Rex Moulton-Barrett, MD 4-25-2019

STANDARDIZED PROCEDURES FOR REGISTERED NURSES PERFORMING NOVATHREAD MATTING OR LIFTS

I. POLICY

- A. Circumstances under which the clincially 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 Practioner (NP) or Physician's Assistant (PA) 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 biostimulant 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 Rhitids, 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 Priicing and NovaThread Procedureal 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, silicone in face, chemotherapy, active uncontrolled psychiatriuc disease
- 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
- 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

Procedureal Pricing", enclosed with this form as

well as the NovaTHread manufacter'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, facial nerve injury 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® a Korean made product which has obtained a 510K from the FDA for soft tissue approximation is used off label in the subdermal and or subcutaneous tissue implantation of a thread like material made from polymerized form P-dioxanone, called Polydioxanone (PDO) for the elevation and or correction of moderate to severe facial, neck, bofy and or hand wrinkles and folds, such as nasolabial folds. The effect is either from the barb fixation pull on the fallne vector or by the scaffolding of fallen skinn folds and / or by the fill of a skin fold with later neocollagenisis of 6 months to 15 years

B. Assessment:

- 1. <u>Subjective:</u> The above patient conditions have been met.
- 2. <u>Objective:</u> 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
- 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. <u>Test Threads</u>:

a. no testing is required

3. <u>Preprocedure Requirements:</u>

- a. procedural patient consent signed, dated and witnessed
- b. pre and post procedure instruction sheet entotled PDO
 Threads Pre & Post Tratment Care will be signed and dated
 by the patientreviewed by patient with adequate time to ask
 any questions prior to the preocedure and forms given to
 patient
- c. Patient may sign a HIPAA compiant photo request form entitled "Office Media Release Form "with accceptance 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 precedure.
- f. Mapping the area to determine placement of threads

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 or Puricin (a hypochlorous acid solution)
- 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. Some necks do not require local anesthetic
- e. Where the entry needle/cannula points are located adnd the number of threads, the g and the length is detailed in an enclosed document called NovaThread Procedural Pricing 2019 and specfically in an enclosed document called "NovaThread Procedural Design 2019"
- e. 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.
- f. Dimpling can be addressed by slight pull back of the thread proximally

<u>Hands:</u>

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 treatmenat 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 midpupilarry line or from alateral horizontal approach from the lateral orbital rim skin (see treatment plannning sheets for method and specifics of Novathread placement)
- b. all other ares 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 theads are applied at 90 degrees to relaxed and animation skin tension lines to create a matting to avoid inward folding at the lineideally placed under the dermis in the subdermal layer
 - li. Twist threads are intended to be placed under a fold as a volumizer 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, placed 0.4-0.5 mm depth from subdermis layer to deeper if larger g providing pull from 2-8 months
- 3. Post treatment cleanse site with alcohol and bacitracin ointment.
- 4. Patient Education:
 - a. See Novathead 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. <u>Documentation:</u>

The following information must be recorded with each treatment.

- a. Photos
- b. Type, Number and size of Threadsa 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.

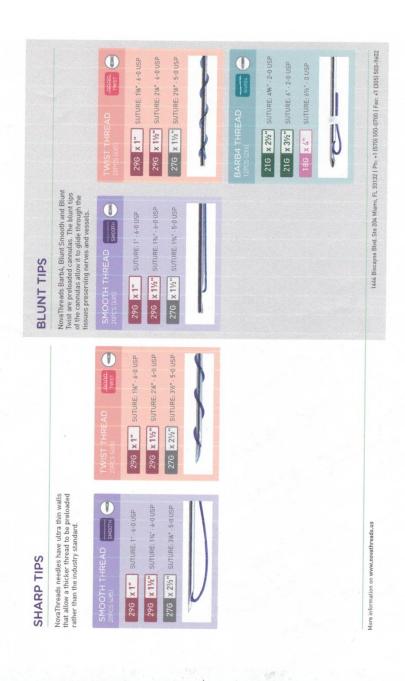
This model will be reviewed annually and documented in the minutes of the meeting and will be kept in the Administrative office of Rex Moulton-Barrett,MD

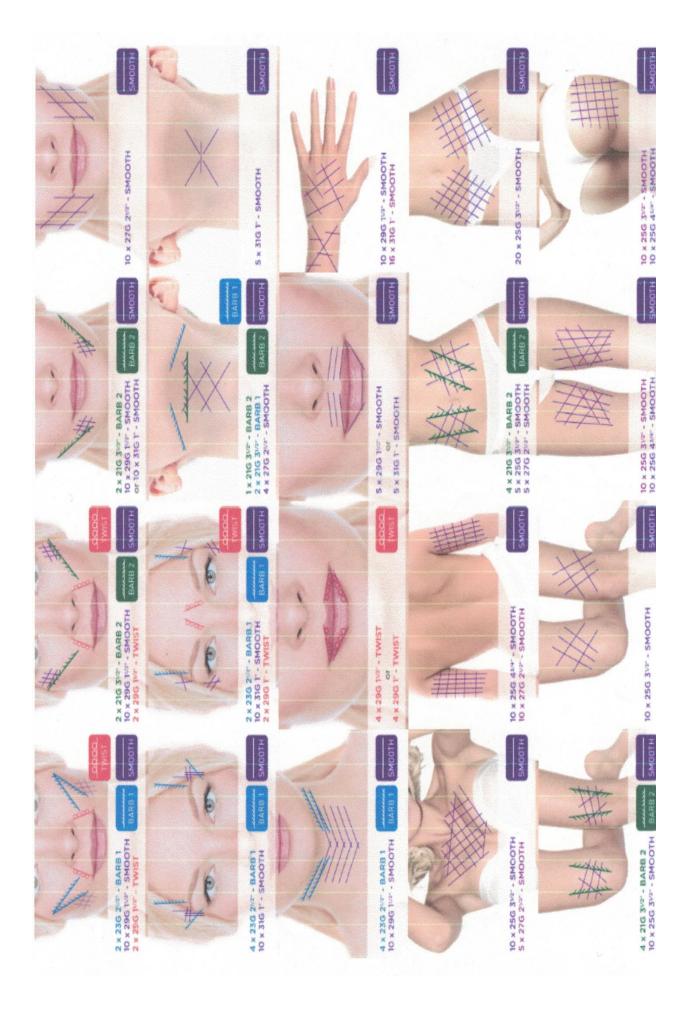
This Standardized Procedure and Protocol (standing orders) have been approved by:

Date: 4-25-2017

Administrative Signature Rex Moulton-Barrett,MD Medical Director

V. SUPPORTING DOCUMENTS





Dr. Rex Moulton-Barrett's Nova Threads Pricing and NovaThread Procedural Pricing 2019

Threads To Be Ordered for Inventory 4/2019

Cost (\$)

| | To Practice | | To Patient | |
|---|-------------|-------|------------|--|
| | Box | Pouch | Pouch | |
| 20 Smooth Blunt 27g x 1 ½ inch length (4 per pouch x 5 pouches=1 box) | 195 | 39 | 300 | |
| 20 Smooth Sharp 29 g x 1 ½ inch length (4 per pouch x 5 pouches=1 box) | 195 | 39 | 300 | |
| 20 Blunt Twist 29 g x 1 ½ inch length (4 per pouch x 5 pouches) | 245 | 49 | 350 | |
| 20 Sharp Twist 29 g x 1 ½ inch length (4 per pouch x 5 pouches) | 235 | 49 | 350 | |
| 12 Blunt Barb 18 g x 4 inch length (2 per pouch x 6 pouches = 1 box) | 549 | 91.5 | 525 | |
| 12 Blunt Barbs 21 g x 3.5 inch length (2 per pouch x 6 pouches = 1 box) | 549 | 91.5 | 525 | |

Areas to Be treated Cost (\$)

| | | To Practice | Patient | Net Income |
|---------------------------|---|--------------------------|--------------|-------------|
| One lip | 1 pouch (4) Blunt Twist 29 g x 1 ½ inch length | 49 | 350 | 301 |
| Smoker's lines1 lip | 1 pouch (4) Blunt Smooth 27g x 1 ½ inch length | 39 | 300 | 251 |
| B Marionette Lines | 3 pouches (12) Blunt Smooth 27 g x 1 ½ inch length | 117 | 590 | 473 |
| Jaw and Cheek Lift | 3 pouches (6) Blunt Barb 18g x 4 inch length | 274.5 | 1299 | 1024.5 |
| Eyebrow Lift Neck Lift | 2 pouches (4) Blunt Barb 21g x 3.5 inch length 2 pouches (4) Blunt Barb 21g x 3.5 inch length 3 pouches of Blunt Smooth (12) 27g x 1 ½ inch length total | 183 183 117 300 | 1050 1350 | 867 1050 |
| B Knee Lift | 2 pouches (4) Blunt Barb 21g x 3.5 inch length 5 pouches (20) Blunt Smooth 27 g inch length total | 183 195 378 | 2050 | 1672 |
| B Buttocks | 3 pouches (6) Blunt Barb 18g x 4 inch length 5 pouches (20) Blunt Smooth 29g x 1 ½ inch length total | 274.5 195 469.5 | 2500 | 2030.5 |
| B Hands | 3–6 pouches (12-24) Blunt Smooth 29g x 1 ½ inch length | 117-234 | 590-1200 | 473-966 |

If combining procedures calculate cost to patient using this formula:

100% stated price for most expensive procedure, 15% off second most expensive procedure and

25% off 3rd or > 3rd procedures

If using threads not listed above for a given procedure follow above pricing providing you are using the same number of pouches, ie blunt and sharps are mostly to same price, different gauges are mostly the same price to the practice.

If using your own choice of thread and or for an unlisted procedure, to determine the cost to the patient:

- 1. always use complete pouches (once a pouch is opened we will not use it on another patient)
- 2. multiple: cost to practice for specific pouch x no. of specific pouches used x 5.5 = cost to patient

Open boxes for Barbs must be used in 2 months, use open boxes for Barbs before opening a new box

Renee Lowe Rep for further questions: 408 688-7755

Dr. Moulton-Barrett's Pre Nova PDO Thread Check List of Medical Supplies

- 1. Numbing cream wipe off entirely before injections
- 2. Gauze pads
- 3. Alcohol / Betadine / or Hypochlorous Acid / Chlorhexidine wipes or prep
- 4. One 3 mL syringe of 1% lidocaine with 1:100,000 epinephrine
- 5. Three 3 mL syringes of 2.7 mL of 1% plain lidocaine and 0.3 mL
- 6. +/- sodium bicarbonate mixed in each 3 mL syringe
- 7. Sterile Gloves and sterle u drape if doing large area, ie face and neck or buttocks
- 8. Ice Packs
- 9. Sharps disposal box
- 10. Headbands*
- 11. DERMarkers (Red is best)*
- 12. One DermaSculpt 22 gauge, 2 and 3/4 inch cannula per patient*
- 13. Scissors and pickups (or suture removal kits)*
- 14.18G needles*
- 15. Ruler*

Dr. Moulton-Barrett's PDO Threads Pre & Post-Treatment Care

Contraindications for the procedure include:

immune system diseases, pregnancy, coagulation diseases, cutaneous neurofibromatosis, acute infectious diseases (i.e., Influenza, etc.), inflammation of the skin in areas to be treated, non-absorbable implant (Silicone) in the zone of thread insertion, current chemotherapy, keloid scarring, bleeding Disorders and some diseases of the blood, neurotic psychological disorders, unrealistic expectations

Pre-treatment care:

- Vitamin E avoid for 10 day
- NSAIDS: Aspirin (Excedrin), ibuprofin (Advil), Aleve avoid for 10 days
- Alcohol avoid 3 days prior to procedur

Post-treatment instructions & what to expect :

- Effects should be noticeable immediately after treatment. However, maximum effect will occur in 4-6 weeks.
- Bruising and swelling is normal and expected. If bruising is visible you can take oral
 Arnica or apply topical Arnica gel or Cearna Arnica patch to areas that are discolored.
- Asymmetry and irregularity of the tissue is common and will typically resolve in one to two weeks
- Pain at the insertion points is normal and may last several days after treatment. Please consult your provider for any pain beyond 2 weeks.

Avoid:

- Excessive movement or animation of the area injected for 2 weeks.
- Massage or manipulation of the tissue for 2 weeks.
- Aesthetic treatments including RF, IPL, Laser, or Microneedling for 4 weeks.
- Strenuous exercise for 1 week after facial treatments and 2 weeks after body treatments. No deep squats for one month if you have had any threads injected into the buttocks area.
- Steam rooms, saunas, hot tubs, or any water source that could be unclean or excessive in temperature for two weeks.
- Taking Ibuprofen for 2 weeks. Acetaminophen may be taken instead, if needed.

When To Call:

Patient Signature:

- If any of the threads are exposed or start to extrude.
- If you develop a reddened, hard, painful nodule over one or more of the threads.
- If you experience increased redness, swelling, or pain at the insertion site.
- Irregularity or visible ridges (buckling) of threads 2 weeks post-treatment.
- If you have any questions regarding your treatment.

| I have read and understood the pre & post-care treatment for PDO Threads. | |
|---|--|
| Patient Name: | |

| | • | | |
|-------|---|--|--|
| | | | |
| Date: | | | |

Dr. Moulton-Barrett's 2019 INFORMED CONSENT FOR PDO THREAD LIFT PROCEDURE

The PDO (polydiaxonone)Threat Lift and Smoothing procedure uses absorbable surgical sutures placed into the subdermal layer of the skin to initiate collagen production. The procedure can result in increased firmness and elasticity of the skin in the treated area. The PDO Lift procedure is effective in most cases, however there is no guarantee a specific patient will benefit from the procedure. The nature of cosmetic procedure may require a patient to return for numerous visits in order to achieve the desired results or to determine whether the treatment may not be completely effective at treating the particular condition.

Alternative Treatments: Alternative forms form of non-surgical and surgical treatment consist of surgical facelift, Nd:YAG laser, full-face C02 laser, dermal fillers, local muscle relaxer (Botox, Dysport, Xeomin), chemical peels or inaction. Every procedure involves a certain amount of risk. An individual's choice to undergo a procedure is based on the comparison of the risk to the potential benefit. Although most patients do not experience adverse complications, you should discuss your concerns and potential risks with your practitioner in order to make an informed decision.

Expectations: It is important to understand the results are not guaranteed, the results are not permanent and most likely the results will not be as dramatic as any facelift. The results therefore are individual as are a patient's satisfaction with the results and for that reason charges for the procedure are non-refundable.

Possible Risks and Side Effects Associated with PDO Threat Lift Procedure:

Discomfort: Some discomfort may be experienced during treatment.

Scarring: May cause scarring; sutures are inserted using a small needle, which must heal. A scar a scar at entry point may occur.

Bruising, Swelling, Infection: With any minimally invasive procedure, bruising of the treat area may occur along with the potential for swelling and is likely. Infection is rare, but with any injection or incision into the skin, the possibility exists.

Bleeding: You may experience some bleeding during the procedure. Hematoma or a small blood clot may occur and may require treatment by drainage. There is a higher risk of bleeding if you have taken any anti-inflammatory medications (Advil, Motrin, Aspirin, Ibuprofen) within the 10 days preceding the procedure.

Damage to Deeper Structures: Deeper structures such as nerves including but not limited to the facial nerve, blood vessels and muscles may be damaged during the procedure. The potential for this to occur varies according to the on the body the procedure is being performed. Injury to deeper structures may be temporary or permanent.

Allergic Reaction: Allergies to tape, suture material or topical preparations have been reported reactions may require additional treatment.

Anesthesia: Local topical anesthesia may be used and can involve risk of allergic reaction.

Pigmentation: There is a possibility of the treatment area becoming lighter or darker than the surrounding skin. This is usually temporary, but on rare occasions, may be permanent. Appropriate sun protection is important.

Partial Laxity Correction: PDO Lift may not correct all your facial laxity or sagging. **Delay Healing**: Complications may ensure as a result of smoking, using a straw, or similar motions. Smoking and similar actions are STRONGLY discouraged. Slight asymmetry, redness, visible sutures, suture breakthrough may require

additional treatment or the removal of the sutures.

Contraindications: Any known allergy or foreign body sensitivities to synthetic biomaterials.

Additional Procedures May Be Necessary:

In some situations, it may not be possible to achieve optimal results with a single PDO Lift procedure and other procedures may be necessary. Although peak results are expected, there cannot be any guarantee or warranty expressed or implied on the results that may be obtained.

The cost of the procedure may involve several charges for serviced provided. The total may include fees charged by Anew Medspa LLC, the cost of supplies, or laboratory tests if necessary. Additional costs may occur should complication develop from the procedure.

I understand that no warranty or guarantee of specific result has been made to me. I realize that, as in all medical treatment, complications or delay in recovery may occur which could lead to the need for additional treatment, and could result in a delay to one's normal daily activities and thus economic loss.

I understand my practitioner may discover other conditions which require additional or different procedures than planned treatment. I authorize my practitioner and his or her associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment.

I understand my cheeks/jowls/face/forehead/neck/ hands/ buttocks may not achieve the desired improvement anticipated.

I understand sutures may extrude, may have to be trimmed or may have to be removed in the future.

I understand the results may relax over time and additional procedures may be required.

I consent to the taking of photos before, during or after the procedure to document my progress.

The nature of the elective procedure, its risks and potential complications have been fully explained to me along with available alternative treatments and their benefits and risks has been discussed. I understand I have the right to refuse treatment. I have been instructed to and agree to abide by all safety precautions and post treatment instructions and have been given a written copy. I understand no refunds will be given for received treatment and no guarantee(s) have been given regarding the results.

I release the facility, medical staff, and other technicians from liability associated with this procedure. This consent is voluntarily executed and shall be binding on my spouse, relative, legal representatives, heirs, administrators, successors and assignees. I also certify that if

I have any changes in my medical history I will notify the Anew Medspa immediately. I also state that I read and write in English. If I have any questions or concerns, I will call Dr. Moulton-Barrett's office at 510 864-1800 or 925 240-8775.

| Patient Signature: _ | | _ | , | Witness: | | |
|----------------------|-------|-------|---|----------|------|--|
| | Date: | | | | | |

Dr. Rex Moulton-Barrett's Office Media Release Form

Authorization and Release Information

- I understand my photographs and or videos may be submitted to Dr. Moulton-Barrett and may be used in connection with publicizing and promoting Dr. Moulton-Barrett. I authorize Dr. Moulton-Barrett to use my name, treatment details and the before and after photographs as defined on this form.
- I hereby irrevocably authorize Dr. Moulton-Barrett to copy, exhibit, publish or distribute the photographs and/or videos for purposes of publicizing Dr. Moulton-Barrett's programs or for any other lawful purpose. These before and after photos may be used in printed publications, multimedia presentations, on websites or in any other distribution media. I agree that I will make no monetary or other claim against Dr. Moulton-Barrett for the use of the photographs.
- In addition, I waive any right to inspect or approve the finished product, including written copy, wherein my likeness or my photographs appear.
- I hereby hold harmless and release Dr. Moulton-Barrett from all claims, demands and causes of action which I, my heirs, representatives, executors, administrators or any other persons acting on my behalf or on behalf of my estate have or may have by reason of this authorization.
- I have read the authorization and release information and give my consent for the use as indicated above.

| Signature: | |
|---------------|--|
| Printed Name: | |
| Date: | |