Informed Consent

Informed Consent for Dermal Filler - Juvederm®, Voluma™ Restylane®, Perlane®, Radiesse® or Belotero Balance®

Patient_________________________________________________  Acct#_____________________

Please initial all of the following sections confirming that you have read and understand each statement.

Introduction

Hyaluronic acid is a naturally occurring substance that is found within all mammals. It is a material that is contained in various soft tissues. Hyaluronic acid can be synthetically produced from a process of bacterial fermentation, chemically stabilized, and purified for use as an injectable soft tissue filler. Restylane, Perlane Juvederm, Voluma and Belotero are made from Hyaluronic acid. These cosmetic dermal fillers are used to enhance facial features or to replace lost volume and restore contours to the skin to smooth away moderate to severe wrinkles and folds, such as the lines from your nose to your mouth (nasolabial folds). Continued treatments are necessary in order to maintain the effect over time. The body will slowly absorb hyaluronic acid once injected. The length of effect is variable.

Radiesse is made of calcium hydroxlapatite, which immediately provides the lift needed to diminish signs of aging. It acts as a scaffold under the skin, providing structure and stimulating your own natural collagen to grow. This natural collagen growth continues for several months. In many patients, correction lasts for a year or more. Continued treatments are necessary to maintain results.

Alternative Treatments

Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, other skin procedures, or dermabration, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

Patient Eligibility

Patients with the following conditions may not receive dermal filler treatments: previous allergic reactions to injectable hyaluronic products or calcium hydroxyappetite, history of a serious allergic reaction, multiple severe allergies, abnormal raised scarring or keloid formation, active inflammation or infection in the treatment area, pregnancy or nursing.
We use a variety of ways to inform our patients about various procedures. Examples include radio, TV and print advertising, the internet, patient seminars, consultations with staff members, phone calls, mailings, brochures, videos and literature. Some of these materials are generated by the product manufacturers and/or advertising companies. Medicine is constantly changing and therefore the information in these materials may have changed. Reading this informed consent, consulting with your provider about the procedure, its alternatives and risks and asking questions is the best way to understand potential complications and decide if this procedure is right for you.

Risks of Dermal Filler Injections

Every procedure to inject soft tissue filler materials involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your provider to make sure you understand the risks, potential complications, limitations, and consequences of filler injections. Upon request, additional information concerning each filler may be obtained from the package insert sheets supplied by the product's manufacturer.

Normal Effects of Dermal Filler Injections

Patients undergoing dermal filler injections may experience the following events.

- **Bleeding and bruising** – It is possible, though unusual, to have a bleeding episode from a filler injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, Ginko biloba and other “herbs/homeopathic remedies” may contribute to a greater risk of a bleeding problem. Inform your provider of all medications and supplements you are currently taking.

- **Swelling** – Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.

- **Erythema** (skin redness) – Erythema in the skin occurs after injections. It can be present for a few days after the procedure.

- **Needle marks** – Visible needle marks from the injections occur normally and resolve in a few days.

- **Acne-like skin eruptions** – Skin eruptions can occur following the injection of dermal fillers. This generally resolves within a few days.

- **Skin lumpiness** – Lumpiness can occur following the injection of dermal fillers. This tends to smooth out over time. In some situations, it may be possible to feel the injected dermal filler material for long periods of time.

- **Visible tissue filler material** – It may be possible to see any type of dermal filler material that was injected in areas where the skin is thin.

- **Asymmetry** – The human face and eyelid region is normally asymmetrical in its appearance and anatomy. It may not be possible to achieve or maintain exact symmetry with dermal filler injections. There can be a variation from one side to the other in terms of the response to dermal filler injections.

- **Pain** – Discomfort associated with injections is normal and usually of a short duration.
Possible Complications

The following are possible complications attributable to the injection of dermal fillers:

- **Infection** – Although infection following injection of dermal fillers is unusual; bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth can occur following a dermal filler treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications may be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

- **Damage to deeper structures** – Deeper structures such as nerves, blood vessels, and the soft tissues may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

- **Skin necrosis** – It is very unusual to experience death of skin and deeper soft tissues after dermal filler injections. Skin necrosis can produce unacceptable scarring. Should this rare complication occur, additional treatments or surgery may be necessary.

- **Granulomas** – Painful masses in the skin and deeper tissues after injections are extremely rare. Should these occur, additional treatments including surgery may be necessary.

- **Migration** – There is a risk that the dermal filler may migrate away from the injection site after treatment. This may or may not be reversible.

- **Combination of procedures** – In some situations, BOTOX injections or other types of tissue filler materials may be used in addition to dermal fillers in order to specifically treat areas of the face or to enhance the outcome from dermal fillers therapy. The effect of other forms of external skin treatments (laser and other light therapies, microdermabrasion, dermabrasion, or chemical peels) on skin that has been treated with dermal fillers is unknown.

- **Pregnancy and nursing mothers** – Animal reproduction studies have not been performed to determine if dermal fillers could produce fetal harm. It is not known if each filler or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive treatments.

- **Drug interactions** – It is not known if dermal fillers react with other drugs within the body.

- **Long term effects** – Dermal filler injections should not be considered as a permanent treatment for the correction of wrinkles and soft tissue depressions. Over time, the material is slowly absorbed by the body and wrinkles or soft tissue depressions will reappear. Continuing treatment (injections) are necessary in order to maintain the effect of dermal fillers. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to dermal filler injections. Dermal filler injections do not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

Additional Treatment

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of dermal filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with dermal filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained with the use of dermal filler injections. The practice of medicine and surgery is not an exact science.
**Patient Responsibility for Costs**

The cost of dermal filler injections may involve several charges. This includes the professional fee for the injections, follow up visits to monitor the effectiveness of the treatment, and the cost of the material itself. It is unlikely that dermal filler injections to treat cosmetic problems would be covered by your health insurance.

Additional costs of medical treatment would be your responsibility should complications develop from dermal filler injections. You would also be responsible for additional forms of treatments or surgery recommended to improve the appearance of facial wrinkles and soft tissue depressions. If additional interim injections of dermal filler are recommended in order to maintain or improve results, you will be responsible for the costs of this additional treatment.

**Off Label Use**

Radiesse, Perlane and Juvederm have been approved to treat areas of facial wrinkling and soft tissue depressions. These products have not been studied for safety and effectiveness in any other anatomic regions other than naso-labial folds and are not FDA approved for any other sites.

When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer is required to produce a “label” to explain its use. Providers, using their best medical judgment, may not follow FDA protocols exactly and/or may use a drug or device for things not on the label. This is called “off-label.” We cannot guarantee to document every off-label use in every patient.

**Disclaimer**

Informed consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your provider may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the entire consent carefully and have all of your questions answered before signing.

**Joint Decision Making**

I understand I must work together with my provider to agree on treatment plan. My provider relies on the information I give. I have fully disclosed my medical history; including allergies, prior surgeries, medications and supplements I am taking, and current health conditions. I understand that following the pre-procedure and post-procedure instructions will affect the success of my procedure. I will follow those instructions carefully, asking questions when they arise.
Communication

We encourage you to be direct about any concerns you are having, particularly during your post-procedure period. Often patients are not sure whether their recovery is typical and we want to address that. We encourage you to bring a list of any questions or concerns you have. State them clearly so your provider can respond to them:

• “I have some concerns today, and they are...”
• “I have one concern today, and it is...”
• “I have no concerns today.”

Medical Records

I understand and agree that this consent document will become a part of my medical record.
PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

I certify that I can speak, read and write English. ________________________________________

The details of this procedure have been presented to me in full in a way that I understand. All of my questions have been answered and, as needed, I have been provided further explanation to my satisfaction. I have read this informed consent (or it has been read to me) and I fully understand the procedure, the possible risks, complications, alternatives and benefits.

I understand that there are other options for treatment available and each of these other options has been fully explained to me to my satisfaction.

I acknowledge that no guarantee has been given by anyone as to the results that may be obtained. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury and sometimes death.

I recognize that during the course of the procedure and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than originally planned. I therefore authorize the physician and assistants, or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

I understand that there is a possibility of rare side effects and I further understand the importance of carefully following the post-care instructions and that failure to comply may increase the probability of complications.

I consent to treatment with dermal filler injections.

I ☐ DO ☐ DO NOT (check one) give permission for photographs and other audio/visual or graphic materials to be used by Medical Eye Center for marketing or educational purposes. Although photographs or accompanying material will not contain my name or other identifying information unless I give subsequent written permission, I am aware that I may still be identified by the photographs.

PATIENT SIGNATURE______________________________________________ DATE ______________________

WITNESS SIGNATURE_____________________________________________ DATE ______________________