DERMAL FILLER CONSENT FORM

PATIENT NAME: ___________________________ DATE: ________

INDICATIONS FOR TREATMENT WITH DERMAL FILLERS:

In general Dermal Fillers are indicated for the correction of facial wrinkles by replacing volume loss and, in the case of Bellafill®, for facial wrinkles and acne scars by stimulating the client’s collagen production. Several of the hyaluronic acid dermal fillers have indication for lip augmentation.

Disclaimer of "Off-Label" use – Bellafill, Radiesse and most Hyaluronic Acid Gels are specifically approved for correction of the nasolabial folds of the face. However, once a product is FDA approved, it may be used in other areas of the face and body as determined by the physician or designated assistant. Therefore, Dermal Fillers may include off-label use in an effort to give the best result possible.

CONTRAINDICATIONS:

- Allergies to ingredients in the filler or a reaction to the filler intended to use or from the same class. Allergic to Lidocaine and present or history of multiple severe allergies
- Some people should not receive Bellafill®, formally known as Artefill, including those who have a positive reaction to the Bellafill® collagen skin test; have a history of severe allergies manifested by a history of anaphylaxis, have a history of allergies to any bovine collagen products; are undergoing or planning to undergo desensitization injections to meat products
- Hyaluronic acid is contraindicated for those who have a history of allergy to gram positive bacterial proteins
- Keloids, dermal skin disease, prone to thick scar formation and/or excessive scarring
- Active viral or bacterial skin infection in area to be injected, sinus or dental infections, autoimmune or inflammatory conditions, uncontrolled diabetes, poor healing or other condition that may interfere or cause negative effects. Patients with any skin outbreaks (e.g. cysts, pimples, rashes, hives, or infection) near the injection site should postpone treatment until they clear.
- Pregnancy
PRODUCTS:

**Bellafill®, formally known as Artefill,** is a dermal implant composed of non-resorbable polymethylmethacrylate (PMMA) microspheres, 30 to 50 microns in diameter, suspended in a water-based carrier gel composed of 3.5% bovine collagen, 92.6% buffered, isotonic water for injection, 0.3% lidocaine hydrochloride, 2.7% phosphate buffer, and 0.9% sodium chloride. The bovine collagen provides an immediate volume-replacing fill and is metabolized out of the body usually within 3 months, leaving the collagen stimulating PMMA microspheres deep in the dermis (skin). Initial_____ Bellafill duration and extent of collagen stimulation varies upon individual factors. Therefore, I understand that there are no guarantees of results or lasting effect. Initial_____ I understand that I will continue to age, Bellafill is not going to take care of all my aging skin needs and I may need more dermal filler treatments in the future. Initial_____ **Hyaluronic acid gel** is a naturally occurring sugar found in the human body. The role of hyaluronic acid in the skin is to deliver nutrients, hydrate the skin by holding water, and to act as a cushioning agent. As a filler it temporarily adds volume to the facial tissue and restores a smoother appearance of the face. Juvederm Volbella® and Ultra® for lip lines and augmentation and Ultra Plus® XC nasolabial folds are some of the hyaluronic acid dermal fillers available. Duration varies upon individual factors. I understand there are no guarantees of results or lasting effect. Initial_____ **Radiesse** dermal filler is a resorbable implant product composed of calcium-based microspheres and gel. As a filler it temporarily adds volume and collagen stimulating effect within the dermis (skin) to help correct volume loss and wrinkles. Duration varies upon individual factors. I understand there are no guarantees of results or lasting effect. Initial_____ POTENTIAL ADVERSE EVENTS:

- **Bellafill®:** Clinical experience with similar products used outside United States suggest that the following adverse events that did not occur in U.S. clinical trials might occur: hypersensitivity to bovine collagen, severe anaphylaxis reaction, drainage of fluid from the injection site, and nodule formation requiring excision or drug treatment.
• With any injectable dermal filler, you can expect mild bruising, swelling and reddening at the treatment site. It may feel firm or lumpy and this is all normal. These side effects are usually gone within 24 hours. If you are taking aspirin or anti-inflammatory drugs or supplements you may experience increased bruising or bleeding at the injection sites. Treatment under the eyes may cause bruising up to a “black eye”.

• The safety and effectiveness of fillers beyond one year have not been established with the exception of Bellafill®. ¹ Based on the 5-year Post-Approval Study on nasolabial folds with 1,008 patients, long-term safety of Bellafill® for up to 5 years has been established.

• Fillers in general: Most side effects are mild or moderate in nature, and their duration is short lasting (7 days or less). The most common side effects include, but are not limited to, temporary injection-site reactions such as: redness, pain/tenderness, firmness, swelling, lumps/bumps, bruising, itching and discoloration.

• With any injection skin procedure there is the risk of skin infection and allergic reaction.

• Rare, but an acknowledged risk, is migration of the filler, nodule or granuloma formation, keloid/hypertrophic scarring, and accidental injection into a blood vessel that may lead to tissue damage.

• Radiesse is radiopaque and visible on CT Scans and possibly on X-Ray.

I have read and understand the possibility of an adverse reaction. Initial ____

ADDITIONAL TREATMENT NECESSARY:

• There are many variable conditions in addition to risk and potential complications that may influence the long term result of treatment. 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 procedure or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, or the results that may be obtained. I understand that there are no guarantees of results or lasting effect and I may need future treatments. Initial____
CONSENT:
I voluntarily request Margaret Larson, ARNP or designated licensed provider to provide dermal filler treatment, which has been explained to me, and my questions regarding such treatment, its alternative, its complications and risk have been answered by Margaret Larson, ARNP, designated licensed provider, and/or written information. The information provided is clear to me and I understand the risks and complications of the treatment. My questions have been fully and completely answered and I have read this document and understand its contents. I understand that there are no guarantees, all sales are final and payment is due at time of treatment. I understand that I will continue to age and may need additional filler treatments in the future. I understand that filler treatments are not going to take care of all my aging skin needs. I hereby give my unrestricted informed consent for treatment with dermal fillers.

____________________  __________  __________________________  ______
Signature of Patient  Date  Signature of Provider  Date