

# ***Informed Consent to Receive Juvéderm® Ultra/Ultra XC ,Juvederm Ultra Plus/Ultra Plus XC and Volbella***

**This document is designed to help inform you concerning Juvéderm® tissue filler injection therapy, its risks and alternative treatments. It is important that you read it carefully and completely. Please initial at the bottom of each page indicating that you have read and understood each page.**

## ***General Information***

Juvederm® is a stabilized hyaluronic acid approved by the FDA for injection into facial tissue to smooth wrinkles and folds; especially around the nose and mouth. Hyaluronic acid (HA) is a naturally occurring sugar found in various soft tissues in the human body. The role of hyaluronic acid in the skin is to deliver nutrients, hydrate the skin by holding water, and to act as a cushioning agent. HA can be synthetically produced from a process of bacterial fermentation, chemically stabilized and purified for use as an injectable soft tissue filler. Juvederm® injections are customized per patient, depending on their needs. These can be performed in areas involving the face and eyelid region, forehead and lips. It cannot, however, stop the process of aging. It can temporarily diminish the look of wrinkles and soft tissue depressions. These injections may be performed as a single procedure, in combination with other treatments such as Botox®, or as an adjunct to surgical procedure. Continuing treatments are necessary in order to maintain the effect of Juvederm® over time. Once injected it will be slowly absorbed by the body. The length of effect is variable per individual; however, studies have shown the results may last as long as 9 months to 1 year.

## ***Procedure***

1. Juvederm® is injected under your skin in the areas of the face to be filled via a small gauge needle (usually 27-30G) and a syringe after the areas have been thoroughly cleaned with alcohol and an antibacterial cleaning solution.
2. An anesthetic (numbing medicine) may or may not be used. 30-45 minutes prior to Juvéderm® injections, a topical anesthetic (EMLA cream) may be applied to reduce discomfort. Ice is also used throughout the procedure to help minimize bruising and swelling as well as to provide local anesthesia. Juvederm® Ultra **XC** and Ultra Plus **XC** contain a small quantity of local anesthetic (lidocaine) which significantly reduces discomfort. Please inform your injector if you have a known allergy or sensitivity to local anesthetics.
3. The depth of the injection(s) will depend on the depth of the wrinkle(s) and the location(s). Multiple injections may be necessary depending on the site, depth of wrinkle and technique used.
4. Following each injection, the sites may be gently massaged to help the Juvéderm® conform to the contour of the surrounding tissues.
5. After the first treatment, additional treatments of Juvederm® may be necessary to achieve the desired level of correction. Periodic touch-up injections help sustain the desired level of correction.

Date: \_\_\_\_\_

Patient Initials: \_\_\_\_\_

## ***Alternative Treatments***

Improvement of skin wrinkles and soft tissue depressions may also be accomplished by other treatments. Options include laser skin surface treatments, chemical peels, microdermabrasion, Botox® injections, alternative types of skin fillers or surgery such as face lift, brow lift or blepharoplasty when indicated. Other options not mentioned here may exist. Risks and potential complications are associated with alternative forms of medical and surgical treatment.

## ***Injection-Site Side Effects***

Although a very thin needle is used, common injection-related reactions could occur. These include: redness, pain/tenderness, swelling, bruising, discoloration or itching at the injection site. You could experience increased bruising or bleeding at the injection site if you are using substances that prolong bleeding such as Plavix, Coumadin, Aspirin, other non-steroidal anti-inflammatory drugs such as Ibuprofen (Motrin, Advil) or Naproxen (Aleve, Naprosyn) or certain herbal products such as Ginkgo Biloba, Ginger, Garlic, Feverfew or Vitamin E.

Occasionally visible lumps/bumps may occur temporarily following the injection; however, these tend to smooth out over time. In some cases, it may be possible to see any type of tissue filler injected in areas where skin is thin.

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.

Skin rash, itching, tenderness and swelling may occur due to skin sensitivity to Juvé derm®. After treatment, you should minimize exposure of the treated areas to excessive sun or UV lamp exposure and extreme cold weather until any initial swelling or redness has gone away. You should also avoid strenuous exercise or alcohol for at least 24 hours after treatment. If you are considering laser treatment, chemical skin peeling, microdermabrasion or any other procedure based on a skin response or if you have had such treatments and the skin has not completely healed, there is a possible risk of an inflammatory reaction in the implant site.

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

## ***Risks of Injections***

Every procedure involves a certain amount of risk and it is important you understand these and the possible complications associated with them. Every procedure also 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 and limitations of Juvederm® and Volbella injections.

**Date:** \_\_\_\_\_

**Patient Initials:** \_\_\_\_\_

## ***Risks of Injections (Continued)***

**Infection** – Although 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 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 dermal filler. This can occur when filler compresses a blood vessel and inhibits the blood supply to a part of the face. The most common symptoms are pain at a location other than the injection site and/or discoloration to the area of the face supplied by the affected blood vessel. Treatment includes hot packs, massage, applying Nitropaste to cause dilation of the blood vessels and possibly injecting the affected area with hyaluronidase which is a protein that will help dissolve the HA filler. Let your injector know if you have a known allergy to bee- or vespid-stings since those individuals are at a higher risk for hyaluronidase sensitivity owing to the presence of hyaluronidase in venom.

**Granulomas** – This is a special type of inflammatory reaction in which a ball-like collection of immune cells forms when the immune system attempts to wall off substances that it perceives as foreign but is unable to eliminate. These reactions may be caused by allergy to the material or immunologic response to the protein in the HA preparations. They may present as warm, red, tender nodules under the skin in the area injected with HA. Treatment may consist of intralesional steroid injections, oral antibiotics or hyaluronidase injections.

**Scarring** – Although this is rare for most patients, you should not attempt Juvederm® injections if you are highly susceptible to keloid or hypertrophic scarring.

## ***Additional Advisories***

**Unsatisfactory Results/Long-term Effects** – Dermal fillers 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 and additional injections may be necessary. Dermal fillers should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the filler material is slowly absorbed by the body and wrinkles or depressions will reappear. Continuing treatments are necessary to maintain the effect. Surgical procedures or other treatments such as Botox®, microdermabrasion, laser skin surface treatments or chemical peels may be recommended in addition to Juvederm® treatments.

**Pregnancy & Nursing Mothers** – Studies have not been performed to determine if dermal fillers would not cause fetal harm nor is it known if their breakdown can be excreted in human breast milk. It is not recommended that pregnant women or nursing women receive dermal fillers.

Date: \_\_\_\_\_

Patient Initials: \_\_\_\_\_

**It is important that you read the above information carefully and have all your questions answered before signing the consent below.**

## ***Informed Consent***

***Juvederm® Ultra/ Juvederm® Ultra Plus***

***Juvederm® Ultra XC/ Juvederm® Ultra Plus XC, or Volbella***

1. I hereby authorize Ms. Sue's Med Spa to perform the following treatment:

**Juvederm® Ultra / Juvederm® Ultra Plus / Juvederm® Ultra XC / Juvederm® Ultra Plus XC, and /or Volbella**

2. I have read and received a copy of this Informed Consent document as well as a copy of the Juvederm® information sheet .

3. I grant authority to administer additional related medical treatments as deemed necessary or advisable in the diagnosis and treatment of my condition.

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

5. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained by this treatment.

6. I consent to be photographed before, during and after the procedure(s) to be performed, for purpose of being included as part of a record.

7. I realize that not having this procedure is an option.

8. I consent to the treatment and/or procedure and the above items 1-7. I have had enough time to consider the information from my physician, I am satisfied with the explanation and all my questions have been answered.

**Print Patient Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Patient Signature:** \_\_\_\_\_

**Injector Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_