

# ***POSTPARTUM FOLLI-CURE THERAPY PROTOCOL***

## **Treatment Need:**

Approximately 90% of the average females hair is growing (Anagen Phase) at any one time, while the other 10% enter a resting phase (Telogen Phase). Every two to three months the resting hair falls out and allows new hair to grow in its place. *Telogen effluvium* is the excessive shedding of hair that occurs one to five months following pregnancy. This is not uncommon, affecting somewhere between 40 to 50% of women.

## **Treatment Title:**

This treatment, Folli-Cure Therapy, (Laser Therapy for hair growth) is an approved FDA therapy as of 02/2007. The treatment is not an “off label” manner use. It involves the use of a low level laser or Photomedicine to slow down loss of hair and also regrow hair on the scalp. This protocol is designed to treat postpartum hair loss patients.

<b>Condition</b>	<b>Treatment of Intervention</b>
Postpartum hair loss	Procedure: Postpartum <i>Folli Cure</i> ™ Therapy Device: Luminary Industries HALO Elite Laser

## **Treatment Type:**

Interventional

## **Treatment Design:**

A treatment provided for females who meet all parameters of the inclusion criteria, and who do not meet any of the exclusion criteria, with no other specified demographic or requirement. The Participants will undergo Postpartum *Folli Cure* Therapy treatments - low level laser therapy or Photomedicine.

## **Introduction:**

The treatment intervention device to be used for this therapy is the HALO Elite. This is a stationary, non-invasive, red and infrared, low energy, non-heating therapeutic laser, as defined in 21 CFR 890.5500. Because they are low power lasers, they have been determined non-significant risk devices. Furthermore the laser classification is that of 3A(R) and is considered a cosmetic device only.

## **Background and Rational:**

Laser therapy or Photomedicine is being successfully used to treat many conditions including Oral Mucositis, Androgenetic Alopecia, Diabetic Ulcers, TB, Acne and Fibroblast Compromised Tissue – wrinkles.

The use of low levels of visible or near infrared light for reducing pain, inflammation and edema, promoting healing of wounds, deeper tissues and nerves, and preventing cell death and tissue damage has been known for over forty years since the invention of lasers.

Unlike other medical laser procedures, Low Level Laser Therapy (LLLT) is not an ablative or thermal mechanism, but rather a photochemical effect comparable to photosynthesis in plants whereby the light is absorbed and exerts a chemical change.

The phenomenon was first published by Endre Mester at Semmelweis University; Budapest, Hungary in 1967 a few years after the first working laser was invented. Mester conducted an experiment to test if laser radiation might cause cancer in mice. He shaved the hair off their backs, divided them into two groups and irradiated one group with a low powered ruby laser (694-nm). The treatment group did not get cancer and to his surprise, the hair grew back more quickly and thicker than the untreated group. He called this “Laser Biostimulation or Photomedicine”.

Laser Therapy works by activating transcription factors and upregulating protective proteins which are anti-apoptotic, and generally promote cell survival. The molecular and cellular mechanisms LLLT suggest that photons are absorbed by the mitochondria; they stimulate more ATP production and low levels of ROS, which then activates transcription factors, such as NF- $\kappa$ B, to induce many gene transcript products responsible for the beneficial effects of Laser Therapy. ROS are well known to stimulate cellular proliferation of low levels of laser therapy.

Laser light has been shown to stimulate cellular metabolism while dramatically increasing blood supply to targeted areas. This unique combination is necessary to heal or restore damaged hair follicle cells. Laser therapy has been shown to increase capillary diameter by 54% and increase lymphatic drainage. This increase is crucial to promoting healthy hair growth by bringing essential nutrients into the hair follicle while allowing the follicular cells to remove detrimental waste products such as DHT.

The HALO Elite uses laser diodes which increase circulation and cellular metabolism. The process of cells absorbing and utilizing light energy is known as photobiomodulation. Very specific monochromatic laser light in the proper dosage (650 nm @ 5mW) will massively nourish individual cells promoting cellular metabolism, health and growth.

Collective scientific theory is that laser therapy stops and or reverses the cycle of follicular miniaturization by stimulating the follicle via cellular energy transfer.

Laser therapy increases capillary capacity and blood flow which delivers cellular nutrition. The higher amount of energy delivered to the scalp and hair cells via laser therapy enables increased nutrient absorption and thus an increase of stronger, thicker and healthier hair.

## **Folli-Cure Therapy**

Laser therapy has been shown to seriously reduce the effects and or formation of Oral Mucositis in bone marrow transplant patients. Laser therapy accomplishes this by minimizing the breakdown of the tissue and rapidly increasing the healing process through cellular stimulation and increased mitochondrial production of ATP (cellular energy). The same process has brought about the FDA approval for laser therapy and the treatment of wounds.

Laser therapy has proven its effectiveness in combating hair loss via two mechanisms. First is the prevention of hair loss (compromised or damaged hair follicles) by bringing the hair follicles back to health through improving the mitochondrial respiratory chain. This keeps current terminal hairs healthy and improves their overall thickness and tensile strength. The Anagen Cycle becomes stronger and often times longer in duration (hair growth cycle). Many follicles that are kept in Telogen/Catogen hair cycles are brought into the growth cycle (Anagen) thus preventing abnormally long shedding periods. The second process is increasing the speed at which hair grows or re-grows. Laser therapy increases cellular proliferation via the increased cellular health and ATP production. The longer Anagen cycles and return to maximum healthy follicles allows for a much faster and thicker hair regrown cycle. Folli-Cure therapy also has been shown to increase capillary blood flow by 54% thereby bringing oxygen/nutrient rich blood to the follicles while removing waste products.

In over 3,500 papers, low level laser therapy has shown no side effects. Low level laser therapy cannot cut, burn, or harm the skin – there is no thermal component. High powered lasers, IPL system, hair removal system operate at high power and are not to be confused with low level lasers.

## **Treatment Parameters:**

Adults who are 18 years old or older, who have experienced postpartum hair loss. All prospective clients must meet all requirements of the stated inclusion criteria and must not meet any of the disqualifiers in the stated exclusion criteria in order to receive treatment. As well, safeguards have been built into this protocol in the inclusion and exclusion criteria to protect the rights and welfare of these subjects.

## **Inclusion Criteria:**

- Participant must be 18 years or older or have an authorization form provided by a parent or legal guardian.
- Participant must have experienced visual and or significant postpartum hair loss.

## **Exclusion Criteria:**

- Patients with Alopecia Totalis or Alopecia Universalis – non postpartum related.
- Active cancers of any type on treatment area (scalp).

## **Guidelines for Evaluation:**

Evaluations are to be made before client initiates hair restoration therapy. Evaluation must be made on basis of inclusion and exclusion criteria with the two most significant guiding factors being client safety and efficacy of therapy for client.

## **Treatment Plan:**

### *Pre Screening:*

All persons having voluntarily made an appointment with HALO Elite provider will be given a Pre-Screening form to fill out. The Pre-Screening forms will ask questions relative to the subjects past and present health conditions. The criteria for inclusion and exclusion are included on this form as well. All clients will undergo individual screening using a digital microscopic camera.

### *Treatment:*

Upon entering the treatment room the client will be asked to confirm or qualify answers or statements provided on the Pre-Screening form. If there are any conditions present which are exclusionary due to contraindications or a failure to meet the necessary inclusion criteria or if any one of the exclusion criteria are met, the client will not be treated. If conditions are not in conflict with known contraindications, and the client is in compliance with all of the inclusion and exclusion criteria, he or she will receive the therapy.

### *Safety:*

The areas where the laser will be used should be clean from hair products and oil/dirt. The client will be required to wear CE marked safety spectacles.

## **Technical Specifications of HALO Elite**

The HALO Elite Laser System is a stationary non-invasive, low energy, non-heating red therapeutic lasers as defined in 21 CFR 890.5500. The laser incorporates Gallium Aluminum Arsenide (GaAlAs) laser diodes delivering a total output power of 5 milliwatts (mW) at 650nm. This device uses only true red laser diodes – Grade A quality and APC Powered with medical quality specs. The diodes are internally cooled for consistent therapeutic results and the treatment area of the patient is also kept cool to prevent perspiration which can reduce therapeutic efficacy of the treatment/therapy by up to 75%. The Halo Elite has a total of 171 lasers set within scalp shaped device for proper therapeutic alignment.

## **Laser Application Duration Protocol**

The participant is to receive 12.5 minute treatments. The treatment duration is 4 months.

### **Month 1:**

- One treatment / week

### **Month 2:**

- One treatment every other week

### **Months 3 - 4**

- One treatment / month

## **PRECAUTIONARY PROTOCOL TREATMENT PLAN**

Clients with some health conditions may still have laser therapy. The treatment must follow the precautionary protocol plan.

1. **Cancer** - the same treatment times as a regular client with the following changes and or precautions
  - No laser therapy over any active cancerous site

### **Potential Risks:**

The likelihood and severity of harm or discomfort anticipated in this treatment are not greater than those encountered in the course of daily life or during the performance of routine physical examinations or test; this treatment involves no more than minimal risks based on the following:

No side effects have been discovered in the hundreds of low level laser studies conducted over the past 30 years. The Food and Drug Administration has approved laser therapy for hair growth along with a classification of “non-significant risk device” as well as a cosmetic device rating. All known contra-indications are part of the exclusion criteria; thereby significantly narrowing the opportunity for harms or discomfort. This type of treatment may involve risks that are currently unforeseeable / not yet know. However, all that are known have been identified, addressed and included in this protocol in a manner that will exclude any person that wishes to receive such treatment who could possibly be harmed.

## **Potential Benefits:**

The benefits of laser therapy have been long documented. Laser therapy for hair rejuvenation is also well documented with benefits that may include but not limited to: Increased hair tensile strength, increased hair count per area, increased circulation, increased lymphatic drainage, increase in cellular health and increased cellular production. Although not all-inclusive, there are many positive benefits of laser hair rejuvenation therapy all of which have been published for years and need not be recited here as there are too many to list.

## **Strategies for Minimizing Risk:**

- \* The Pre-Therapy Screening form will contain all of the inclusion and exclusion criteria as well as personal information that may exclude the potential client. It will also include all of the necessary information included in the “contra-indications” section of this protocol. This will significantly reduce the possibility of harm or discomfort.
- \* Every patient must fill out the Pre-Therapy Screening form in its entirety or he / she will not be allowed to participate.
- \* The Laser Technician will review the Pre-Therapy Screening form to insure that the information is complete and does not disqualify the perspective patient.
- \* Prior to receiving therapy, the Pre-Therapy Screening form will be verbally reviewed with the each perspective client to insure accuracy and qualified participation.
- \* All sections of this protocol will be meticulously adhered to in order to insure safety, consistency and proper therapy for all participants.
- \* Any person who is not certain that they are physically able to have this therapy due to current medication or recent medical events will be referred to his or her Doctor for advice and counsel and will not be allowed to receive the therapy.

## **Technical Review:**

Patients will be given an informed consent form to fill out and sign, and HALO Elite therapy provider is encouraged to:

- Discuss the purpose of the therapy with the client and explain that we are using a device that has been designed according to the parameters of the FDA approved protocol and the parameters of published clinical trials and scientific studies.
- Explain the therapy protocol to the client and advise them how the therapy is administered.
- Screen the subject in accordance with the Inclusion / Exclusion criteria.

- Review the Pre-Therapy Screening form with the client. Give the client an opportunity to ask questions and ask if they understand what has been explained to them.

We the undersigned have reviewed in its' entirety all of the content of protocol #82988-CPT. We resolve to concur that the information and treatment parameters and requirements are sufficient to carry out the treatment identified herein and do furthermore concur that protocol #82988-CPT, is acceptable for use to treat all individuals who meet the criteria contained herein. It is understood that this is the only protocol approved for use to provide HALO Elite Therapy for the purpose of hair rejuvenation and hair regrowth for postpartum hair loss.

**IN WITNESS WHEREOF,**

We have executed the foregoing this \_\_\_\_\_ day of \_\_\_\_\_ In the year of \_\_\_\_\_.

\_\_\_\_\_  
Director - Print Name

\_\_\_\_\_  
Director - Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness: Print

\_\_\_\_\_  
Witness: Signature

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Date