DaVinci Body Sculpting

coolsculpting®

TREATMENT CONSENT FORM

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. This procedure is not a treatment for weight loss. The CoolSculpting procedure does not replace traditional methods such as diet, exercise, or liposuction. **Initial:** ____

Clinical studies have shown that the CoolSculpting procedure can break down fat cells to change the appearance of visibly localized bulges of fat that is just beneath the skin on 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 the banana roll) and upper arm. Following the procedure, the treated fat cells are naturally processed by the body over a period of months. Visible results can vary from person to person. **Initial:** ____

WHAT YOU CAN EXPECT:

Temporary Sensations / Symptoms:

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.

»These side effects can happen during a treatment:

- The suction pressure of a vacuum applicator may cause sensations of deep pulling, tugging, and pinching. A surface applicator may cause sensations of pressure. You may experience intense cold, stinging, tingling, aching or cramping as the treatment begins. These sensations generally lessen during treatment as the area becomes numb. **Initial:** ____

»These side effects can happen immediately after a treatment:

- The treated area may look or feel stiff after the procedure and transient blanching (temporary whitening of the skin) may happen. **Initial:** ____
- Bruising, redness, firmness, cramping, tingling, and stinging may happen. **Initial:** ____

»These side effects can happen one to two weeks after a treatment:

- You may feel numbness in the treated area that can last for several weeks after the procedure. Prolonged redness, swelling, itching, tingling, numbness, tenderness to the touch, pain in the treated area, cramping, aching, bruising, and/or skin sensitivity have also been reported. **Initial:** ____
- You may have a feeling of fullness in the back of the throat. (Initial if the submental area is to be treated. If the area under the chin or jawline is not being treated, please write N/A). **Initial:** ____

»These other side effects can happen within one to two weeks after submental (under the chin) and submandibular (under the jawline) area treatments:

- Cold exposure to a nerve close to your tongue called the hypoglossal nerve may cause tongue deviation (turning). **Initial:** ____
- Cold exposure to a nerve in the face called the marginal mandibular nerve may cause lower lip weakness. **Initial:** ____
- Cold exposure to a gland below the jaw called the submandibular gland may cause dry mouth or a decrease in saliva production in your mouth. **Initial:** ____

Potential Side Effects / Risks

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 these side effects 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 and this can make them difficult to measure. We have provided estimates for how likely a side effect may happen. These are listed in the parentheses below.

Rare side effects may happen in 1-10 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%) **Initial:** _____
A small percentage of patients have experienced gradual development of visibly enlarged tissue in the treatment area. The enlarged tissue may feel hard and may appear in the shape of the applicator used during CoolSculpting® treatment. This may appear two to five months after treatment, is distinguishable from temporary swelling and will not resolve on its own. Surgical intervention may be required.

» **Late-onset pain** (About 1 out of 6,000 treatments, 0.017%) **Initial**:_____
This has a typical onset several days after a treatment and resolution within several weeks.

» **Severe pain** (About 1 out of 6,000 treatments, 0.017%) **Initial**:_____
Patients may experience pain of varying severity, which more commonly can be described as mild to moderate, and in rare instances can be severe.

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

» Some patients have reported the following conditions in areas of the body treated with CoolSculpting®: hardness, discrete nodules, burns, frostbite (local injury due to cold), nerve pain, skin laxity, extensive tissue damage, and fat tissue death. Surgical intervention may be required to address these conditions if they develop. More details are provided below. **Initial**_____

» **Hyperpigmentation** (About 1 out of 11,000 treatments, 0.009%) **Initial:** _____
Dark coloration of the skin may happen after treatment. Typically, it resolves spontaneously.

» **Freeze burn or "frostbite"** (About 1 out of 15,000 treatments, 0.006%) **Initial:**_____
First- and second-degree freeze burn may happen during treatment. It typically resolves without additional side effects with proper care. Surgical intervention may be required to address this condition if it develops.

» **Subcutaneous induration** (About 1 out of 30,000 treatments, 0.003%) **Initial:** _____
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.

» **Cold panniculitis** (About 1 out of 60,000 treatments, 0.002%) **Initial:** ____
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.

» **Treatment area demarcation** (About 1 out of 20,000 treatments, 0.005%) **Initial**: ____
A small percentage of patients have experienced excessive fat removal in the treatment area, resulting in an unwanted indentation. The indentation may be improved through corrective procedures.

» **Vasovagal symptoms** (About 1 out of 30,000 treatments, 0.003%) **Initial:** ____
You may have dizziness, light-headedness, nausea, flushing, sweating, or fainting during or immediately after the treatment.

» **Hernia** (About 1 out of 185,000 treatments, 0.001%) **Initial:** ____
Some patients have reported development of a hernia, or worsening of an existing hernia, following CoolSculpting treatment. Surgical intervention may be required to correct hernia formation or exacerbation.

» Patient experiences may vary. Some patients may experience a delayed onset of the previously mentioned symptoms. Contact your physician immediately if any unusual side effects occur or if symptoms worsen over time. **Initial:** ____

» I understand that any of these known side effects may occur and there is no way to predict who may experience them. **Initial:** _____

» I understand that other unknown side effects may also occur following CoolSculpting® treatment, but elect to voluntarily proceed with CoolSculpting®. **Initial:** _____

» No one associated with the medical practice or the manufacturer of CoolSculpting® has provided any information which contradicts any of the risks that have just been described. **Initial:** _____

Results

» You may start to see changes in as early as 1-3 months after your CoolSculpting procedure. Your body will continue to naturally process the injured fat cells from your body for months after your procedure. **Initial:** ____

» Results vary from person to person. You may decide that additional treatments are necessary to achieve your desired outcome. Although highly unlikely, it is possible that you will not experience any noticeable result from the procedure. **Initial:** ____

» Particular results cannot be guaranteed, given that each individual's body may react differently to stimuli. **Initial:** ____

Do you currently have or have had any of the following?

» Cryoglobulinemia (a condition in which an abnormal level of proteins thicken the blood in cold temperatures), or paroxysmal cold hemoglobinuria or cold agglutinin disease (blood disorders in which cold temperatures lead to red blood cell death). ……...**Yes / No**

» Known sensitivity to cold such as cold urticaria (hives triggered by cold), Raynaud's disease (disorder in which cold leads to reduced blood flow in the fingers, which appear white, red, or blue), pernio or Chilblains (itchy and/or tender red or purple bumps that occur as a reaction to cold). ……...……...**Yes / No**

» Poor blood flow in the area to be treated……..……..……...**Yes / No**

» Neuropathic (nerve) disorders such as post-herpetic neuralgia (pain in the areas of your skin where you had shingles) or diabetic neuropathy (nerve pain from diabetes)……...……..**Yes / No**

» Impaired skin sensation ……...…….…**Yes / No**

» Open or infected wounds ……...…….……...**Yes / No**

» Bleeding disorders or use of blood thinners ……..…..…**Yes / No**

» Recent surgery or scar tissue in the area to be treated……..……....**Yes / No**

» A hernia or history of hernia in the area to be treated or adjacent to treatment site ……...**Yes / No**

» Skin conditions such as eczema, dermatitis, or rashes……..……....**Yes / No**

» Pregnancy or lactation (making breast milk or breast feeding) ……...……..**Yes / No**

» Any active implanted devices such as pacemakers and defibrillators ……..…….....**Yes / No**

» Any major health problems such as liver disease ……..……..……..**Yes / No**

» Any known sensitivity to fructose, glycerin, isopropyl alcohol (rubbing alcohol) or propylene glycol ……..……**Yes / No**

» Any chronic pain ……..……**Yes / No**

» Any anxiety disorder ……..……**Yes / No**

Pictures will be obtained for medical records. If pictures are used for education and marketing purposes, all identifying marks will be cropped or removed. **Initial:** ____

As with most medical procedures, there are risks and side effects. These have been explained to me in detail. I accept these risks by proceeding with this elective treatment. I have read the above information, and I give my consent to be treated with the CoolSculpting® procedure by the physician(s) in this practice and his/her designated staff.

Print Name: _____ Signature:_____ Date: _____

Clinician Name: _____Signature:_____ Date: _____