

INJECTABLE FILLER INFORMED CONSENT

I, _____ understand that Dr. Biggerstaff and/or Avery Carrigan will be injecting in the following areas:

Choose filler(s): Belotero, Radiesse, Voluma, Restylane or Juvederm.

_____ is a restorable implant product approved by the United States Food and Drug Administration for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

Risks and complications that may be associated with injectable fillers and the implant procedure include, but are not limited to:

(Initial)

- ____ 1. **Facial Bruising, Redness, Swelling, Itching and Pain:** I understand that there is a risk of bruising, redness, swelling, itching and pain associated with the procedure. These symptoms are usually mild and last less than a week but can last longer. Patients who are using medications that can prolong bleeding, such as aspirin, warfarin, or certain vitamins and supplements, may experience increased bruising or bleeding at the injection site.
- ____ 2. **Nodules, and palpable material:** I understand that there is a risk that small lumps may form under my skin due to the filler material collecting in one area. I also understand that I may be able to feel the filler material in the area where the material has been injected. Any foreign material injected into the body may create the possibility of swelling or other local reactions to a filler material.
- ____ 3. **Migration:** I understand that filler may move from the place where it was injected.
- ____ 4. **Infection:** As with all transcutaneous procedures, I understand that injection of any filler material carries the risk of infection.
- ____ 5. **Allergic Reactions:** I understand that fillers should not be used in patients with severe allergies, a history of anaphylaxis, or history of presence of multiple severe allergies or hypersensitivity to any of the ingredients in the fillers.
- ____ 6. **Keloids/Scarring:** I understand that the safety of fillers in patients with known susceptibility to keloid formation or hypertrophic scarring has not been studied.
- ____ 7. **Accidental Injection into a Blood Vessel:** I understand that fillers can be accidentally injected into a blood vessel, which may block the blood vessel and cause local tissue damage, or potentially even a heart attack or stroke.
- ____ 8. **Blindness:** I understand there is a small risk that filler injections to the forehead can cause permanent blindness.
- ____ 9. **Duration of effect:** I understand that the outcome of treatment with fillers will vary among patients. In some instances, additional treatments may be necessary to achieve the desired outcome.
- ____ 10. **The need for more filler:** I understand that the outcome of treatment with fillers will vary among patients. In some instances, additional treatments may be necessary to achieve the desired outcome.
- ____ 11. **Substances/Implants:** No studies of interactions of fillers with drugs or other substances or implants have been conducted.
- ____ 12. **Pregnancy/Age:** The safety of fillers for use during pregnancy, in breastfeeding women or anyone under the age of 21 has not been established.
- ____ 13. **Off-Label FDA:** There are many devices, medications, 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 physician believe it to be safe and effective. Examples of commonly accepted "Off-Label" use of drugs or devices include the use of aspirin for prevention of heart disease, retinoids for skin care, and injection of botulinum toxin for wrinkles around the eyes.
- ____ 13. **Radiesse:** I understand Radiesse (a specific filler) is radiopaque, and therefore may show up on certain type of x-rays while still present, you should inform your primary care physician you have had Radiesse and are having any type of X-ray of scans performed.

This above list is not meant to be inclusive of all possible risks associated with dermal fillers, as there are both known and unknown side effects and complications associated with any medication of dermal filler injection procedure. I understand that medical attention may be required to resolve complications associated with my infection.

I understand that I should minimize exposure of the treated area to the sun or heat for approximately 24 hours after treatment or until any initial swelling or redness goes away.

I have discussed the potential risks and benefits of fillers with my doctor. I understand that there is no guarantee of any particular results of any treatment. 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 below, I acknowledge that I have read the foregoing informed consent, have had the opportunity to discuss any questions that I have with my doctor to my satisfaction, and consent to the treatment described above with its associated risks. 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 filler injection and the facility from liability associated with this procedure.

Patient Signature

Date

Doctor Signature

Date