Rex Moulton-Barrett, MD
3-11-2020

STANDARDIZED PROCEDURES FOR REGISTERED NURSES / PHYSICIAN'S ASSISTANT/ NURSE PRACTITIONER PERFORMING PROFOUND DERMAL & SUBQ THERAPY

I. POLICY

A. Circumstances under which the clincially trained RN/NP/PA may perform Profound.

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 Profound. A good faith history and physical will be completed prior to initiation of therapy. The patient's Profound Consent Form and Pre and Post Procedure Instruction Sheet will be discussed in-depth with and signed by the patient. (forms attached).
   - b. The RN or MD, PA, NP will then treat the patient with Profound Dermal or SubQ, providing that the patient meets patient criteria, and Medical History & Physical, Consent and Pre/Post instruction Sheet 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. The patient is informed that Profound microneedle thrapy is FDA approved for soft tissue electrocoagulation with a skin tighening.
   - e. It is the clinical choice of the MD/NP/RN/PA to select the appropriate SubQ versus Dermal or both and or location and numbers placed of points of treatemnt and position of micronedles for reduction of fat, skin tightening 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 " Profound Procedural Pricing 2020". The patient should be made aware that additional therapy in the future may be necessary in order to achieve the desired result and based on the providers best estimate of which / how many additional treatmentsmight 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 including lidocaine, marcaine and / or epinephrine.
   c. No NSA'a, no anticoagulation, bleeding disorders
   d. No recalcitrant or active herpes simplex
   e. Age < 18 and > 79 years of age
   f. 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 therapy
   i. Keloid formation and significant hypertrophic scarrring
   j. Accutane in the last 12 months
   k. Pacemaker / internal defibrillator
   l. Significant autoimmune collagen vascular disease

5. Precautions:
   a. Hands & Wrist : No Clinical studies to support beneficial use
   b. Face & Neck: Limited to Dermal Profound at this time: recommended location, 3-4 mm advancement placement, cross hatching, are referenced in a a document "Quick Refernce Guide" but may be individulalized with appropriate charting notes
   c. Body: Use of Dermal recommendations as set out in the Quick reference Guide.The use of Dermal on non head and neck will follow the same precautrions and oprovisions and setting as as for the head and neck
   c. Patients should be aware of potential adverse events following Radiofrequency heat energy micro needle insertion as well as thermal injury. These include redeness, swelling, bruising, infection, facial nerve injury, sensory changes, pigmenation changes, burns to the skin, scarring, acne or milia formation, pain and tenderness.
   d. Patients should be given to understand 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:

i. The administration of Profound Dermal a joint Candela and Syneron product which has obtained a 510K from the FDA for soft tissue coagulation and is

used off label in the tightening mild to moderate to facial, neck, body wrinkles and folds, such as jowls. The effect is from subsequent collagen remodelling which can take effect from 4-6 weeks contines for in excess of 6 months with most signifianct results seen at 12 weeks after therapy.

ii. Profound SubQ a joint Candela and Syneron product which has obtained a 510K from the FDA for soft tissue coagulation and is used off label in the reduction of body cellulite and subcutaneous fat associated with wrinkles and folds, such as lateral hips. The effect is from subsequent lipolysis and collagen remodelling which can take effect from 4-6 weeks and contines for in excess of 6 months with significant results seeen at 12 weeks after therapy.

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. Profound console, handpieces and cartridges can be stored at room temperature
   b. each cartridge is designated to an individual patient and is not shared, or reused with up to 150 insertions per cartridge
   c. Cartridges have a no - timed - out year shelf life.

2. Profound Tests:
   a. no testing is required. However, if ther is a real concern regarding pigmentary changes in a Fitzpatrick III-V consider a post auricular test with a single cartridge use and associated cost.
3. Pre-procedure Requirements:
   a. Good faith History and Physical obtained by MD, NP, PA
   b. procedural patient consent signed, dated and witnessed
   c. Profound pre and post procedure instructions sheet will be signed and dated by the patientreviewed by patient with adequate time to ask any questions prior to the procedure 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 Profound

D. **Dermal Treatment:**

Unlike SubQ treatement is indicated for mild to moderate rhytids

a. A procedure set up following The "Profound Check List of Medical Supplies" will be followed (see form enclosed labelled 'A' under supporting documents 'V')

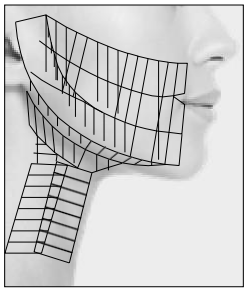
b. Patient will remove all make-up from treatment area.
c. Define areas to be treated.
d. Prep site with alcohol and betadine iodine or Puricin (a hypochlorous acid solution)
e. Verify the handpeice has been cleaned with wavicide wipe
f. Use treatment non latex sterile gloves for injection and if desired by patient 25 g needle with 0.1-0.2ml ml of lidocaine may be injected to site of pilot hole needle insertion
g. followed by use of tumescent narrow sydney Coleman fat grafting cannula for infiltration of local anestheic: ½ %lidocaine, ¼ % marcaine, 1: 200,000 epinephrine of sufficient volume to provide anesthesia to the treated area only 5-30mls total.
Alternatively a 3-5 multineedle mesotherapy needle on a 5 ml syringe may be used to achieve local anesthesia.

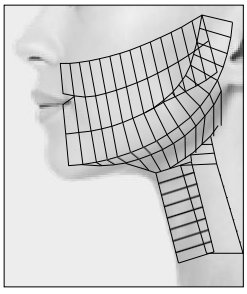
Face | Small Surface Area

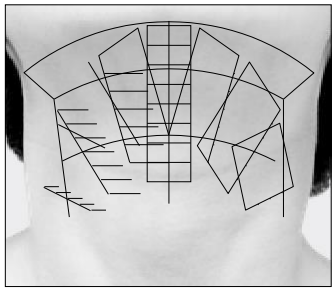
- 1% Lidocaine with Epinephrine 1:100,000
- 8.4% Sodium Bicarbonate (1:9)
- 5 cc syringes & 18-guage needles to draw up anesthetic
- 30-gauge, 4mm linear 3-port multi-needle injectors
- Upon infiltrating, mimic the Dermal cartridge needle deployment at a 25º angle. In this example, 0.4-0.5cc blebs/wheels of 1% Lidocaine with Epinephrine 1:100,000 was infiltrated every 1cm into treatment area.

f. Face: see Basic Treatment Parameters

Cartridge	Indication	Temperature[1]	Duration[1]	Depth	Spacing[2, 12]	Density[2, 12]
Dermal (25°)	Facial Wrinkles	67-68°C / 153-4°F	3 – 4 seconds	1 - 2 mm	3 - 4 mm	Assess baseline condition

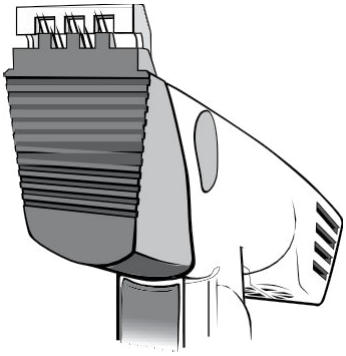


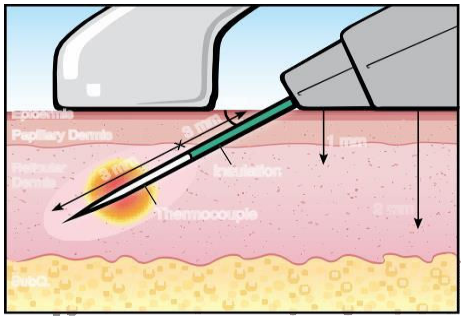




g. turn system on and select Dermal, allow for calibration to complete
h. connect electrosode cartridge to the treatment handpiece
i. select temperature to 68C and duration 4 seconds
j. aim hand piece into the air and hit trigger once and visually inspect the needles and coating to confirm no damage

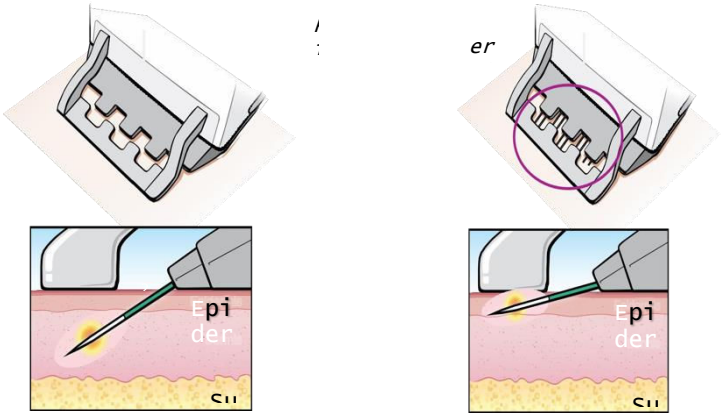
k. apply directly and firmly on skin and turn from standby to ‘Treat Mode’,





this ensures the cooling plate is in direct contact with the epidermis

- Protect the microneedles against longitudinal bending during treatment. Bent needles can lead to cartridge failure where the needles can no longer slide within the cartridge. In such an event, the system will automatically detect the failure, deactivate the affected needle-pair and issue a screen message to replace the cartridge.
- Do not move the treatment handpiece when the microneedles are deployed in the skin to avoid bending and/or damage to the tissue. If the microneedles need to be re-inserted, use the trigger to retract the needles, and re- insert again.
- Avoid applying excessive downward force in or towards areas where thin dermis and prominent boney structures are present. This will help ensure the microneedles are not damaged by the bone when deployed. Examples of such areas are the mandibular edge, and zygomatic bone.
- Prior to delivery of the RF, always verify that the microneedles have advanced completely into skin and that no portion of electrodes are visible superficially.



Proper Insertion Incorrect Insertion

- You must visually inspect the microneedle insertion on every deployment. The electrodes must be inserted evenly and at consistent depth.

- If the electrodes are not correctly deployed and fully inserted into skin at the correct depth, do not apply treatment.
- Click twice on the trigger to activate the microneedles
- Leave the applicator's cooling plate on the skin for 2-4 seconds beyond the completion of each treatment application.

j. Horizontally advance 6mm following the pattern aboveand follow from k. onwards again repeat or cross hatching depends on the severity of the skin

k. The treatment dose is controlled by using 3 primary parameters:

Lesion Temperature: 67ºC

Treatment Duration: 3-4 seconds

Treatment Density: spacing between successive insertions based on Provider assessment of anatomical location and assessment of severity of baseline condition.

Baseline Condition	Treatment Duration	Treatment Density/Spacing	Assessment Considerations
Mild to Moderate	3 seconds	• 4mm (about width of cold plate) • 1 pass	• Adequate to thin dermal tissue. • Rhytids may be more localized, superficial, with a few that may be deep.
Moderate to Significant	3-4 seconds	• 2-3mm • 1 pass	• Thick dermal tissue, increased volume. • Rhytids extensively distributed, deep, & dense.
Mild to Moderate	4 seconds	• 4mm • Crosshatch (Additional treatment passes may be considered for more severe baselinecondition)	• Grade I-II Cellulite: dimples are subtle & more superficial, dimples resolve once in prone position. • Mild SubQ volume, with or without adipose tissue herniation.

i. When the treatment duration has elapsed, the microneedles will automatically retract. If, for any reason, the microneedles need to be retracted duering treatment, release the trigger. Alternatively, the microneedles can be removed from the skin by withdrawing the treatment handpiece in the opposite direction of the needles insertion.

ii. Visually inspect the treatment area. Note any abnormal skin blanching which can be a sign of superficial burns.

iii. Minor beading of blood at the insertion location is expected and somewhat desirable as it gives a visual indication of the insertion location from which the distance to the next application can be gauged. If bleeding occurs, pressure applied for several seconds with sterile gauze may be required.

E. **SubQ Treatment:**

Unlike Dermal the treatment is indicated for mild to moderate cellulite

a. A procedure set up following The “Profound Check List of Medical Supplies” will be followed (see form enclosed labelled ‘A’ under supporting documents ‘V’)

b. Patient will remove all make-up from treatment area.

c. Define areas to be treated.

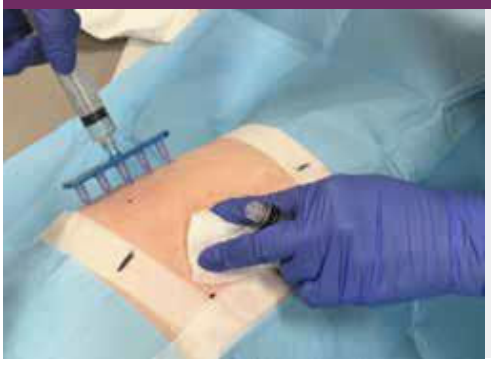
d. Prep site with alcohol and betadine iodine or Puricin (a hypochlorous acid solution)

e. Verify the handpeice has been cleaned with wavicide wipe

f. Use treatment non latex sterile gloves for injection and if desired by patient 25 g needle with 0.1-0.2ml ml of lidocaine may be injected to site of pilot hole needle insertion

g. followed by use of tumescent narrow sydney Coleman fat grafting cannula for infiltration of local anestheic: ½ %lidocaine, ¼ % marcaine, 1: 200,000 epinephrine of sufficient volume to provide anesthesia to the treated area only 10-60mls total/side.
Alternatively a 3-5 multineedle mesotherapy needle on a 5 ml syringe may be used to achieve local anesthesia.

Cellulite | Large Surface Area



- 0.5% Lidocaine with Epinephrine 1:200,000
- 8.4% Sodium Bicarbonate (1:9)
- 10 cc syringes & 18-guage needles to draw up anesthetic
- 30-gauge, 6mm linear 5-port multi-needle injectors
- Upon infiltrating, mimic the SubQ cartridge needle deployment at a 75° angle. In this example, 1.0cc of 0.5% Lidocaine with Epinephrine 1:200,000 was infiltrated every 1-2cm into treatment area.

h. turn system on and select Dermal, allow for calibration to complete

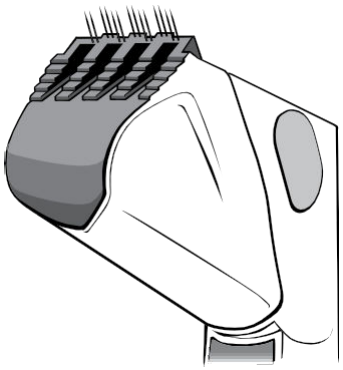
i. connect electrosode cartridge to the treatment handpiece

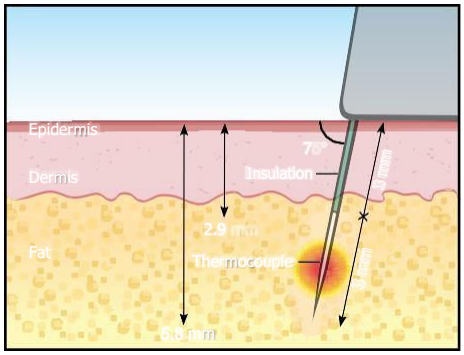
j. select temperature to 68C and duration 4 seconds

Cartridge	Indication[12]	Temperature[1]	Duration[1]	Depth	Spacing[2, 12]	Density[2, 12]
SubQ (75°) *Fig. C*	Cellulite	67°C / 153°F	4 seconds	2.9 - 5.8 mm	3 - 4 mm	Assess baseline condition

k. aim hand piece into the air and hit trigger once and visually inspect the needles and coating to confirm no damage

l. apply directly and firmly on skin and turn from standby to 'Treat Mode',





m. Horizontally advance 6mm following the pattern aboveand follow from k. onwards again repeat or cross hatching depends on the severity of the skin

n. The treatment dose is controlled by using 3 primary parameters:

Lesion Temperature: 67ºC

Treatment Duration: 3-4 seconds

Treatment Density: spacing between successive insertions based on Provider assessment of anatomical location and assessment of severity of baseline condition.

Baseline Condition	Treatment Duration	Treatment Density/Spacing	Assessment Considerations
Mild to Moderate	4 seconds	• 4mm • Crosshatch (Additional treatment passes may be considered for more severe baselinecondition)	• Grade I-II Cellulite: dimples are subtle & more superficial, dimples resolve once in prone position. • Mild SubQ volume, with or without adipose tissue herniation.
Moderate to Significant	4 seconds	• 2-3mm • Crosshatch (Additional treatment passes may be considered for more severe baselinecondition)	• Grade II-III Cellulite; dimples are deep, globally distributed, & do not resolve in prone position. • Substantial SubQ volume, with moderate to severe adipose tissue herniation.

o. When the treatment duration has elapsed, the microneedles will automatically retract. If, for any reason, the microneedles need to be retracted duering treatment, release the trigger. Alternatively, the microneedles can be removed from the skin by withdrawing the treatment handpiece in the opposite direction of the needles insertion.

i. When the treatment duration has elapsed, the

microneedles will automatically retract. If, for any reason, the microneedles need to be retracted duering treatment, release the trigger. Alternatively, the microneedles can be removed from the skin by withdrawing the treatment handpiece in the opposite direction of the needles insertion.

ii. Visually inspect the treatment area. Note any abnormal skin blanching which can be a sign of superficial burns.

iii. Minor beading of blood at the insertion location is expected and somewhat desirable as it gives a visual indication of the insertion location from which the distance to the next application can be gauged. If bleeding occurs, pressure applied for several seconds with sterile gauze may be required.

3. Post treatment – cleanse site with alcohol and bacitracin ointment.
4. <u>Patient Education:</u>
   a. See Profound 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.
   h. Immediately following treatment, cleanse the treated area with sterile NS and gauze to remove dried blood and residual antiseptic.
   i. Apply Provider choice of healing dressing, such as a thin coat of antibiotic ointment or Aquaphor® equivalent to the treated areas as per standard medical procedure. The treated area should be kept as hydrated as possible for oneweek post treatment and should have a consistent glazed-like appearance at all times.
   j. The treated area should be cleansed 3-5 times daily with tepid water and gentle cleanser prior to each reapplication of the healing dressing. Avoid wash cloths, harsh irritants, and scrubs. Pat dry and do not rub.
   k. Patients should avoid excessive sun exposure on the treatment area and use a sunblock (SPF 30+) for one month following the procedure.
   l. Apply ice pack to reduce swelling and discomfort.
5. <u>Follow-up:</u>
   a. a routine follow-up should be made 10 days after the procedure

. b. 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. Treatment Sheet to be completed location, temperature, duration, cross hatching, advancement distance ie 3-4mm
   d. Map of specific areas treated and cartridge placement and whether or not lidocaine was injected and amount injected
   e. Patient response to treatment.
   f. Post procedure note 10 days

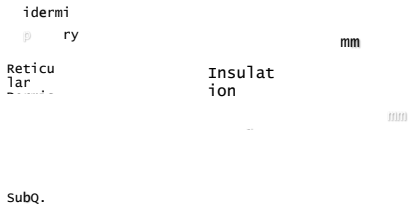
III. REQUIREMENTS FOR RN

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 cannnula followed by formal hands on training in Profound 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 Profound 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 Profound Drmal and SubQ which are currently being used in the Alameda and or Brentwood offices of R. Moulton-Barrett,MD.
   b. Profound 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

A. Dr. Moulton-Barrett's Pre Profound Medical Supplies Check List

1. Tongue depressors
2. Marking pen
3. Non sterile boxed gloves
4. Multi-needle plate injectors (5 port linear and 3 port linear)
5. Local (Physician's choice) Typically Mix of: 1/2% Lido w/epi. 1:250,000 and 1/4% Marcaine in NS
6. Injectable volume: 60mls face (30ml / side), 300mls for thigh laterally (150ml/side)
7. 25 g 1/12 inch needle with 10cc syringe for face and ports and 60 cc Syringes for body
8. small tumescent RL bag for larger volume,
9. Mentor one way valve kit
10. 18 Gauge needles, small fat grafting tumescent needle
11. Sterile U Drape
12. Gauze (4x4)
13. Plastic Kidney Basin
14. Alcohol wipes
15. Betadine iodine solution, box of sterile gauze for application
16. Soft tissues and paper towels
17. Sterile gauze
18. Hair cap or head band
19. Sterile Gloves
20. Sterile Gauze moistened in NS for cooling
21. Antibiotic ointment and Aquaphor
22. Sunscreen with at least SPF 30
23. Topical anesthetic
24. Patient chart: intake form, pink medical history and physical, informed consent, treatment record
25. Camera for photo documentation with standard blue background
26. Bacitracin ointment
27. Ice pack for face
28. ABD's and Surginet for thighs

B. Profound Procedural Check List

1. Patient applies moisturizer one day before to area to be treated
2. Signed and dated good faith history and physical by MD, or PA
3. +/- oral antibiotics ideally taken 20 minutes prior to case and pain medication
4. Photos obtained with name
5. Signed and dated Consent, BP and PR documentation, Post-Instruction Sheet, F/U appointment
6. Markings
7. Inject ports for local and then prep and drape split sheet
8. Attach at front of unit correct handpiece for therapy: S/Q versus Dermal each have cradle, align dots and to attach rotate to right clockwise
9. using non sterile boxed gloves on hands attach cartridge to handpiece
10. Remove red security tab from the cartridge before use (Dermal flat face, SubQ rounded angled face)
11. Verify the needles are fully retracted
12. Verify the homing pin is in the correct position with protruding from the side towards the handle
13. Place cartridge on handpiece
    (Dermal handpiece has cooling plate, cartridge 5 sets needles, 25 degrees)
    (SubQ handpiece no cooling plate, cartridge 7 sets of needles, 75 degrees)
14. Position the console for good working distance and position operator stool
15. Lock wheel base lever
16. Turn on main power switch at rear of console then turn on the on/off switch at front console
17. Settings: auto self-check: red / green LED handpiece flashes, then handpiece selection on screen appears
18. Press Dermal or SubQ on screen and will remain in Standby mode
19. Pre-Treatment SetUp Touch Screen: Choose area, see Quick Reference Guide: Temp & Time
    67C and 4 seconds for Dermal, 67C and 4 seconds SubQ
20. Verify needles at correct angle with single click of handle
21. If using dermal verify cooling plate is cold and green snowflake is showing on screen
22. When ready press green far lower right corner of screen
23. During therapy green bar from left to right and system beeps
24. Move forwards 3-4mm after each insertion (for Dermal over the cooling plate)
25. At end of therapy note number of insertions, to clear press ‘New Session’, If changing cartridges turn off console first, double side press to remove cartridge.
26. SetUp for time, date, audio, brightness, screen saver at 10 minutes from treat to standby, calibreate touch, auto start off ie 2 triggers or autostart on: single trigger to deploy, accept
27. If system not responding correctly Under SetUp, Touch Calibrate, ‘Start calibration’

C. Dr. Rex Moulton-Barrett Before and After Instruction for Profound Treatment Updated 3/2020

PRETREATMENT INSTRUCTIONS

1. pre-treatment you moisturize skin in the morning and evening, and drink at least 8 glasses of water per day to completely hydrate your skin and optimize treatment results
2. You may be provided an antiviral prophylaxis 1 day prior to the Profound treatment and to continue after the treatment
3. Topical retinoid therapy / Obaje Nu-Derm should be discontinued 3-4 days prior to treatment
4. Avoid any prolonged exposure to the sun, if you must be in the sun use a zinc oxide sunscreen of at least SPF 30+
5. Remove all substances from the intended treatment area, including topical anesthetics, hairspray, gel, makeup, lotions, deodorants, self-tanning products and ointments. Do not use flammable products in the vicinity of the Profound device.

INTRAOPERATIVE CARE

Test spot areas may be performed to gauge appropriate endpoints and optimum treatment parameters

POST-TREATMENT CARE

1. Immediately after treatment, patients experience:
   - redness is a clinical endpoint confirming therapy was given
   - bruising may last for 3-5 days, however for more aggressive treatments this may last longer
   - swelling may start within 2-10 minutes and may last 3-5 days
   - crusts at the insertion site of the needles may slough off in 12-48 hours
   - pain may be none to moderate in the first 24 hours, avoid non steroidals: ie no aspirin, no advil, no aleve
   - tenderness to skin touch may last up to 14-28 days
   - itching, tingling or reduced sensation may be experienced for up to 20 days
   - pigmentation changes may include decreased or increased pigment especially in darker skinned patients
2. Cool compresses, gel packs shold be applied to the face for 30+ minutes after treatment + 24 hours
3. Before discharge topical ointment or Aquaphor will be applied to the face
4. Resume usual skin care products and make-up after 3 days from therapy depending on the skin reaction
5. There are no restrictions on bathing except to treat the skin gently, avoid scrubbing or trauma to the treated area, as if you had sunburn.
6. Wash treated area with simple soap and water 3times daily and immediately reapply Aquaphor for 5 days
7. Sleep with slightly elevated head first night
8. Please change pillowcase each night or use a clean towel each night to protect bedding
9. Please avoid sleeping with pets for first 48 hours
10. Avoid sun exposure to reduce the chance of hyperpigmentation (darker pigmentation).
11. The use of a zinc oxide sun block SPF 30+ at all times throughout the course of treatment is recommended.
12. Clinical testing suggests that wrinkle improvement can continue to develop for 3 to 6 months following treatment. Clinical literature suggests that the dermal remodeling process following non-ablative RF treatments can continue for 6 to 12 months. Retreatment with the Profound system is not recommended prior to 6 months following the initial treatment.

Call Dr. Moulton-Barrett's office at 510-864-1800 (Alameda) or 925-240-8775 (Brentwood) with any questions or concerns.

By signing below the patient acknowledges they have received and understand the above instructions

Signed : **dated:**

Witnessed: **dated:**

Consent For the Office of Dr Rex Moulton-Barrett for Profound Therapy

Updated 3/2020

Dr Moulton-Barret or his designated employee representative has explained to me that I am a good candidate for Profound treatment and that although the treatment has been shown to be highly effective, no guarantees can be made that I will benefit from treatment.

Contraindications to this procedure include but are not limited to pregnancy, pacemaker/internal defibrillator, allergy to lidocaine, epinephrine, Marcaine, active skin infections, autoimmune collagen vascular disorders, recurrent herpes simplex to the skin in the planned treatment area without oral suppression medication, keloid formation to the skin, significant hypertrophic scarring, accutane in the previous 12 months, anticoagulation therapy and or a significant bleeding tendency.

I understand that the most common side effects and complications of this laser treatment are the following:

1. Pain. The sharp, burning sensation of Microneedle and RF emission may produce a moderate amount of discomfort. Topical anesthetics, anesthetic injections, may be used to block the pain during the procedure.
2. Prolonged skin redness. The treated areas may initially appear red in color. The redness will fade over the following couple of days.
3. Skin darkening (hyper-pigmentation). “Tanning” of the skin can occur in the treated areas and will eventually fade within a few months. This reaction is more common in patients with olive or dark skin tones and can worsen if the treated area is exposed to the sun.
4. Skin lightening (hypo-pigmentation). Light spots can appear in an area of skin that has already received prior treatment or can be a delayed response to the treatment. The pale areas can darken or re-pigment in several months, but could be permanent.
5. Scarring. The risk of this complication is minimal, but it can occur whenever the skin’s surface is disrupted. Strict adherence to all advised postoperative instructions will reduce the possibility of this occurrence.
6. Infection. A skin infection in the postoperative period can result. This risk is minimized by the appropriate use of antibiotics and good skin care, including frequent hand washing.
7. Allergic reaction. It is possible that an allergic reaction to an anesthetic, topical cream or oral medication can occur.
8. Acne or milia formation. Flare-up acne or formation of milia can occur in the postoperative period.

By providing my signature below, I, _____ acknowledge that I have read and understood all of the information written above as well as that contained within the information sheet. I feel that I have been adequately informed of my alternative treatment options, the risks of the proposed surgery, and the risks of not treating my condition. I hereby freely consent to the laser surgery to be performed by Dr Moulton-Barrett’s or his trained and designated employee RN, PA and or NP and authorize the taking of clinical photographs to document my clinical process.

_____ _____

Patient Signature / Date Witness Signature / 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: _____ _____ _____

History and Physical Intake Form

Name:

Date:

Sex:

Age:

Fitzpatrick Skin Type:

Reason for treatment: skin laxity and or cellulite therapy and location:

Last exposure to UV Light:

Ethnicity:

Passive tan:

Self-tanning lotion:

Medical History

Pacemaker / defibrillator/ metal implants

Active skin infection

Skin disorders including keloids and HTS

H/O Skin cancer or premalignant moles

H/O Bleeding Disorder, NSA in last 10 days, Anticoagulants

Severe Medical Condition: CHF, transplant / immunosuppressant meds, steroids, autoimmune

HSV

Pregnancy/Lactation

Tattoo

Medication taken:

Allergies:

Comments:

Dr. Moulton-barrett's Profound SubQ and or Dermal Treatment Sheet

Area(s) Treated	Dermal	SubQ	Pulse Duration	Temperature	Passes	XHatch
_____	☐	☐				
_____	☐	☐				
_____	☐	☐				

Date of Service: ____ _____ 20___

Treating Provider: _____ RN, PA, NP, MD