the T-handle, gently pull the T-handle body and turn body towards the open icon until markings align to unlock the InvisiGrip. Slide the T-handle body towards the T-handle to expose the gripper blades. FIGURE 2: Handle and Nosepiece UNLOCKED
5. Apply pressure on the open head of the device, while carefully moving the T-handle back and forth until resistance is felt, as shown in Figure 3. The resistance is that of the pins being secured to the vein wall. FIGURE 3: Press on open head
6. While maintaining traction on the T-handle, slowly rotate the T-handle and catheter 360°. This engages additional pins allowing a firm grip on the vein wall, as shown in Figure 4. FIGURE 4: Twist handle 360°
7. While maintaining traction on the T-handle, slide the T-handle body distally and turn T-handle body towards the closed icon until markings align as shown in Figure 5. This closes the device and secures the vein. FIGURE 5: Close device
8. Pull device, while holding the T-handle, with a slow and steady pull to begin invaginating the vein as shown in Figure 6. Continue applying traction to fully exteriorize the invaginated vein. FIGURE 6: Pull slowly
9. Once the vein is visible, exchange the traction on the stripper to direct traction on the invaginated vein trunk by using grasping forceps or manually.
   • If the vein breaks, the device can be reinserted at the groin, advanced slightly proximal to the approximate location of the break, and the process repeated until the entire vein is removed.

CAUTION: Federal (U.S.A) Law restricts this device to sale by or on the order of a physician.
Complications
In common with other vein stripping procedures, complications may occur. These may include saphenous nerve damage, ecchymosis, seroma, leg swelling, post-operative bleeding (Hematoma), infection, and thromboembolic complications.

Re-sterilization/Repackaging
This device is single-use only. Do not reuse, reprocess, or re-sterilize. The cleanliness and sterility of the re-processed device cannot be assured. Reuse of the device may lead to cross contamination, infection, or patient death. The performance characteristics of the device may be compromised due to reprocessing or re-sterilization since the device was only designed and tested for single use. The shelf life of the device is based on single use only. If for any reason this device must be returned to LeMaitre Vascular, place it in its original packaging and return it to the address listed on the box.

Limited Product Warranty; Limitation of Remedies
LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. LeMaitre Vascular makes no representation regarding the suitability for any particular treatment in which this device is used, which determination is the sole responsibility of the purchaser. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular’s sole option) following the purchaser’s return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user’s information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.
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