

## Introduction

Before beginning your treatments, please review this important information. Results and patient experience may vary.

### 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 an abnormal opening

**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

**Non-Invasive** – not requiring the introduction of instruments into the body

**Obesity** – defined as a Body Mass Index (BMI) greater than 30

**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 Gland** – salivary gland situated below the lower jaw

**Submental** – under the chin; “double chin”

**Surgical Intervention** – surgical treatment

**Transient** – lasting only for a short time

**Vasovagal Symptoms** – dizziness, lightheadedness, nausea, flushing, sweating, or fainting during or immediately after the treatment

## What is it?

The CoolSculpting® System is a medical device that may reduce the layer of fat under your skin by using non-invasive controlled cooling. It is intended to affect the appearance of the submental area (otherwise known as the double chin), thighs, abdomen, and flanks (also known as love handles) bra fat, back fat, fat under the buttocks (also known as banana roll) and upper arms. It is not a treatment for obesity or a weight loss solution and it does not replace traditional methods such as diet, exercise or liposuction.

## What does it do?

The CoolSculpting® 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 three weeks after your CoolSculpting® 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 approximately four months after your procedure. Results may take up to 4 months to become visible.

## How is it used? What does it feel like?

The CoolSculpting® 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 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 but this feeling typically goes down within 10 minutes as the area becomes numb. In some cases you may feel pulsatile massage. Upon removal of the applicator, you may see the frozen bulge (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® procedure will affect reduce the appearance of a visible bulge in the treatment area.

## Are there any reasons I should not get the CoolSculpting® 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® is not a treatment a weight loss solution for obesity. 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 area (double chin), thighs, abdomen, flanks (love handles), bra fat, back fat, fat under the buttocks (banana roll) or upper arms have not been established.

## What are possible side effects?

The following effects can occur 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. These sensations subside 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.

### One to two weeks after a treatment:

- Redness, bruising, and swelling.
- Tenderness, cramping, and aching.
- Itching, skin sensitivity, tingling, and numbness. Numbness 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 occur with submental area treatments:

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

## Are there any other possible side effects that can occur?

There are some rare side effects that have been seen both in clinical studies and commercial use:

- **Paradoxical hyperplasia:** Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment, possibly even after a visible result is noticed. Surgical intervention is required for correction may be required.
- **Late-onset pain:** A typical onset several days after a treatment and resolution within several weeks.

- **Freeze burn (“frostbite”):** First and second degree freeze burn which may occur during treatment. It typically resolves without additional side effects with proper care.
- **Vasovagal symptoms:** Dizziness, lightheadedness, nausea, flushing, sweating, or fainting during or immediately after the treatment.
- **Subcutaneous induration:** Generalized hardness and/or discrete nodules within the treatment area, which may develop after the treatment, and may be accompanied by pain and/or discomfort.
- **Hyperpigmentation:** Dark coloration of the skin may occur after treatment. Typically, it resolves spontaneously.
- **Hernia:** Treatment may cause new hernia formation or worsen pre-existing hernia, which may require surgical repair.

#### What are other precautions I should know about?

If you have any of the below conditions, you may not be an appropriate candidate for the CoolSculpting® procedure. Inform the CoolSculpting® physician if you have any of these conditions prior to 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 and glycerin.
- 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.
- Recent surgery or scar tissue in the area to be treated.
- 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 did clinical studies show?

ZELTIQ® 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 healthy adult volunteers. The CoolSculpting® 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
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	41/19
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 studies?

**Flank:** Reported side effects included pain during or post-treatment, bruising of the treated area, temporary numbness, tingling, redness, and swelling. During treatment, two side effects were reported: pain and discomfort. Each of these resolved after treatment was discontinued. Following treatment, two side effects were reported: bruising and minor cramping in the treatment area. 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 mild erythema and one case of 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 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 cause you concern. You may also contact the ZELTIQ® CoolSculpting® Product Support line at 1-888-ZELTIQ1.

For more information or further questions about the CoolSculpting® procedure, visit [www.CoolSculpting.com](http://www.CoolSculpting.com) or call ZELTIQ® at 1-888-935-8471 (1-888-ZELTIQ1).

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#### Results and patient experience may vary.

In the U.S., the CoolSculpting procedure is FDA-cleared for the treatment of visible fat bulges in the submental area, thigh, abdomen and flank, along with bra fat, back fat, underneath the buttocks (also known as banana roll) and upper arms. In Taiwan, the CoolSculpting procedure is cleared for the breakdown of fat in the flank (love handle), abdomen, and thigh. Outside the U.S. and Taiwan, the CoolSculpting procedure for non-invasive fat reduction is available worldwide. ZELTIQ, CoolSculpting, the CoolSculpting logo, and the Snowflake design are registered trademarks of ZELTIQ Aesthetics, Inc. © 2017. All rights reserved. IC02211-B