



## **Dermal Filler Injectable Informed Consent**

**The purpose of this form is to inform you about the risks, benefits, and alternatives to dermal fillers. This form is not intended to address all possible risks. Instead, it is intended to address the most commonly-encountered risks. Please read this form carefully before signing it. If you have any questions after reading the form, please do not hesitate to ask your provider for more information.**

- Dermal filler treatment involves the injection of stabilized hyaluronic acids in order to smooth moderate to severe facial wrinkles and folds or shape facial contours. Dermal fillers have been approved by the U.S. Food and Drug Administration (FDA) for the cosmetic treatment of moderate to severe facial wrinkles and soft tissue depressions. While hyaluronic acid is a naturally occurring substance that is found in human soft tissues, the FDA-approved filler products we will use are hyaluronic acids that have been synthetically produced by a process of bacterial fermentation, and then chemically stabilized and purified. The hyaluronic acid found in these products is biocompatible and not an animal product, so there is little risk of animal-based disease transmission or allergic reactions. The filler treatments are customized for patients depending on their particular needs and can be performed in multiple areas of the face.

I understand and acknowledge that the dermal fillers used in this treatment cannot stop the process of aging. They can, however, temporarily diminish the appearance of wrinkles and soft tissue depressions. These injections may be performed alone or in combination with other treatments, such as neuromodulators. Dermal filler injections may require the use of regional nerve blocks or a topical anesthetic application to reduce discomfort. Soft tissue fillers produce temporary swelling, redness and needle marks, which resolve after a few days. The duration of the effect of dermal fillers injections is variable and temporary. Continuing treatments are necessary in order to maintain the effect over time. After the dermal fillers are injected, they will be slowly absorbed by the body. Despite such injections, alterations in the face may still occur as the result of aging, weight loss or gain, sun exposure, or other circumstances, and may necessitate future surgery or other treatments. Dermal fillers do not produce permanent tightening of the skin or improvement in wrinkles.

### **Possible risks and complications**

I understand that the majority of patients do not experience complications from dermal filler injections, and I have discussed the risks associated with this procedure with my provider. I understand and acknowledge that the risks may include, but not be limited to the following:

- **Bleeding and bruising:** It is possible, though unusual, to have a bleeding episode from an injection. Should you develop post-injection bleeding, emergency treatment or surgery may be necessary. Bruising in soft tissue may also occur. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba, and other herbs and homeopathic remedies may increase the risk of bleeding and bruising. Do not take any of these products for seven days before or after injections of dermal fillers unless you have been advised to do so by your cardiologist or primary care physician.

- **Swelling:** Swelling (edema) is a normal occurrence following the injection of dermal fillers. It usually decreases after a few days, but if it is slow to resolve, medical treatment may be necessary.
- **Erythema (skin redness):** Erythema occurs in the skin after injections. It can be present for a few days after the procedure.
- **Needle marks:** Visible needle marks from injections occur normally and resolve in a few days.
- **Acneiform skin eruptions:** Acne-like skin eruptions can occur following the injection of dermal fillers. These generally resolve within a few days.
- **Skin lumpiness:** Lumpiness can occur following the injection of dermal fillers. This condition tends to smooth out over time. In some situations, however, it may be possible to feel the injected tissue filler material for long periods of time.
- **Visible tissue filler:** It may be possible to see dermal fillers through the skin if they are injected into an area where the skin is thin.
- **Asymmetry:** The human face is normally asymmetrical in its appearance and structure. It may not be possible to achieve or maintain exact symmetry with tissue filler injections. There can be variations from one side to the other, even after injections of dermal fillers, that may require additional injections.
- **Pain:** Discomfort associated with injections of dermal fillers is normal and usually of short duration.
- **Skin sensitivity:** Skin rash, itching, tenderness and swelling may occur following injections of filler products. I understand that, after treatment, I should avoid exposing the treated area to excessive sun, ultraviolet lamps, and extremely hot or cold temperatures until any initial swelling or redness has gone away. I also understand that if I undergo laser treatment, chemical peels or any other skin procedures after treatment with dermal fillers, there is a risk of an inflammatory reaction at the implant site.
- **Accidental intra-arterial injection:** Dermal fillers can accidentally be injected into arteries and block blood flow. This could cause necrosis in facial skin and other structures, loss of vision or other consequences. This is a very serious, but rare, occurrence. I understand that dermal fillers made from hyaluronic acid may be dissolved by hyaluronidase if my condition warrants.
- **Damage to deeper structures:** Deeper structures, such as nerves and blood vessels, may be damaged during injections of dermal fillers. Injury to deeper structures may be temporary or permanent.
- **Infection:** Bacterial, fungal and viral infections can occur following injection with dermal fillers. The reactivation of the herpes simplex virus, commonly referred to as a cold sore, is one such infection. This can occur both in individuals who have had prior cold sores and in those who have not. I understand that I should ask my provider for a Valtrex prescription if I plan to have an injection in an area where I have had a prior cold sore. Should any other type of skin infection occur, additional treatment, including antibiotics, may be necessary.
- **Allergic reactions and hypersensitivity:** As is the case with the use of all biologic products, allergic and anaphylactic reactions may occur as a result of an injection with dermal fillers. I understand that I should not have injections with dermal fillers if I have a history of multiple severe allergies, a history of anaphylaxis or allergies to gram-positive bacterial proteins. Allergic reactions may require additional treatment.
- **Scarring:** It is possible that injections with dermal fillers could promote excessive scar formation. I understand that I should not receive these injections if I have a history of keloid formation or other forms of excessive scarring at treatment sites.
- **Granulomas:** Granulomas are masses similar to scar tissue. Rarely, granulomas develop in the skin and deeper tissues after injections with dermal fillers. Should a granuloma develop, additional treatments, including surgery, may be necessary.
- **Skin disorders:** In rare instances, granuloma, abscess, localized necrosis and urticaria have occurred after injections of dermal fillers into areas with active inflammation or infection (e.g. cysts, pimples, rashes or hives).
- **Antibodies to dermal fillers:** Antibodies can reduce the effectiveness of dermal fillers or produce a reaction during subsequent injections. The health significance of antibodies to hyaluronic acid tissue fillers is unknown.

- **Anesthetic reactions:** It is possible to have a reaction to the anesthetic applied before injection or the lidocaine anesthetic mixed with dermal fillers. Such reactions include light-headedness, rapid heart rate (tachycardia) and fainting. Medical treatment of these conditions may be necessary.

### **Hyaluronidase Injections**

I understand that dermal fillers made from hyaluronic acid may be dissolved by hyaluronidase if my condition warrants. Use of hyaluronidase carries some risk. I understand that hyaluronidase is an enzyme that breaks down hyaluronic acid fillers, but can also break down naturally occurring hyaluronic acid present in the body. Thus, the results of hyaluronidase treatment can be unpredictable. There may be loss of volume and some skin laxity. Some adverse effects may be recognized immediately; others can take up to 14 days to appear. Very rarely (0.05% – 0.69% of cases), allergic reactions requiring immediate medical attention result from hyaluronidase treatment.

### **Possible filler treatment consequences**

I understand that, in addition to the known risks associated with filler treatment, there are unknown risks and potential consequences of filler treatment, which may include, but are not limited to, the following:

- **Combination of procedures:** The long-term effect of combining injections of dermal fillers with other treatments—for example, non-hyaluronic acid fillers, neuromodulators, lasers, microdermabrasion, chemical peels and others—is unknown.
- **Unknown risks:** The long-term consequences of injecting dermal fillers are unknown. It is possible that unpredictable complications may arise from the use of dermal fillers.
- **Pregnancy and nursing mothers:** It is not known if dermal fillers are safe during pregnancy or if their breakdown products are excreted in human milk. Because the risk is unknown, pregnant women and nursing mothers should not receive injections of dermal fillers injections.
- **Drug interactions:** It is not known if dermal fillers react with other drugs within the body.

I understand and acknowledge that injection of dermal fillers may not achieve my desired outcome. For example, the amount of correction may be inadequate or excessive. If under-correction occurs, I may be advised to consider additional injections of filler. I understand that dermal fillers may migrate from their original injection sites and produce visible fullness in adjacent tissue or other unintended effects. I also understand that my tissue's response to dermal fillers may be poor or inadequate, and that additional injections of dermal fillers or surgery may be necessary to achieve my desired result. I acknowledge that while good results are expected, I may be disappointed with the results of the procedure. I understand there is no guarantee of results of any treatment.

I consent to the administration of anesthetics and understand that all forms of anesthesia involve risk, and possible complications include injury and, rarely, death. I am aware that dermal fillers contain lidocaine. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained. I acknowledge that there are alternative methods of treatment, including foregoing treatment, which I have discussed with my provider. I understand that there are risks to the proposed treatment. I certify, to the best of my knowledge, that I am not pregnant or breastfeeding at the time of treatment. I certify that I have not consumed alcohol within four hours of the proposed procedure/treatment. I certify that all my questions regarding the proposed procedure/treatment have been answered.

Printed Name: \_\_\_\_\_

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