MEDICAL AESTHETICS
HINGHAM | EASTON | MILTON

JUVÉDERM® COLLECTION CONSENT FORM

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INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about the collection of JUVÉDERM® XC filler injections, its risks, as well as alternative treatment(s). The collection includes JUVÉDERM® Ultra, Ultra Plus, Voluma XC, Volbella XC, and Vollure XC.

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 as proposed by Hingham Medical Aesthetics and agreed upon by you.

GENERAL INFORMATION

JUVÉDERM® XC injectable gel is a smooth, colorless hyaluronic acid (HA) gel that contains a small quantity of local anesthetic (lidocaine). HA is a naturally occurring sugar found in the human body. The role of HA in the skin is to deliver nutrients and help the skin retain its natural moisture and softness. XC indicates the addition lidocaine, which helps to improve the comfort of the injection. JUVÉDERM® Ultra XC and Ultra Plus XC injectable gels are manufactured using HYLACROSS® technology, and JUVÉDERM® Voluma XC, Volbella XC, and Vollure XC injectable gels are manufactured using VYCROSS® technology. All produce long-lasting results at the treatment site.

Hyaluronic acid has been FDA approved for the cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions. JUVÉDERM® XC is delivered by injection. JUVÉDERM® Ultra XC is FDA-approved to replace volume loss in the nasolabial folds and/or lips for up to 12 months. JUVÉDERM® Ultra Plus XC is FDA-approved to replace volume loss in the nasolabial folds for up to 12 months. Voluma XC is FDA-approved to replace volume loss in the check and surrounding area of the mid-face for up to 24 months. Volbella XC is FDA-approved to replace volume loss in the lips for up to 12 months. Vollure XC is FDA-approved to replace volume loss in the nasolabial folds for up to 18 months.

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. Continuing treatments are necessary in order to maintain the effect of fillers over time. Once injected, filters 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 treatments 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 HYALURONIC ACID 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 hyaluronic acid filler injections. Additional information may be obtained from the package insert sheets supplied by the manufacturers.

SPECIFIC RISKS OF HYALIRONIC ACID FILLER INJECTIONS

BLEEDING & BRUISING:

It is possible, though unusual, to have a bleeding episode from 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 post-injection bleeding, it may require emergency treatment. Aspirin, anti-inflammatory medications, platelet inhibitors, amleoagulams, Vitamin E, ginkgo blloba and other herbs / homeopathlc 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. Damage to the skin or the lips may occur.

ERYTHEMA (SKIN REDNESS):

Erythema in the skin occurs after injections. It 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 call 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. If you have a history of cold sores please notify your provider. 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.

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 injection. 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. These may occur weeks or months after your injection. Should these occur, additional treatments including treatment 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 rapture of the filler material at the injection site or through the skin may occur, which may be caused by tissue reaction or infection.

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 treatment 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 causes poor healing.

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 reaction is rare but may occur. 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 arc 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 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, 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 hypcrtropbic scarring. The safety of patients has not been studied.

UNSATISFACTORY RESULT:

Filler injections done 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. Unsatisfactory results may NOT improve with each additional treatment.

UNKNOWN RISKS:

The long term effect of hyaluronic acid filler beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of hyaluronic acid filler as a soft tissue filler may be discovered.

COMBINATION OF PROCEDURES:

The safe use of tissue fillers with BOTOX® or other dermal therapies has not been evaluated in a controlled, clinical study.

PREGNANCY AND NURSING MOTHERS:

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

DRUG INTERACTIONS:

It is not known if hyaluronic acid filler reacts with other drugs within the body.

LONG - TERM EFFECTS:

Hyaluronic acid filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the hyaluronic acid filler material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing hyaluronic acid filler treatment (injections) is necessary in order to maintain the effect of hyaluronic acid 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 hyaluronic acid filler injections. Future treatment or other treatments may be necessary. Hyaluronic acid filler injection does 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 risks 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 hyaluronic acid filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional treatment or other treatments may be necessary. The practice of medicine and treatment 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 scaring (keloids) and /or thick scarring (hypenrophic 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 treatment or by injection of a medication to dissolve the hyaluronic acid filler, the same adverse events typically associated with treatment may occur. It may be difficult to remove the filler material.

The safe use of tissue fillers repeatedly over a long period of time has not been evaluated in a controlled, clinical study. The safety of these products is unknown when used during pregnancy, while breast feeding, or in patients under 18 years of age.

ADDITIONAL ADVISORIES

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 forming blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition (such as 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, Warfarin, Coumadin, Xarelto, Efficient or Pradaxa, discuss management of these medications around the time of treatment with your provider. If you have an adverse reaction, stop the drugs immediately and call your provider for further instructions. If the reaction is severe, go immediately to the nearest emergency room.

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 provider and either delay treatment, or avoid tanning until the provider says it is safe to resume. The damaging effect of sun exposure occurs even with the use of sun block or clothing coverage.

IMPORTANT COMMITMENTS / TRAVEL PLANS:

Any treatment holds the risk or complications that may delay healing and your return to normal life. Please let the provider know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of treatment can occur. There are no guarantees that you will be able 10 resume all activities in the desired time frame.

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

MENTAL HEALTH DISORDERS AND ELECTIVE TREATMENT:

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

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 provider believes it to be safe and effective.

PATIENT COMPLIANCE:

Follow all physician instructions carefully; this is essential for the success of your outcome. Personal and vocational activity needs to be restricted.

DISCLAIMER:

Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including a decision not to proceed with treatment. 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 or 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 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 provider 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.

AUTHORIZATION (S):

_____ (Patient Initials) I acknowledge that I have been informed about the Off-Label FDA Status of JUVÉDERM® Voluma XC and I understand it is not experimental and accept its use.

_____ (Patient Initials) For women: I confirm that I am not pregnant or breastfeeding and do not intend to become pregnant anytime during the course of treatment.

_____ (Patient Initials) Before and after treatment instructions have been discussed with me. The procedure, potential benefits and risks, and alternative treatment options have been explained to my satisfaction.

_____ (Patient Initials) I understand that the procedure is purely elective, that the results may vary with each individual and multiple treatments may be necessary.

_____ (Patient Initials) I have read and understand all information presented to me before consenting to treatment.

_____ (Patient Initials) I have had all my questions answered. I freely consent to the proposed treatment.

_____ (Patient Initials) Photographic documentation will be taken for teaching and before/after purposes. I hereby □ do □ do not authorize the use of my photographs and understand that all attempts will be made to conceal my identity.

I, _____ hereby authorize _____ to perform JUVÉDERM® XC injection on me. I understand that I am a patient of Medical Aesthetics MA, a medical practice led by a Harvard-trained Board Certified Plastic Surgeon with over two decades or medical aesthetic experienced, and that my licensed provider is an employee of the practice.

PATIENT SIGNATURE DATE TIME

and/or

RESPONSIBLE RELATIVE OR GUARDIAN RELATIONSHIP

PROVIDER'S NAME PROVIDER'S SIGNATURE