Rex Moulton-Barrett, MD
04-2016

STANDARDIZED PROCEDURES FOR REGISTERED NURSES PERFORMING RADIESSE ® INJECTIONS TO THE FACE

I. POLICY

A. Circumstances under which the clincially trained RN may perform Radiesse® 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 Nurse Practioner who is trained and qualified will assess the patient prior to treatment to ensure the patient is a candidate for Restylane. The patient's Medical History Questionnaire will be discussed in-depth with patient. (Questionnaire attached).
   - b. The RN will then treat the patient with Radiesse, 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 18 years of age, or parent/legal guardian may authorize treatment.
   - c. Informed consent given and consent form completed.
4. Contraindications:
   - a. Pregnancy.
   - b. For patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
   - c. No NSA'a, no anticoagulation, bleeding disorders
   - d. No recalcitrant herpes zoster or perioral simplex
   - e. Age < 26 and > 79 years of age
   - f. active facial infection
5. Precautions:
   - a. Face: Injection should be limited to 1.5ml per nasolabial fold injection for a total of 3mL per treatment session per patient. Each syringe to be mixed with 0.26ml of up to 2% lidocaine or use Radiesse+
   - b. Patient is aware of potential adverse events following injection of Radiesse®. These are bruising, redness, swelling, tenderness and itching.

c. intravascular injection can lead to skin necrosis or blindness as well as cerebral infraction. Therefroe injection should be made slowly and without undue force.
d. overfilling is not indicated

II. PROTOCOL

A. Definition:

The administration of the Radiesse is a 25-45 micron particle opaque dermal filler which is composed of calcium hydroxappetite suspended in a water based gel carrier is for subcutaneous implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. When combined with lidociane it is termed “Radiesse+”

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

C. Plan:

1. Storage:
   a. Store Radiesse® at room temperature up to 59-90º F. Refrigeration is not needed. Do not freeze and protect from sunlight.
      Radiesse® must be used prior to expiration date on the package. Radiesse is packaged sterile in syringes of 0.8 and 1.5mls and sold by the box.
   b. expiration is 3 years from the date of manufacter
2. Test Implant:
   a. Radiesse® does not require a test implant.
3. Treatment:
   a. Patient will remove all make-up from treatment area.
   b. Define areas to be treated. Prep site with alcohol.
   c. Inject area to be treated: Face:
   d. apply topical anesthetic for 20 minutes +/- ice
   e. prep with chlorhexidine or betadine iodine solution followed by alcohol wipes.
   f. Inject using internal diameter 27 g needle or 25 external diameter needle
   g. after mixing 1.5ml Radiesse with 0.26ml of 2% lidocaine or 0.8ml with 0.11mls of 2% lidocaine versus: use Radiesse+
   h. inject
   i. massage any irregularities using bimanual technique
   j. apply ice for up to 24 hours

3. Post treatment – cleanse site with alcohol.
4. Patient Education:
   a. See Radiesse postcare 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 swelling, pain and bruising could last for several days: respectively.
f. Inform patient redness and slight swelling may occur at the injection site.
g. Patient to notify office should any concerns or questions arise.
h. Inform patient that 76% will see results last 6 months and 30% will see results in excess of 2 ½ years.

5. Follow-up:
   a. Patient may leave with ice to reduce swelling and discomfort.
   b. 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, Radiesse® comes with a patient record label that is part of the syringe label. Remove it by pulling the flap marked with three small arrows. This label is to be attached to patient records to ensure traceability of the product.

III. REQUIREMENTS FOR RN

A. Education:

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

B. Training:

1. Training by R. Moulton-Barrett, MD , and / or together with qualified a Registered Nurse or MD specifically trained in Radiesse® 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 R. Moulton-Barrett,MD.

5. Previous Experience:
   a. No previous injectible experience necessary prior to training
   b. Initial Evaluation: Successful completion of Radiesse education, training and demonstration of competency to MD.
4. Physician will review and sign-off all patient charts within 7 working days post procedure.
5. On-going evaluation:
   a. MD will observe random and or quarterly injection technique including but not limited to BoTox, Xeomin and fillers which are currently being used in the Alameda and or Brentwood offices of R. Moulton-Barrett,MD.
   b. Injection technique includes evaluation of patient safety including sterile technique, needle management, patient tolerance / comfort, location and amount of injection relative to the degree of the rhytid and post injection management of the patient.
   c. All evaluation will be documented in the RN evaluation book which is kept in the adminstraive office at all times.

IV. DEVELOPMENT OF PLAN

The Medical Director and Administrator have developed this Standardized Procedure and Protocol Policy (standing order) for the administration of Rasdiesse as a comprehensive working model.

This model will be reviewed annually and documented in the minutes of the meeting and will be kept in the Administrative office of Rex Moulton-Barrett,MD

This Standardized Procedure and Protocol (standing orders) have been approved by:

Rex Moulton-Barrett,MD

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Administrative Signature Date: 4-14-2016