BOICE-WILLIS CLINIC, PA

Patient Name: _____ DOB: _____ MRN: _____

Informed Consent

Facial Volume Filler Injection

Patient Name: _____ DOB: _____ MRN: _____

INSTRUCTIONS

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

This consent covers injection using:

___ **Sculptra**® - Sculptra® Aesthetic is a man-made material called poly-L-lactic acid, which is 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 targets the underlying causes of facial aging. It takes 6 to 8 weeks to see results and can last for up to 2 years. 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 number of small and larger lumps was low and most resolved without treatment.

___**Radiesse**® - **Radiesse**® is an injectable filler composed of smooth calcium hydroxylapatite (CaHA) microspheres in a gel carrier. **Radiesse**® is injected under the skin and provides an immediate one-to-one correction of facial wrinkles. Over time, the gel is absorbed, leading to gradual collagen growth. Results are clinically proven to last a year or more in many patients. The results are long-lasting, but not permanent. The CaHA microspheres naturally degrade and are metabolized by the body's normal processes.

___**Bellafill**® is improves nasolabial folds and moderate to severe, atrophic, distensible facial acne scars on the cheek in patients over the age of 21. Patients who have had a positive reaction to the Bellafill® Skin Test; have a history of severe allergies; have known cow collagen allergies; are allergic to lidocaine; have bleeding disorders; or are prone to thick scar formation and/or excessive scarring should not receive Bellafill®. You may experience temporary swelling, redness, pain, bruising, lumps/bumps, itching, and discoloration at the treatment site. These side effects are usually transient and typically resolve within 7 days. You may experience lumps/bumps/papules that may occur more than one month after injection and that may persist. Less common side effects include rash and itching more than 48 hours after treatment; persistent swelling or redness; lumps/bumps; acne; and increased sensitivity at treatment sites. Infrequently, granulomas may occur and may be treated by your surgeon. Be sure to call your surgeon immediately if you notice any unusual skin reactions around the treatment area. Based on a 5-year Post Approval Study on 1008 patients, the long-term safety of Bellafill® for up to 5-years has been established.

_____ - 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 regarding 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 form for this procedure as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

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 Botulina Toxin A (BTA), 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.

Continuing treatment is necessary in order to maintain the effect of fillers over time. Once injected, fillers will be slowly absorbed by the body. The duration of the effects of the injections is variable.

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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 treatment, 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 should be based on a comparison between the risks and the potential benefits. 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 experience bleeding after a filler injection or local anesthesia used during the procedure. Injury to the blood supply and bruising in soft tissues may occur. Should you develop 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. Be sure to discuss the use of these medications with your plastic surgeon.

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. Swelling around the lower eyelid may persist for long periods of time.

Pain:

Discomfort associated with injections is normal and usually of short duration. Long-term pain is rare.

Needle Marks:

Visible needle marks from the injections normally occur and resolve within 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. Damage to the skin or the lips may occur.

Skin Loss:

On rare occasions, filler can be injected into blood vessels. Embolization may occur, resulting in loss of blood flow to the skin and resulting skin loss. Should this occur the area of the skin could blanch and become very painful. Notify your surgeon immediately should this occur, as there are treatment options available to improve blood flow and prevent significant skin loss.

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Erythema (Skin Redness):
Redness of the skin occurs after injections and can be present for a few days after the procedure.

Vision Abnormalities:
Vision abnormalities, including blindness, may occur in rare instances.

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

Stroke:
In rare cases, dermal fillers can block oxygen supply to the brain, resulting in a stroke.

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 variation between one side of the face and the other in terms of response to injection. This may require additional injections.

Damage to Deeper Structures:
There is a potential for injury to deeper structures including nerves, blood vessels, muscles, and other structures during any injection 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.

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.

Leakage or Rupture of the Filler Material:
In rare cases, leakage or rupture of the filler material at the injection site or through the skin may occur, which may be caused by tissue reaction or infection.

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Skin Necrosis:
It is very unusual to experience damage to the skin and deeper soft tissues after injections. Skin loss can produce unacceptable scarring. Should this complication occur, additional treatments, or surgery may be necessary.

Open or Draining Wounds:
Rarely, the filler substance may cause an infection (biofilm formation) or possible necrosis of the area from blood-vessel occlusion, resulting in decreased blood flow to the affected area, which can negatively affect the healing process.

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. Severe allergic reactions are rare but may occur. Allergic reactions may require additional treatment. Allergy testing is required for particular types of filler materials (Bellafill).

Drug and Local Anesthetic Reactions:
There is a 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 could involve light-headedness, a rapid heartbeat (tachycardia), or fainting. Medical treatment of these conditions may be necessary.

Antibodies to Fillers:
The 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-Vascular Injection:
On rare occasions, fillers could be accidentally injected into blood vessels 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 risks and consequences of accidental intravascular injection of fillers are 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 a 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 effects of tissue fillers beyond one year are unknown. Additional risk factors or complications attributable to the use of tissue fillers may be discovered in the future.

Pregnancy and Nursing Mothers:
Animal reproduction studies have not yet been performed to determine whether tissue fillers could lead to fetal harm. It is not known if tissue fillers or its breakdown products are 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 any other drugs within the body.

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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 facial and eyelid appearance may occur as a 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 specifically 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 WARNINGS:

Dermal Fillers should NOT be Used if Any of the Following Apply:

- Skin is infected or inflamed. Soft tissue filler injection should be delayed until the inflammatory condition has been managed.
- Skin is prone to excessive scarring (keloids) and/or thick scarring (hypertrophic scars).
- Bleeding disorder is known.
- History of severe allergies or anaphylaxis is known.
- Allergy to collagen or eggs is known.
- Allergy to animal product is known.
- Allergy to lidocaine is known.
- Allergy to bacteria is known.

Although these fillers may be removed through surgery, the same adverse events typically associated with surgery may occur. It may be difficult to remove the filler material.

The safe use of tissue fillers repeatedly over a long period has not been evaluated in a controlled, clinical study.

The safety of these products during pregnancy, while breastfeeding, or in patients under 18 years of age is unknown.

GENERAL RISKS OF SURGERY

Healing Issues:

Certain medical conditions, dietary supplements, and medications may delay or interfere with healing. Patients with massive weight loss may experience a delay in healing that could result in the incisions coming apart, infection, or tissue changes resulting in the need for additional medical care, surgery, or 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 period depending on 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 be 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. The collection of blood that can occur under your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to an increased risk of bleeding and additional surgery. It is important to follow post-operative instructions and limit exercise and strenuous activity for the instructed time. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Hematomas 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 a risk of blood-related infections such as hepatitis and HIV (AIDS). Your surgeon may provide medications after your surgery to prevent blood clots. Medications that are used to prevent blood clots in veins can cause bleeding and decreased blood platelets.

Infection:

Infection, although uncommon, can occur 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 a history of methicillin-resistant Staphylococcus aureus (MRSA) infections, open wounds, recent upper respiratory infections/pneumonia, ingrown toenails, insect bites, tooth abscesses, or urinary tract infections. Infections in other parts of the body, may lead to an infection in the operated area. Post-operative infections often result in more extensive scarring and predispose to revision surgery.

Ileus:

The return of bowel function following surgery is important. An ileus is a disruption in bowel function caused by the failure of peristalsis or hypomobility of your bowels/gut resulting in a lack of defecation and possibly repeated vomiting. Anesthetics and medications like pain medications given to you at the time of surgery can contribute to the development of an ileus in the post-operative period. An ileus can result in abdominal distention, vomiting, inability to absorb oral medications and possibly hospitalization. Repeated vomiting could result in aspiration pneumonia or respiratory failure. It is essential to have regular bowel function after your surgery.

Scarring:

All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, this surgery will result in long, prominent scars that are permanent. 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 also a possibility of visible marks left on the skin from sutures. These scars may become raised, red, or discolored in the first few weeks/months, but usually settle down over time. However, some patients are prone to "hypertrophic" or "keloid" scars i.e. prominent, raised, red scars that do not settle. Further treatment with medication and/or surgery may be required.

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.

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Skin Sensitivity:
Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but on rare occasions it may be chronic.

Major Wound Separation:
Wounds may separate after surgery. Should this occur, additional treatment including surgery may be necessary.

Sutures:
Most surgical techniques use deep sutures. These sutures may be noticeable after your surgery. Sutures may spontaneously poke through the skin, become visible, or cause irritation that requires suture removal.

Damage to Deeper Structures:
There is a potential for injury to deeper structures including nerves, blood vessels, lymphatics, 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.

Fat Necrosis:
Fatty tissue found deep in the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is a possibility of contour irregularities in the skin that may result from fat necrosis.

Surgical Anesthesia:
Both local and general anesthesia involve risk. There is a 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. If you are a chronic pain patient in regular contact with a Pain Therapy Practitioner, you may be asked to see this practitioner preoperatively to assist you in the management of your pain disorder in the post-operative period. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.
Certain nerve endings may become involved in healing scars from 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 in scar tissue formation. Often, massage therapy and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your surgeon.

Cardiac and Pulmonary Complications:
Pulmonary complications may occur secondary to blood clots (pulmonary emboli), fat deposits (fat emboli), pneumonia, 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 migrating 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 associated with any surgery or anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heartbeats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

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Venous Thrombosis (Clot) 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. A personal history of bleeding and clotting problems may also 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. It is important to notify your physician of any previous allergic reactions.

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 currently take regularly. Provide your surgeon with a list of medications and supplements you are currently taking.

Surgical Wetting Solutions:
There is a 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.

Fat/Air Embolism:
In rare cases, fat particles or air can enter the vascular system and can travel to the heart, lungs, or brain. This can result in significant complications including death.

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 symmetrical 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 same applies to the breast and trunk area. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations are, the better your results will appear to you. 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 the 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. Unsatisfactory results may NOT improve with each additional treatment.

ADDITIONAL ADVISORIES

Medications and Herbal Dietary Supplements:
There are potential adverse reactions that occur as a result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with blood clot formation, and therefore may contribute to more bleeding issues. If you have a medical condition (such as a heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting such as Plavix®, Coumadin®, Xarelto®, Effient®, or Pradaxa®, discuss the management of these medications around the time of surgery with your plastic surgeon. Your plastic surgeon may sometimes coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a medical condition, do not stop them without discussing it first with your plastic surgeon. Stopping these medications abruptly may result in a heart

attack, stroke, or death. Be sure to check with your physician about any drug interactions that may exist with any medications 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 of 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 surgery can be timed accordingly. There are no guarantees that you will be able to resume all activities in the desired timeframe. Allow at least 10-14 days to travel via airplane.

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

Body Piercing:
Individuals who currently wear body jewelry in the surgical region are advised that an infection could develop from this activity. Body jewelry should be removed prior to your surgical procedure.

Nails:
To determine your vital signs during surgery your anesthesia provider may require access to your fingernails for monitoring. Make sure to have at least two fingernails free of nail polish or acrylic nails on the date of your surgery.

Jewelry:
Jewelry should not be brought with you at the time of your surgical procedure. Items, such as earrings, wedding rings, and necklaces should be removed and placed in a safe place.

Future Pregnancy and Breastfeeding:
This surgery is not known to interfere with pregnancy. If you are planning a pregnancy, your breast skin may stretch and offset the results of surgery. You may have more difficulty breast-feeding after this operation.

Female Patient Information:
It is important to inform your plastic surgeon if you use birth control pills or estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, meaning there may be a risk of unplanned conception and pregnancy.

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ntimate Relations After Surgery:
Surgery involves the coagulation 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 to return to surgery to control the bleeding. It is wise to refrain from intimate physical activities until your physician states it is safe.

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

REVISION POLICY:
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 advised, 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.

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 wounds will heal 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 associated with this surgery. Other complications and risks can occur but are less common. 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, regarding 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 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 to return to surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

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ATTESTATIONS

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 of significant surgical complications, such as skin loss 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 these types of complications. Please indicate your current status regarding the 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.

___ I have been advised to stop smoking immediately and have been informed of the risks, benefits, expectations, and alternatives to my surgery if I continue smoking.

It is important to refrain from smoking for 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 timeframe, and I 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 or blood 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 your smoking habits with your surgeon.

COMMUNICATION ACKNOWLEDGEMENT – CONSENT
There are many ways to communicate with you. It is important to keep appointments and let us know if problems or issues arise. Methods of communication include telephone, text, pager, answering service if available, email, and regular mail. If an emergency arises, keep us alerted to your progress so we may aid in any necessary treatments. Please do not leave a message after hours or on weekends on the office answering machine if any urgent or emergent situation exists, as there will be a delay in retrieving such messages. All attempts will be made to preserve your privacy in accordance with HIPAA rules.

Please confirm below all acceptable ways of communicating with you:

____ Telephone
- ____ Home (- -)
- ____ Work (- -)
- ____ Cell (- -)

____ Text
____ Pager – Answering Service if available
____ Email – with up to date email address (@)
____ Regular Mail and Delivery

 _____ **Patient Initials**

Patient Name: _____ DOB: _____ MRN: _____

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 a decision not to proceed with surgery. This document is based on a thorough evaluation of scientific literature and relevant clinical practices to describe a range of generally acceptable risks and alternative forms of management of a particular disease or condition. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of 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 your questions answered before signing the consent on the next page.

 _____ **Patient Initials**

Patient Name: _____ DOB: _____ MRN: _____

CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Karen Szymanski, DO, MPT and assistants that may be selected to perform **Facial Volume Filler Injection.**

   I have received the following information sheet: **Facial Volume Filler Injection.**

2. I recognize that during 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 procedures that are in the exercise of his or her professional judgment and deemed 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 has begun.

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

4. I understand what my surgeon can and cannot do, and understand that there are no warranties or guarantees, implied or specific regarding 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 of 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 being photographed or televised before, during, and after the or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed in the pictures.

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

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

8. 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.

9. I realize that not having the procedure is an option. I opt out of having this procedure _____.

10. 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 (1-10).
I AM SATISFIED WITH THE EXPLANATION.

_____
Patient or Person Authorized to Sign for Patient

Date/Time _____ Witness _____

_____ **Patient Initials**