

INFORMED CONSENT – JUVÉDERM® FILLER INJECTION

This is an informed-consent document which has been prepared to help your provider inform you concerning Juvederm®-based (Non-Animal Stabilized) tissue filler injection therapy, its risks, and alternative treatments. Juvederm® injectable gel is a colorless gel that is injected into facial tissue to smooth wrinkles and folds, especially around the nose and mouth. Juvederm® gel is a naturally occurring sugar found in the human body. The role of Juvederm® in the skin is to deliver nutrients, hydrate the skin by holding in water, and to act as a cushioning agent.

GENERAL INFORMATION The injection will utilize a stabilized Hyaluronic Acid filler used to smooth moderate to severe facial wrinkles and folds around the nose and mouth or shape facial contours. Juvederm® has been FDA approved for the cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions.

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. 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.

RISKS OF 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 Juvederm® Filler injections. Additional information concerning Juvederm may be obtained from the package-insert sheets supplied by Allergan Aesthetics.

Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections.

Normal Occurrences During Tissue Filler Injections

Bleeding and Bruising: It is possible 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,

Patient Initials _____

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.

Specific Risks of Filler Injections

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.

Patient Initials _____

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 Juvederm® tissue fillers may reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to Juvederm® 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 in additional treatments.

Unknown Risks: The long term effect of Juvederm® Filler beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of Juvederm® Filler as a soft tissue filler may be discovered.

Combination of Procedures: In some situations, Botox® injections or other types of tissue filler materials may be used in addition to Juvederm® Filler 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 Juvederm® Filler is unknown.

Patient Initials _____

Pregnancy and Nursing Mothers: Animal reproduction studies have not been performed to determine if Juvederm® Filler could produce fetal harm. It is not known if Juvederm® Filler or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive Juvederm® Filler treatments.

Drug Interactions: It is not known if Juvederm® Filler reacts with other drugs within the body.

Long-Term Effects: Juvederm® Filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the Juvederm® Filler material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing Juvederm® Filler treatment (injections) is necessary in order to maintain the effect of Juvederm® 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 Juvederm® Filler injection. Future surgery or other treatments may be necessary. Juvederm® Filler injection does not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

ADDITIONAL ADVISORIES

Female Patient Information: It is important to inform your provider if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant.

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 clotting and can cause more bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Alieve. 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 provider. 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 provider for further instructions.

ADDITIONAL TREATMENT NECESSARY There are many variable conditions in addition to risk and potential complications that may influence the long-term result of Juvederm® Filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Juvederm® 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.

FINANCIAL RESPONSIBILITIES 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. By signing the consent for this procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all current and future treatments.

Patient Initials _____

INFORMED CONSENT - JUVEDERM® FILLER INJECTION CONSENT FOR TREATMENT

I recognize that during the course of the procedure and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above provider 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 provider at the time the procedure is begun. I acknowledge that I have been informed about the risks and consequences and accept responsibility for the clinical decisions that are made along with the financial costs of all current and future treatments.

I consent to be photographed 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.

I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. I understand what my provider can and cannot do. I understand there are no warranties or guarantees, implied or specific about my outcome and acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained. I acknowledge all of my questions have been answered. I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives.

I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. I understand what my provider can and cannot do. I understand there are no warranties or guarantees, implied or specific about my outcome and acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained. I acknowledge all of my questions have been answered. I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives.

I acknowledge this consent form is valid for all future JUVEDERM filler injections and agree to alert my aesthetic nurse specialist at Malisse Skin Bar If there are any future changes to my medical history.

I declare I have read this Informed Consent (or it has been read to me), I understand the information contained in it including the fee structure and acknowledge I will not receive any refunds or credits for any procedures or treatment(s). I understand the inherent (specific) risks of the procedure(s) I seek, as well as those additional risks and complications, benefits, and alternatives and hereby release Malisse Skin Bar, its aesthetic nurse specialists, medical director, officers, members and employees from any liability associated with this procedure/injection.

I have no further questions and give my consent to proceed.

Patient Signature
(Person Authorized to Sign for Patient)

Date

Patient Name (Please Print)

Signature
Malisse Skin Bar’s Aesthetic Nurse Specialist