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TREATMENT CONSIDERATIONS 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 occur in the treatment area during and after a treatment. These effects are temporary and generally resolve within days or weeks.

» 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 subside during treatment as the area becomes numb. **Initial:**

»The treated area may look or feel stiff after the procedure and transient blanching (temporary whitening of the skin)

may occur. **Initial:**

» Bruising, swelling, redness, tenderness, cramping, and aching can occur in the treated area and the treated area may appear red for one to two weeks after treatment. **Initial:**

» After submental or submandibular area treatment, a feeling of fullness in the back of the throat may occur (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:**

» You may feel numbness in the treated area that can last for several weeks after the procedure. Prolonged swelling, itching, tingling, numbness, tenderness to the touch, pain in the treated area, cramping, aching, bruising and/or skin sensitivity have also been reported. Numbness can last for several weeks after the treatment. **Initial:**

**Potential Side Effects / Risks**

» Paradoxical Hyperplasia - 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. The enlargement requires surgical intervention for correction, such as liposuction. **Initial \_\_\_\_\_**

» Late-onset pain with a typical onset several days after a treatment and resolution within several weeks.

**Initial**: \_\_\_\_\_\_\_\_

» You may have dizziness, light-headedness, nausea, flushing, sweating, or fainting during or immediately after the treatment. **Initial:**

» Treatment area demarcation -- 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. **Initial**: \_\_\_\_\_\_\_\_

» Some patients have reported the following conditions in areas of the body treated with CoolSculpting®: darker skin color, hardness, discrete nodules, burns, frostbite (local injury due to cold), nerve pain, extensive tissue damage, and fat necrosis. Surgical intervention may be required to address these conditions if they develop. **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. **Initial \_\_\_\_\_**

»Skin laxity can also develop in the treated area and surgical intervention may be required for correction. **Initial:**

» 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 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 or diabetic neuropathy……...……………………..**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**

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:**

By signing below, I hereby authorize my CoolSculpting® physicians, health care professionals, or other health care providers (collectively, my “Health Care Providers”) to disclose and transmit my protected health information to Allergan and/or its designated service providers (collectively, “Allergan”) in order for Allergan to: (i) help enable my treatment and provide me with communications about my treatment (ii) operate, administer, register me in and/or provide me with access to Allergan programs and services; (iii) identify products and services that may be of interest to me and to provide me with communications about any such products and services; and (iv) develop, evaluate and improve products, services, materials and programs related to my condition or treatment. I authorize any protected health information disclosed by my Health Care Providers pursuant to this authorization to be transmitted electronically in whatever form and through whatever media, including the internet, as required by the purposes set forth. This authorization is made pursuant to 45 CFR § 164.524.

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:

Witness
Print Name:                                                          Signature:                                                                       Date:

Physician(s):                                                                                Practice Name:

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