

STANDARDIZED PROCEDURES FOR REGISTERED NURSES PERFORMING
NOVATHREAD MATTING OR LIFTS

I. POLICY

A. Circumstances under which the clinically trained RN/NP/PA may perform NOVATHREADS ® placement.

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, Nurse Practitioner or Physician's Assistant who is trained and qualified will assess the patient prior to treatment to ensure the patient is a candidate for Novathreads. The patient's Medical History Questionnaire will be discussed in-depth with patient. (Questionnaire attached).
 - b. The RN will then treat the patient with The NovaThread, 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.
 - d. Hollow sharp needle and or Micro-cannulas and threads are approved for the implantation of NovaThreads and/or bio-stimulant injectable products.
 - e. It is the clinical choice of the MD/NP/RN/PA to select the appropriate sharp versus blunt microcannula, the gauge and length of the thread and or location and numbers placed of threads for the elevation, support and/or bio-stimulant for the correction or enhancement of but not limited to: Cheeks, Hands: dorsal skin, Mandibular region, Marionette lines, Mentalis/Chin, Malar fat pads, Nasal Labial Folds, Tear Troughs, Jowls, Anterior and lateral Neck, Eyebrows and Forehead, Upper & Lower lips, Upper & Lower Rhytids, General Mild to Moderate Skin Laxity, Brow ptosis, Buttocks and Breasts.
 - f. The price of the procedure is based on a pre-set usual and customary fee for the specific site as detailed in the enclosed document entitled " Nova Threads Pricing and NovaThread Procedural Pricing 2019". The patient should be made aware that additional threads may be necessary in order to avoid the desired result and based on the providers best estimate of which / how many additional pouches might be used. The quoted a price should be in writing and specify from X to Y dollars and it should be understood payment is expected at

the termination of the procedure.

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's, no anticoagulation, bleeding disorders
 - d. No recalcitrant herpes zoster
 - e. Age < 18 (< 26 yrs. for Radiesse) and > 79 years of age
 - f. Moderate to severe midfacial ptosis and jowling, poor skin quality : very thin skin, wide, heavy and prominent platysmal bands
 - g. Active herpes simplex if perioral threads planned
 - h. Active infection of the face and or neck or area of planned thread insertion
5. Precautions:
 - a. Hands & Wrist : 29 g Smooth Threads should be limited 24 (6 pouches) per hand treatment session.
 - b. Face & Neck: Thread placement: location, size, length, sharp versus blunt, nyumbers used are indiviudalized but shall follow the 2019 Dr. Moulton-Barrett docuament entitled "Nova Thread Procedural Pricing", enclosed with this form as well as the NovaThread manufacturer's recommendation of gauze per zone of the hand, neck, hand & body
 - c. Pateints should be aware of potential adverse events following injection using a sharp needle and or cannula insertion as well as placement of threads. These include redeness, swelling, bruising, contour irregularity and granuloma formation, infection and the need for removal.
 - d. Patients should be given to understnd that this is not a facelift procedure and the results are neither permanent nor guaranteed and therefore the procedure is non refundable

II. PROTOCOL

A. Definition:

The administration of Novathreads® is for supficial subcutaneous implantation for the elevation and or correction of moderate to severe facial, neck, bofy and or hand wrinkles and folds, such as nasolabial folds.

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. Novathread boxes and pouches can be stored at room temperature
 - b. each pouch is designated to an individual patient and is not shared
 - c. smooth and Twist boxes may be open and have a 2 year shelf life. However, barb boxes must be used within 2

months of opening. Each Barb box contains 6 pouches, each pouch contains 2 barbs

2. Test Threads:

- a. no testing is required

3. Preprocedure Requirements:

- a. procedural patient consent signed, dated and witnessed
- b. pre and post procedure instruction sheet entitled PDO Threads Pre & Post Treatment Care will be signed and dated by the patient reviewed by patient with adequate time to ask any questions prior to the precedure and forms given to patient
- c. Patient may sign a HIPAA compliant photo request form entitled " Office Media Release Form " with acceptance of photo release clause
- d. obtain photos using standard Am Soc Plastic Surgery poses
- e. images to be uploaded into encrypted HIPAA compliant Nextech Cloud platform on day of procedure.

3. Treatment:

- a. A procedure set up following The "Pre Nova PDO Check List of Medical Supplies" will be followed (see form enclosed)
- b. Patient will remove all make-up from treatment area.
- c. Define areas to be treated. Prep site with alcohol and betadine iodine
- d. Use treatment non latex sterile gloves for injection and if desired by patient 30 g needle with 0.1-0.2ml ml of lidocaine may be injected to site of pilot hole needle insertion followed by use of kit needle 29-18g needle vertically through the skin to place hole at intended site to either directly to thread a sharp needle based thread or using a blunt micro cannula introduce the thread.
- e. Where the entry needle/cannula points are located and the number of threads, the g and the length is detailed in an enclosed document called NovaThread Procedural Pricing 2019 and specifically in an enclosed document called " NovaThread Procedural Design 2019"
- f. place thread with technique of reaching end point and withdrawal of needle and or cannula with gentle firm pressure over distal thread to avoid thread disinsertion.

Hands:

- a. may apply topical anesthetic for 20 minutes +/- ice
- b. prep with chlorhexidine or betadine iodine solution followed by alcohol wipes.
- c. Lift or 'tent' the skin with a pinch technique to elevate the skin
- d. May Inject 0.1ml 1% lidocaine with epinephrine to site of introduction.
- e. inject between 8-24 (2-6 pouches) smooth threads (see treatment plan sheets)
- f. may apply ice for up to 24 hours

Face:

- a. must be approached from subcutaneous plane and for example the nasojugal fold from inferior to orbital rim to the level of the orbital rim, using either a inferior placement of the cannula

through the cheek at a plane of the midpupillary line or from alateral horizontal approach from the lateral orbital rim skin (see treatment planning sheets for method and specifics of Novathread placement)

- b. all other areas of the face are similar to that of a needle and using the same apply distal pressure as you withdraw technique to avoid disinsertion.
- c. As a rule:
 - i. straight threads are applied at 90 degrees to relaxed and animation skin tension lines to create a matting to avoid inward folding at the line.
 - ii. Twist threads are intended to be placed under a fold to push out the fold and add volume to the fold
 - iii. Barb threads are applied at 90 degrees lateral to prominent folds and may also be used to lift subcutaneous fat such as jowls

3. Post treatment – cleanse site with alcohol and bacitracin ointment.

4. Patient Education:

- a. See Novathread 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.
- e. Inform patient that swelling, pain and bruising could last for 12, 10, 21 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.

5. Follow-up:

- a. Patient may leave with ice to reduce swelling and discomfort.
- b. a routine follow-up should be made 10 days after the procedure
- c. Subsequent treatment scheduled upon patient's desire for further additional correction.

6. Documentation:

The following information must be recorded with each treatment.

- a. Photos
- b. Type, Number and size of Threads used
- c. lot numbers. Note: For ease, Novathread® comes with a serial number that is part of the pouch packaging.
- d. Map of specific areas treated and site of cannula placement and whether or not lidocaine was injected and amount injected
- e. Patient response to treatment.
- f. Post procedure note 10 days

III. REQUIREMENTS FOR RN

A. Education:

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

B. Training of RN/PA/NP:

1. Training by R. Moulton-Barrett,MD, and qualified Registered Nurse specifically trained in cannula followed by formal hands on training in Novathreads with product knowledge and witnessed and supervised proper hands on 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 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 Novathread education, training and demonstration of competency to MD.
6. Physician will review and sign-off all patient charts within 7 working days post procedure for RNs and 10 working days for PA's
7. On-going evaluation:
 - a. MD will observe random and or quarterly injection technique including Novathreads 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 Novathreads.

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
Medical Director

Date: 4-25-2017

Administrative Signature