COOLTOUCH TRIO™ 25W TREATMENT GUIDELINES - ENDOVENOUS LASER PROCEDURE

The following is a safe start guide based upon the clinical observations of experienced physicians*.

**WARNING**
Possible neural and cutaneous injury. Treatment of the vein in the lower leg is associated with an increased risk of neural and cutaneous injury.

**WARNING**
Possible complications specific for closed endovenous therapy include:
- Vascular disruption
- Inadvertent deep vein penetration and thrombosis, particularly at the saphenofemoral junction
- Collateral tissue injury, particularly neural and dermal

I. Patient Selection and Preparation

1. Perform and document a thorough exam of all veins contributing to vascular insufficiency and reflux:
   - History of venous insufficiency with symptoms
   - Confirm diagnosis with Doppler and Duplex Ultrasound
   - Document CEAP classification

2. Contraindications - Patients with the following conditions may not be appropriate candidates for treatment:
   - Coagulopathy
   - Arteriovenous malformations in the vein segment being treated
   - Ongoing deep vein thrombosis
   - Non-palpable pedal pulses
   - Peripheral artery disease, indicated by ankle-brachial index of < 0.70
   - Pregnancy
   - Inability to ambulate
   - Active localized or systemic infection or immunocompromised

3. The following are potential complications from a surgical treatment of venous disease: ecchymosis, pain, edema, paresthesia, hematoma, phlebitis, thrombus, skin thermal injury/pigmentary changes and infection. The patient should be informed of potential complications, alternative treatments and expected outcomes (see sample consent forms in the CoolTouch Trio Owner's Reference Guide).

* This safe start treatment guideline is based in part on a percutaneous access approach utilized by Robert A. Weiss, MD, Maryland Laser Skin & Vein Institute, LLC, Hunt Valley. Mitchel P. Goldman, MD, Dermatology / Cosmetic Associates of La Jolla, Inc., La Jolla, CA has contributed to the development of a surgical vein access approach that can be used in this procedure.
II. Procedure Technique

1. Procedure room setup:

   - Ultrasound Tech
   - Sterile Assistant
   - Sterile Table
   - Mayo Stand (Optional)
   - CoolTouch CTEV Laser with Pull-Back

2. Set up procedure table with sterile supplies and drapes.
   - Assemble vein access introducers and flush with normal saline.

3. Patient examination:
   - Have patient complete and sign informed consent form.
   - Identify and map the vein to be treated with the patient in a standing position, using a continuous wave Doppler and Duplex ultrasound and/or a vein transilluminator.
   - Take photographs of the area being treated.
   - Document vein length and diameter.
   - Administer oral sedation, if desired by the physician, approximately one hour before the procedure.

   - Using ultrasound, mark the vessel with a permanent-type skin marking pen, noting important landmarks, such as potential access site, the position of the saphenofemoral junction (SFJ) or other pertinent junctions, any large, dilated portions of the vein or large perforators.
   - Use steps to avoid vasospasm including: heat packs, 2% Nitroglycerin ointment to the access site, keep patient and room warm, present calm, confident atmosphere, use of music headphones for patient, avoid multiple needle sticks whenever possible.
   - Reverse Trendelenburg position may be used to dilate small veins on the leg for easier access.

   **NOTE: Keep patient warm to avoid vasoconstriction of the vein.**

5. Prep and drape the patient:
   - Perform surgical skin prep using Hibiclens®, or other skin disinfectant that will not remove vein markings.
   - Drape with sterile drapes such as a split sheet or laparotomy drape allowing access to the entire length of the vein being treated.
   - Place the ultrasound probe in sterile sleeve.
6. Laser Safety:
   - Make sure that all individuals in the treatment room have the appropriate laser eyewear protection, including the patient, as directed by the laser safety officer.
   - Place the laser treatment sign on all doorways entering the treatment room.

7. Set up the CoolTouch Trio laser system:
   - Open the sterile laser fiber onto the sterile field.
   - DO NOT remove the protective cap from the SMA connector end of the laser fiber. The plastic cap is on all fibers (See Figure 1).
   - Pass the SMA connector end of the laser fiber to the non-sterile assistant.
   - Remove the SMA Connector Protective Cap, connect the fiber to the laser system, turn the laser on and depress footswitch to conduct a shutter test.
   - Remove the Fiber Data Card from the fiber package and insert the Card into the Card Reader Slot located on the top of the laser console (See Figure 2).
   - Insert the Card label side up with the arrows pointing into the card slot until the card snaps into place (See Figure 3). Refer to the Fiber Data Card Process insert that comes with the CoolTouch CTEV fiber.
   - Set the laser with starting treatment parameters (see step #14.)
   - Press the Aim button on system panel to check the quality of aiming beam at the distal end of the fiber. Hold the distal end of the fiber approximately one inch away from a non-reflective surface. The aiming beam should appear bright and round with little or no scatter (refer to Fiber Preparation Instruction Guide).
   - A folded towel may be used to help keep the fiber on the sterile field.

**CAUTION: LASER FIBER DAMAGE**
Handle the laser fiber with care to ensure that it has not been kinked, punctured, fractured or damaged. Do not leave fiber where it can be kinked, stepped on, pulled or tightly coiled (coil > 6 inch diameter). Do not clamp the fiber with a hemostat or other instrument. A damaged fiber can cause accidental laser exposure to personnel or the patient. Always verify the presence of the aiming beam before beginning treatment. Absence or dimness of the aiming beam may indicate damage or breakage to the laser fiber.

8. Obtain percutaneous access of the vessel being treated using a Seldinger Technique. The length and size of the access devices will vary depending on the length and size of vein being treated and the fiber selected.

**NOTE:** When using the standard 600um fiber with a blunt tip, the use of a long 5F introducer sheath is recommended. This is to avoid perforation of the vein while attempting to advance the fiber. A short, 4Fx12 cm sheath can be used with the
“protected-tip” SaphFire™ 2.5F fiber. In addition, the SaphFire increases the ability to access tortuous veins not previously accessible.

9. Advance sheath
   - Advance the introducer sheath over the wire until it is approximately 2 cm below the SFJ or the SPJ or at the appropriate distance based on the junction or vein being treated.
   - Confirm position of the sheath’s tip with ultrasound.

10. Once the sheath is in the desired position, the following methods should be used to reduce vein size*:
    - Position patient in 20° - 30° Trendelenburg
    - Elevate the extremity being treated
    - Use a sheath with a side arm. A syringe (20cc) is then attached to the stopcock on the sidearm and by withdrawing on the syringe; blood can be exsanguinated from the vein.

11. Inject local anesthesia around the vein being treated
    - Using ultrasound, observe infiltration of tumescent anesthesia* solution around the vein.
    - 250 ml or less of tumescent solution (depending on the length of the vein being treated) is sufficient to provide thermal protection for the surrounding tissue and provide adequate patient comfort.

12. Advance laser fiber
    - Advance the laser fiber through the introducer sheath until it is approximately 2 cm below the SFJ or the SPJ or at the appropriate distance based on the junction or vein being treated.
    - Confirm position of the fiber tip with ultrasound.
    - Visualize the aiming beam through the patient’s skin (the room lights may need to be darkened at this point for adequate visualization).

13. Remove or pull out any introducer sheath at the access site
    - Removal of the sheath will prevent the laser fiber from entering the sheath during the automatic pull-back.
    - Reconfirm fiber tip position once the sheath has been pulled out.

**WARNING**

_The sheath must be removed from the vein before the application of laser energy. This will eliminate the possibility of laser energy being applied to the inside of the sheath and will prevent damage to the sheath and fiber. Removing the sheath (introducer) assists in the correct operation of the JouleTracker, reduces the amount of residual blood in the vein, assists in reducing the vein diameter, and improves ablation outcomes._

* A patent for the method of using Tumescent Anesthesia to compress the vein during endovenous ablation has recently been issued. This patent is currently being litigated in the courts. The patent covers only the use of Tumescent Anesthesia to compress the vein. It does not cover Tumescent Anesthesia in general or for the purpose of providing a thermal heat sink or anesthesia. CoolTouch cannot teach Tumescent Anesthesia that compresses the vein. However, we recommend Tumescent Anesthesia for the purpose of providing a heat sink or for anesthetizing the surrounding tissue. CoolTouch believes that vein compression can be useful for blood drainage which can be accomplished in a superior manner by leg elevation and suction prior to the use of tumescent anesthesia. Use of the CoolTouch Trio laser in conjunction with veins that are visibly compressed during the injection of tumescent anesthesia could constitute patent infringement.

14. Set up the PullBack Device:
15. Set starting laser treatment parameters using 600 µm and SaphFire fibers:
   - If using 1.0mm/sec pull-back speed set power to 6 Watts* at 50 Hz, if using a start speed of 2.0mm/sec set power to 12 Watts.
   - Use 0.5 mm / sec @ 6W or 1.0mm/sec @ 12W when starting near the SFJ for the first 4-5 cm
   - Switch to the higher pull-back speed where the vein has narrowed or when treating smaller veins
   - Set laser system to READY mode.

*NOTE: As with any clinical procedure there are many variables involved. The starting energy of 6W @ 1.0mm/sec or 12W @ 2.0mm/sec is a guideline. In any given treatment the required energy might need to be changed.

16. Begin laser treatment for two to three seconds without fiber pull-back
• View tissue response under ultrasound observation. When treating near the junction, where residual blood may be present do not activate the PullBack pull-back device for the first 2-3 seconds of treatment to ensure that the area is heated sufficiently to close the first section of vein.

• If the desired tissue effect in the vein is not seen, increase wattage.

• Indications of adequate tissue response include:
  ♦ Slowing or stopping of forward movement of flow
  ♦ Thickening of the vein wall
  ♦ Contraction of the vein
  ♦ Decrease in size of the vein lumen

**NOTE: A valuable technique to ascertain whether or not the area just below the SFJ is closed is to (with the laser and PullBack off) gently advance the fiber and probe the closed area under ultrasound guidance to determine if the vein is completely closed.**

17. Activate the PullBack
• Always observe fiber movement using ultrasound.
• When treating a large or dilated segment of a vein or a large perforating vessel, stop the PullBack for several seconds while continuing with the laser treatment. Alternatively you can slow the pull-back speed to half-speed.

**CAUTION: PATIENT OVERTREATMENT**
*Changing the pull-back speed will change the fluence per linear centimeter delivered to the vein.*

**CAUTION: PATIENT UNDERTREATMENT**
*Stop the PullBack if laser treatment is interrupted to avoid untreated segments of the vein. Not doing so may result in under treatment or no treatment.*

**CAUTION: AIMING BEAM**
*Do not continue laser treatment unless the aiming beam is present and fiber movement is confirmed.*

18. Continue to observe the aiming beam through the skin and the tissue effect in the vein with the ultrasound. Place fingers on either side of the fiber at the exit point from the skin to verify movement and to support the fiber as it is being pulled out.

19. When fiber is several centimeters from the access site, stop laser treatment. Remove the introducer sheath completely from the vein. Resume laser treatment by using manual pull-back of the fiber, continue firing laser until the fiber exits the vein.

20. Switch off the PullBack as soon as the fiber is completely out of the vein to prevent blood on the fiber from being pulled into the device.

21. Following the treatment, observe the appearance of the vein with the ultrasound:
• Vein appears more dense and thickened (more echogenic)
• Vein is less compressible with pressure from the ultrasound probe
• Vein lumen is noticeably smaller in size
• Vein does not demonstrate spontaneous flow

22. Document laser treatment parameters including:
- Fiber type and size, Watts and Hz
- Pull-back speed
- Vein diameter and length
- Press the data button on the system panel to display and document:
  - Total number of pulses
  - Total energy delivered
  - Total exposure time
- Turn off the laser system once the parameters have been recorded.

**NOTE:** All treatment parameters are removed from memory following a power-off of the laser system. Therefore it is important to document treatment parameters prior to the laser being turned off.

23. Apply dressings at the completion of the procedure:
- Steri-Strips®
- Absorbent dressing over access site
- 3-inch self-adherent tape wrap
- 30 - 40 mm Hg compression hosiery should be placed over dressings with the patient lying down.

**IV. Post-Treatment Instructions**

1. The patient should begin walking immediately after dressings and hosiery are in place.

2. Post-treatment care (refer to sample post-treatment instruction forms in the CoolTouch Trio Owner’s Reference Guide) will vary with physician preference and should include instructions for:
   - Dressing and wound care
   - Use of compression stockings
   - Activity level
   - When to return for follow-up appointments

**V. Supplies for Procedure**
1. **Ancillary Supplies:**
   - Sterile drapes, table cover, mayo stand cover, towels, gowns and gloves
   - Small sterile basins
   - Sterile surgical permanent-type skin marking pen and ruler
   - Sterile saline
   - #15 or #11 scalpel blade
   - Sterile ultrasound probe cover with gel
   - Additional packets of sterile ultrasound gel
   - Sterile 4 x 4 gauze
   - Supplies for patient skin prep

2. **Medications:** (will vary based upon physician preference)
   - Light oral sedation may be given to the patient on arrival at the discretion of the physician (e.g. Valium 10 mg p.o.)
   - Inderal 20 mg p.o. given just before beginning vascular access
   - Nitroglycerin ointment 2%, applied over access site for small veins

3. **Anesthesia Supplies:** (will vary based upon physician preference)
   - 30g ½ inch needle, syringe
   - Local anesthesia
   - 18g 1½ inch needle to withdraw medications
   - Tumescent anesthesia solution\(^1,2,3\)
   - 20g - 21g 3½ inch needle
   - Sterile IV tubing, infiltration pump and tubing or refilling syringe system

4. **Vein Access Supplies:**
   - Heat pack for access site
   - Long introducer kit (depending on vein size and length) with 5F x 45 cm straight introducer, vessel dilator and 0.035 inch x 125 cm stainless steel double-ended guide wire
   - 18g or 19g thin-wall percutaneous needle that will allow the passage of the 0.035 inch guide wire
   - 5 F Micro-introducer access kit may be needed for smaller vein access
   - 4 F Micro-introducer access kit may be used when working with protected tip SaphFire fibers, or when a longer sheath is not needed

5. **Dressings:**
   - Steri-Strips\(^\circledR\)
   - Sterile 4 x 4 gauze
   - Absorbent gauze pad
   - Self adhesive conform-type bandage wrap
   - 30 – 40 mm Hg compression stockings

6. **CoolTouch Laser Equipment:**
   - CoolTouch Trio 25W 1320 nm laser system
   - CoolTouch laser fiber
   - Fiber Preparation Kit for Re-usable fibers (includes fiber stripper and cleaving tool)
   - CoolTouch PullBack\(^\text{TM}\) device

7. **Ancillary Equipment:**
   - Duplex ultrasound
   - Doppler and/or vein transilluminator
   - Patient treatment bed that can be positioned in Trendelenburg, reverse Trendelenburg and height adjustable is recommended.
   - Table for procedure setup

**References:**