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INNOVATIVE COMPREHENSIVE SKINCARE

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# BELLAFILL® INFORMED CONSENT

**Bellafill is indicated for the correction of nasolabial folds and moderate to severe, atrophic,distensible facial acne scars on the cheek in patients over the age of 21 years.**

Bellafill® is an FDA approved dermal filler made of sterile polymethylmethacrylate (PMMA) microspheres in a purified bovine collagen gel carrier. This consent outlines the information and risks associated with Bellafill® when used for the for the correction of nasolabial folds and moderate to severe, atrophic, distensible facial acne scars on
the cheek in patients over the age of 21 years.

**How Bellafill® works**
Bellafill® is a dual-acting injectable dermal filler. First, the collagen provides immediate volume below nasolabial folds or pitted acne scars to lift them to the level of the surrounding skin.1 The PMMA microspheres remain in place and create a base that provides structural support to the skin. Most patients can expect to maintain the correction they see early after treatment. However, every patient's skin is unique and it is recommend to begin with a conservative amount and continue with touch up treatments as needed to achieve optimal results. Optimal correction of all the areas that you are concerned with may take several syringes and/or treatment sessions. A discussion of how many syringes and treatment sessions that will be required, along with associated costs related to treatment(s), should take place prior to any treatment.

**Skin Test**
You will receive a "Bellafill® Skin Test" before your first treatment. A very small amount of Bellafill® (0.1cc) will be injected into the skin of your forearm. The purpose of this test is to confirm that you are not sensitive to the ingredients contained in Bellafill®. You should observe your skin test site daily and notify your physician should you see and redness, swelling, hardness and or itching over a 4 week period of time.
Approximately 4 weeks later your Bellafill® skin test results will be reviewed by your physician. It is negative, you may then receive your Bellafill® treatment.

**Procedure Description**
An injection or topical application of numbing medicine, such as lidocaine, may be used, if desired. Bellafill® also contains lidocaine to minimize treatment discomfort. One or more injections of Bellafill® will be placed under the skin's surface. Some massage may be done immediately after the injection. Ice or cooling packs may be placed
over injection points.

**Contraindications**

• Bellafill® is contraindicated for patients displaying a positive response to the required Bellafill® Skin Test. Refer to the Bellafill® Skin Test Instructions for Use for complete instructions for administration and evaluation of the skin test.
• Bellafill® is contraindicated for patients with severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies.
• Bellafill® contains lidocaine and is contraindicated for patients with known lidocaine hypersensitivity.
• Bellafill® contains bovine collagen and is contraindicated for patients with a history of allergies to any bovine collagen products, including but not limited to injectable collagen, collagen implants, hemostatic sponges, and collagen-based sutures, because these patients are likely to have hypersensitivity to the bovine collagen in Bellafill®.
• Bellafill® is contraindicated for patients undergoing or planning to undergo desensitization injections to meatproducts, as these injections can contain bovine collagen.
• Bellafill® is contraindicated for patients with bleeding disorders.
• Bellafill® is contraindicated for use in lip augmentation and injection into the vermilion or the wet mucosa of the lip.
• Bellafill® should not be used in patients with known susceptibility to keloid formation or hypertrophic scarring.

**WARNINGS**

• The safety of Bellafill® when used within 6 months of collagen, botulinum toxin, or other wrinkle therapies has not been studied.
• A Bellafill® Skin Test must be administered and evaluated prior to injection of Bellafill®. Patients demonstrating a positive skin test or 2 equivocal skin tests should not be considered candidates for treatment. Patients demonstrating an anti-bovine collagen serum IgG level outside of the normal range at baseline also should not be considered candidates for treatment. Refer to the Bellafill® Skin Test Instructions for Use.
• Use of Bellafill® at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples rashes, or hives) or infection is present should be deferred until the inflammatory process has been controlled.
• Bellafill® must not be implanted into blood vessels. Localized superficial necrosis and scarring may occur after injection in or near blood vessels, such as in the lips, nose, or glabellar area. It is thought to result from the injury, obstruction, or compromise of blood vessels.
• As with all dermal filler procedures, Bellafill® should not be used in vascular rich areas. Use of similar products in these areas, such as glabella and nose, has resulted in cases of vascular embolization and symptoms consistent with ocular vessel occlusion, such as blindness. For additional information please see the Post-Marketing Surveillance Section in Adverse Events.

**PRECAUTIONS**

• Bellafill® contains non-absorbable PMMA microspheres. Implantation is permanent and will not be reversed without physical removal.

• The safety of Bellafill® for use during pregnancy and in breastfeeding females has not been established.
• Bellafill® is packaged in a sealed tray containing individual treatment syringes with sterile needles for single patient use, packaged in a box. The tip of the syringe is sealed with a tamper evidence cover. Do not use if the seal on the tray lid or syringe is broken or removed. Do Not Resterilize.
• The safety of injecting greater amounts than 3.5 cc per treatment site or 8.9 cc overall has not been established.
• The safety and effectiveness of Bellafill® for the treatment of non-distensible atrophic acne scars has not been established. The use of Bellafill® for ice pick or sinus tract scars has not been studied.
• The safety and efficacy of Bellafill® for nasolabial fold wrinkles and cheek acne scars have not been established in patients under the age of 21 years. There is limited information on the safety of Bellafill® in patients less than 36 years of age. In the pivotal Acne Scar study of Bellafill®, the incidence of injection site reactions in subjects less than 36 years old (30 subjects) was similar to the incidence in subjects above the age of 36 (113 subjects). The majority of these injection site reactions were mild in severity.
• The safety in patients with known susceptibility to hyperpigmentation, keloid formation and hypertrophic scarring has not been studied. Formation of hyperpigmentation, keloids or hypertrophic scars may occur after dermal filler injections including Bellafill®. In the pivotal Acne Scar study of Bellafill®, the incidence and severity of adverse events in 34 subjects with Fitzpatrick Skin Types V and VI was similar to that reported in 109 patients with Fitzpatrick Skin types I - IV and no unique adverse events associated with these patient subgroups were observed.
• As with all transcutaneous procedures, Bellafill® injection carries a risk of infection. The usual precautions associated with injectable materials should be followed.
• The safety of Bellafill® in patients on immunosuppressive therapy has not been established.
• The safety of Bellafill® in patients with connective tissue disorder has not been established.
• Bruising or bleeding may occur at Bellafill® injection sites. Use of Bellafill® in patients who have undergone therapy with thrombolytics, anticoagulants, or inhibitors of platelet aggregation within 3 weeks preceding treatment has not been studied.
• Patients should minimize exposure of the treated area to excessive sun, UV lamp exposure and extreme cold weather at least until any initial swelling and redness has resolved.
• If laser treatment, chemical peeling or any other procedure based on active dermal response is considered after treatment with Bellafill®, there is a possible risk of eliciting an inflammatory reaction at the implant site. This also applies if Bellafill® is administered before the skin has healed completely after such a procedure.
• The use of Bellafill® in anatomical spaces other than the dermis for correction of nasolabial folds and for acne scars on the cheek has not been studied. Refer

to the clinical studies section for more information on implantation sites that have been studied.
• The use of Bellafill in patients with thin or flaccid skin has not been studied and the cosmetic results forthese patients are unknown.
• Long-term safety and effectiveness of Bellafill beyond one year has not been established.
• Bellafill® should not be mixed with other products before implantation of the device.

**POTENTIAL SIDE EFFECTS:**
**Nasolabial Fold: Adverse Events:**
Adverse events that were reported in greater than 1 % of the 391 Bellafill® treated subjects who participated in the
**Nasolabial Fold** Studies are listed below. The majority of the events were mild to moderate in severity
Lumpiness at the injection area occurred in 13/391 subjects. Seven (7) events occurred more than one month after injection and 6 events occurred three months after injection. Duration varied from 4 weeks to unresolved or unknown at 26 weeks. Persistent swelling or redness occurred in 13/391 subjects. Two (2) events occurred 3 months after treatment, duration varied from 5 weeks to unresolved or unknown at 26 weeks. Increased sensitivity
occurred in 7/391 subjects. Two (2) events occurred three months after treatment, duration varied from 4 weeks to unresolved or unknown at 26 weeks. Rash or itching occurred in 5/391 rash, itching more than 48 hours after injection duration varied from 3 weeks to 6 weeks.
**Acne Scar: Physician Diagnosed Adverse Events:**
Adverse events of special interest were followed separately for the study. These included hyper and hypopigmentation, hypertrophic scarring or keloid formation and the appearance of granulomas. None of these adverse events were reported.
46/143 (32%) of Bellafill**®** and 16/50 (32%) of Control subjects experienced at least one all cause (related and
unrelated) Treatment-Emergent Adverse Event.
14 Bellafill**®** and no Control subjects experienced Treatment-Related Adverse Events (TRAEs). Twelve (12)adverse events were mild, one (1) case of injection site reaction was moderate in severity, and one (1) injection site bruising was severe in intensity. Eleven (11) events resolved and three (3) cases of injection site reaction (lumpiness directly after injection) persisted throughout the study. Two (2) of these events were deemed by the
investigator to be mild and one event was deemed to be of moderate severity.
Note: Please also review the product label in consultation with your treating physician.
**Patient Diary Cards reported the following short-lived events:**
Redness **(erythema),** swelling, bruising, pain, itching, lumps/bumps and discoloration. When these events were reported by subjects, the majority were mild and most resolved with two weeks. The events that happened most often in subjects in the clinical study after the Bellafill® treatment were swelling

(69.2%), redness **(erythema**) (66.2%), pain (63.8%), bruising (59.2%), lumps/bumps (57.7%), itching (25.4%) and discoloration (21.5%). Most of these events (41.5%) were mild and resolved in an average of one week. In the pivotal Acne Scar study the incidence of injection site reactions was similar in subjects under the age of 36 compared to subjects above the age of 36. The majority of these injection site reactions were mild in nature.

**Bruising:**

**This can and will happen occasionally even in the best injector's hands so please plan your treatment accordingly.**

To avoid or minimize bruising:

• Avoid alcohol consumption 10 days prior to your treatment.

• Avoid taking any medications, herbal remedies or supplements that are known to thin blood 10 days prior to your treatment. Examples include, but are not limited to blood thinners, anticoagulant medication, aspirin products, ibuprofen products, any nonsteroidal anti-inflammatory drugs, St John's Wort, Vitamin E,
gingko biloba, fish oil, and other omega acid supplements.

**Potential Complications**

Although rare, complications with any dermal filler can occur.
Known complications of Bellafill® include but are not limited to:

• Infection frequently manifested by granulomas or painful, red nodules.

• Heavy scar formation in the area of the injection (keloid formation or hypertrophic scarring)

• Compromise of tissue due to obstruction of blood vessels at the time of injection which could result in tissue necrosis (tissue death).

• If injected into a dermal vessels, may cause vascular occlusion, infarction of embolic phenomena.

• Exacerbation of chronic conditions such as herpes simplex outbreaks and dermatologic conditions like
peri-oral dermatitis.

**No Guarantees**

Because all individuals are different, it is not possible to completely predict the benefits from this treatment. By signing this document you acknowledge that guarantees as to the final results of your treatment have not been made. You understand that additional treatments of any sort require additional fees.

I understand and agree that all services rendered to me are charged to me directly and that I am personally responsible for payment.

I am not pregnant or trying to become pregnant nor am I nursing at this time.

The nature and purpose of the treatment have been explained to me. I have read and understand this agreement in its entirety. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement. Alternative methods of treatment and their risks and benefits have been explained to me and I understand that I have the right to refuse treatment.

I release Audubon Dermatology, LLC, Dr. Hooper, Dr. Jackson and all medical staff, from liability associated with the procedure. I certify that I am a competent adult of at least 18 years of age. This consent form is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.

Client's Name (Please Print):_____

Client's Signature:_____

Date:_____