

LipoSelection only by VASER® Informed Consent

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you concerning LipoSelection only by VASER, its risks, and alternative treatment.

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

LipoSelection only by VASER is a surgical technique to remove unwanted deposits of fat from specific areas of the body, including the face and neck, upper arms, upper and lower back, abdomen, buttocks, hips, inner and outer thighs, knees, calves, and ankles. This is not a substitute for weight reduction, but a method for removing localized deposits of fatty tissue.

LipoSelection using VASER technology may be performed as a primary procedure for body contouring or may be combined with other surgical techniques.

The best candidates for LipoSelection only by VASER are individuals of relatively normal weight who have excess fat in particular body areas. Having firm, elastic skin will result in a better final contour after lipoplasty. Skin that has diminished tone due to stretch marks, weight loss, or natural aging will not reshape itself to the new contours and may require additional surgical techniques to remove and tighten excess skin. Body-contour irregularities due to structures other than fat cannot be improved by this technique. Lipoplasty itself will not improve areas of dimpled skin known as “cellulite”.

The LipoSelection procedure is performed utilizing advanced proprietary technology. A patented grooved solid metal probe is first inserted through small skin incision(s). Ultrasonic energy emitted from sides and end of the probe as it is passed back and forth breaks down fatty deposits. A hollow metal surgical instrument known as a cannula is then inserted and is 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. Because the LipoSelection procedure is unique in that it first targets and dissolves fat cells and then draws off emulsified fat, leaving the collagen matrix intact, surgical trauma, complications and the potential for post-operative pain and bruising are minimized while skin retraction is optimal.

There are a variety of different techniques used for lipoplasty and care following surgery. LipoSelection only by VASER may be performed under local or general anesthesia, and requires the infiltration of fluid containing dilute local anesthetic and epinephrine into areas of fatty deposits. This technique can reduce discomfort at the time of surgery, as well as reduce post-operative bruising.

Support garments and dressings are worn after surgery to control potential swelling and promote healing, to provide comfort and support, and to help skin better fit new body contours. 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 TREATMENT

Alternative forms of management consist of not treating the areas of fatty deposits. Diet and exercise regimens may be of benefit in the overall reduction of excess body fat.

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.

RISKS AND SIDE EFFECTS OF LIPOSELECTION ONLY BY VASER

Every surgical procedure involves a certain amount of risk, and it is important that you understand the risks involved with LipoSelection only by VASER. An individual’s choice to undergo a surgical procedure is based on the comparison of the 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 LipoSelection only by VASER.

- **Patient Selection.** Individuals with poor skin tone, medical problems, obesity, or unrealistic expectations may not be candidates for LipoSelection only by VASER.

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- **Allergic reactions.** Rarely, local allergies to tape, suture material, or topical preparations utilized in lipoplasty 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 lipoplasty 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 LipoSelection procedure, and consult your doctor before taking anything.
- **Change in skin and skin sensation.** A temporary decrease in skin sensation may occur following LipoSelection only by VASER. 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 various lipoplasty procedures.
- **Chronic pain.** Chronic pain and discomfort following LipoSelection only by VASER is unusual.
- **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 lipoplasty 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 LipoSelection only by VASER.
- **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 hospitalization and additional treatment. In some circumstances, pulmonary emboli can be life-threatening or fatal.
- **Scarring.** Although the incisions created for LipoSelection only by VASER 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 LipoSelection only by VASER has reduced the incidence and severity of seromas associated with lipoplasty procedures, such fluid accumulation is possible and could require additional treatments or surgery to promote drainage.
- **Skin discoloration and/or swelling.** Although LipoSelection only by VASER typically reduces or eliminates the skin discoloration and swelling normally resulting from lipoplasty procedures, such could occur and, in rare situations, persist for extended periods of time. The incidence of permanent skin discoloration is rare.
- **Skin contour irregularities.** As LipoSelection only by VASER selectively targets fat cells, leaving other essential tissues intact, 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 LipoSelection treatment.
- **Surgical anesthesia.** All forms of surgical anesthesia or sedation, whether administered locally or generally, carry risks including the possibility of complication, injury, and even death. You will probably be required to sign a separate anesthesia consent form in preparation for your surgery.
- **Surgical shock.** LipoSelection only by VASER 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 LipoSelection by VASER treatment, hospitalization and additional treatment would be necessary. Individuals undergoing LipoSelection procedures to remove large volumes of fat are at greater risk of complications. Patients contemplating large-volume lipoplasty – that is, greater than 5000 cc, may be advised to undergo post-operative monitoring and aftercare that involves overnight hospitalization.
- **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 hospitalization may be necessary.

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- **Ultrasonic technology.** Risks associated with the use of ultrasound in lipoplasty treatments 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 LipoSelection by VASER could potentially be discovered.
- **Other.** While we have attempted to assist you in building realistic expectations for your LipoSelection by VASER 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 LipoSelection only by VASER. Even though risks and complications are unusual, the risks cited above are particularly associated with lipoplasty 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.

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 VASER equipment specific to your procedure. Based upon whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. As an elective, cosmetic procedure, LipoSelection only by VASER is 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(s). 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.

ARBITRATION. Any and all disputes, claims or controversies arising between the parties shall be submitted for binding arbitration for final resolution. The laws governing any such arbitration shall be that of the state of Michigan, and any and all costs incident to the said arbitration shall be equally borne between the parties.

Consent for Surgery / Procedure or Treatment

I have received and read the following information sheet:

LipoSelection only by VASER® Informed Consent (VASER Assisted Lipoplasty)

I understand that LipoSelection only by VASER is an elective surgery procedure to remove body fat from specific area(s) 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.

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 to the procedure or treatment proposed, as detailed in the preceding information pages.

I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.

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

I consent to the disposal of any tissue, medical devices or body parts which may be removed.

I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.

Having discussed the reasonable expectations of LipoSelection only by VASER with me and answered all of my questions to my satisfaction, I hereby authorize Dr Jeffrey A. Cole and such assistants as may be selected to perform LipoSelection only by VASER 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 LipoSelection only by VASER and to the above.

I understand that the practice of medicine is not an exact science and although good results are expected there can be no guarantee as to the results.

Patient Signature

____/____/____
Date

Witness Signature

____/____/____
Date