

### Smartlipo<sup>™</sup> FAQs (Frequently asked questions)

#### LaserBodySculpting<sup>SM</sup>, Laserlipolysis

The Smartlipo<sup>™</sup> is the first laser system designed for LaserBodySculpting<sup>SM</sup> and for the disruption of fat cells. It is ideal for treating localized deposits of unwanted fat, fat tissue irregularities and for coagulating tissue leading to a tightening effect.

Smartlipo is ideal for treating small areas of the face, neck, arms, male breasts (gynecomastia), and other areas of loose or lax skin (flabby skin).

#### How does the Smartlipo work?

Smartlipo laserlipolysis is a minimally invasive surgical procedure. The procedure disrupts the fat cells through a thermal and photodisruptive action – heating and shattering the fat cell membrane. The laser coagulates the underlying vessels due to the hemostatic properties of the laser, resulting in less bleeding, bruising, trauma as well as less down time. As an added benefit, the system has also been reported to promote tissue tightening through bulk thermal heating and tissue coagulation.

The procedure is commonly performed under local and tumescent anesthesia. A laser fiber is introduced through a handpiece and detachable cannula. The cannula is then inserted through a 1 to 2 mm incision in the skin and into fat pockets. The cannula, with the tip of the fiber exposed approximately 2 mm, is then moved in a “back and forth” fanning motion. The laser’s aiming beam can be visualized through the skin, allowing the physician to identify the treatment area. As the fiber tip comes in contact with the fat cells it ruptures the cell membranes and releases the fatty oil from the fat cells. This end product may then be aspirated from the site.

#### What are the benefits of Smartlipo?

- Treats unwanted fat and fat tissue irregularities
- Promotes tissue coagulation resulting in skin tissue tightening



- Treats flabby or lax skin and areas of high vascularity
- Minimal edema and bleeding due to the laser's hemostatic properties
- Minimal bruising
- Causes less trauma and faster healing time than traditional liposuction



#### What type of system is used?

The Smartlipo is an Nd:YAG laser with high peak power and a high rep rate of 40 Hz. The laser energy is delivered using a 300 micron fiber which is threaded through the handpiece and cannula.

#### Are there disposable costs associated with the procedure?

Laserlipolysis with the Smartlipo system has very few disposable costs associated with the procedure. The handpiece and cannulas are re-usable and would only be replaced due to normal wear and tear. The fiber is warranted by the manufacturer for one use. However, the fiber is a “cut and cleave” design, meaning you could simply continue to trim down the end of the fiber after each case.

#### Does this procedure have FDA Clearance?

The Smartlipo has been cleared by the FDA for laser-assisted lipolysis. It is also cleared for incision, vaporization, ablation and coagulation of soft tissue.

#### Who can use the Smartlipo?

Currently, only physicians who have previous liposuction experience are able to purchase the Smartlipo laser. Prior liposuction experience will shorten the learning curve significantly. Those without prior liposuction training and experience should be trained based on the guidelines of the American Academy of Cosmetic Surgery.

#### How is training for the Smartlipo system handled?

Once a customer purchases the unit, they will receive training on the procedure at a designated Cynosure training site.

Due to the nature of the product and procedure there will be no demonstration of the Smartlipo system.

**Does laser-assisted lipolysis produce lasting results?**

Yes! The Smartlipo procedure permanently destroys the treated fat cells. Adults do not create new fat cells. When a person gains weight, that person's fat cells simply expand. Should you gain weight, that fat will most likely be deposited in areas where the procedure was not performed.

**Who is a good candidate for the procedure?**

Ideal candidates are in good health, close to normal body weight and have realistic expectations for the results. If the person has areas of fat that will not respond to diet and exercise, then that person is a candidate for laser-assisted lipolysis.

**How many treatments are required?**

For most patients, typically only one treatment is required. The session may last from 45 minutes to one hour for each area treated. Laserlipolysis is also an ideal choice for "touch ups" and revisions.

**How can facilities become training sites?**

Cynosure is very interested in establishing training sites for the Smartlipo through out the country. The qualified training centers should perform 10-20 liposuction cases per month and be willing to follow Cynosure training guidelines.

**How does the Smartlipo compare to the Vaser?**

Smartlipo is a laser system with the energy transmitted through the fiber (which is threaded through the cannula) and deposited directly to the tissue, disrupting the fat cells. The laser's aiming beam allows visualization of the treatment area.

The Vaser is an ultrasonic device that transmits energy throughout the entire probe and not just the tip. The energy is more difficult to control and has been known to cause burns near the incision. The probe is much larger than the laser fiber and requires a larger skin incision.

The company provides the system and all accessories to the customer and charges \$500 per procedure with a minimum of 4 procedures per month.

**How does the Smartlipo compare to the new ultrasound systems such as Ultrashape or Liposonix?**

These systems are non-invasive and deposit focused ultrasound energy that does not differentiate between fat and other structure within the body. Extreme care must be taken to guide the system through out the treatment area. The scanner remembers where the system had fired. For example, the Ultrashape device has a 5 mm spot size used via a scanning mode. A 10x10 cm area can take over one hour to treat.

**Case Studies**