



# Informed Consent

## Facial Volume / Filler Injection

## **INSTRUCTIONS**

This is an informed-consent document which has been prepared to help your plastic surgeon inform you about facial volume/filler injections, its risks, and alternative treatments.

This consent covers injection using:

\_\_\_ **Sculptra®** - Sculptra Aesthetic is made from a synthetic material called poly-L-lactic acid, which is gradually and naturally absorbed by the body as it works to replace lost collagen. Poly-L-lactic acid has been used for decades in dissolvable stitches and as a facial injectable since 1999 in over 30 countries. Sculptra Aesthetic targets the underlying causes of the signs of facial aging. It can give you noticeable results that emerge subtly and can last for up to 2 years. It begins to work within the deep dermis, where your skin's structure is reinforced as Sculptra Aesthetic helps to replace lost collagen. Sculptra Aesthetic is intended for use in people with healthy immune systems as a one-time treatment regimen of up to 4 injection sessions that are scheduled about 3 weeks apart for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate. Side effects of Sculptra Aesthetic may include injection site discomfort, redness, bruising, bleeding, itching, and swelling. Other side effects may include small lumps under the skin that are sometimes noticeable when pressing on the treated area. Larger lumps, some with delayed onset with or without inflammation or skin discoloration, have also been reported. In a key clinical study the numbers of small and larger lumps were low and most resolved without treatment.

\_\_\_ **Radiesse®** - RADIESSE Volumizing Filler is an injectable implant composed of synthetically produced smooth calcium hydroxylapatite (CaHA) microspheres (diameter of 25µm to 45µm) suspended in a sodium carboxymethylcellulose gel carrier. RADIESSE Volumizing Filler is approximately 30% CaHA and 70% gel carrier by volume. RADIESSE Volumizing Filler is injected into the skin in a minimally invasive procedure. Injection of the product provides an immediate one-to-one correction of the facial wrinkle. There is no skin sensitivity testing or reconstitution required. Over time, the gel is absorbed, and fibroblasts appear. The process of neocollagenesis begins, stimulating the gradual growth of the patient's own collagen. The collagen that forms results in extended correction and increased patient satisfaction. Results are clinically proven to last a year or more in many patients. The cosmetic results are soft and natural-looking, and feel like the patient's own tissue. The results are long-lasting, but not permanent. The CaHA microspheres naturally degrade to calcium and phosphate ions, which are metabolized by the body's normal processes.

\_\_\_\_\_ - There may be new facial volume/injection fillers in the future. Check with your doctor about their FDA approval and safety. Nothing is permanent, so ask about longevity and reasonable expectations about appearance.

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 this procedure as proposed by your plastic surgeon and agreed upon by you.

## **GENERAL INFORMATION**

Semi-permanent filler injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips. Fillers cannot stop the process of aging. They can however, temporarily diminish the look of wrinkles and soft tissue depressions.

Filler injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. Filler injections require regional nerve blocks or local anesthetic injections to diminish discomfort. Soft tissue fillers produce temporary swelling, redness, and needle marks, which resolve after a few days time.

Continuing treatments are necessary in order to maintain the effect of fillers over time. Once injected, fillers will be slowly absorbed by the body. The length of effect for injections is variable.

### **ALTERNATIVE TREATMENTS**

Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, dermabrasion, or other skin procedures, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

### **INHERENT RISKS OF FACIAL VOLUME/FILLER INJECTIONS**

Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of facial volume/filler injections.

### **SPECIFIC RISKS OF FACIAL VOLUME/FILLER INJECTIONS**

#### **Bleeding and Bruising:**

It is possible, though unusual, to have a bleeding episode from a filler injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba and other "herbs / homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before or after filler injections.

#### **Swelling:**

Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

#### **Pain:**

Discomfort associated with injections is normal and usually of short duration.

#### **Needle Marks:**

Visible needle marks from the injections occur normally and resolve in a few days.

#### **Acne-Like Skin Eruptions:**

Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.

#### **Skin Sensitivity:**

Skin rash, itching, tenderness and swelling may occur following injections. After treatment, you should minimize exposure of the treated area to excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. If you are considering laser treatment, chemical skin peeling or any other procedure based on a skin response after filler treatment, or you have recently had such treatments and the skin has not healed completely, there is a possible risk of an inflammatory reaction at the implant site.

#### **Erythema (Skin Redness):**

Erythema in the skin occurs after injections. It can be present for a few days after the procedure.

#### **Infection:**

Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth can occur following a tissue filler treatment. This applies to both individuals with a past history of herpes simplex virus infections and individuals with no known history of herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection.

from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

**Under / Over Correction:**

The injection of soft tissue fillers to correct wrinkles and soft tissue contour deficiencies may not achieve the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of tissue fillers due to factors attributable to each patient's situation. If under correction occurs, you may be advised to consider additional injections of tissue filler materials.

**Asymmetry:**

The human face is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with tissue filler injections. There can be a variation from one side to the other in terms of the response to injection. This may require additional injections.

**Damage to Deeper Structures:**

Deeper structures such as nerves and blood vessels may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

**Skin Lumpiness:**

Lumpiness can occur following the injection of fillers. This tends to smooth out over time. In some situations, it may be possible to feel the injected tissue filler material for long periods of time.

**Visible Tissue Filler Material:**

It may be possible to see any type of tissue filler material that was injected in areas where the skin is thin.

**Granulomas:**

Painful masses in the skin and deeper tissues after a filler injection are extremely rare. Should these occur, additional treatments including surgery may be necessary. Fillers should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives).

**Migration of Filler:**

The filler substance may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

**Skin Necrosis:**

It is very unusual to experience death of skin and deeper soft tissues after injections. Skin necrosis can produce unacceptable scarring. Should this complication occur, additional treatments, or surgery may be necessary.

**Allergic Reactions and Hypersensitivity:**

As with all biologic products, allergic and systemic anaphylactic reactions may occur. Fillers should not be used in patients with a history of multiple severe allergies, severe allergies manifested by a history of anaphylaxis, or allergies to gram-positive bacterial proteins. Allergic reactions may require additional treatment.

**Drug and Local Anesthetic Reactions:**

There is the possibility that a systemic reaction could occur from either the local anesthetic or epinephrine used for sensory nerve block anesthesia when tissue filler injections are performed. This would include the possibility of light-headedness, rapid heartbeat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

**Antibodies to Fillers:**

Presence of antibodies to tissue fillers may reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to tissue fillers is unknown.

**Accidental Intra-Arterial Injection:**

It is extremely rare that during the course of injection, fillers could be accidentally injected into arterial

structures and produce a blockage of blood flow. This may produce skin necrosis in facial structures or damage blood flow to the eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection of fillers is unknown and not predictable.

**Scarring:**

Fillers should not be used in patients with known susceptibility to keloid formation or hypertrophic scarring. The safety of patients has not been studied.

**Unsatisfactory Result:**

Filler injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response from filler injection(s). Additional injections may be necessary. Surgical procedures or other treatments may be recommended along with additional treatments.

**Unknown Risks:**

The long term effect of tissue fillers beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of tissue fillers may be discovered.

**Combination of Procedures:**

In some situations, Botox® injections or other types of tissue filler materials may be used in addition to facial volume/filler injections in order to specifically treat areas of the face or to enhance the outcome from tissue filler therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with tissue fillers is unknown.

**Pregnancy and Nursing Mothers:**

Animal reproduction studies have not been performed to determine if tissue fillers could produce fetal harm. It is not known if tissue fillers or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive tissue filler treatments.

**Drug Interactions:**

It is not known if tissue fillers react with other drugs within the body.

**Long-Term Effects**

Facial volume/filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time most filler material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing filler treatment (injections) is necessary in order to maintain the effect of the filler. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to these filler injections. Future surgery or other treatments may be necessary. Volume filler injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

**Additional Treatment Necessary:**

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with facial volume/filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery 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.

**GENERAL RISKS OF SURGERY**

**Healing Issues:**

Certain medical conditions, dietary supplements and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming

apart, infection, and tissue changes resulting in the need for additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. There may also be a longer recovery due to the length of surgery and anesthesia. Patients with significant skin laxity (patients seeking facelifts, breast lifts, abdominoplasty, and body lifts) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and recurrence of skin looseness will occur at some time in the future, quicker for some than others. There are nerve endings that may become involved with healing scars from surgery such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your surgeon.

**Bleeding:**

It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or you may require a blood transfusion, though such occurrences are rare. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Do not take any aspirin or anti-inflammatory medications for at least ten days before or after surgery, as this may increase the risk of bleeding. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time, usually in the first three weeks following injury to the operative area. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

**Infection:**

Infection is unusual after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is important to tell your surgeon of any other infections, such as ingrown toenail, insect bite, or urinary tract infection. Remote infections, infection in other part of the body, may lead to an infection in the operated area.

**Scarring:**

All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is the possibility of visible marks in the skin from sutures. In some cases scars may require surgical revision or treatment.

**Firmness:**

Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may be necessary.

**Change in Skin Sensation:**

It is common to experience diminished (or loss of) skin sensation in areas that have had surgery. Diminished (or complete loss of) skin sensation may not totally resolve.

**Skin Contour Irregularities:**

Contour and shape irregularities may occur. Visible and palpable wrinkling of skin may occur. Residual skin irregularities at the ends of the incisions or “dog ears” are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

**Skin Discoloration / Swelling:**

Some bruising and swelling will normally occur. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

**Skin Sensitivity:**

Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations it may be chronic.

**Delayed Healing:**

Wound disruption or delayed wound healing is possible. Some areas of the skin may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to tissue from past surgery or radiation therapy may be at increased risk for wound healing and poor surgical outcome. Smokers have a greater risk of skin loss and wound healing complications.

**Damage to Deeper Structures:**

There is the potential for injury to deeper structures including nerves, blood vessels, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

**Surgical Anesthesia:**

Both local and general anesthesia involves risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

**Shock:**

In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

**Pain:**

You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

**Cardiac and Pulmonary Complications:**

Pulmonary complications may occur secondarily to blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life-threatening or fatal in some circumstances. Inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of swelling in your legs or blood clots that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

**Venous Thrombosis and Sequelae:**

Thrombosed veins, which resemble cords, occasionally develop in the area of the breast or around IV sites, and usually resolve without medical or surgical treatment. It is important to discuss with your surgeon any birth control pills you are taking. Certain high estrogen pills may increase your risk of thrombosed veins.

**Allergic Reactions:**

In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur

in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

**Drug Reactions:**

Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important for you to inform your physician of any problems you have had with any medication or allergies to medication, prescribed or over the counter, as well as medications you now regularly take.

**Asymmetry:**

Symmetrical body appearance may not result after surgery. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to normal asymmetry in body features. Most patients have differences between the right and left side of their bodies before any surgery is performed. Additional surgery may be necessary to attempt to diminish asymmetry.

**Persistent Swelling (Lymphedema):**

Persistent swelling can occur following surgery.

**Unsatisfactory Result:**

Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. The body is not asymmetric and almost everyone has some degree of unevenness which may not be recognized in advance. One side of the face may be slightly larger, one side of the face droopier. The breast and trunk area exhibits the same possibilities. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations as to results, the better your results will be in your eye. Some patients never achieve their desired goals or results, at no fault of the surgeon or surgery. You may be disappointed with the results of surgery. Asymmetry, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Size may be incorrect. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery to improve your results.

**ADDITIONAL ADVISORIES**

**Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):**

Patients who are currently smoking or use tobacco or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying and delayed healing and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

\_\_\_ I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing surgical complications.

\_\_\_ I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

\_\_\_ I have smoked and stopped approximately \_\_\_\_\_ ago. I understand I may still have the effects and therefore risks from smoking in my system, if not enough time has lapsed.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired. I acknowledge that I will inform my physician if I continue to smoke within this time frame, and understand that for my safety, the surgery, if possible, may be delayed.

Smoking may have such a negative effect on your surgery that a urine test just before surgery may be done which will prove the presence of Nicotine. If positive, your surgery may be cancelled and your



surgery, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking to your surgeon.

**Sleep Apnea / CPAP:**

Individuals who have breathing disorders such as “Obstructive Sleep Apnea” and who may rely upon CPAP devices (constant positive airway pressure) or utilize nighttime oxygen are advised that they are at a substantive risk for respiratory arrest and death when they take narcotic pain medications following surgery. This is an important consideration when evaluating the safety of surgical procedures in terms of very serious complications, including death, that relate to pre-existing medical conditions. Surgery may be considered only with monitoring afterwards in a hospital setting in order to reduce risk of potential respiratory complications and to safely manage pain following surgery.

Please consider the following symptoms of sleep apnea:

- ☐ I am frequently tired upon waking and throughout the day
- ☐ I have trouble staying asleep at night
- ☐ I have been told that I snore or stop breathing during sleep
- ☐ I wake up throughout the night or constantly turn from side to side
- ☐ I have been told that my legs or arms jerk while I'm sleeping
- ☐ I make abrupt snorting noises during sleep
- ☐ I feel tired or fall asleep during the day

It is important for you to inform and discuss any of the above symptoms that you have experienced with your surgeon.

**Off-Label FDA Issues:**

There are many devices, medications and injectable fillers and botulinum toxins that are approved for specific use by the FDA, but this proposed use is “Off-Label”, that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your physician believes it to be safe and effective.

☐ I acknowledge that I have been informed about the Off-Label FDA status of \_\_\_\_\_ and I understand it is not experimental and accept its use.

**Medications and Herbal Dietary Supplements:**

There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Aleve. It is very important not to stop drugs that interfere with platelets, such as Plavix, which is used after a stent. It is important if you have had a stent and are taking Plavix that you inform the plastic surgeon. Stopping Plavix may result in a heart attack, stroke and even death. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

**Sun Exposure – Direct or Tanning Salon:**

The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

**Travel Plans:**

Any surgery holds the risk of complications that may delay healing and your return to normal life. Please

let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

**Long-Term Results:**

Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your surgery.

**Body-Piercing Procedures:**

Individuals who currently wear body-piercing jewelry in the surgical region are advised that an infection could develop from this activity.

**Female Patient Information:**

It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

**Intimate Relations After Surgery:**

Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery to control bleeding. It is wise to refrain from intimate physical activities until your physician states it is safe.

**Mental Health Disorders and Elective Surgery:**

It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

**DVT/PE Risks and Advisory:**

There is a risk of blood clots, Deep Vein Thrombosis (DVT) and Pulmonary Embolus (PE) with every surgical procedure. It varies with the risk factors below. The higher the risk factors, the greater the risk and the more involved you must be in both understanding these risks and, when permitted by your physician, walking and moving your legs. There may also be leg stockings, squeezing active leg devices, and possibly medicines to help lower your risk.

There are many conditions that may increase or affect risks of clotting. Inform your doctor about any past or present history of any of the following:

- \_\_\_\_\_ Past History of Blood Clots
- \_\_\_\_\_ Family History of Blood Clots
- \_\_\_\_\_ Birth Control Pills
- \_\_\_\_\_ Swollen Legs
- \_\_\_\_\_ History of Cancer
- \_\_\_\_\_ Large Dose Vitamins
- \_\_\_\_\_ Varicose Veins
- \_\_\_\_\_ Past Illnesses of the Heart, Liver, Lung, or Gastrointestinal Tract.

\_\_\_\_\_ I understand the risks relating to DVT/PE and how important it is to comply with therapy as discussed with my surgeon. The methods of preventative therapy include:

- \_\_\_ Early ambulation when allowed
- \_\_\_ Compression devices (SCD/ICD)
- \_\_\_ ASA protocol when allowed (Aspirin)

- \_\_\_ Heparin protocol when allowed  
\_\_\_ Enoxaparin protocol when allowed

The risks of DVT/PE may be almost as great as the prophylactic therapy when involving Aspirin, Heparin, and Enoxaparin. Be aware that if your surgery is elective, those patients with very high risks should consider not proceeding with such elective surgery.

### **ADDITIONAL SURGERY NECESSARY (Re-Operations)**

There are many variable conditions that may influence the long-term result of surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of body structures. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with this surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery 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. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon will discuss the options available should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology and lab testing.

### **PATIENT COMPLIANCE**

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

### **REVISION POLICY**

Surgical revision surgery is a common part of elective surgery. Your procedure will not stop you from aging, sagging, scarring, or experiencing ongoing skin changes that are more genetically controlled. If revision surgery is either desired or advisable within one year after the initial surgery, there may be a physician's fee. Additionally, there may be fees associated with the hospital, facility, anesthesia, pathology, lab, and any supplies such as implants, etc. Revision policy and courtesy discounts only apply to patients who comply with post-op orders and visits.

### **HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic surgical operations or any resulting complications. Please carefully review your health insurance subscriber-information pamphlet. Most insurance plans exclude coverage for secondary or revisionary surgery due to complications of cosmetic surgery. It is unethical and fraudulent to bill insurance for cosmetic procedures. We cannot participate in such activities.

### **FINANCIAL RESPONSIBILITIES**

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and



do not have your name attached, may contain internal codes the websites plan to “scrub” or delete. We will notify you if there has been a violation from these other sources, and we will protect your privacy to the best of our ability.

**PATIENT CONSENT FOR USE OF CREDIT CARDS, DEBIT CARD, AND FINANCING - DISCLOSURE OF PROTECTED HEALTH INFORMATION**

It may become necessary to release your protected health information to financial parties, credit card entities, banks, and financing companies, when requested, to facilitate your payment.

Services that are performed and are paid with a credit card, debit card, or financing third party are not eligible for payment challenges after services are provided. By signing this form, I am irrevocably consenting to allow Dr. \_\_\_\_\_ to use and disclose my protected health information to any credit card entity, bank, or financing company when they request such information to process an account and assist with payment.

\_\_\_\_\_ I will not challenge such credit, debit, or financing card payments once the services are provided. The practice encourages complete post-op care and follow-up interaction to address any issues that might arise, which are further addressed in the Revision Policy.

\_\_\_\_\_ I agree that this non credit card challenge agreement is irrevocable.

**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), including no surgery. 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 plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the current 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.**



## CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. \_\_\_\_\_ and such assistants as may be selected to perform the following procedure or treatment:  
  
I have received the following information sheet:
2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. 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.
4. I understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts that may be removed.
8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. I realize that not having the operation is an option.
12. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
  - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
  - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
  - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12).  
I AM SATISFIED WITH THE EXPLANATION.

\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

Date \_\_\_\_\_ Witness \_\_\_\_\_