

# SculpSure Frequently Asked Questions

## Results/Efficacy

### **Q: How long will the improvement in my appearance last?**

**A:** The treated fat cells are permanently destroyed and will not regenerate. SculpSure is intended for those who maintain a healthy lifestyle, yet experience stubborn fat in treatable areas, such as the flanks, abdomen, inner and outer thighs, back, and under the chin. As long as significant weight gain is not experienced, you will maintain your SculpSure results.

### **Q: Will SculpSure cause “shelving”, “shark bites”, lumpy or uneven areas?**

**A:** SculpSure’s light-based technology targets and heats fat cells, destroying their structural integrity. The feathering of heat spread provides a natural smooth contour, unlike cryolipolysis, which uses fat-freezing technology and has had reported instances of both the above side effects.

### **Q: Will my stubborn fat be completely eliminated?**

**A:** During a SculpSure treatment, fat cells in the treated area are disrupted with heat and naturally eliminated over time. However, it is unlikely that all fat cells will be removed from the treated area.

### **Q: How many treatments will I need?**

**A:** Every client is different. Most clients see the best results when they have a series of treatments. Ask your treatment provider about the treatment plan that is right for you.

### **Q: Will I lose weight?**

**A:** SculpSure is not a weight loss solution, and therefore does not result in weight loss following treatment.

### **Q: How soon will I see results after a SculpSure treatment?**

**A:** Many clients start to see results as early as six weeks following treatment, as the body begins to evacuate the destroyed fat cells, with optimal results usually seen 12 weeks after your final treatment.

### **Q: What kind of results can I expect to see?**

**A:** Your treatment area will look smaller and more contoured. You may even notice that your clothes fit better!

### **Q: Will I see results after one treatment?**

**A:** Most clients require a series of treatments to achieve the results they desire. Results can be seen at six weeks after treatment, with optimal results typically seen at 12 weeks.

### **Q: How much fat will SculpSure remove?**

**A:** While every client is different, some studies show up to 24% of fat cells can be destroyed in the treated area.\*1

## **Pre-Treatment**

### **Q: Who is a good candidate for SculpSure?**

**A:** SculpSure candidates have stubborn fat in areas that seem resistant to diet and exercise. SculpSure is intended for non-invasive fat reduction of the abdomen, flanks, back, inner and outer thighs and the submental (under the chin) area. SculpSure is not a weight loss solution and is ideal for candidates with a BMI of up to 30 for body treatments and up to 43 for under the chin treatments.

### **Q: How should I prepare for my SculpSure treatment?**

**A:** Be sure that your skin is free of lotions or creams, that you have eaten a meal and are well-hydrated.

### **Q: Can I get treated while pregnant?**

**A:** We do not recommend treatment for pregnant or lactating mothers.

### **Q: Do I have to take any medication before or after my SculpSure treatment?**

**A:** There is no need for any medications with the SculpSure treatment. Client feedback helps us determine appropriate settings during the treatment.

### **Q: Can I get a SculpSure treatment if I have had other procedures done?**

**A:** During your consultation, it is important to share your medical history, including prior treatments, so that your treatment provider can determine if SculpSure is right for you. Recent surgeries in the treatment area need to be discussed with the treatment provider.

### **Q: Can I get a SculpSure treatment right before a special event?**

**A:** SculpSure treatments will not require any change in your normal daily routine. You may experience mild tenderness after your treatment, but this should not affect your daily activities. However, if your intent is to have results before the event in question, please plan ahead for optimal results – 6-12 weeks post-treatment. You will need to adjust your timeline accordingly.

### **Q: What is the minimum / maximum BMI permissible with SculpSure?**

**A:** SculpSure for the body (flanks, abdomen, thighs, and back) is intended for clients with a BMI of 30 or less. Patients contouring the under-chin area can have a BMI of up to 43. However, it is more important to consider the body composition of each client and expectations. Your provider will assess your areas of concern and determine if your body type is appropriate for treatment.

### **Q: What areas of my body can I have treated with SculpSure?**

**A:** SculpSure is FDA cleared for treatment of the abdomen, flanks, inner and outer thighs, bra fat, and submental(under the chin) areas.

### **Q: How much does a SculpSure treatment cost?**

**A:** Your provider will develop a customized treatment plan based on your desired results. Ask your treatment provider for the treatment package that is right for you.

## During your treatment

### **Q: How long does a treatment take?**

**A:** Each SculpSure treatment takes 25 minutes to complete. Multiple treatment areas may be recommended in a single day to achieve optimal results.

### **Q: What should I expect during a treatment?**

**A:** You will be comfortably positioned on a treatment bed or chair, and applicators will be attached to the desired treatment area with a belt. During the first 4 minutes of the treatment, the build phase occurs, during which the temperature of the fat cells are heated to target treatment temperature. After the build phase, the temperature will be sustained for an additional 21 minutes (sustain phase). Your practitioner will monitor your comfort level during treatment and adjust the settings accordingly. You may experience a little discomfort, approximately 3.7 out of 10 on a pain scale.\*2

### **Q: Who will perform my SculpSure treatment?**

**A:** Regulations vary from state to state on who is authorized to perform your treatment. Check your local laws to see who can perform SculpSure treatments. They may be performed by nurses, aestheticians, medical assistants, and physicians, depending on state regulations.

### **Q: How many areas can you treat in one day?**

**A:** You can treat as many areas as you want, however it is not recommended to treat the same area within the same day. We recommend 4-6 weeks between treatments on the same areas.

### **Q: Does the SculpSure treatment hurt?**

**A:** Most clients feel an intermittent tingling and peaks of deep heating, followed by a comfortable cooling sensation. Most clients find the treatment tolerable.

### **Q: How is the sensation of a SculpSure treatment described?**

**A:** Some clients will experience sensations which range from prickling, pinching, pressure and peaks of moderate deep heat and cooling.

## Post-Treatment

### **Q: What should I expect after a treatment?**

**A:** Many clients report tissue tenderness when the treated area is touched; however the treatment is generally well-tolerated and does not prevent you from resuming your daily activities. Most clients report the sensation is similar to having done a vigorous workout. This feeling typically resolves in less than 2 weeks.

### **Q: When can I schedule my next treatment?**

**A:** Prior to leaving the office after your first appointment, you should schedule your next treatment appointment for 4-6 weeks. Your SculpSure treatment provider will discuss the best treatment regimen for you.

**Q: Can I exercise and resume my normal activities on the day of treatment?**

**A:** Yes, there is no restriction on exercise and you can resume your normal activities immediately following treatment.

In fact, exercise may help stimulate the metabolic process. Staying well-hydrated during the elimination stage will encourage this process as well.

**Q: Will SculpSure leave loose skin where my fat has been eliminated?**

**A:** To date, there have been no reported cases of increased skin laxity post treatment. However, if you have severe laxity in the treatment area, SculpSure may not provide you with the results you want. Ask your treatment provider if SculpSure is right for you.

**Q: Why do you recommend that I massage after a SculpSure treatment?**

**A:** Gently massaging the treatment area after SculpSure may help stimulate lymphatic drainage, and may enhance your results.

**Q: Can I treat areas other than my flanks and abdomen?**

**A:** Currently the SculpSure device is FDA-cleared for treatment of the flanks, abdomen, back, inner and outer thighs, and submental (under the chin) areas.

**Q: Is it possible to treat the same area again sooner than the recommended 4-6 weeks?**

**A:** To date, there have been no formal studies looking at the potential effects of treating sooner than 4-6 weeks.

**Q: What is the protocol for maintenance treatments?**

**A:** Maintenance treatments can be performed at the discretion of the client and SculpSure treatment provider. The fat cells that are destroyed during treatment will never come back. However, the fat cells that do remain can increase in volume. Maintaining a healthy lifestyle and staying well-hydrated will give you long-lasting results.

**Q: Do I have to wear a compression garment after my SculpSure treatment?**

**A:** There is no need to wear a compression garment following treatment.\*4

**Q: How much time will I need to heal?**

**A:** There is no downtime after a SculpSure treatment. You can resume your normal activities, including exercise, immediately post-treatment.

## **How SculpSure Works**

**Q: Where does the treated fat go?**

**A:** The destroyed fat cells will be eliminated naturally through your body's lymphatic system.

**Q: Why is the SculpSure treatment only 25 minutes when other treatments last much longer?**

**A:** We are able to heat fat and maintain the temperature efficiently and effectively to achieve fat destruction in a short amount of time. This is based on 7 years of extensive research.

**Q: How is SculpSure different from other fat reduction procedures?**

**A:** SculpSure is the world's first and only FDA-cleared light-based device for non-invasive lipolysis. SculpSure offers versatility with four applicators, which can be placed in a variety of configurations. Contact Cooling™ ensures a safe and tolerable treatment for all skin types. Unlike cryolipolysis, SculpSure does not require a painful post-treatment massage, or result in shelving or shark bites. With SculpSure, the results are natural looking.

**Q: How deep does the laser energy penetrate?**

**A:** The depth of penetration will depend on the thickness of fat for that individual patient. Internal temperature testing has shown that SculpSure can heat fat as deep as 3 cm below the dermis. If the fat thickness is less than that, the laser energy will only target the fat cells, and not affect tissue, muscle, or underlying organs.

**Q: Can SculpSure improve my cellulite?**

**A:** The potential side effect on cellulite has not been studied in conjunction with SculpSure.

**Q: How does SculpSure induce cell death?**

**A:** SculpSure is a hyperthermic laser treatment. The laser energy increases the temperature of the fat cells between 42-47°C. Numerous studies have shown, using in vivo, ex vivo and theoretical analysis, that if you increase the temperature of fat to a certain temperature and maintain that temperature for a period of time, the fat cells will be permanently destroyed.\*5

**Q: What happens to the destroyed fat that is released in the body?**

**A:** To date, there haven't been any studies published that have demonstrated the exact process of fat clearance post non-invasive procedures. However, there have been many studies that show that serum lipid and serum liver values remain stable post treatment. These findings are consistent with SculpSure's research that studied serum lipid and liver values at various time points post treatment. It is widely accepted that the body processes the destroyed fat through the lymphatic system and basic metabolic pathways.

**Q: What does non-invasive mean?**

**A:** Non-invasive procedures do not require an incision through the skin or the removal of tissue from the body as with a surgical procedure. Many times patients do not want to endure anesthesia and/or a prolonged healing process. SculpSure provides results without incisions or downtime.

## **Side effects**

**Q: What are the possible side effects of a SculpSure treatment?**

**A:** The most common side effects include mild swelling, mild redness, tissue tenderness, and tissue firmness (small, hardened areas in the deep fat layer). All side effects seen during clinical studies resolved on their own. Your treatment provider will review these side effects with you.

### **Q: Will SculpSure raise my cholesterol?**

**A:** Studies have shown that the SculpSure treatment will not raise your cholesterol.<sup>3</sup>

### **Q: Can you treat a client with a hernia repair?**

**A:** A client can be treated if the hernia has been addressed and you are not placing the applicators over scar tissue. Please consult the treating physician regarding their best practices.

## **SculpSure vs. the Competition**

### **Q: How does SculpSure compare to CoolSculpting®?**

**A:** SculpSure is a laser treatment that heats your fat cells, while CoolSculpting uses cold to freeze them. SculpSure uses four non-suction applicators that can be configured many ways to provide a fully-customizable treatment. CoolSculpting uses various applicators, some of which require strong vacuum suction to pull skin and fat into a freezing chamber. CoolSculpting requires longer treatment times, while SculpSure takes just 25 minutes per area. After your SculpSure treatment, there are minimal side effects, and you can resume your normal activity immediately. SculpSure and CoolSculpting produce similar results in terms of the amount of fat you will lose, however, with CoolSculpting, there is a risk of increased fat volume in the treated area, as well as irregularities such as shelving or shark bites. SculpSure's results leave you with a smooth and natural body contour.\*<sup>6</sup>

### **Q: How does the pain in the days following a SculpSure treatment compare to CoolSculpting?**

**A:** SculpSure patients report only mild tissue tenderness that can last up to 2 weeks. CoolSculpting has reports of delayed-onset pain often resulting in the need for medical intervention.

### **Q: Is SculpSure an alternative to liposuction?**

**A:** SculpSure is a non-invasive treatment to reduce areas of localized fat. For clients that aren't candidates for liposuction, or simply don't want the risk or downtime associated with surgery, SculpSure may be a great alternative. Be sure to discuss your expectations with your treatment provider to decide what's best for you.

\*1. Clinical and Histological Evaluations of a 1060nm Laser Device for Non-Invasive Fat Reduction – John W. Decorato, MD., F A C S. Rafael Sierra, Ph.D., Bo Chen, Ph.D., Westford, MA, 2014. \*2. Bass L, Doherty S. Non-Invasive Fat Reduction Of The Abdomen With A 1060nm Diode Laser. Paper presented at: 2015 Annual American Society for Laser Medicine and Surgery Conference; April 22-26; Kissimmee, FL. \*3. Data on file. Decorato, John W., et al. Subcutaneous Adipose Tissue Response to a Non-Invasive Hyperthermic Treatment Using a 1,060nm Laser. *Lasers in Surgery and Medicine*, vol. 49, no. 5, 2017, pp. 480–489., doi:10.1002/lsm.22625.

Individual results may vary and are not guaranteed. SculpSure is intended for non-invasive fat reduction of the submental (under the chin) area, abdomen, flanks, back, inner and outer thighs. SculpSure is not a weight loss solution or for people who are obese. ©2018 Hologic, Inc. All Rights Reserved. Cynosure and SculpSure are registered trademarks of Cynosure, Inc. A Smarter Way To Sculpt is a trademark of Cynosure, Inc. 921-7026-062 R1 4/18