

**STANDARDIZED PROCEDURE FOR REGISTERED NURSES(RN) AND MEDICAL ASSISTANTS (MA) / FRONT OFFICE (FO) PERFORMING COOLSCULPTING**

**I. POLICY**

**A. Circumstances under which the RN may perform COOLSCULPTING(CS)**

1. Setting:
  - a. Aesthetic Medicine Program, in designated Cool Sculpting Room
2. Applicable Device:
  - a. Once clinically trained and certified upon completion and having passed the qualifying on line examination by Zeltiq, Inc , the RN can treat patients using the the CS Devise.
  - b. CS is a class II devise and therefore the placement and removal of devise on/from the skin may only be performed by an Registered Nurse(RN), Physician's Assistant (PA), Nurse Practitioner (NP) or Medical Doctor (MD). Patient scheduling, education and comfort management during the procedure and light massage may be performed by a medical assistant/front office staff. FO staff with a letter of verification of training personally by the MD and witnessed by the MD of their proficiency are allowed to participate equivalent to a certified MA regarding the above.
  - c. CS is used for the removal of unwanted excessive fat in a patient not over 20% greater than ideal body mass ( ie. 20%> weight for BMI 25 for that height), ie:

<u>height feet</u>	<u>weight &lt; than</u>
5,0	153
5, 1	158
5,2	163
5,3	169
5,4	174
5,5	181
5,6	185
5,7	192
5,8	196
5,9	202
5,10	208

3. Supervision:
  - a. Physician, PA or NP will assess patient and/or review chart prior to treatment should there be any question regarding the patients suitability for CS. This will involve a comprehensive initial health risk assessment followed by a care plan that addresses goals and objectives, services and benefits provided, and measurable outcomes.

- b. No direct MD or RN supervision required during treatment.
- c. MD will be available for questions or concerns in person or by phone.
- d. All charts will be reviewed and signed by the MD within 10 days of laser treatment
- e. All consent forms must be signed by the RN prior to the onset of treatment and then counter signed by the MD according to 'd.'

4. Patient Conditions:

- a. Consultation regarding patient's chief complaint completed. Specifically location of unwanted fat
- b. Ensure patient is a candidate for CS by discussing precautions below.
- c. Relative contraindications include:
  - Is using anticoagulants and or non-steriodals
  - Pregnancy
  - > than 20% above ideal body mass, see above
  - Recent or active use of accutane
  - Cryogloulinanemia, cold agglutinins, paroxysmal cold hemagglutinins
- d. Patient is aware of potential risks, such as pain which may last several weeks
- e. Patient understands that results are not immediate and may take several months
- f. Patient may understands that multiple treatments may be required to obtain desired result for a given area, the number of which and the frequency of which as well as the cost including a package price is to be determined and documented in the chart prior to the onset of the first treatment
- g. Informed consent given and consent form completed.
- h. for MimiCool: clean shaven,

## II. PROTOCOL

### A. Definition:

- 1. CS is the removal of unwated fat by crypolipolysis through apoptosis

### B. Assessment:

1. Subjective:

The patient complains of unwanted fat and has had a relevant medical history obtained inlcuding but not limited to contraindications for the procedure

2. Objective:

Patient presents with unwanted fat, and has had a good faith relevant physical from which there are no contraindications ot the procedure.

### C. Plan:

1. Preparation for treatment:

- a. Patient to remove any lotions, creams and deodorant from area to be treated.

- b. Ideally the patient should avoid non steroidal use for 10 days prior to the treatment

2. Treatment:

- a. Hand piece to be cleaned with isopropyl alcohol or Saniwipes and dried off with towel prior to each treatment.
- b. Input patient data into computer of CS
  - Photos all 6 positions, input into the computer
  - Witnessed consents obtained
- c. Start treatment at the given parameters unless reasons are noted to start at higher settings (such as pop offs). Parameters vary according to location of the pannus and body type. Parameter sheet is discussed and provided at training/educational class.

Body Treatment Check List:

1. Patient has been marked with pen using plastic template design patient has been positioned on reclining chair
2. CS machine has been turned on
3. CS applicator is chosen appropriate to template design
4. Applicator connector into connector plate, turn lock lever 180 degrees to right
5. CS applicator placed within support control arm
6. Place liner on the applicator
7. Insert Coolcard into applicator slot
8. Applicator is authenticated, choose 'cooling only 60 minutes', 'gelpad' verification and press 'next'
9. CS liner gelpad has been placed on the skin, if applying over umbilicus, place small piece of gelpad in umbilicus
10. Adjust vacuum at '60' and turn on to activate vacuum
11. Apply vacuum to gelpad, if no leaks press cool 'start', then have 10 minutes to hit cancel button
12. Automated timer actuates and 3,2,1 minute beeper warning at 57-60 minutes
13. At 60 minutes, grasp applicator and turn off and remove
14. With gloves on remove and wipeoff the gelpad area and commense manual hand massage for 1 minutes aggressive and 1 minute light revascularization massage.
15. After completion above may transport patient away or commense next cycle
16. After completion remove plastic sleeve and clean with Saniwipes

Submental Fat Check List:

1. Place Mini Cool applicator into Ap adaptor, lock 180 degrees
2. Place card in either Ap adaptor or applicator head
3. Mark out apex of submental fat, sides, submental creas and thyroid lamina in standing position
4. Mark with non permanent pen the outside of template
5. Place plastic sheath over the the head of applicator

6. Smooth out wrinkles and fold over sides
7. Place applicator in control arm with 90 angles for support
8. Place patient's head in blue stability pillow and inflate to comfort in semi sitting position
9. Verfiy the applicator head rotates exactly onto the neck
10. Start machine, choose yes for has gel, suction 50 mmHg
11. Use perforator tool to puncture liner, place gel trap extractor in center of base of suction head of applicator
12. Apply propylene glycol to skin with tongue blade from syringe 1cm outside markings
13. Apply applicator head with suction to neck and start cycle
14. Inflate small pillow under the applicator head on chest for comfort
15. At end of 45 minute cycle, turn off cycle
16. Remove applicator head
17. Remove excess propylene glycol
18. Commense massage gently in circular motion 1 minute and vertical 1 minute
19. Remove applicator head with head hook
20. Clean head assembly with Saniwipes

e. Monitor for response of patient's skin and increase parameters only if indicated.

f. Expected responses:

- Erythema
- hardending

Note: These expected skin responses should resolve within several hours and 3 minute massage will help resolve any contour irregularity as well as help in increasing fat dissolution.

3. Patient Education:

- a. Any prolonged pain, redness and swelling should be reported to RN, PA, NP or MD.
- b. Any severe pain reaction which continues more than a fe w days should be reported immedicately to Zeltiq
- c. patient given post procedure instruction sheet

4. Follow up:

- a. Subsequent treatments to the same area no less than 4-6 weeks apart . A maximum of 2 treatments can be peformed to the same area.
- b. Other areas can be treated simultaneously or at convenient timing thereafter without restriction.

5. Documentation: The following information must be recorded in patient's chart with each treatment.

- a. Patient's verbal response to last treatment (if any).
- b. Area treated.
- c. Photos taken using standardized positioning 1-4 and entered into the computer not greater than the end of the 4 week period
- c. Parameters used.

- d. Patient's response to treatment.
- e. Any conditions or problems that may have arisen prior or during treatment, such as: tanned skin and sensitivity. Note: If infection is present, no treatment should take place.
- f. Procure physician's review and sign-off on patient charts within 10 days post treatment.

### III. REQUIREMENTS FOR RN and For Front Office / Medical Assistant

- Education:**
1. Graduate of RN program with current California RN license.
  2. Certified Medical Assistant or Certified with letter of verification from MD regarding proficiency and in office training as medical assistant
  3. Completion Zeltiq In service course and passing training examination: for RN & medical assistant /front office staff

**Training:**

1. Formal Cryolipolysis education and training covering the biophysics and the safe use of CS training of choice. Successful completion of basic training program devoted to the principles of cryolipolysis, instrumentation and physiological effects and safety requirements. The initial program should include clinical applications of various applicators in the particular locations, how to place successfully and using the protective coolsculpting pad, positioning the patient, Card insertion and actuation of the treatment using the hand held or unit control pad, turning off the device and hands-on practical sessions with CS with the appropriate therapeutic delivery systems.2.
2. Experience: No previous experience necessary prior to the above training. See Initial Evaluation below.
3. Initial Evaluation: Successful completion of appropriate CS training.
4. Ongoing evaluation:
5. Random MD visits during treatment sessions. MD will observe 1 treatment quarterly, specifically:
  - a. Safety and efficacy issues
  - b. Contraindications and Precautions
  - c. Complications and side effect
  - d. Managing complications and adverse events (side effects)
  - e. Consultation, Assessment, and Patient education
  - f. Safe application of CS
  - g. Formal completion on on ine inservice and vendor presentation followed by observed CS by qualified MD,PA or NP
6. Formal re-education CS by product representatives to increase knowledge, experience and proficiency in the proper administration of the product.

### IV. DEVELOPMENT OF PLAN

The Medical Director and Administrator have developed this Standardized Procedure and Protocol Policy (standing order) for the administration of CS 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  
Medical Director

Date: 12-14-2015

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Administrative Signature

Date: