# Informed Consent for Juvederm® Injections

**INSTRUCTIONS**
This is an informed consent document which has been prepared to help us inform you concerning Juvederm® (Non-Animal Stabilized Hyaluronic Acid, Allergan©) tissue filler injection therapy, its risks, and alternative treatments. 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.

**INTRODUCTION**
Juvederm® is a stabilized hyaluronic acid 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. Hyaluronic acid is a naturally occurring substance that is found within all mammals. It is a material that is contained in various soft tissues. Hyaluronic acid can be synthetically produced from a process of bacterial fermentation, chemically stabilized, and purified for use as injectable soft tissue filler (non-animal, stabilized hyaluronic acid, Allergan©). The hyaluronic acid in Juvederm® is biocompatible and is a totally non-animal product; there is little risk of animal-based disease transmission or allergic reaction. Juvederm® 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. Juvederm® cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles and soft tissue depressions. Juvederm® injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®, or as an adjunct to a surgical procedure. Juvederm® injections may require regional nerve blocks or local anesthetic injections or topicals to diminish discomfort. Soft tissue fillers, including Juvederm®, 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 Juvederm® over time. Juvederm® once injected will be slowly absorbed by the body. The length of effect for Juvederm® 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, 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 JUVEDERM 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® injections.

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

**Bleeding and Bruising**
It is possible, though unusual, to have a bleeding episode from a Juvederm® 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 Juvederm® injections.

**Pain Discomfort**
Pain Discomfort associated with Juvederm® injections is normal and usually of short duration. 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. Erythema (Skin Redness) in the skin occurs after injections. It can be present for a few days after the procedure. 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 Lumpiness**
Lumpiness can occur following the injection of Juvederm®. 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.

**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 filer injections. There can be a variation from one side to the other in terms of the response to Juvederm® injection. This may require additional injections.

**Skin Sensitivity**
Skin rash, itching, tenderness and swelling may occur following Juvederm® 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 Juvederm® 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 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.

**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.

**Skin Necrosis**
It is very unusual to experience death of skin and deeper soft tissues after Juvederm® 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. Juvederm® 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.

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

**Granulomas**
Painful masses in the skin and deeper tissues after a Juvederm® injection are extremely rare.
Should these occur, additional treatments including surgery may be necessary.

**Skin Disorders**
Juvederm should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives). In rare instances, granuloma or abscess formation, localized necrosis and urticaria have been reported.

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

**Accidental Intra-Arterial Injection**
It is extremely rare that during the course of injection, Juvederm® 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 Juvederm is unknown and not predictable.

**Under / Over Correction**
The injection of soft tissue fillers including Juvederm® 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.

**Migration of Juvederm®**
Juvederm® may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.

**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.

**Unsatisfactory Result**
Juvederm® 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 Juvederm® injection(s). Additional Juvederm® injections may be necessary.

**Unknown Risks**
The long term effect of Juvederm® beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of Juvederm 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® 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® is unknown.

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

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

**Long-Term Effects**
Juvederm® injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the Juvederm® material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing Juvederm® treatment (injections) is necessary in order to maintain the effect of Juvederm. 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® injections.

**HEALTH INSURANCE**
Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same.

**ADDITIONAL TREATMENT NECESSARY**
There are many variable conditions in addition to risk and potential complications that may influence the long-term result of Juvederm® injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Juvederm injections. There is no guarantee or warranty expressed or implied, on the results that may be obtained.

**FINANCIAL RESPONSIBILITIES**
The cost of Juvederm® injection may involve several charges. Additional costs of medical treatment would be your responsibility should complications develop from Juvederm® injections.

**DISCLAIMER**

 

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered.

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.

I have read and understand the following Informed Consent Material for my specific procedure:
JUVEDERM®

The risks, benefits, and alternatives of the procedure(s) were explained to me. I understand the specific risks in the consent material for my surgery and understand the significant risks of bleeding, infection, blindness, injury to neighboring structures, capsule contracture(if implants involved), lumpiness, asymmetry, pulmonary emboli, deformity, skin loss or necrosis, healing problems, poor scars, loss of sensation(feeling), appearance/psychological changes, unsatisfactory result, need for future revision surgery and anesthesia. I understand the anticipated results and limitations of the surgery procedure(s).

**The following instructions were explained to me:**
Pre and Post procedure instructions, DVT prevention instructions, and medications to avoid instructions. I agree to follow all instructions, to follow up as directed, and to notify the office if any problems or questions arise.

_____ _____
Patient Signature Date Witness Print Name

_____ _____
Witness Signature Date Witness Address Line 1

 