



**ABSOLUTE**  
COSMETIC MEDICINE

# VASERSMOOTH™ PATIENT INFORMED CONSENT FORM

## INSTRUCTIONS

This is an informed consent document that has been prepared to help educate you on the VASERsmooth™ procedure, its risks, and alternative treatment options. It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page, and sign the consent for surgery as proposed by your surgeon.

## INTRODUCTION

### What is Cellulite?

Cellulite affects an estimated 85% of post-pubescent women. The association with women is linked to the effect of the estrogen hormone on the skin and soft tissues, which we do not fully understand. The cellulite results in dimpled, uneven skin with a "cobblestone" or "orange peel" appearance.

The tissue changes in cellulite include:

1. Fibrous septae attachments of the skin extending into the underlying fat and even connecting to the underlying muscle.
2. A thickened fat layer.
3. Fat lobules herniating up into the skin-fat interface.
4. Reduced skin blood circulation.

Understanding these changes that occur with cellulite helps to direct the proper treatment.

The most common areas of the woman's body affected by cellulite are the posterior thigh and the buttock. However, cellulite may affect other areas as well:

- Mid-section or abdomen
- Flanks or hips
- Back

This procedure is not a substitute for weight reduction. It is a method for treating the fibrous tissue bands, and removing localized deposits of fatty tissue, if appropriate. Liposuction removes unwanted deposits of fat from anywhere in the body, however, liposuction alone does not treat changes associated with cellulite. The best candidates for a VASERsmooth™ procedure are individuals of relatively normal weight who have excess fat in particular body areas, along with the presence of fibrous bands below the skin that can cause dimpling associated with the appearance of cellulite. Having firm, healthy, and elastic skin will result in a better final contour following a VASERsmooth™ procedure. Skin that has diminished tone due to stretch marks, weight loss, the natural aging process, or other medical conditions may not reshape itself to the new contours desired and may require additional surgical techniques to remove and tighten excess skin. Unfortunately, you can be your optimal body weight and still have aesthetically displeasing cellulite. Lipoplasty itself will not improve areas of dimpled skin known as cellulite. The VASERsmooth™ procedure is designed to address this condition by reducing the appearance of cellulite, but the results cannot be guaranteed for any extended period of time.

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### WHAT IS VASERSMOOTH™?

The VASERSmooth™ procedure uses ultrasound energy performed with a specialized VASERSmooth™ probe to disrupt the fibrous attachments observed immediately under the skin in cellulite.

The VASERSmooth™ procedure is performed utilizing advanced, proprietary technology. A patented grooved titanium probe with beveled edges is inserted through small incisions. The probe is passed back and forth, under the skin, using ultrasonic energy to emulsify the undesired fat and cut the fibrous bands under the skin that are considered to be the primary causes of unsightly cellulite. If local areas of excess fat are noted, a small amount of liposuction can be performed. The target of the VASERSmooth™ probe is the fibrous septae noted by the pre-treatment skin markings, which are the cause of the dimpling or indentations in cellulite. The specially designed VASERSmooth™ probe disrupts these fibrous attachments located immediately under the skin surface until smooth, unabated movement of the probe is appreciated by the surgeon. If needed, a hollow metal surgical instrument known as a cannula is then inserted and directed through the area of emulsified fat cells. The cannula is attached to a vacuum source, which provides gentle suction to remove the emulsified fat if the surgeon deems it necessary.

The VASERSmooth™ procedure is unique in that it first targets fat cells and then cuts the fibrous bands causing the dimples associated with cellulite. Therefore, complications and the potential for post-operative pain and bruising are minimized while the skin condition is optimal.

There are a variety of different techniques used for treating cellulite and care following surgery. VASERSmooth™ treatments may be performed under local or general anesthesia, and require the infiltration of fluid containing dilute local anesthetic and epinephrine into the treatment areas. This technique can reduce discomfort at the time of surgery, as well as reduce post-operative bruising. Support garments and dressings are typically worn after surgery to control potential swelling and promote healing, to provide comfort and support, and to help skin better fit new body contours. While unlikely, your surgeon may recommend that you make arrangements to donate a unit of your own blood that would be used if a blood transfusion were necessary after surgery.

### ALTERNATIVE TREATMENTS

Alternative forms of management consist of not treating the areas of fatty deposits and only addressing the fibrous bands. Diet and exercise regimens may also be of benefit in the overall reduction of excess body fat and cellulite. Direct removal of excess skin and fatty tissue may be necessary in addition to lipoplasty in some patients. Risks and potential complications are associated with alternative forms of treatment that involve surgery.

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## RISKS AND SIDE EFFECTS

Every surgical procedure involves a certain amount of risk, and it is important that you understand the risks involved with the VASERsmooth™ procedure. An individual's choice to undergo a surgical procedure is based on the comparison of risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your surgeon to make sure you understand the risks, potential complications, and consequences of the VASERsmooth procedure.

**Patient Selection:** Individuals with poor skin tone, medical problems, or unrealistic expectations may not be candidates for the VASERsmooth™ procedure.

**Allergic Reactions:** Rarely, local allergies to tape, suture material, or topical preparations utilized in VASERsmooth™ procedures have been reported. More serious systemic reactions due to drugs administered during surgery and prescription medicines may require additional treatment.

**Asymmetry:** Due to factors such as skin tone, bony prominence, and muscle tone, which can contribute to normal asymmetry in body features, it may not be possible to achieve symmetrical body appearance through VASERsmooth™ procedures.

**Bleeding:** While unusual, it is possible to have a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or require a blood transfusion. Non-prescription herbs and dietary supplements can increase the risk of surgical bleeding. Do not take any aspirin or anti-inflammatory medications for 2 weeks before surgery, as this may increase the risk of bleeding. Please review our medication alert for products and ingredients to be avoided for 2 weeks prior to and 2 weeks following your scheduled VASERsmooth™ procedure, and consult your doctor before taking anything.

**Change in Skin and Skin Sensation:** A temporary decrease in skin sensation may occur following the VASERsmooth™ procedure. This usually resolves over a period of time. Diminished or complete loss of skin sensation that does not totally resolve could potentially occur, as it infrequently has with similar procedures.

**Chronic Pain:** Chronic pain and discomfort following the VASERsmooth™ procedure is unusual.

**Damage to Deeper Structures:** Injury to deeper structures including nerves, blood vessels, and muscles is rare and the injury is almost always temporary.

**Infection:** Infection is unusual following this type of surgery. Should an infection occur, treatment including antibiotics or additional surgery may be necessary. Although extremely rare, life-threatening infections such as toxic shock syndrome could occur after surgery, regardless of the technology utilized.

**Long-term Effects:** Subsequent alterations in body contour may occur as a result of aging, weight loss or gain, pregnancy, or other circumstances not related to the VASERsmooth™ procedure.

**Pulmonary Complications:** In extremely rare cases, fat droplets could become trapped in the lungs to create a possibly fatal complication called fat embolism syndrome. Pulmonary complications may occur secondarily to blood clots (pulmonary emboli) or partial collapse of the lungs after general anesthesia. Should either of these complications occur, you may require hospitalisation and additional treatment. In some circumstances, pulmonary emboli can be life-threatening or fatal.

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### RISKS AND SIDE EFFECTS CONTINUED

**Scarring:** Although the incisions created for the VASERsmooth™ procedure are minimal and good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues in rare cases. Such scars may be unattractive and of a different color than surrounding skin. Additional treatments, including surgery, may be necessary to treat abnormal scarring.

**Seroma:** While the incidence and severity of seromas associated with VASERsmooth™ procedures are not common, such fluid accumulation is possible and could require additional treatments or surgery to promote drainage.

**Bruising and/or Swelling:** Although the VASERsmooth™ procedure can reduce or eliminate bruising and swelling normally resulting from surgical cellulite procedures, such could occur, and, in rare situations, persist for extended periods of time.

**Skin Contour Irregularities:** Skin contour irregularities and depressions in the skin are unlikely but possible. Visible and palpable wrinkling of skin can occur, particularly when large quantities of fat cells are removed and/or the skin is lacking good elasticity. Post-operative skin contour irregularities could necessitate additional treatments including surgery.

**Skin Loss:** Additional treatments including surgery could be necessary in the unlikely event that skin loss occurs following your VASERsmooth™ procedure.

**Surgical Anesthesia:** All forms of surgical anesthesia or sedation, whether administered locally or generally, carry risks including the possibility of complications, injury, and even death. You will probably be required to sign a separate anesthesia consent form in preparation for your surgery.

**Surgical Shock:** The VASERsmooth™ procedure could conceivably cause severe trauma, particularly when multiple or extensive areas are treated in a single session. Although serious complications are a rarity, infections or excessive fluid loss could lead to severe illness and even death. Should surgical shock occur following your VASERsmooth™ treatment, hospitalisation and additional treatment would be necessary. Individuals undergoing VASERsmooth™ procedures to remove large volumes of fat are at greater risk of complications. Patients contemplating large volume procedures (greater than 5000 cc removed) may be advised to undergo post-operative monitoring and aftercare that involves overnight hospitalisation.

**Lidocaine Toxicity:** There is the possibility that large volumes of fluid containing dilute local anesthetic drugs and epinephrine that is injected into fatty deposits during surgery may contribute to fluid overload or systemic reaction to these medications. Additional treatment including hospitalisation may be necessary.

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**RISKS AND SIDE EFFECTS CONTINUED**

**Ultrasonic Technology:** Risks associated with the use of ultrasound in lipoplasty and lipoplasty-related treatments such as cellulite reduction include the aforementioned and the following specific risks:

**Burns:** Ultrasonic energy may produce burns and tissue damage either at the incision site or in other areas if the probe touches the undersurface of the skin for prolonged periods of time. If burns occur, additional treatment and surgery may be necessary.

**Probe Fragmentation:** Ultrasonic energy produced within the probe(s) may cause disintegration (fragmentation) of the surgical instrument. The occurrence and effect of this is unpredictable. If this should occur, additional treatment including surgery may be necessary.

**Unknown Risks:** The long term effect on tissue and organs of exposure to short-duration, high intensity ultrasonic energy is unknown. The possibility exists that additional risk factors resulting from the use of ultrasound in VASERsmooth™ treatments could potentially be discovered.

**Unsatisfactory Results:** Although good results are expected, with estimates above 90% in patient satisfaction using minimally invasive techniques, there is no guarantee on the ultimate outcome. Possible results are cosmetically less acceptable deformities or indentations, asymmetry, and a surgical scar. Additional surgery or non-invasive treatments such as VASER Shape may be required to improve results.

**Other:** While we have attempted to assist you in building realistic expectations for your VASERsmooth™ treatment, you may be disappointed with your surgical results. However infrequent, it may be necessary in your case to perform additional surgery to improve results.

**ADDITIONAL SURGERY NECESSARY**

There are many variable conditions in addition to risk and potential surgical complications, that may influence the long term result of your VASERsmooth™ procedure. Even though risks and complications are unusual, the risks cited previously are particularly associated with lipoplasty and lipoplasty-related procedures utilizing suction and/or ultrasound technologies. Other complications and risks can occur, but are even more uncommon. If complications should occur, additional surgery or other treatments may be necessary. The practice of medicine is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained.

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### FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending upon where the surgery is performed. Due to the proprietary nature and expense of the technology utilized, your bill may reflect a separate and additional fee for the use of VASERsmooth™ equipment specific to your procedure. Depending upon whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges that are not covered. As an elective, cosmetic procedure, VASERsmooth™ treatments are not typically covered by insurance, placing full responsibility for payment upon the patient. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day surgery charges incurred due to remedial surgery are also the responsibility of the patient.

### DISCLAIMER

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition, along with disclosure of risks and alternative forms of treatment. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your surgeon may provide you with additional or different information that is based on all the facts in your particular case and the state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

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I have received and read the following information sheet: VASERsmooth™ Informed Consent.

1. I understand that VASERsmooth™ is an elective surgery procedure to reduce and remove the fibrous septae that can cause the condition referred to as cellulite from specific areas of the body. The procedure has been explained to me in a way that I understand. I have had the opportunity to ask questions, and my questions have been answered. Alternative methods of treatment have been discussed with me.
2. I acknowledge that no guarantee has been given by anyone as to the results that I may obtain. Although a good result is expected, I understand that there are risks associated with the procedure or treatment proposed, as detailed in the preceding information pages.
3. I consent to the administration of any anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
5. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
6. I realise that not having the operation is an option.
7. I have had an opportunity to have my questions answered.
8. I authorize my surgeon, and the VASERsmooth™ equipment manufacturer, Sound Surgical Technologies LLC, to use my pre- and post-operative photographs for presentation and publication.

Having discussed the reasonable expectations of the VASERsmooth™ procedure with me and having answered all of my questions to my satisfaction, I hereby authorize my surgeon \_\_\_\_\_ and his assistants as may be selected, to perform the VASERsmooth™ procedure and any other procedure(s) that in their judgment may be necessary or advisable should unforeseen circumstances arise during surgery.

With my signature below, I hereby consent to having the VASERsmooth™ procedure and to all statements above.

Patient's signature: \_\_\_\_\_ Date: \_\_\_\_\_

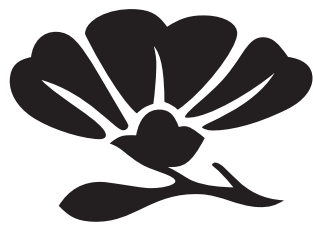
Witness's signature: \_\_\_\_\_ Date: \_\_\_\_\_

I, \_\_\_\_\_, certify that I or a member of my staff has discussed all of the above with the patient and have answered all questions regarding the VASERsmooth™ procedure. I believe the patient fully understands what has been explained and answered.

Surgeon's signature: \_\_\_\_\_ Date: \_\_\_\_\_

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