



## Laser-Assisted Lipolysis Treatment Guidelines

*The CoolLipo Trio laser system is for use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue and treatment of fine lines and wrinkles. For use in treatment of back acne and atrophic acne scars. The CoolLipo Trio laser system is indicated for the treatment of reflux of the great and small saphenous veins associated with varicose veins and varicosities. Also for laser assisted lipolysis.*

### Introduction

The CoolTouch Trio laser system combines the unique characteristics of the 1320 nm wavelength, different pulse lengths and a special fiber that have been optimized to produce two different tissue effects. In the ABLATE mode of the Trio laser, a short pulse length combined with unique fiber characteristics results in a photoacoustic effect that produces an acoustic explosive shockwave. This causes a destruction of the adipose cell walls, resulting in easier removal of unwanted fat. This is a unique treatment mechanism among medical lasers that differs dramatically from conventional thermal laser-tissue interaction.

Utilizing a much longer pulse length, the THERMAL mode of the Trio laser produces a photothermal tissue effect that results in percutaneous skin tightening. This mode is used to treat areas with skin laxity without significant underlying fat or loose skin as a result of the fat removal during traditional liposuction. The unique properties of the 1320nm wavelength gently heat, contract and stimulate collagen production in dermis and fibrous septae in remaining adipose tissue to produce a smoother, tighter and more firm appearance to the skin.

***Treatment methodologies can vary depending on physician experience, physician preference, patient selection, treatment area and the desired results.***

Examples of possible treatment pathways include:

- *Simultaneous laser assisted lipolysis and lipoaspiration using the combination Duet™ handpiece followed by skin tightening*
- *Laser assisted lipolysis followed by conventional liposuction, followed by skin tightening*
- *Conventional liposuction (no laser lipolysis) followed by skin tightening*
- *Laser assisted lipolysis with manual aspiration followed by skin tightening*
- *Laser assisted lipolysis, with no aspiration followed by skin tightening*

***WARNING: POSSIBLE NEURAL AND CUTANEOUS INJURY  
Treatment for the removal of tissue may increase the risk of neural and cutaneous injury in the treatment area.***

## **I. Patient Selection and Preparation**

1. Perform history and exam of the patient to determine appropriateness of the procedure for the following conditions:
  - Small focal areas of unwanted fat, such as the neck, that are unresponsive to diet and exercise
  - Areas of skin laxity without significant underlying fat deposits
  - As an adjunct to standard liposuction to enhance the removal of adipose tissue through liquefaction
  - To tighten areas following traditional liposuction that has resulted in laxity in the overlying skin
  - Patients with realistic expectations and goals
2. Contraindications - Patients with the following conditions may not be appropriate candidates for treatment:
  - Patients desiring removal of large volumes of tissue
  - Patients with unrealistic expectations
  - Patients with prior trauma, surgery or who have scar tissue or excessive fibrosis in the treatment area
  - Pregnancy
  - Bleeding disorders or history of thrombophlebitis
  - Active localized or systemic infection or immunocompromised
3. **Complications:**
  - Some side effects are considered normal and expected, such as mild bruising, discomfort pain, slight edema, asymmetry, contour imperfections
  - Other complications associated with standard liposuction include: dysesthesia, hematoma, skin injury, hyperpigmentation, infection, and seroma
  - More severe complications are usually associated with large volume standard liposuction procedures
  - The patient should be informed of potential complications, alternative treatments and expected outcomes

## **II. Procedure Technique**

1. Assemble supplies and equipment for the procedure (see list of supplies)
2. Pre-treatment:
  - Have patient complete and sign informed consent document(s)
  - Identify and mark the areas to be treated, if desired
  - Take photographs of the area being treated
  - Administer oral sedation, if desired by the physician, approximately one hour before the procedure
  - Position patient on treatment bed
  - Begin prophylactic antibiotics, as indicated
3. Prep and drape the patient:
  - Perform surgical skin prep using a skin disinfectant solution
  - Drape the treatment area with sterile drapes to create a sterile field
4. 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
  - Do not use flammable drape materials or solutions that could be ignited in the event of a break in the laser fiber

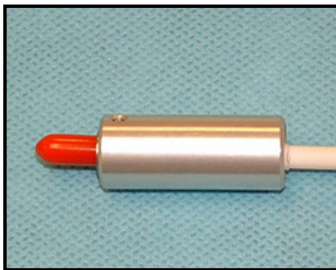
- Additional precautions should be taken in the presence of anesthesia gases and oxygen during general anesthesia when performing procedures near the patient's airway
- Place the laser treatment sign on all doorways entering into the treatment room

**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 (smaller than a 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.**

- Set up the CoolLipo laser system:
  - Open the sterile CoolLipo laser fiber and laser hand piece onto a sterile field
  - DO NOT remove the protective cap from the SMA connector end of the laser fiber. (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 fiber
  - A folded towel may be used to help contain the fiber on the sterile field

**Figure 1**



**Fiber SMA Connector with Protective Cap**

**Figure 2**



**Card Reader Slot**

**Figure 3**



**Card Inserted into Card Reader Slot**

- Assemble the CoolLipo laser fiber and laser hand piece
  - Insert the laser fiber through the hand piece until it extends 4-6 mm outside the distal end of the cannula
  - Tighten the connector at the proximal end of the hand piece until it is snug and the fiber position is fixed within the hand piece
  - Press the "Aiming" 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 CoolTouch CoolLipo Fiber Preparation Instruction Guide 7115-0036)
- Tumescent anesthesia:
  - Provides anesthesia to the treatment area for patient comfort

- Hydro-dissects and creates a plane in the tissue
- Provides a heat sink to protect non-target tissue from damage
- Use a short, 30g needle to first numb the skin
- A long 22-25g (3 ½ inch) needle or an infusion cannula designed specially for tumescent anesthesia may be used to infiltrate adipose tissue
- Use a #11 scalpel blade to slightly enlarge access sites for the laser fiber hand piece
- Access sites will vary depending on the anatomy of the treatment site

8. Laser lipolysis treatment parameters - **ABLATE MODE:**

- Set the laser system to ABLATE mode for starting laser-assisted lipolysis
- See Trio Energy Matrix (CoolTouch document #7110-0094) for additional information on photoacoustic lipolysis and skin tightening treatment parameters

**WARNING: POSSIBLE MORBIDITY AND MORTALITY**  
*The CoolLipo Trio is a high-powered 25-watt laser. Inappropriate settings, and/or inexperience with laser lipolysis and liposuction increase the risk of neural and cutaneous injury in the treatment area and may cause morbidity and/or mortality.*

**CAUTION: LASER ENERGY SETTINGS**

*As with any clinical procedure there are many variables involved. The starting energies recommended in the table below are guidelines. In any given treatment the required energy might need to be increased or decreased.*

<b>Treatment Area:</b>	<b>Ablate Mode</b>
Abdomen	10 Watts
Under arms	8 Watts
Thighs	8 Watts
Chin/submental	6-8 Watts

9. Begin laser treatment:

- Set laser system to READY mode
- Insert the laser fiber and hand piece into tissue
- Observe the presence of the aiming beam in tissue. The aiming beam **MUST** be visible before firing the laser to prevent damage to the laser hand piece

**CAUTION: POSSIBLE HEATING OF THE LASER HAND PIECE**

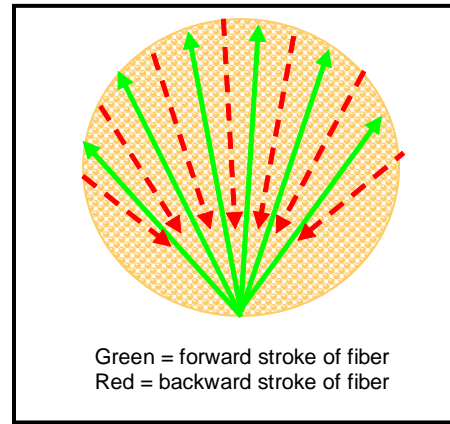
*Do not begin laser treatment with the fiber inside or adjacent to the tip of the cannula. Rapid heating of the cannula by the laser beam may damage the cannula and may cause damage to tissue.*

10. Treatment techniques for laser lipolysis - **ABLATE MODE**

- Keep the laser fiber moving at all times in a gentle back and forth movement of the laser hand piece while firing the laser to achieve a smooth, uniform delivery to tissue
- The aiming beam should appear diffuse or fuzzy in tissue (See Figure 4). A pinpoint red aiming beam can indicate that the fiber is too close to the skin surface
- Avoid over delivery of laser energy near the access site by limiting the amount of laser treatment as the fiber is moved back towards the access site (See Figure 5)



**Figure 4**  
**Diffuse Appearance of Aiming Beam**



**Figure 5**  
**Avoid Concentration Energy Delivery Near Access site**

Green = forward stroke of fiber  
Red = backward stroke of fiber

- When operating properly in the ABLATE mode, an audible popping sound can be heard coming from the fiber tip indicating that an ablative photoacoustic tissue effect is occurring. If this sound is not heard, stop treatment and remove the fiber. Re-cleave the fiber and re-insert cleaved fiber into laser hand piece and continue procedure

**NOTE: If the wrong fiber or an inadequate level of power is used, the acoustic effect may not occur resulting in minimal tissue ablation and possible under treatment.**

- The patient may describe a “fluttering” sensation and pressure but should not feel discomfort. Additional tumescent anesthesia may be needed if there is any pain in a given area
- It is recommended that the physician place one hand on the outside of the skin to help gauge the movement of the laser hand piece and to detect heat on the skin surface

11. Clinical endpoints:

- Will vary based on size and volume of treatment area
- Loss of resistance to laser fiber and hand piece passage through tissue
- Palpation of the treated area has an overall soft, smooth and even contour
- Bilateral treatment area should be evaluated for symmetry and similar amounts of treatment energy, time and amount of aspirate removed
- “Skin pinch test” - no more than 1 finger width (1 inch) of tissue between fingers

12. Treatment techniques for skin tightening - **THERMAL MODE:**

- Changing the mode to THERMAL will change treatment to produce a thermal effect for skin tightening, rather than a lipolysis mode
- Starting skin tightening settings are listed below. See Trio Energy Matrix (CoolTouch document #7110-0094) for additional information
- The laser energy produces heat which shrinks and tightens collagen percutaneously

<b>Treatment Area:</b>	<b>Thermal Mode</b>
Abdomen	8 Watts
Under arms	6 Watts
Thighs	6 Watts
Chin/submental	5 Watts



**Figure 6**  
**Pyrometer Measuring Skin Temperature**

- A pyrometer may be used to accurately monitor the skin temperature by first taking a baseline temperature and watching for a rise in the skin temperature as the laser energy is delivered (see Figure 6)

13. Document all laser treatment parameters including:

- Fiber type and size, watts and ablate/thermal mode
- Press the data button on the system panel to display and document:
  - ◆ Total number of pulses
  - ◆ Total energy delivered (in joules)
  - ◆ 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 laser shut down.**

14. Apply dressings at the completion of the procedure:

- Steri-Strips<sup>®</sup> for the access sites (they may be left open for ease of drainage)
- Compression garment, such as a chin strap, for procedures on the neck

#### **IV. Post-Treatment Instructions**

1. Post-treatment care will vary with physician preference and should include instructions for:

- Dressing and wound care
- Use of cold packs to reduce bruising, if ordered
- Use of compression garment
- Activity level
- When to return for follow-up appointments
- Medications for discomfort and antibiotics, if ordered

## V. Supplies for Laser-Assisted Lipolysis with Liposuction

1. Ancillary Supplies:
  - Patient treatment bed
  - Procedure mayo stand with tray or cart
  - Sterile drapes and towels to create a sterile field (should be fire-retardant)
  - Sterile drapes, table cover, mayo stand cover (optional) towels, sterile gloves
  - Sterile saline 250cc size or less
  - Sterile 4 x 4 gauze
  - Supplies for patient skin prep (basin, prepping solution and 4x4s or prep sticks)
2. Tumescent Anesthesia Supplies
  - Syringes for mixing solution
  - Lidocaine, epinephrine and IV solution based on physician preference
  - 18g needle for mixing and drawing up meds
  - 27g or 30g ½ inch needle for local injection
  - 22-25g 3½ inch needle or tumescent infusion cannula
  - Syringes or self-filling syringe system for manual infusion
  - Infusion pump and matching pump tubing set for automated infusion
3. CoolTouch Laser Equipment:
  - CoolTouch CoolLipo 1320 nm laser system
  - Sterile CoolLipo Fiber
  - Sterile CoolLipo Handpiece
  - Fiber Preparation Kit for Re-usable fibers (includes instructions, cleaving tool and fiber stripper)
4. Ancillary Instruments and equipment:
  - Small sized liposuction cannula system for small, delicate treatment areas
  - Spatula-tip cannula for areas with thin skin, such as an 16g (8cm) Finesse Micro-cannula (HK Surgical #HK16F8)
  - Larger and/or longer sized liposuction cannulas for larger treatment areas
  - 20 cc Syringes for manual aspiration
  - Liposuction aspirator machine, aspirator tubing and canister for mechanical removal of fat
  - #11 Scalpel or sharp-point scissors to open access site
  - Towel clips (optional) to secure drapes and hold tubing on the sterile field
5. Dressings:
  - Steri-Strips® (optional)
  - Sterile 4 x 4 gauze
  - Absorbent pads such as Maxi pads or special pads for liposuction
  - Extra gauze and pads for patient to take home
  - Compression garment, such as a chin strap for the neck, fit to the patient before the procedure
6. Supplies for re-processing CoolLipo fibers:
  - Instrument disinfectant soap or solution
  - Small plastic basins for soaking instruments and fiber separately
  - Instrument cleaning brushes for all cannulas
  - Ultrasonic cleaner sized to fit liposuction cannulas (optional)
  - Steam Sterilizer or Autoclave with a chamber large enough for longest instruments
  - Various sizes of sterilization pouches:
    - Must have one size approximately 7 x 11 inch so that the laser fiber is coiled no smaller than 6 inch diameter
    - Narrow and longer pouches for the laser hand piece and any other liposuction cannulas as needed
7. Patient supplies and positioning aides
  - Pillows (at least 2)
  - Cervical neck roll
  - Blankets, sheets, water proof drape for treatment bed
  - Patient robe or gown
  - Patient monitoring equipment such as blood pressure monitor, stethoscope, pulse oximeter, depending on level of sedation.