Rex Moulton-Barrett, MD
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STANDARDIZED PROCEDURES FOR REGISTERED NURSES & PHYSICIAN'S ASSISTANTS PERFORMING BELAFIL (PREVIOUSLY ARTIFILL) INJECTIONS

I. POLICY

A. Circumstances under which the clinically trained RN/PA may perform Bellafill injections.

1. Setting:
   - a Brentwood: Doctor's Office, Suite J-5, 1280 Central Blvd,
   - b. Alameda: Alameda Hospital, 4th Floor Doctor's Offices

2. Supervision:
   - a. The Physician or Registered Nurse who is trained and qualified will assess the patient prior to treatment to ensure the patient is a candidate for Bellafill. The patient's Medical History Questionnaire will be discussed in-depth with patient. (Questionnaire attached).
   - b. The RN will then treat the patient with Bellafill, providing that the patient meets patient criteria, and Medical History Questionnaire has been completed.
   - c. The physician will review the treatment rendered and sign the chart upon review.

3. Patient Conditions:
   - a. Consultation regarding patient's chief complaint completed.
   - b. Patient must be at least 21 years of age or 15 years of age with parental / guardian written consent
   - c. Informed consent given and consent form completed.
   - d. Specific Indications:
     1. correction / improvement of deepended nasolabial folds
     2. acne scars: rollable and able to flatten with stretch
     3. HIV3 lipoatrophy
     4. Zygomatic arch augmentation

4. Contraindications:
   - a. Pregnancy.
   - b. For patients with severe allergies including lidocaine allergy, manifested by a history of anaphylaxis or history or presence of multiple severe allergies or collagen skin test positive or 2

equivocal skin tests at or before 3 weeks from injection or bovine collagen allergic

c. patients demonstrating anti-bovine IgG
c. patients prone to excessive scarring, breast feeding
d. injection into the vermillion border or wet mucosa of the lip
e. patients with bleeding disorders
f. patients with known susceptibility to keloid/hypertrophic scarring

5. Precautions:
   a. In patients with no known collagen allergy
   b. A negative intradermal collagen skin test > = to 5 days: 96% of reactions occur within 48 hours before the planned injection, with no reaction: mean 96%.
   c. The injection should be limited to nasolabial fold or acne scars
   d. Patient should be aware of potential adverse events following injection of Bellafill®. These are bruising, redness, swelling, tenderness and itching, granulomas: the latter occurs in 1.2 and 1.6% of nasolabila nd acne scar patients, respectively.
   e. Bellafil should be used for the 3 S's: smooth, soft shoulder and saucer like acne depressions of the face and not for icepick, boxcar or sinus like scars
   e. > 5 yr data re longevity and safety has not been established
   f. do C02 laser after the procedure, laser at least 4 weeks before
   g. do not reinject until at least 1 month after last treatment if HIV +
   h. wait at least 3 months after last Accutane treatment

II. PROTOCOL

A. Definition:

1. Bellafill is an injectable comprised of 80% of 3.5% bovine collagen solution surrounding 20% 30-50 micron PMMA (polymethylmethacrylate) microspheres and in suspension with 0.3% lidocaine. The bovine collagen is replaced by autologous collagen 3 months after the injection.
   It is injected subcutaneously as a permanent implantation filler for the correction of nasolabial folds and moderate to severe, atrophic, distensible facial acne 'rolling' scars on the cheek. Bellafil is not indicated for narrow 'icepick' or 'boxcar' scars.

2. 4 Week Bellafill skin-Test contains 0.3% lidocaine, 3.5% bovine collagen, phosphate buffer and sodium chlorine. Place intradermal volar forearm 0.1ml Provide the patient with a Bellafill Skin Test Results Card. Positive results: erythema +/- induration, swelling, itching for >24 hours. Equivocal reaction: systemic symptoms and no skin changes during 4 weeks.

B. Assessment:

1. Subjective: The above patient conditions have been met.
2. Objective: The patient presents with soft tissue deficits as described in A. definition above.
3. Acne scar rating scale: (ASRS)

Score	Description
1	**Minimal –** Depth up to 0.5mm. Visibility = Perceptible with tangential lighting
2	**Mild –** Depth >0.5mm to <1.5mm. Visibility = Moderately detectable with tangential lighting
3	**Moderate –** Depth = ≥1.5mm to <2.5mm. Visibility = Easily seen with tangential lighting
4	**Severe –** Depth = ≥2.5mm in depth. Visibility = Substantial shadowing with tangential lighting

C. Plan:

1. Storage:
   a. Store Bellafill standard refrigerator temperatures. Refrigeration is needed. Do not freeze and protect from sunlight. Bellafill must be used prior to expiration date on the package. Bellafill is packaged sterile in a vacuum 1ml syringe and sold in multiple syringe boxes.
   b. remove to room temperature 15 minutes before injection
2. Test Implant:
   a. Bellafill does require a test 0.1ml intradermal injection on the volar antecubital fossa of the non - dominant forearm. This should be injected in a patient with contraindications including beef allergies or sever allergies including to lidocaine. The result is read at 5 days.
3. Treatment:
   a. Patient will remove all make-up from treatment areas
   b. photos and consents obtained
   c. apply topical BLT or Fasttet to area for 20 minutes prior to injection
   d. the skin should be cleaned with betadine iodine and alcohol
   e. use sterile gloves
   f. intravascular injection has been associated with skin necrosis, cerebral infarction and blindness. Therefore, inject the product very slowly and with great force and stop immediately if blanching of skin occurs.
   g. Inject area to be treated using a 26 g needle in the deep dermis plane from the 1ml prefilled and refrigerated syringe, bevel up.

h. For acne scars: subsize with 26 g needle first to create a space for injection and release to scar which is pulling the area downwards.
i. Use retrograde linear threading technique for nasolabial folds. Acne scars serial puncture and linear retrograde techniques. No overfilling should be done, fill to desired 100% correction.The first injection should not be greater than one 1ml syringe to acnes scars or nasolabial folds and after waiting a minimum of 8-12 weeks to monitor for potential complications then in the abseence of serious complications no more than 1ml per nasolabiial fold should be injected per side.
j. for zygomatic acrh augmentation inject by depot 0.2mls per point and massage onto bone.
k. Post treatment – cleanse site with alcohol.
l. Immediate massage to even out any contour irregularities
m. the safety of injecting >3.5mls has not been studied and the office of Dr. Moulton-Barrett will not inject more than 1ml in total the first injection and no more than 1ml per side thereafter no sooner than 3 months later.
n. discard any remaining product after treatment

4. <u>Patient Education:</u>
   a. See Bellafill post-care sheet and give copy to patient.
   b. Avoid strenuous exercise, extensive sun exposure and extensive heat.
   c. Avoid all alcoholic beverages for 4 hours following injection.
   d. Instruct patient not to massage treatment sites for 4 days.
   e. Inform patient that temporary swelling, redness, pain, bruising, lumps/bumps, itching, and discoloration at the treatment site. These side effects are usually transient and typically resolve within 1–7 days. Complications occur in 12% of patients including: Lumps/bumps/papules that may occur more than one month after injection and that may persist. Less common side effects include rash and itching more than 48 hours after treatment, persistent swelling or redness, lumps/bumps, acne, and increased sensitivity at treatment sites. Infrequently, granulomas may

occur: 1.2% for nasolabial folds and 1.6% for acne scars

f. Patient to notify Dr Moulton-Barrett should any concerns or questions arise.

5. Follow-up:
   a. Patient may leave with ice to reduce swelling and dyscomfort.
   b. reinjections should follow at 3 month intervals
   c. Subsequent treatment scheduled upon patient's desire for further additional correction .
6. Documentation:

The following information must be recorded with each treatment:

a. Number and size of syringes used
b. Syringe lot numbers
c. Specific areas treated
d. Amount of material used
e. Patient response to treatment.
f. Procure physician review and sign-off of all patient charts within 7 days post procedure.

Note: For ease, Bellafill comes with a serial number that is part of the syringe label. The number is to be attached to patient records to ensure traceability of the product.

III. REQUIREMENTS FOR RN/PA

A. Education:

1. Graduate of RN/PA program with current California RN license.

B. Training:

1. Training by Dr. Rex Moulton-Barrett or trained and qualified Registered Nurse specifically trained in Bellafill product knowledge and proper technique.
2. Formal education from product company to gain knowledge, experience and proficiency in the proper administration of product.
3. Initial Evaluation: Successful completion of in-service education, training and demonstration of competency to MD, including proctoring of (at least) 3 treatments.
4. On-going evaluation:
   a. Random MD visits during treatment sessions. MD will observe 1 treatment quarterly.
   b. Annual performance evaluation by Program Manager.