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STANDARDIZED PROCEDURES FOR REGISTERED NURSES PERFORMING JUVEDERM VOLUMA XC® INJECTIONS

I. POLICY

A. Circumstances under which the clinicially trained RN, PA and or NP may perform Voluma® 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 NP who is trained and qualified will assess the patient prior to treatment to ensure the patient is a candidate for Voluma. The patient's Medical History Questionnaire will be discussed in-depth with patient. (Questionnaire attached).
   - a. The employee RN will then treat the patient with Voluma, providing that the patient meets 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. guardian may authorize treatment.
   - . c. Informed consent given and consent form completed.
   - d. age >= 21 and <65 years
   - e. deep injection of the lateral cheek to correct age related volume loss
4. Contraindications:
   - a. Pregnancy.
   - b. For patients with severe allergies including gram positive organisms and lidocaine allergy manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
   - c. facial infection, including active acne
   - d. coagulatopathy, anticoagulation, non steroidal use and vitamin E useage within 10 days of injection
5. Precautions:
   - a. Injection should be limited to 10ml per treatment area or a maximum of 20mls. Studies average was 6ml per side: 2ml x3 per ZMArch, Anteromedial Cheek, SubMalar. Lowest success ful 1.3ml total. The usual volume per side which most patientw will require is 1ml / side
   - b. Patient is aware of potential adverse events following injection of Voluma. These inlcude bruising, redness, swelling, facial nerve injury and hematoma, asymmetry, tenderness and itchin
   - c. above comlications are ususally self limiting within 14 days of injection.

d. no intravascular injection should be performed and no in vascular rich areas such as the nose, glabella or within the orbit
e. Voluma is packaged for single patient use

II. PROTOCOL

A. Definition:

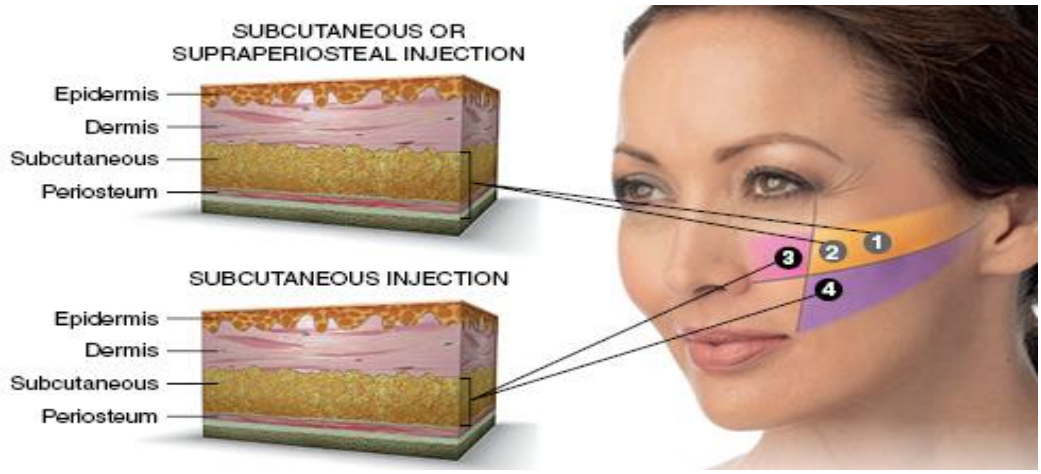
The administration of the Voluma XC is for deep cheek implantation for the correction of age related mid face volume loss. The compound utilises Yycross technology referring to tight crosss linking gel and may last up to 2 years> Voluma is a strepococcus equi bacteria formulated to a concentration of 20mg/ml and 0.3% lidociane in a buffer.

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 Voluma XC at room temperature up to 77º F. Refrigeration is not needed. Do not freeze and protect from sunlight.
   Voluma® must be used prior to expiration date on the package. Voluma XC is packaged sterile in 1ml syringes and sold by the box. Order Voluma® per patients scheduled requirements.
2. Test Implant:
   a. VolumaXC does not require a test implant.
3. Treatment:
   a. Patient will remove all make-up from treatment area.
   b. Define areas to be treated: mark zones: 1,2,3,4 with Expo pen
   Mark line from corner of eye to corner of mouth
   Mark line on lower border of zygomatic arch
   Mark the 4 points for injection



c. Prep site with dabbed betadine solution then alcohol wipe using gloves

d. Inject Technique:
remove tip cap and place the 27 g needle
Inject in order lateral to medial and then inferior:

i. 1(lateral zygomatic arch) , then
ii. 2 (medial zygomatic arch): 2 x .2ml one medial and one lateral to point in 'V' type horizontal pattern then
iii. 3 (anteromedial cheek), then
iv. 4 (submalar)

Each injection with needle 0.2mls to supraperiosteal location: deepest in zone 1 and 2 to periosteum and less deep 3,4 over periosteum by 1cm or less
Plan to use one syringe per side
Apply pressure and massage for contour

e. Post treatment: cleanse with alcohol and massage antibiotic ointment to provide appropriate contour
f. Voluma® 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.

4. Emergency Treatments:
   a. If blanching continues inject 15 units (0.15mls) or > hyaluronidase (150U/ml)
   b. if visual loss noted inject 150 units hyaluronidase into peribulbar intra orbital muscle: 1cm, 0.1ml or 15Ux 10 injections
   c. for severe allergic reactions call 911, and institute epipen, steroids and benedryl in resusitation brief case in MD's room by tall cabinet
5. Patient Education:
   a. See Voluma® 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 bruising could occur and last 7-10 days.
   f. Inform patient redness and slight swelling may occur at the injection site.
   g. Patient to call us should any concerns or questions arise.
   h. Reinjection should be at least 4 weeks after the current injection
6. 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.
7. 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 working days post procedure.

III. REQUIREMENTS FOR RN

A. Education:

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

B. Training:

1. Training by Dr Rex Moulton-barrett and the Allergan Training nurse under the supervsiion of Dr Rex Moulton-Barrett for Registered Nurse employees of Dr Moulton-Barrett specifically trained in VolumaXC product knowledge and proper technique.
2. Formal education from product company to gain knowledge, experience and proficiency in the proper administration of product.
3. Understanding the relevant anatomy. It is imperative not to inject Voluma XC into the parotid gland and duct, infra-orbital neurovascular bundle, and vessels present in the antero-medial cheek, including those in the glabella and nose. Doing so can result in vascular embolization, occlusion of vessels, ischemia/infarction, and blindness.

C. Evaluation:

1. Successful completion of in-service education, training and demonstration of competency to MD, including proctoring of (at least) 1 treatment.

. On-going evaluation:

2. Random MD visits during treatment sessions. MD will observe treatment quarterly.
3. Annual performance evaluation by Dr Moulton-Barrett