Colorado Facial Plastic Surgery
Mario Imola, MD, DDS, FRCSC, FACS
David M. Kowalczyk, MD, MBA
Creating Beautiful Faces

Aesthetics by Design
Creating Beautiful Skin

NON-PERMANENT INJECTABLE FILLER CONSENT

Belotero, Expressions, Hyaluronidase, Juvederm Ultra XC, Juvederm Ultra Plus XC, Perlane, Restylane, Restylane Silk, Radiesse, Sculptra, Voluma XC

Patient Name _____

Injectable fillers are biosynthetic semi-solid implants inserted using a syringe plus needle/cannula combination for the purpose of facial cosmetic enhancement. They are injected into specific facial sites with the goal of increasing facial volume and thereby modifying facial shape and/or restoring a more youthful appearance. A variety of different injectable fillers are currently available:

- **Hyaluronic Acid (HA)** fillers are structurally identical to the normal matrix found in the dermis layer of human skin. These fillers exist as a viscous clear gel that produce an immediate volume effect immediately following injection. FDA approved HA fillers include: **Juvederm, Restylane, Perlane, Belotero**.
- **Calcium Hydroxyapatite (CaHA)** fillers consist of calcium-hydroxyl-phosphate crystals suspended in a gel carrier. CaHA is identical to the mineral component of human bone and the gel carrier is a cellulose-based gel with water and glycerin that allows for injection. The gel component provides an immediate volume effect whereas the CaHA component stimulates fibroblasts to produce collagen and provides a delayed volume effect. Currently, only 1 FDA approved CaHA filler is available: **Radiesse Cosmetic.**
- **Poly-L-lactic Acid (PLA)** fillers consist of poly-lactic acid crystals suspended in an aqueous carrier for injection. Lactic acid is an intermediate metabolite normally found within the human body. PLA fillers do not have an immediate volume effect. Instead they rely solely on the stimulation of fibroblasts to produce collagen and the volume effect builds over a period of several weeks. The only PLA filler available at the present is **Sculptra**.

HA and CaHA fillers are usually used to achieve a desired effect at specific sites in 1 treatment session. PLA fillers are more commonly used to achieve a more generalized volume increase using a series of 2 to 4 treatment sessions.
_____***Patient Initials***

FDA approval for injectable fillers varies slightly between the different fillers but in essence all of the fillers listed above have obtained FDA approval for the cosmetic improvement of facial wrinkles and folds. The initial FDA approvals for injectable fillers were usually based on the correction of the nasolabial folds. From a practical standpoint the usual and customary standard of care is such that injectable fillers are injected into all areas of the face as an "off-label" use with an acceptable risk profile except for the red lip. Only Restylane has officially obtained FDA clearance in the lips, however, many providers successfully inject other HA fillers into the lips as an "off-label" use with acceptable outcomes and complication rates.
_____***Patient Initials***

I understand that as with any medical procedure, injectable fillers are associated with adverse effects, risks and complications:

- Temporary swelling, redness and bruising at the injection site are the most common adverse effects and most people will experience a variable degree of these.
- Undesirable or less than ideal cosmetic outcomes can occur such as contour irregularities, underfill, overfill and/or asymmetry. In these cases treatment with additional filler may be required.
- Granuloma or nodules consisting of small areas of localized inflammation or scar formation are uncommon but can occur. These nodules are usually not visible and tend to resolve on their own but can persist indefinitely. PLA fillers are more commonly associated with granulomas and nodules.
- Infection at the injection site is a rare occurrence.
- Allergic responses such as hives, rash or anaphylaxis to injectable fillers are very rare but have been reported.
- Skin necrosis (death), either partial or full-thickness, is a rare occurrence following injectable fillers. Skin necrosis is believed to be caused by vascular compromise whereby the skin at risk suffers a critical interruption in blood flow. This usually occurs within a few hours following injection and is associated with dark skin discoloration with or without localized pain. Such an event is considered an emergency and should be reported to the provider as quickly as possible. Several emergency measures can be implemented to prevent or limit the impending skin death.
- Scarring is a rare event. Pin-point scarring at the injection site can occur on occasion but almost always resolves. Broad areas of scarring can occur following skin necrosis or infection.

- Visual impairment is an extremely rare occurrence that can follow the injection of facial fillers. As of July, 2013 approximately 20 cases of visual impairment have been reported since fillers came into widespread use during the early 2000's.

_____*Patient Initials*

I understand that the results are temporary and repeated injections will be required to maintain the cosmetic effect. Most providers quote the duration profile for the different filers as follows:

HA Fillers: 6-9 months.
CaHA Fillers: 9-18 months.
PLA Fillers: 12 – 24 months following a series of treatments.

_____*Patient Initials*

Absolute contraindications to the use of injectable fillers include the following:

- A known allergic response to the injectable filler being considered.
- A known history of anaphylaxis or severe allergic responses to environmental antigens in general.

Relative contraindications to the use of injectable fillers include the following:

- Pregnancy.
- Breast-feeding women.

_____*Patient Initials*

I have been advised of the expected benefits associated with injectable fillers, the risks involved in such treatment and alternative treatment options including no treatment at all. I am aware that the practice of medicine and injectable fillers is not an exact science and I acknowledge that guarantees have not been made to me as to the result of the procedure, nor are there any guarantees against unfavorable results. This consent is valid for one year and supersedes any prior informed consent for injectable filler treatment. I certify that I have read, and fully understand the above- initialed paragraphs, and that I have had sufficient opportunity for discussion and to ask questions.

_____*Patient Initials*

I consent to injection with the injectable fillers indicated below:
Belotero_____ Expressions_____ Hyaluronidase _____ Juvederm/Voluma_____ Restylane/Perlane_____
Radiesse_____ Sculptra_____

Patient's Signature: _____ Date: _____

Clinician's Name: _____ Signature: _____ Date: _____