

miami skin + vein

Consent Form for Restylane Filler Treatment

This is a consent form for filler treatment using the Restylane family of products. Please read it carefully before signing.

This disclosure is not meant to alarm you; it is simply an effort to better inform you. Being informed will help you make the decision whether to undergo treatment.

What is Restylane? Restylane fillers are clear sterile injectable gels composed of hyaluronic acid, a natural substance that already exists in the body. They are non animal-based and free from animal protein, non-permanent and metabolized by the body. All Restylane portfolio fillers, except for Restylane, contain lidocaine to reduce discomfort associated with treatment. The fillers in the Restylane portfolio are:

- Restylane
- Restylane-L
- Restylane Lyft
- Restylane Silk
- Restylane Refyne
- Restylane Defyne
- Restylane Kysse
- Restylane Contour

Indications for Treatment: Filler injections are given to temporarily correct facial wrinkles, lines, folds, or scars, for lip augmentation, for replacement of volume to the face, cheeks, orbital rims, nose, temples, etc. Each of the fillers above has been approved by the FDA (Food and Drug Administration) for use; either for correction of facial wrinkles or lines, or for lip, chin or cheek augmentation ("on-label" use).

All the fillers above are also used "off-label" for the lips, eyelids, nose, cheeks, temples or other facial and body cosmetic corrections. The safety and effectiveness of treating face and body areas "off-label" has not been approved or studied by the FDA; however, fillers have been extensively used in all areas of the face and many parts of the body depending on the filler and the technique. Patients should understand this "off-label" aspect of the treatment prior to giving consent for filler treatment.

Alternatives to treatment: There are alternatives to the specific filler injections above, including no treatment at all, fat injections, or other facial soft tissue augmentation or implants, as well as Botox, Dysport, laser skin resurfacing, chemical peels, cosmeceuticals, or plastic surgery for wrinkle reduction.

Results: The actual degree of improvement cannot be predicted or guaranteed. Furthermore, the effect will gradually wear off and additional treatments will be necessary to maintain the desired effect. Results depend on the type of filler, the amount or volume of the filler, and the injection technique. Using multiple syringes often results in a more dramatic improvement. The patient is responsible for the cost of each filler syringe and treatment without guarantee of results.

Side effects and complications include but are not limited to:

Potential allergic reaction. As with any product, allergies can develop during or after injection. Patients with known allergies to these fillers or numbing medications should avoid these injections. Most of the fillers contain lidocaine and if you have a known allergy to lidocaine, you should avoid this treatment.

Injection site and other reactions: a lumpy or "thick" feeling at or just under the skin, bruising, hematoma, redness, discoloration, induration, scars, itching, pain, nerve damage, infection, over-correction, granulomas, palpable or visible material, tenderness, swelling, asymmetry or shifting can occur.

One of the serious risks with filler treatment is unintentional injection into a blood vessel. The chances of this happening are small, but if it does happen, complications can be serious, and may be permanent. These complications include vision abnormalities, ophthalmoplegia (paralysis of muscles that control eye movement), ptosis (droopy eyelid), **blindness, stroke**, and skin changes including necrosis and permanent scarring of the skin.

A 2015 publication by Belezny et al showed 98 published cases of filler-related visual compromise reported in the medical literature between 1906 and 2015. A follow up paper by the same team published in 2019 showed a further 48 published cases from January 2015 through September 2018 bringing the total number of cases of filler related visual compromise reported in the medical literature up to 146 cases. Although the reported incidence is still small, the rate appears to be increasing and is probably underreported.

Certain parts of the face, such as the nose, glabella (between the eyebrows), forehead, and nasolabial folds are associated with a higher risk of vascular occlusion given vascular anatomy although occlusion can occur with any filler injection including on any of the other parts of the face or body.

If you experience changes in your vision, nausea, vomiting, signs of a stroke (including difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance or blanching of the skin, or unusual pain during or shortly after treatment, you should notify Dr. Patel immediately.

Injections of any filler material, particularly into the lip area and around the mouth, could trigger a recurrence of herpes (fever blisters, cold sores, shingles) and this outbreak may be severe in nature. This could lead in some cases to scarring. Please disclose any medical history, including prior herpes outbreaks, to Dr. Patel.

Further treatment for additional improvement, or correction of side effects or complications may be necessary. When required, depending on event, treatments may include massage/manipulation, warm compress, corticosteroids, antibiotics, antihistamines, NSAIDs, aspiration/drainage of the product, hyaluronidase injections and surgery. I understand I may be responsible for all such costs.

Most humans have facial asymmetry and therefore perfect symmetry is unrealistic in most cases.

Precautions and contraindications: Due to potential for an allergic reaction, fillers are not recommended for patients with severe allergies or a history of anaphylaxis to components of the filler.

The risk of bruising or bleeding may be increased by medications with anticoagulant effects, such as aspirin, non-steroidal anti-inflammatory drugs (e.g. Ibuprofen, Aleve, Motrin, Celebrex, etc), high doses of Vitamin E, and certain herbal supplements and foods (Ginkgo Biloba, St. John's Wart, Flaxseed, nuts, fish oil, Omega-3, etc).

The safety of fillers in pregnant or breast-feeding women has not been established and is therefore not recommended for these women.

Local anesthesia may be used to reduce the discomfort of the procedure including the topical application of anesthetic cream or ointment and/or injections of anesthetic for a nerve block or local infiltrative anesthesia.

By signing below, you consent that you have read the above consent, understand it, and have had the risks, benefits, and alternatives explained to you, and have had the opportunity to ask questions and refuse treatment. You have chosen this treatment voluntarily and no guarantees about results have been made. Further treatments may be needed. To the best of your knowledge, you are not pregnant or breastfeeding and do not have an allergy to lidocaine or any of the components of Restylane fillers. You give informed consent for Restylane filler injections today as well as future treatments as needed by Dr. Shaun Patel. Further information is available upon request.

Patient signature

Date:

Witness signature

Date:
