



CONSENT-COOLSCULPTING ELITE

Consent:

Consent- CoolSculpting Elite INFORMED CONSENT INTRODUCTION

Thank you for choosing Advanced Dermatology for your cosmetic skincare treatments. We value the opportunity to consult you on your aesthetic concerns and desires in the effort to promote healthy youthful skin.

Cosmetic treatments (injectable and laser, light or other energy-based therapy) are procedures that have both benefits and risks that need to be considered. A series of documents called Informed Consents have been prepared for you by Advanced Dermatology, LLC to help you make an informed decision. Informed Consent documents are used to communicate information about treatments, along with disclosure of risk and alternative treatment(s). It is important that you read these documents carefully and completely. ***Only when you have no questions or concerns do you initial each page, indicating that you have read and fully understand all the items it discusses. When you arrive at the end of the document, please sign the consent for the procedure. If you have any remaining questions or concerns, do not sign the consent until getting these questions answered by Dr. Taub, one of her staff members or Advanced Dermatology's Cosmetic Coordinator at 847-459-6400.***

FINANCIAL RESPONSIBILITY: All cosmetic, injectable and laser, light or other energy-based treatments are considered a cosmetic procedure and therefore not covered by insurance. We will not submit these treatments to your insurance and require that you pay at the time of service. You will receive Financial Protocols for each treatment that is recommended for you that are valid for 90 days from the date of our recommendation. Should the price change after 90 days you would be responsible for any increase in cost.

WHO WILL PERFORM MY TREATMENTS: We have a variety of highly skilled providers for each of our services. Amy Taub, MD, Anne Marie Leger, MD, Monika Kaniszewska, MD, Emily Oehler, PA-C, Steven Prus, PA-C, Ann Cameron Schieber, PA-C, Jessica Dooley, PA-C, Elana Block MSN, RN, Alla Molchanov, Lic. Cosm., Emily Jamieson, Lic. Esth. (LE), Rachel Walker, LE, Nicole McNellis, LE, Alyssa Conner, LE, and Brittany Hartnett, Lisc. Cosm. all perform cosmetic treatments at Advanced Dermatology. All providers at Advanced Dermatology have been specifically trained by Dr. Taub and are all licensed professionals in the state of Illinois. Dr. Taub reviews and approves every treatment performed at Advanced Dermatology. Dr. Taub is a board-certified dermatologist with over 20 years in practice and is Medical Director and Founder of Advanced Dermatology. We have taken great measures to ensure that your treatment is performed safely and effectively. We attend national meetings frequently to keep updated on the latest, best and safest techniques and remain at the forefront of cosmetic dermatology.

DISCLAIMER: What your Physician, Physician Assistant, Laser Provider, Esthetician, Cosmetologist, and/or Cosmetic Coordinator have discussed with you and included again in these documents are the material risks, both common and uncommon, that they feel a reasonable person would want to know, understand, and consider in deciding if this treatment is something they would like to proceed with. Some risks cannot be foreseen. It is important that you read the information contained in each consent document and have all your questions answered before signing the consent. Questions and concerns can be answered in the office through a consultation appointment or by calling 847-459-6400.

CoolSculpting™ (Cryolipolysis): INFORMED CONSENT BOOKLET

The CoolSculpting® 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. CoolSculpting is a way to effectively reduce fat in targeted areas of the body; It is not a treatment for weight loss. The CoolSculpting procedure does not replace traditional methods such as diet, exercise, or liposuction.

During a CoolSculpting procedure, an applicator is applied to the skin surface to deliver precisely controlled cooling to slowly cool fat cells. The fat and skin in the area is drawn into the applicator with vacuum pressure that may initially cause some discomfort or an unfamiliar sensation. You may also experience an uncomfortable cold sensation that usually subsides within 5-10 minutes after the procedure begins. The cold gradually damages the cells such that they are

gradually eliminated through the body's normal metabolic processes. As soon as the procedure is complete, you can immediately return to your normal activities including work and exercise.

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. If repeat treatments are recommended, they should be spaced 6 to 8 weeks apart. A complimentary follow-up consultation with photos is strongly advised after the total number of recommended treatments are completed.

WHO IS A GOOD CANDIDATE: Anyone with excess fat in an area that can be pinched at least one inch between the fingers and is in the current recommended treatment zones as stated above and as discussed in your consultation. This is not a procedure for weight loss or for people who have obesity. It works best for people who have isolated pockets of fat and who understand the risks, costs and time necessary to achieve the full benefit of the procedure and who has realistic expectations of the outcome.

WHO IS NOT A GOOD CANDIDATE: You are not a good candidate for this procedure if you have an allergy to cold, cryoglobulinemia, paroxysmal cold hemoglobinuria, have a hernia (for treatments on the abdomen), or a recent surgical procedure in the area to be treated or if you are pregnant or nursing as well as 12 months post-childbirth and for those that have too much fat in an area including issues with obesity. Additionally, anyone with conditions including but not limited to cold urticaria, areas of impaired peripheral circulation, raynaud's disease, scar tissue or extensive skin conditions such as eczema or dermatitis at the area of treatment impaired skin sensation, open or infected wounds, areas of recent bleeding or hemorrhage are not good candidates.

PRE TREATMENT CARE: It is recommended that you are well hydrated prior to your treatment. You will be in a treatment room anywhere from 1-3 hours+, so your access to a restroom will be limited while the treatment is in progress. You will have access to restroom breaks in between treatments. You are welcome to bring snacks and work or reading material to your treatment.

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.

»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.

Bruising, redness, firmness, cramping, tingling, and stinging may happen.

»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.

You may have a feeling of fullness in the back of the throat if you are having a treatment under the chin.

»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).

Cold exposure to a nerve in the face called the marginal mandibular nerve may cause lower lip weakness.

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.

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%)

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%)

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%)

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.

» **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%)

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%)

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%)

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%)

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%)

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%)

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.

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

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

» 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.

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

MULTIPLE TREATMENTS AND MAINTENANCE TREATMENTS: The amount of CoolSculpting treatments per area will be discussed in your consultation and will vary among patients. Treatments should be spaced 6-8 weeks apart. Results vary by individual and are not guaranteed. A complimentary follow-up consultation with photos is required after the total number of recommended treatments are completed.

MAXIMIZING TREATMENT RESULTS: Your weight will be obtained prior to each treatment. Health eating patterns, adequate water intake, regular exercise, and healthy lifestyle choices are recommended for maximum results. Weight gain may have a negative effect on the results.

PATIENT SATISFACTION: Most of our patients/clients have been happy with their results, although results are variable and we cannot provide you with any guarantee of your results.

POST TREATMENT CARE: There is little to no recovery time after the procedure. Certain activities or tight clothing may be uncomfortable immediately after your treatment, however, you may resume your normal activities on the same day as your procedure, including work and exercise.

Do not touch the equipment while in the room. Laser equipment is dangerous and a misfire could cause skin or eye damage that is permanent.

CONSENT FOR PROCEDURE

I have read all pages contained in this document and hereby authorize the following provider(s): Amy Taub, MD, Anne Marie Leger, MD, Monika Kaniszewska, MD, Emily Oehler, PA-C, Steven Prus, PA-C, Ann Cameron Schieber, PA-C, Jessica Dooley, PA-C, Elana Block MSN, RN, Alla Molchanov, Lic. Cosm., Emily Jamieson, Lic. Esth. (LE), Rachel Walker, LE, Nicole McNellis, LE, Alyssa Conner, LE, and Brittany Hartnett, Lisc. Cosm. to perform the following procedure: **CoolSculpting™ (cryolipolysis).**

I recognize that during the course of the procedure unforeseen conditions may necessitate different procedures than those described above. I therefore authorize the provider(s) to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable.

I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.

I consent to photographic use for medical, scientific, and/or educational purposes for the appropriate portions of the face and/or body.

For purposes of advancing medical education, I consent to the admittance of observers to the procedure.

IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
THE ABOVE PROCEDURE TO BE UNDERTAKEN
THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
THERE ARE RISKS TO THE PROCEDURE PROPOSED
ANY QUESTIONS I MAY HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION

I consent to the procedure and the above listed items. I am satisfied with the explanation.

My Physician discussed my procedure, I understand the risks and benefits of the procedure have read the consent form I understand and I received a copy. I agree.