

## Disclosure and Consent for Treatment with Dermal Fillers Restylane®, Sculptra®, Voluma®, Belotero® and Juvederm ®

Patient Name: \_\_\_\_\_

Dermal filler procedures involve the careful injection of sterile gel or protein material into the skin. The anticipated result is a smoother, more youthful appearance or other cosmetic improvement. *It is not possible to guarantee results and there are RISKS.*

Dr. Foster has done at least 15,000 dermal filler injections since 1999. During that time there have been a few serious complications, including arterial injection with skin necrosis and one rejection of an FDA-approved filler material, Evolence®, with scarring of the chin (Evolence is no longer on the market). There have also been cases of prolonged inflammatory reactions causing noticeable swelling and bumps for several months. Late onset nodules like these can occur with all dermal fillers. In some of these cases, antibiotics and other treatments have been required. The most common location for this to occur seems to be the undereye area.

### PRECAUTIONS

- The safety for use in patients under 18 years for JUVÉDERM® XC, and for patients under 35 years or over 65 years for JUVÉDERM VOLUMA® XC, has not been established
- The safety and effectiveness of JUVÉDERM® XC for the treatment of anatomic regions other than facial wrinkles and folds, and of JUVÉDERM VOLUMA® XC for regions other than the mid-face, have not been established
- The safety for use during pregnancy, in breastfeeding females, and in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied
- Use with caution in patients on immunosuppressive therapy
- Patients who are using products that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at treatment sites
- If laser treatment, chemical peel, or any other procedure based on active dermal response is considered after treatment, or if the product is administered before the skin has healed completely, there is a possible risk of an inflammatory reaction at the treatment site
- Patients who experience skin injury near the site of implantation may be at a higher risk for adverse events
- Dermal filler implantation carries the risk of infection. Standard precautions associated with injectable materials should be taken
- The safety of JUVÉDERM VOLUMA® XC injectable gel for use in patients with very thin skin in the mid-face has not been established
- The long-term safety of repeat treatments with JUVÉDERM VOLUMA® XC has not been established
- Patients may experience late onset nodules with use of dermal fillers including JUVÉDERM VOLUMA® XC

Sign here AND turn page over to finish reading and sign the 2<sup>nd</sup> page.

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

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### CONTRAINDICATIONS

JUVÉDERM® XC and JUVÉDERM VOLUMA® XC should not be used in patients who have severe allergies marked by a history of anaphylaxis or history or presence of multiple severe allergies, and should not be used in patients with a history of allergies to gram-positive bacterial proteins or lidocaine.

Complications may include: allergic reaction, hyperpigmentation/discoloration, infection, scar formation, broken capillaries, pain, and migration of the material. Bell's Palsy and shingles can occur after facial injections, and while treatable, occasionally leave facial asymmetry or scarring. While extremely rare, vision loss from injection of filler into a blood vessel near the eye has been reported. Inadvertent injection into an artery can cause significant injury and scarring. Nerve injury can cause facial asymmetry, numbness or chronic pain. These are rare events, but you are hereby fully informed that these things are possible and by undergoing this treatment you accept this risk. Additionally, if any of these complications occur, the treatment of them can be costly and you could miss work or lose income. By agreeing to have this procedure, you are also taking full responsibility of the expense of such treatment and/or disability.

Mild to moderate localized swelling and/or bruising accompanied by soreness may last 3-10 days or more. Persistent or increasing redness, swelling, tenderness or any open sore should be reported immediately. Although we do not believe there will be long-term adverse effects or diseases related to the injection of these materials, this is a relatively new procedure and the long-term effects have not been studied.

By signing below you agree that you have been given the opportunity to ask questions regarding treatment, and that you have sufficient information to give this informed consent. You certify that you have read this form or have had it read to you and that you understand its contents. You are taking responsibility for the risks and all possible complications of the procedure and hereby give your informed consent for Dr. Foster to inject your face, neck and/or hands with any of the above dermal fillers today and on all future visits.

*You are hereby informed that there are RISKS to this as with any medical procedure.*

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