

# HIPAA INFORMATION AND CONSENT – NOTICE OF PRIVACY PRACTICES



THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

This notice is provided to briefly summarize how we handle your health information and provides details of our privacy policies and procedures.

**How we may use and disclose your health information:** We use health information about you for treatment, to get paid for treatment, for administrative purposes, and to evaluate the quality of care that you receive. For example, your health information may be shared with other providers to whom you are referred. Information may be shared by paper, mail, electronic mail, or other methods. We may use or disclose your health information without your authorization for appropriate medical reasons, for any situation beyond those we will ask for your written authorization before using or disclosing your health information. If you sign an authorization to disclose information, you can later revoke it to stop any future uses and disclosures.

**Your rights:** In most cases, you have the right to look at or get a copy of your health information that we use to make decisions about you. If you request copies, we may charge you a cost-based fee. You also have the right to request a list of certain types of disclosures of your information that we may have made. If you believe your health information is incorrect or information is missing, you have a right to request that we correct the existing information or add the missing information.

**Our legal duty:** We are required by law to protect the privacy of your health information, provide this notice about our privacy practices, follow the privacy practices that are described in this notice, and see to your acknowledgement of receipt of this notice. We may change our privacy policies at any time. Before we make a significant change in our policies, we will change our notice and post the new notice in the waiting area. You can also request a copy of our notice at any time. For more information about our privacy policies, contact the person listed below.

**HIPAA/HI-TECH notice:** We are required to notify you that we use e-mail and text correspondence for purposes of office operations, including but not limited to appointment and treatment reminders. If you wish to decline this means of communication, you must do so in writing, or you may "opt out" on any email correspondence through the link provided. We discourage the use of text messaging for details about your treatment because those messages are the property of telecommunication companies and therefore your privacy is NOT protected. Any text message or email you send to any member of our staff indicates that you waive your rights to privacy regarding that message as well as any and all other incidences of messaging via the same means with any member of the office staff. Any verbal or written request to send treatment related details via email or text will be followed.

**VIRTAUL CONSULTATIONS:** To offer virtual consultations and information, our office may use Facetime and/or Zoom as a means of communication, only if approved by you. By accepting and communicating by Facetime, you waive your rights to privacy regarding anything disclosed during a video conference call.

**Privacy complaints:** If you are concerned that we have violated your privacy rights, our privacy policies, or if you disagree with a decision we made about access to your health information, you may contact the person listed below. You may send a written complaint to the U.S. Department of Health and Human Services. The person listed below can provide you with the appropriate address upon request.

If you have any questions please contact our Privacy Officer, Jessie Poole at 214-897-3006.

**Acknowledgement of receipt of Notice of Privacy Practices:** Please sign and date below to acknowledge that you have received this Notice of Privacy Practices.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## MEDICAL DISCLAIMER AND CONSULTATION CONSENT



This notice is provided to briefly summarize how we provide general information, especially in the consultation process when considering CoolSculpting and/or CoolTone.

Our website and our initial consultations are designed to provide general information. Any general information provided should not be considered medical advice. It is intended for informational purposes and is not a substitute for a professional medical opinion, a diagnosis, or a treatment. We offer this information solely for educational purposes and any specific medical history and/or medical advice will be given only after your medical clearance appointment\*.

Never ignore professional medical advice in seeking treatment because of something you have read online or heard from a non-medical person. If you think you have a medical emergency, contact your qualified medical provider or immediately dial 911.

General Information: In most cases, our initial consultations are provided to gather general information regarding body contouring procedures and are not intended to establish a standard of care. If you would prefer to meet with a physician in your initial visit, you always have access to our medical director. No information provided by anyone besides our medical director or an appropriate medical professional should be interpreted with the intention to give medical advice or instruction on the accurate use of body contouring procedures. Element Body Lab will not answer unsolicited e-mails requesting personal medical advice without a doctor-patient relationship established.

\*Medical Clearance: CoolSculpting and CoolTone are prescriptive medical devices and there are risks and side effects to consider. A medical clearance will be required and provided by a qualified medical professional prior to you paying for or receiving treatment at Element Body Lab. You can consult with our medical professional prior to making any decision or undertaking any action or not undertaking any action related to any healthcare problem or issue you might have at any time, now or in the future relating to the procedure(s). If you have specific medical questions related to body contouring outside of general information requests, they will be addressed during your medical clearance with a high-level medical provider (NP, PA, or MD). Our high-level medical providers are not incentivized or rewarded, nor do they receive any financial gain by qualifying or "clearing" you for the treatment. Their job is to ensure that the treatment is a safe option, to diagnose, and to develop a detailed treatment plan for any unlicensed medical professional they oversee.

Concerns and/or complaints: If you are concerned that we have violated our policies, or if you disagree with a decision we made about how information is disseminated, you may contact the person listed below or reach out to our medical director to initiate re-evaluating our processes.

If you have any questions please contact our Compliance Officer, Jessie Poole at 214-897-3006, who can connect you with our medical director upon request.

Acknowledgement of receipt of Medical Disclaimers and Consultation Consent: Please sign and date below to acknowledge that you have received and reviewed this document.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Aesthetic procedures and retail products must be paid for in full at the time of service or delivery of goods. Payments for services can be made by cash, credit card, or financing through an approved third party lender.

### PRICING AND TREATMENT POLICY:

The standard pricing of products and services is subject to change at any time with or without warning or notice. Treatment prices may vary from client to client based on individual programs or recommendations of products or services, tailored for client-specific needs. Treatment programs are non-transferable in part or whole to any other treatment or individual. All pre-payments for any aesthetic treatments expire 1 year from the date of purchase, including treatments such as CoolSculpting or CoolTone. After the one year period, unused treatments will be considered forfeited.

Refunds will be provided where required under Texas Consumer Laws. We offer complimentary consultations in order to provide you with information regarding our treatments and products, while all due care and skill is exercised in treating our clients, ultimately it is your responsibility to determine if the treatment or product is right for you before purchasing.

In the event of a refund, 5% of the original transaction will be deducted to cover processing fees and service charges. In the event of refunding a prepaid package, the client forfeits any prepaid discounts on packages and the refund will be based on retail value of treatments performed.

### CHARGEBACKS

If a chargeback occurs, then you agree that you will be solely responsible for the amount of the disputed payment and any additional fees or penalties which are charged by the payment processor (collectively, the "Chargeback Amount"). We will use reasonable efforts to notify you if a payment processor notifies Element Body Lab that a Chargeback has occurred, and you agree to assist Element Body Lab as necessary to investigate and resolve the Chargeback. In the event that a Chargeback occurs and Element Body Lab pays any Chargeback Amounts to the payment processor that is attributable to payments processed on your behalf, you further agree to pay to Element Body Lab any Chargeback Amount associated with such Chargeback, and hereby authorize Element Body Lab to obtain the Chargeback Amount in, plus a service fee equal to the greater of \$15 or such amount that is charged by any third party and/or any other financial institution(s) ("Service Fee(s)"). If a Chargeback is resolved in your favor and the payment processor gives Element Body Lab a credit for some or all of the Chargeback Amount, then we shall refund to you such credited amounts. The Service Fee is non-refundable. In the event that you request a refund of any payments, you will be responsible for any and all credit card or third party processing fees.

CLIENT INITIALS \_\_\_\_\_

PRODUCT SALES POLICY:

All product sales are final. In the case of a documented adverse reaction to any product, an exchange or credit may be issued within 10 days of the original purchase.

PROCEDURE DATE POLICY:

In order to secure a date for any procedure, a non-refundable deposit must be paid in full. The remaining balance is due in full prior to or at the beginning of treatment.

CANCELLATION AND RESCHEDULE POLICY:

If treatment is cancelled or rescheduled with less than 3 days (72 hours) notice, a non-refundable cancellation or rescheduling fee of \$200 is applied. If treatment is cancelled or rescheduled due to a documented medical emergency, any remaining balance less non-refundable cancellation fee stated above shall be applied to a future mutually agreeable procedure date.

Client Signature: \_\_\_\_\_ Date: \_\_\_\_\_

# PATIENT PHOTOGRAPHY RELEASE FORM



I authorize Element Body Lab, it's employees and representatives, to take photographs and/or video of my body for medical purposes to be used for my patient care, marketing, literature and/or case presentations.

I understand that:

- Photographs and/or video are taken to capture treatment outcomes for treatment and the experience at Element Body Lab
- They may be used for print, visual, or electronic media including but not limited to, scientific presentations, websites and for purposes of informing the medical profession or general public about the procedure. These uses may also include marketing on behalf of Element Body Lab.
- They may be released to ZELTIQ Aesthetics, Inc., an Allergan Affiliate and may be used for print, visual or electronic media including but not limited to, scientific presentations, websites, general marketing, and for purposes of informing the medical profession or general public about the CoolSculpting procedure on behalf of Allergan.
- The images taken of me may be published by the physician, Allergan and their agents and representatives.
- It is specifically understood that I will not be identified by name. However, I understand that in some circumstances the photographs/videos may portray features that will make my identity recognizable, such as facial features, tattoos, or birthmarks and that my identity may be disclosed in connection with the medical treatment I am undergoing.
- I have the right to revoke this authorization in writing at any time through a written revocation to Element Body Lab and Allergan, however I understand the permanent nature of information published either in print, electronic or world wide web content and that materials published often get republished by other parties, which are not controlled by Element Body Lab.

I hereby release Element Body Lab, Allergan and their agents and representatives from any and all claims and demands arising out of, or in conjunction with, the use of the photographs.

I certify that I have read this release carefully and fully understand its terms.

If under 18, guardian or parent must sign.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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 obesity or a weight-loss solution. The CoolSculpting procedure does not replace traditional methods such as diet, exercise or liposuction.

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 the period of months. Visible results can vary from person to person.

## WHAT YOU CAN EXPECT:

### Temporary Sensations / Symptoms:

» 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 subside 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 occur.
- 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.

» 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 swelling, itching, tingling, numbness, tenderness to the touch, pain in the treated area, cramping, aching, bruising and/or skin sensitivity also have been reported.
- You may have a feeling of fullness in the back of the throat after submental area treatment (chin and/or jawline).

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

- Cold exposure to a nerve close to your tongue called the hypoglossal nerve may cause tongue deviation (turning)
- 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.

Client Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## 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, 0.333%). 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 and 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%) 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.

Client Signature: \_\_\_\_\_ Date: \_\_\_\_\_

- » 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 a hernia, following a CoolSculpting treatment. Surgical intervention may be required to correct hernia formation or exacerbation.

### Disclosures

- » 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 now 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®.

### 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 body may react differently to stimuli.

Client Signature: \_\_\_\_\_ Date: \_\_\_\_\_



Pictures will be obtained for medical records. If pictures are used for educational and marketing purposes, all identifying marks will be cropped or removed and an additional photo consent must be signed.

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 information in this form, and I give my consent to be treated with the CoolSculpting procedure at Element Body Lab, and by the designated staff under an overseeing medical director.

I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

I DULY AUTHORIZE THE FOLLOWING TECHNICIANS TO PERFORM MY COOLSCULPTING PROCEDURE UNDER THE SUPERVISION OF THE OVERSEEING MEDICAL DIRECTOR: AMIR BALUCH, MD.

*Jessie Poole Credentials: CoolSculpting Certified Provider, CoolSculpting University, Masters - Clinical (2019),*

*CoolSculpting University Graduate (2018), CoolSculpting Honorary Trailblazer Distinction (2018)*

*CoolSculpting Sales Advisory Board Member (2018)*

*Jenn McGregor Credentials: CoolSculpting Certified Provider (2021); CoolSculpting University Graduate (2022)*

I understand that the medical director is available for a consultation with me by phone or appointment by contacting Element Body Lab at (214) 897 - 3006.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

The CoolTone™ treatment is a non-invasive procedure that is intended to firm and tone the treatment area by delivering controlled electromagnetic stimulation to induce strong muscle contractions. This procedure does not replace traditional healthy behaviors, such as exercise and diet.

The CoolTone procedure is intended to provide non-invasive electromagnetic stimulation for the improvement of abdominal tone, strengthening of the abdominal muscles, development for firmer abdomen, and strengthening, toning, and firming of buttocks and thighs. Results may vary.

## WHAT YOU CAN EXPECT:

### Temporary Sensations / Symptoms:

- » I may experience muscular pain in the treatment area following a CoolTone treatment.
- » I may experience temporary muscle spasm, joint or tendon pain in the treatment area following the CoolTone treatment.
- » I may experience redness at or near the treatment site.

### Contraindications

Active applicator should never be placed over implanted electrical devices like cardiac pacemakers, cochlear implants, intrathecal pumps, hearing aids, etc.

CoolTone should be used with caution in persons with Graves' disease, active bleeding disorders, or seizure disorders.

Women who are close to menstruation may find that it comes sooner, or cramping is increased / intensified with CoolTone treatments. Therefore, it is not recommended to undergo treatment during this time of the month. I understand that this and other unknown side effects may occur.

NOTIFY YOUR PROVIDER IF YOU HAVE ANY OF THE FOLLOWING:

- Cardiac pacemaker
- Cochlear implants

Client Signature: \_\_\_\_\_ Date: \_\_\_\_\_

- Intrathecal pumps
- Hearing aids
- Defibrillators
- Neurostimulators
- Drug pumps
- Metal IUD (such as a Paraguard)
- Other implanted device(s)
- Graves' disease
- Active bleeding disorders
- Seizure disorders
- Malignant tumor
- Heart problems
- Hemorrhagic conditions
- Epilepsy
- Pulmonary insufficiency
- Fever (currently)
- In the treatment area
  - Areas of skin that lack normal sensation
  - Metal or electronic implants
  - Recent surgical procedure (6 months or less)
- For females:
  - Menstruating (currently or expected in 2 days)
  - Pregnant

### Disclosures

» 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 now way to predict who may experience them.

» I understand that other unknown side effects may also occur following CoolTone treatment but elect to voluntarily proceed.

### Results

» 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 body may react differently to stimuli.

Client Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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

» Pictures will be obtained for medical records. If pictures are used for marketing purposes, a separate consent authorizing will be signed.

I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

I DULY AUTHORIZE THE FOLLWING TECHNICIANS TO PERFORM MY COOLSCULPTING PROCEDURE UNDER THE SUPERVISION OF THE OVERSEEING MEDICAL DIRECTOR: AMIR BALUCH, MD.

*Jessie Poole Credentials: CoolSculpting Certified Provider, CoolSculpting University, Masters - Clinical (2019),*

*CoolSculpting University Graduate (2018), CoolSculpting Honorary Trailblazer Distinction (2018)*

*CoolSculpting Sales Advisory Board Member (2018); CoolTone Certified Provider*

*Jenn McGregor Credentials: CoolSculpting University, Masters - Clinical (2023), CoolSculpting Certified Provider (2021);*

*CoolSculpting University Graduate (2022); CoolTone Certified Provider*

I understand that the medical director is available for a consultation with me by phone or appointment by contacting Element Body Lab at (214) 897 - 3006.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## INFORMATION AUTHORIZATION FORM



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.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_