



# STEPHAN

## SURGICAL ARTS

### **Patient Education and Consent: Hyaluronic Acid Dermal Filler Products**

**(Juvederm® Ultra XC, Juvederm® Ultra Plus XC, Juvederm Voluma® XC, Juvederm Volbella® XC, Juvederm Vollure™ XC, Restylane®, Restylane-L®, Restylane® Lyft with Lidocaine, Restylane® Silk, Restylane® Refyne, Restylane® Defyne, Revanesse® Versa, Belotero®, etc)**

This informed consent is intended to help your cosmetic surgeon inform you about hyaluronic acid dermal filler injection therapy including its risks, benefits, and alternatives.

#### **General Information**

Hyaluronic acid dermal fillers are sterile gels consisting of stabilized hyaluronic acid. These dermal filler injections are given to correct facial wrinkles and/or for lip augmentation. Each of these dermal fillers have specific FDA (Food and Drug Administration) indications (i.e. treatment for the nasolabial folds). Use of the products in these areas that were specifically approved by the FDA is considered “on-label” use and use anywhere else on the face or body is considered “off-label” use. Off-label use is not malpractice; it has become quite standard to use these products in an off-label manner in the United States and other countries.

#### **Alternative Treatments**

The primary alternative to dermal filling agents includes not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may also be accomplished by other treatments: laser treatments, chemical skin-peels, dermabrasion, other skin

procedures, alternative types of tissue fillers, or surgery such as a blepharoplasty, facelift, or brow lift when indicated. Each of these alternative treatments have their own risks.

### **Risks of Hyaluronic Acid Dermal Filler Injections**

Every type of 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 a risk-vs-benefit analysis. Although most 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 dermal filler injections. The specific risks associated with dermal fillers include, but are not limited to, the following:

- 1) **Bleeding and Bruising:** Serious bleeding from dermal filler injections is extremely, extremely rare. However, mild bruising may occur. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba, alcohol, and other herbs or homeopathic remedies may contribute to a greater risk of bleeding/bruising. Do not take these for seven days before or after dermal filler injections. If you are prescribed any blood thinning medications, you must speak with the physician who prescribed the medication prior to stopping it. Again, do not stop these medications before speaking with your prescribing physician.
- 2) **Swelling:** Swelling of the area injected is relatively common. This swelling decreases after a few days. If the swelling is very slow to resolve, additional medical treatment may be necessary.
- 3) **Pain:** If pain occurs during the injections, it is normally very short-lived.
- 4) **Skin Sensitivity:** After treatment, minimize exposure of the treated area(s) to the sun or extreme cold weather until after any initial swelling has resolved.
- 5) **Needle Marks:** Needle marks may be visible after the procedure. This normally resolves in a few days.
- 6) **Acne-Like Skin Eruptions:** Acneiform skin eruptions can occur following the injection of tissue fillers. This generally resolves within a few days.
- 7) **Skin Erythema (Redness):** This is relatively common after dermal filler injections. It may last for a few days after the procedure.
- 8) **Infection:** Infection following the injection of dermal fillers is unusual. However, 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 infection and individuals with no known history of Herpes simplex virus infection. **If you think that you may have herpes simplex, you must inform your provider so that pre-procedural antiviral medication can be prescribed.** A bacterial infection at the site of injection may require antibiotic medication treatment or an additional procedure.
- 9) **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.
- 10) **Under/Over Correction:** The injection of dermal fillers may not achieve the desired outcome. The amount of correction may be inadequate or too much. If under correction occurs, you may need to consider additional dermal filler injection.

- 11) Lumpiness: The overlying skin can become lumpy following the injection of dermal fillers. This normally smooths out over time. It may be possible to feel the dermal filler under the skin for prolonged periods of time.
- 1) Damage to Deeper Structures: Deep structures (nerves, blood vessels, eyeballs) may be damaged during injections of dermal fillers. This is very rare.
- 12) Granulomas: It is extremely rare to form a granuloma, which may result in a painful mass in the skin and/or deeper tissues. Additional treatment may be necessary if these occur.
- 13) Filler Material Visible Through the Skin: It is possible to see dermal filler material through the skin if used in an area of skin that is thin.
- 14) Skin Necrosis: Skin necrosis is extremely rare. If it occurs, it may result in unacceptable scarring, and additional procedures/surgery may be necessary.
- 15) Allergic Reactions: The injection of any substance into the skin has the potential to produce an allergic reaction. This is very rare with dermal fillers, which are made of the same material that lies within our bodies. Therefore, routine testing for allergies to dermal fillers is not performed. However, **you must inform us if you have a history of multiple severe allergies, severe allergies manifested by a history of anaphylaxis, or allergies to gram-positive bacterial proteins.**
- 16) Reaction to Local Anesthesia: There is a small risk of systemic reaction(s) to the anesthetic used. There is a possibility of light-headedness, rapid heartbeat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.
- 17) Antibodies to Dermal Fillers: The significance of antibodies to dermal fillers is unknown.
- 18) Accidental Intra-Arterial Injection: The injection of dermal fillers into blood vessel is extremely rare. If a dermal filler is injected into an artery, this may block the blood flow and produce skin necrosis in the face or damage blood flow to the eye, resulting in loss of vision. The risk and consequences of accidental intravascular injection of dermal fillers is unknown and unpredictable.
- 19) Unknown Risks: The long-term effects of dermal filler on tissues is unknown. The risk (and consequences) of accidental intravascular injection is unknown. There is a possibility that additional risks of dermal fillers will be discovered in the future that are not covered in this informed consent.
- 20) Unsatisfactory Result: There is a possibility of inadequate/poor response to dermal filler injections. Additional injections may be necessary to achieve the desired result. In addition, the duration of the results of dermal fillers vary from product to product and from person to person.
- 21) Scarring: **If you have a propensity to form hypertrophic scars or keloids, you must let your provider know.** This may limit your ability to receive dermal filler treatment.

## Medications

As stated above: Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba, alcohol, and other herbs or homeopathic remedies may contribute to a greater risk of bleeding/bruising. Stop these medications 7 days prior to your dermal filler injection appointment. However, never stop a prescribed medication without first speaking with your prescribing physician. Stopping a prescribed blood thinner (i.e. Plavix, Coumadin, etc) without your physician's consent may increase your risk of heart attack, stroke, or even death.

### **Pregnancy**

Pregnant women or nursing mothers should not receive dermal filler injections. The risk to the fetus/infant has not been studied, and therefore, is not known.

### **Mental Health Disorders and Cosmetic Surgery/Procedures**

All patients seeking to undergo elective procedures and/or surgery should have realistic expectations and be of sound judgment. Please discuss any history of significant emotional depression or mental health disorders with your provider before any elective procedure or surgery.

### **Additional Treatment Necessary**

There are many variables which affect the longevity of dermal filler injection effects. Most dermal filler results last for 6-9 months. After this, the individual will require additional injections to continue to experience the results.

### **Photography**

Photography will likely be performed before and after your treatment with dermal filler agents. This is standard practice for cosmetic procedures. The photographs will only be used for internal uses unless additional consent for the release of photographs is obtained from the patient.

### **Financial Responsibilities**

We make every effort to help you achieve the results that you seek. However, these are cosmetic injections and are non-refundable as the product cannot be returned. The cost of dermal filler injections bundles several charges. This includes the product itself, professional fees for the injections, and follow-up visits.

### **Right to Discontinue Treatment**

The patient may discontinue treatment at any time. The results will slowly fade over time.

**I understand and agree that all services rendered will be charged directly to me, and I am personally responsible for payment. I further agree, in the event of non-payment, to bear the cost of collection, and/or court costs and reasonable legal fees, should they be required. By signing this document, I**

**acknowledge that I have read the foregoing informed consent and consent to the treatment described above with its associated risks. I understand that the risks listed above are the primary risks that are currently known. Additional risks may be discovered in the future. I understand that I have the right not to consent to this treatment and that my consent is voluntary. I hereby release the doctor, the person performing the dermal filler injection, and the facility from liability associated with this procedure.**