



## PATIENT IMPORTANT SAFETY CONSIDERATION FORM

This document is intended to educate patients on the potential side effects and safety concerns associated with the CoolSculpting® procedure.

### Introduction

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

### Glossary of terms

**Aesthetic** - cosmetic, related to beauty

**Abdominoplasty** - surgical operation involving the removal of excess flesh from the abdomen

**Cold urticaria** - allergic skin reaction to cold

**Dermatitis** - skin inflammation

**Deviation** - turning away or aside from normal position

**Diabetic neuropathy** - nerve damage due to diabetes

**Draw (vacuum)** - pulling into

**Eczema** - condition that is characterised 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 runs parallel to 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 of 30 or greater

**Onset** - the beginning

**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" by the US Food and Drug Administration

**Raynaud's disease** - excessively reduced blood flow in response to cold

**Sensation** - a feeling

**Spontaneously** - by itself without extra treatment

**Submental** - under the chin

**Submandibular** - under the jawline

**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**® procedure is a non-invasive 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.<sup>1\*</sup> This procedure is not a treatment for weight loss.<sup>2</sup> The **CoolSculpting**® procedure does not replace traditional methods such as diet, exercise or liposuction.

\*Data obtained from cryolipolysis investigations using a porcine model.



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### What does it do?

Clinical studies have shown that the **CoolSculpting**<sup>®</sup> procedure can break down fat cells to change the appearance of visibly localised bulges of fat that is just beneath the skin on the submental (under the chin) and submandibular (under the jawline) areas, thighs, abdomen and flanks, along with bra fat, back fat, underneath the buttocks (also known as banana rolls), and upper arms.<sup>2-13</sup> Following the procedure, the treated fat cells are naturally processed by the body over a period of months.<sup>14</sup> Visible results can vary from person to person.

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

The **CoolSculpting**<sup>®</sup> system should only be used by, or by order of, a physician. Your practitioner will discuss your individual treatment plan and 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 or cramping as the treatment begins but these sensations typically subside as the area becomes numb. Upon removing the applicator, you may see a frozen bulge at the treatment area. The physician may apply a manual massage to rewarm and smooth out the treated area.<sup>15</sup>

### Are there any reasons I should not get the CoolSculpting<sup>®</sup> procedure?

You should inform your physician of your entire medical history. You should not have the procedure if you are seeking treatment for obesity as **CoolSculpting**<sup>®</sup> is not a weight-loss treatment. You should not have the procedure if you have one of the below conditions:<sup>15</sup>

- **Cryoglobulinaemia**, a condition in which an abnormal level of cryoglobulins (proteins which thicken in cold temperatures) are present in the blood
- **Paroxysmal cold haemoglobinuria**, 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
- **Pregnancy and lactation**

### What other warnings do I need to be aware of?

The **CoolSculpting**<sup>®</sup> procedure has not been studied in children, those who are pregnant or lactating, or patients with any of the following conditions. If you have one of the following conditions, inform your **CoolSculpting**<sup>®</sup> healthcare provider as you may not be an appropriate candidate for **CoolSculpting**<sup>®</sup> treatment.<sup>15</sup>

- 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
- 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



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- Active implanted device such as pacemaker or defibrillator
- Chronic pain
- Anxiety disorder

### What are the possible side effects?

The following effects can happen frequently in the treatment area during and after treatment. These effects are temporary and generally resolve within days or weeks.<sup>15</sup>

#### During treatment:<sup>15</sup>

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

#### Immediately after treatment:<sup>15</sup>

- Redness and firmness
- Transient blanching and/or mild bruising around the edges of the treatment area
- Tingling and stinging

#### One- to two-weeks after treatment:<sup>15</sup>

- Redness, bruising and swelling
- Tenderness, cramping and aching
- Itching, skin sensitivity, tingling and numbness; numbness can persist up to several weeks after treatment
- Sensation of fullness in the back of the throat after submental area treatment

There are other side effects that can happen following treatment of the submental and submandibular areas:<sup>15,16</sup>

- 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 treatment. The risks of the following side effects are small, but possible.

We can estimate how likely these side effects could happen.<sup>16</sup> We do this by first counting how many of these side effects have been reported by people treated with **CoolSculpting**<sup>®</sup>.<sup>16</sup> Then, we count the number of treatment cycles of **CoolSculpting**<sup>®</sup> devices used around the world.<sup>16</sup>

Rare side effects are not reported by people as often, and this can make them difficult to measure. We have provided estimates for how likely a side effect may happen, which are listed in the parentheses below.<sup>16</sup>

**Rare side effects** may happen in 1-10 out of 10,000 **CoolSculpting**<sup>®</sup> treatments (between 0.01% to 0.1%).<sup>16</sup> These include:

- **Paradoxical hyperplasia** (about 1 out of 3,000 treatments, 0.033%)<sup>16</sup>  
Visibly enlarged tissue volume within the treatment area, which may develop 2-5 months after treatment. Surgical intervention may be required.<sup>15</sup>
- **Severe pain** (about 1 out of 6,000 treatments, 0.017%)<sup>16</sup>  
Patients may experience pain of varying severity, which can be more commonly described as mild to moderate and, in rare instances, severe.<sup>15</sup>



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- **Late-onset pain** (about 1 out of 6,000 treatments, 0.017%)<sup>16</sup>

A typical onset several days after treatment and resolution within several weeks.<sup>15</sup>

**Very rare side effects** may happen in less than 1 out of 10,000 **CoolSculpting**<sup>®</sup> treatments (less than 0.01%).<sup>16</sup>

These include:

- **Hyperpigmentation** (about 1 out of 11,000 treatments, 0.009%)<sup>16</sup>  
Hyperpigmentation may occur after treatment.<sup>15</sup> Typically, it resolves spontaneously.<sup>15</sup>
- **Freeze burn or "frostbite"** (about 1 out of 15,000 treatments, 0.006%)<sup>16</sup>  
First- and second-degree freeze burn may occur during treatment. This typically resolves without additional side effects with proper care.<sup>15</sup>
- **Treatment area demarcation** (about 1 out of 20,000 treatments, 0.005%)<sup>16</sup>  
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.<sup>15</sup>
- **Vasovagal symptoms** (about 1 out of 30,000 treatments, 0.003%)<sup>16</sup>  
Dizziness, lightheadedness, nausea, flushing, sweating or fainting during or immediately after the treatment.<sup>15</sup>
- **Subcutaneous induration** (about 1 out of 30,000 treatments, 0.003%)<sup>16</sup>  
Generalised hardness and/or discrete nodules within the treatment area, which may develop after the treatment, and may present with pain and/or discomfort.<sup>15</sup>
- **Cold panniculitis** (about 1 out of 60,000 treatments, 0.002%)<sup>16</sup>  
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 possibly 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.<sup>15,16</sup>
- **Hernia** (about 1 out of 185,000 treatments, 0.001%)<sup>16</sup>  
Treatment may cause new hernia formation or worsen pre-existing hernia, which may require surgical repair.<sup>15,16</sup>

### When should I notify my healthcare professional?

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.

If you experience any unanticipated side effects please contact us at 1-800-668-6424.



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### Disclaimers

CoolSculpting® is not a weight-loss procedure and should not replace a healthy diet and active lifestyle.

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This content is intended for the **Canadian** adult (>18 yrs) audience only. You should always consult a healthcare professional to help you decide if Allergan Aesthetics body contouring is right for you and to provide you with a full list of side effects. To report a side effect, please contact Allergan Aesthetics at 1-800-668-6424.

To learn more about Allergan Aesthetics body contouring treatment, please visit [ca.CoolSculpting.com](http://ca.CoolSculpting.com) for further information. Actual results may vary. Material produced and funded by Allergan Aesthetics, an AbbVie company.

Adverse events should be reported to your local regulatory authority and Allergan Aesthetics office.

### References:

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