Dermal Filler Consent Form

I _____(Patient Name) hereby authorize _____(Medical Provider Name) to perform the dermal filler procedure. The medical provider obtained my medical history and found me eligible for treatment.

INDICATIONS: In general, dermal fillers are indicated for the correction of facial wrinkles by replacing volume loss and specifically 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 indications for lip augmentation. Disclaimer of "Off-Label" use – Bellafill, Radiesse and 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 medical provider 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/past 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; and/or 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 areas to be injected, sinus/dental infections, autoimmune or inflammatory conditions, uncontrolled diabetes, poor healing or other conditions that may interfere or cause negative effects. Patients with skin outbreaks (e.g. cysts, pimples, rashes, hives, infection) near injection site should postpone treatment until they clear. Pregnancy and/or breast feeding is a contraindication.

PRODUCTS FOR FILLER:

☐ **Bellafill®** 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. 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_____**

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☐ **Hyaluronic acid** 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. Hyaluronic acid dermal fillers available include Restylane, Juvederm, Belotero, Revanesse Versa, RHA collection, and other product brands. 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 include hyaluronic acid gels:** 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. In the rare event of a complication, there is a reversible agent called hyaluronidase that can be used to dissolve the product.

☐ **Radiesse** is radio-opaque 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 procedures 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_____**

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MEDICAL HISTORY

I have informed the medical provider of all my known allergies and all medications I am currently taking, including prescriptions, over-the-counter remedies, herbal therapies, antiplatelet or anticoagulation medications. I have been advised about which of these medications I should avoid taking on the days surrounding the procedure. I understand that the medical provider will rely on my documented medical history, as well as other information obtained from me in determining whether to perform this procedure. I have provided and agree to continue to provide accurate and complete information about my medical history and conditions. I herein state that I am not pregnant or nursing and do not have any contraindication to this procedure.

FOLLOW-UP TREATMENT

I agree to follow up with the medical provider at the recommended intervals at the Valley Health Clinic office location(s) and to contact the clinic if there is any change in my condition, medical history or any problem I may experience. I agree to call the office immediately and/or use the after hours number _____ should any unusual side effects occur. I understand that in case of a medical emergency, I should call 911 or go to an emergency medical facility.

CONSENT FOR TREATMENT:

I _____(Patient NAME) voluntarily request _____(Medical Provider/Injector NAME) who is a licensed clinician to provide elective, aesthetic treatment. The procedure has been explained to me and my questions regarding such treatment, its alternative, its complications, and its risk have been answered. The information provided is clear and I understand the risks/complications of the treatment. My questions have been fully answered and I have read this document to 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 treatments/products in the future. I understand that aesthetic treatments are not going to take care of all my aging skin needs. I hereby give my unrestricted informed consent for treatment of designated aesthetic procedure/product. I also understand that this consent is valid for future treatments unless the policies of the office or the known risks for the procedure/product change. By signing this form I acknowledge that guarantees as to the final results of my treatment have not been made.

Initials: _____ I release the device manufacturer, medical provider/injector(s), and staff of Valley Health Clinic LLC and Revive Aesthetics LLC from any and all liability associated with any injuries and/or current or future conditions resulting from the skincare procedures or products.

Initials: _____ I authorize before, during and after the procedure(s) the taking of photographs to be part of my patient profile that may be used for educational, promotion or advertising purposes without disclosing my identity. I also release Valley Health Clinic LLC and its associated staff including Revive Aesthetics LLC from any liability in connection with the use of such photographs and/or videos. My name will not be used to identify these photographs without my written approval.

NOTE: THIS CONSENT FORM IS VALID UNTIL ALL OR PART IS REVOKED BY ME IN WRITING.

_____	_____	_____
Patient Name Printed	Patient Name Signed	Date
_____	_____	_____
Medical Provider Name Printed	Medical Provider Name Signed	Date

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