

About CoolSculpting® Elite



Introduction

Before beginning your **CoolSculpting® Elite** treatments, please review this important information. Results and patient experience may vary. This is not meant to cover all aspects of the **CoolSculpting® Elite** treatment. Please contact your healthcare provider for additional details.

Glossary of terms

- Aesthetic** - cosmetic, related to beauty
- Deviation** - turning away or aside from normal position
- Draw (Vacuum)** - pulling into
- Abdominoplasty** - surgical operation involving the removal of excess flesh from the abdomen
- Cold Urticaria** - allergic skin reaction to cold
- Dermatitis** - skin inflammation
- Diabetic Neuropathy** - nerve damage due to diabetes
- Eczema** - condition that is characterized by inflamed or irritated skin
- Flank** - the area between the ribs and the hips from the sides of the abdomen wrapping to the back
- Hernia** - a bulging of an organ or tissue through surrounding muscle or tissue
- Hypoglossal Nerve** - nerve supplying the muscles of the tongue
- Marginal Mandibular Nerve** - nerve that parallels the jawline supplying the muscles of the lower lip and chin
- Mild Contour Irregularity** - uneven bulge reduction following treatment
- Noninvasive** - not requiring the introduction of instruments into the body
- Obesity** - defined as a Body Mass Index (BMI) of 30 or greater
- Peripheral Circulation** - blood flow that reaches the upper and lower extremities of the body
- Post-herpetic Neuralgia** - nerve pain due to complication from chickenpox or shingles
- Propylene Glycol** - water soluble molecule found in most personal care products. Generally Recognized As Safe (GRAS) by FDA
- Raynaud's Disease** - excessively reduced blood flow in response to cold
- Onset** - the beginning
- Sensation** - a feeling
- Spontaneously** - by itself without extra treatment
- Submandibular** - under the jawline
- Submental** - under the chin
- Surgical Intervention** - surgical treatment
- Transient** - lasting only for a short time
- Vasovagal Symptoms** - dizziness, lightheadedness, nausea, flushing, sweating, or fainting

What is it?

The **CoolSculpting® Elite** procedure is a noninvasive procedure that is intended to break down fat cells that are just beneath the skin by delivering controlled cooling at the surface of the skin. The **CoolSculpting® Elite** procedure is FDA-cleared for the treatment of visible fat bulges in the submental (under the chin) and submandibular (under the jawline) areas, thigh, abdomen and flank, along with bra fat, back fat, underneath the buttocks (also known as banana roll) and upper arm. It is also FDA-cleared to affect the appearance of lax tissue with submental area treatments. The **CoolSculpting® Elite** procedure is not a treatment for weight loss. It does not replace traditional methods such as diet, exercise, or liposuction.

What does it do?

The **CoolSculpting® Elite** technology uses controlled cooling to target and freeze a portion of the fat cells under your skin. In the weeks that follow treatment, the body naturally begins to process the fat cells that were frozen during treatment and removes them from the treatment site thereby affecting the appearance of the treated bulge. You may start to see changes in as early as four weeks after your **CoolSculpting® Elite** procedure and will experience the most dramatic results after one to three months. Your body will continue to naturally process the injured fat cells for weeks to months after your procedure. Results may take up to 6 months to become visible. Visible results can vary from person to person.

How is it used? What does it feel like?

The **CoolSculpting® Elite** System is a prescription use only device and may only be used by or on the order of a physician. Your practitioner will discuss your individual treatment plan and will select the appropriate applicator for your needs. Some applicators use vacuum and others do not. During your treatment, a gel or gelpad and applicator are applied to the targeted area. Applicators that use vacuum will draw the tissue into the applicator cup. You may feel deep pulling, tugging, and mild pinching. With a non-vacuum surface applicator, you may experience sensations of pressure. Controlled cooling is then delivered to the targeted fat so you may feel intense cold, stinging, tingling, aching, cramping or discomfort as the treatment begins but these sensations typically subside as the area becomes numb. In some cases you may feel pulsatile massage. Upon removal of the applicator, you may see a frozen bulge at the treatment area (known as a "butterstick"). The physician may apply manual massage to rewarm and smooth out the treated area.

What will it accomplish?

For most patients, the **CoolSculpting® Elite** procedure reduces the appearance of a visible fat bulge in the treatment area.

Are there any reasons I should not get the CoolSculpting® Elite procedure?

You should inform your physician of your entire medical history. You should not have the treatment if you are seeking treatment for obesity as **CoolSculpting® Elite** is not a weight loss treatment. You should not have treatment if you have one of the below conditions:

- **Cryoglobulinemia**, a condition in which an abnormal level of cryoglobulins (proteins which thicken in cold temperatures) are present in the blood.
- **Paroxysmal cold hemoglobinuria**, a blood disorder in which a change from cold to warm temperatures leads to red blood cell death.
- **Cold agglutinin disease**, an autoimmune disease in which exposure of blood to cold temperatures leads to red blood cell death.

What should my physician warn me about?

The safety and effectiveness for the treatment of areas other than the submental (under the chin) and submandibular (under the jawline) areas, thigh, abdomen and flank, along with bra fat, back fat, underneath the buttocks (also known as banana roll) and upper arm have not been established.

What are other warnings I should know about?

The **CoolSculpting® Elite** procedure has not been studied in children, those who are pregnant or lactating, or patients with any of the below conditions. If you have one of the following conditions, inform your **CoolSculpting® Elite** healthcare provider as you may not be an appropriate candidate for **CoolSculpting® Elite** treatment.

- Known sensitivity to cold such as cold urticaria or Raynaud's disease, pernio, or Chilblains
- Known sensitivity or allergy to isopropyl alcohol, propylene glycol, fructose, or glycerin. Use may result in allergic reactions, including anaphylaxis
- Impaired peripheral circulation in the area to be treated
- Nerve pain such as post-herpetic neuralgia or diabetic neuropathy
- Impaired skin sensation
- Open or infected wounds
- Bleeding disorders or simultaneous use of blood thinners. Use may increase the risk of bleeding
- Recent surgery or scar tissue in the area to be treated. Use may increase the risk of wound separation or rupture
- Hernia in or adjacent to the treatment site
- Skin conditions such as eczema, dermatitis, or rashes in the area to be treated
- Active implanted device such as pacemaker or defibrillator
- Chronic pain
- Anxiety disorder

What are possible side effects?

The following effects can happen frequently in the treatment area during and after a treatment. These effects are temporary and generally resolve within days or weeks.

During a treatment:

- Sensations of pulling, tugging, and mild pinching at the treatment site
- Intense cold, tingling, stinging, aching, cramping, and discomfort. These sensations lessen as the area becomes numb

Immediately after a treatment:

- Redness and firmness
- Transient blanching and/or mild bruising around the edges of the treatment area
- Tingling and stinging
- Skin inflammation
- Throat discomfort/soreness after submental treatment

One to two weeks after a treatment:

- Redness, mild to moderate bruising (in rare instances can be severe), and swelling
- Tenderness, cramping, and aching
- Itching, skin sensitivity, tingling, and numbness. Sensory alteration can persist up to several weeks after a treatment
- Sensation of fullness in the back of the throat after submental area treatment

There are other side effects that can happen with submental and submandibular area treatments:

- Cold exposure to the hypoglossal nerve may cause tongue deviation following treatment of the submental and submandibular areas.
- Cold exposure to the marginal mandibular nerve may cause lower lip weakness following treatment of the submental and submandibular areas.
- Cold exposure to the submandibular gland may cause dry mouth, or decrease in saliva production, following treatment of the submental and submandibular areas.

Are there any other possible side effects that can happen?

The following side effects can happen in the treatment area, during and after a treatment. The risk for the side effects listed below is small, but possible.

We can estimate how likely it is that a side effect could happen. We do this by first counting how many of these side effects have been reported by people treated with **CoolSculpting®** or **CoolSculpting® Elite**. Then we count the number of treatment cycles of **CoolSculpting®** and **CoolSculpting® Elite** used around the world.

Rare side effects are not reported by people as often, this can make them difficult to measure. We have provided estimates for how likely it is that you could have a certain side effect. These are listed in the parentheses below.

Rare side effects may happen in 1 to 10 out of 10,000 **CoolSculpting®** treatments (between 0.01% to 0.1%). These include:

- **Paradoxical hyperplasia:** (About 1 out of 3,000 treatments, 0.033%) The gradual development of a visibly enlarged tissue volume, of varying size and shape, in the treatment area two to five months after the treatment. This is distinguished from temporary swelling and will not resolve on its own. Surgical intervention may be required.
- **Severe pain:** (About 1 out of 6,000 treatments, 0.017%) Patients may experience pain of varying severity, which more commonly can be described as mild to moderate, and in rare instances, can be severe.
- **Late-onset pain:** (About 1 out of 6,000 treatments, 0.017%) A typical onset several days after a treatment and resolution within several weeks.

Very rare side effects may happen in less than 1 out of 10,000 **CoolSculpting® Elite** treatments (less than 0.01%). These include:

- **Hyperpigmentation/Hypopigmentation:** (About 1 out of 11,000 treatments, 0.009%) Dark/light coloration of the skin may happen after treatment. Typically, it resolves spontaneously.
- **Freeze burn ("frostbite"):** (About 1 out of 15,000 treatments, 0.006%) Patients may experience freeze burns which typically resolve with proper care. Very rarely, second and third-degree burns may occur.
- **Treatment Area Demarcation (TAD):** (About 1 out of 20,000 treatments, 0.005%) An aesthetic outcome of treatment in which the patient experiences excessive fat removal in the treatment area, resulting in a visible disruption to the continuous contour of fat, or unwanted indentation in the treated area.
- **Vasovagal symptoms:** (About 1 out of 30,000 treatments, 0.003%) Dizziness, lightheadedness, nausea, flushing, sweating, or fainting might happen during or immediately after the treatment.
- **Subcutaneous induration:** (About 1 out of 30,000 treatments, 0.003%) Generalized hardness and/or discrete nodules within the treatment area, which can develop after the treatment and be accompanied by pain and/or discomfort.
- **Cold panniculitis:** (About 1 out of 60,000 treatments, 0.002%) Cold panniculitis results from injury to adipose tissue exposed to cold and may result in a mild to severe inflammatory response. In mild cases, the symptoms are self-resolving and may include redness, swelling, skin nodules, warmth, tenderness, and possible low-grade fever. These cases typically resolve without long-term side effects. In more severe cases, an intense inflammatory response may result in more extensive tissue damage, including fat tissue death, which may require medical or surgical intervention.
- **Hernia:** (About 1 out of 185,000 treatments, 0.001%) Treatment may cause new hernia formation or worsen preexisting hernia, which may require surgical repair.
- **Headache/Occipital Pain:** (About 1 out of 200,000 treatments, 0.000%) Patients may experience pain relating to device noise/posture during treatment.

What did clinical studies show?

CoolSculpting® Elite has conducted clinical studies in the submental area, thighs, abdomen, flanks, and upper arms. It has also been studied with modified treatment parameters (MTP). The procedure has been exclusively studied in adult volunteers. The **CoolSculpting® Elite** System has not been studied in children or those who are pregnant or lactating.

STUDIES:

Treatment Site	Number of Patients	Number of Treatments Per Treatment Site	Follow-Up Timeframe (post final treatment)
Flanks	60	Up to 3	6 months
Abdomen	60	Up to 2	4 months
Inner Thigh	45	1	4 months
Outer Thigh	40	1	4 months
Modified treatment parameters	45	Up to 2	4 months
Submental Area	60	Up to 2	3 months
Upper Arm	30	1	3 months

DEMOGRAPHIC DATA:

Treatment Site	Average Age (years)	Average Weight (pounds)	Number of Male/Female Subjects
Flanks	44	179.5	19 / 41
Abdomen	48	153.9	4 / 56
Inner Thigh	48.1	147.1	0 / 45
Outer Thigh	43.2	150.3	0 / 40
Modified treatment parameters	44.1	150.3	11 / 34
Submental Area	49.3	196.1	12 / 48
Upper Arm	45.7	168.8	0 / 30

What are the Photographic evaluation and Ultrasound results?

To demonstrate efficacy and the change in appearance in the treatment site, three independent physicians reviewed before and after photographs for each patient and were asked to identify the before photograph.

Efficacy has also been shown through ultrasound measurements which measure the reduction of the fat layer after treatment.

Treatment Site	Percent Correct Identified	Ultrasound Results	Subject Satisfaction
Flanks	88.6	18.7% reduction	82.1%
Abdomen	85.3	-1.9mm	62%
Inner Thigh	90.5	-2.8mm	93.3%
Outer Thigh	83.9	-2.5mm	86.5%
Modified treatment parameters	85	-3.92mm	88.37%
Submental Area	91.4	-2.0mm	83.3%
Upper Arm	85.2	-3.2mm	63.3%

What side effects have been seen in the clinical studies? (Remember every patient may have a different experience)

Flank: Reported side effects included pain during or posttreatment, bruising of the treated area, temporary numbness, tingling, redness, and swelling. During treatment, one patient reported pain at the first application site. Each of these resolved after treatment was discontinued. All side effects during this study resolved without any medical intervention by 4 weeks after treatment.

Abdomen: There were two cases of pain, two cases of numbness, two cases of nausea, and one each of: anxiety, vasovagal episode, headache, and menorrhagia.

Inner and Outer thighs: Side effects reported during the studies included numbness and mild contour irregularity. A mild case of hyperpigmentation (dark coloration of the skin) lasted beyond 16 weeks. This is a rare side effect that typically resolves spontaneously.

Modified treatment parameters: Side effects included numbness, pain, and hyperpigmentation, and subcutaneous induration. One treatment was not completed due to a first-degree burn. Three cases of numbness lasted beyond 16 weeks after treatment.

Submental Area: Four side effects reported: two cases of redness, one case of hyperpigmentation, and one case of sensation of fullness in the back of the throat due to swelling. Clinical safety assessment showed anticipated side-effects, all of which resolved over the course of the study.

Upper Arm: Side effects included redness, edema, numbness, and tingling. There was one case of minor tingling in the fingers post device removal, which resolved within 20 minutes. Seven cases of numbness lasted beyond 12 weeks after treatment.

What other treatments are available to me?

There are a variety of medical devices available in the United States that may be used for fat reduction treatment. As an alternative to utilizing cold, other devices may use other modes/means of treatment such as radio frequency, ultrasound, heat, laser, and other mechanical means. In addition, surgery such as abdominoplasty or liposuction may be an option. You may discuss these treatments with your physician.

When should I notify my physician?

Be sure to report to your physician (1) any side effect that lasts for more than two weeks and (2) any other symptom that causes you concern. You may also contact the **CoolSculpting® Elite** Product Support line at 1-888-935-8471.

For more information or further questions about the **CoolSculpting® Elite** procedure, visit www.CoolSculpting.com or call 1-888-935-8471.



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