MELADINE INFORMATION AND TRAINING MANUAL
Meladine Client Manual

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Disclaimer:

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SECTION 1: INTRODUCTION TO MELADINE

1.1 OVERVIEW OF MELADINE, NATURAL MELANIN ENHANCER

1.1.1 What is Meladine?
Laser hair removal has provided an effective solution for millions of people looking to rid themselves of unwanted hair. The lasers use the naturally occurring melanin in the hair follicle as a target to selectively disable the follicle while leaving surrounding skin structures intact. However, lighter hair has too little melanin to provide an effective target for the laser, so people with non-pigmented hair have not been suitable candidates for laser hair removal...until now.

Meladine is the only product on the market that has proven to aid lasers in treating non-pigmented hair (white, gray, blonde, etc.) for laser hair removal. Meladine is an all-natural, safe and gentle product that naturally increases the pigmentation in a patient’s hair follicle, allowing hair removal lasers to effectively target and cauterize the hair.

In addition to the obvious benefits of treating non-pigmented hair, Meladine is highly effective in treating all “in-between” shades as well. Since the product will absorb into any hair it is applied to, Meladine will help lasers to target any hair it may have trouble with—from various shades and textures of red to the thinnest brown and black hair. If effectively integrated into regular service offerings, Meladine has the potential to increase every laser hair removal business by up to 30%.

First introduced in late 2001, Meladine continues to make product advances. Since Meladine’s conception, Creative Technologies has actively pursued product improvements. FDA clearance, product formulation advances, improvements in packaging and continued studies have made Meladine into the successful product it is today. Creative Technologies welcomes customer feedback and is committed to the steady improvement of our products.

1.1.2 How Meladine Works
When sprayed on the desired area, Meladine’s liposome delivery system selectively deposits natural melanin directly into the hair follicle. The result is temporary melanin-rich follicles, which allows patients with lighter hair colors to benefit from laser hair removal.

Melanin is delivered to the hair follicle via liposomes, which are tiny, microscopic spheres of natural soy lecithin with melanin at their center. These liposomes are absorbed selectively by the hair follicle. Because the melanin will be deposited in the bulb and bulge, the patient will not experience coloration to the hair shaft in the area being treated—the only coloration will occur within the follicle.
Because the surrounding epidermis does not absorb the liposomes as well, the patient will not experience coloration or staining of the skin. Subsequently, Meladine will not alter the effects of the laser on the skin, it will only enhance the hair follicle where the melanin is deposited. Residual Meladine left on the skin that is not absorbed into the hair shaft will simply be washed off (or covered up by makeup, etc.).

The liposomes contained in Meladine, while small enough to effectively penetrate the hair follicle, do not penetrate deep enough to be taken up by the bloodstream.

1.1.3 How to Use Meladine

For Fine, Soft Vellus Hair:
Patients will begin daily treatment regimen a minimum of 2 weeks prior to laser treatment

For Coarse Hair:
Patients will begin daily treatment regimen 6 weeks prior to laser treatment

Daily Regimen:
• It is important that the hair be clipped or shaved daily. Do not wax, tweeze, or use depilatories on the area between treatments.
• Always apply Meladine to clean skin. Do not use cosmetic preparations prior to application of Meladine.
• In the morning, hold sprayer 3-5 inches away from skin, spray the area to be treated with Meladine, and allow to dry. Repeat this spraying and drying process 6 times. It is imperative that Meladine be allowed to dry between each spray.
• Gently patting the Meladine into the skin, using only the finger tips, may help with absorption.
• Repeat spraying and drying process 6 times in the evening.
• Alternate Directions for Coarse Hair: If it is not practical to begin regimen 6 weeks prior to laser treatment, patient may use Meladine for 4 weeks, but should increase the number of applications to 8-10 in the morning and 8-10 in the evening.

NOTE: The directions above represent the minimum a patient can do to achieve success. It is extremely important to note that the more Meladine applications a patient uses, the more melanin is deposited in the hair follicle, which forms a better target for the laser.

Please note that the separate instructions for vellus and coarse hair reflect the difference in thickness of each type. Thin vellus hair readily absorbs the liposomes contained in Meladine while thick, coarse hair absorbs the liposomes at a lower rate. Although the difference between the two regimens may seem large, patients with coarse hair have experienced much higher rates of success when they follow the longer regimen. Remember, it is extremely important to choose which regimen to follow based on the texture, not the color, of the hair.
It is imperative that the topical hair be removed to aid with absorption. The best way to remove the majority of topical hair is by shaving. Clipping the hair, although not as efficient, is an alternative. Depilatories, waxing and tweezing must be avoided because these methods remove the hair below the surface of the skin.

Meladine must always be applied to clean skin. Cosmetics and lotions may be used after applying Meladine; however, it is recommended that the patient wait up to one hour before applying other topical products or before washing their skin (entering a pool, etc). For Contraindications see 3.2.8

The spraying and drying process is necessary to build a sufficient melanin deposit in the hair follicle. Holding the bottle 3-5 inches from the area to be treated helps to ensure that the patient will cover a large area with each spray. This will help the patient to conserve product and will also apply a light “mist” to the skin which should be sufficient. If Meladine is applied too thickly (so that the product begins to drip off the skin), the patient will only waste product.

If desired, patients may use their fingertips to gently pat or spread the Meladine on the area to be treated, however the patient must be careful not to vigorously rub the Meladine into their skin as this may rupture the fragile liposomes. Patients should not use applicator tools of any sort (cotton balls, makeup sponges, etc) because the liposomes will absorb into the applicator instead of the hair follicle, wasting the product.

1.2 Keys to Successful Treatments

The following three points are critical success factors to treating with Meladine. All three are of equal importance and are critical to receiving successful results.

1.2.1 Key #1: Patient Compliance
Successful treatment with Meladine begins with patient compliance. In order for Meladine to work, it must first be applied correctly and consistently. If the patient does not comply with the full extent of the instructions, he will not build a sufficient melanin deposit in the hair follicle for the laser to target. As we will discuss in more detail, at best, a compliant patient will build a melanin deposit that is the equivalent of a fine, light brown hair. When a patient is not compliant with the directions, he is building a target that is lighter than even a light brown hair and is not likely to be effectively targeted by the laser.

When a patient adheres to the suggested regimen, he is much more likely to experience higher rates of success. Remember that additional applications, above what is recommended, may help to achieve a stronger melanin deposit.
Clearly explaining the application regimen and the significance of it (building a target for the laser, etc.) will motivate the patient to be more compliant with the directions.

1.2.2 Key #2: Sufficient Laser Treatment
Proper laser treatment with Meladine begins with applying sufficient energy levels to the pretreated hair. While this may seem obvious, it is important to understand that, no matter what texture or color the hair may be on the surface, *Meladine treated hair will react to the laser as if it were a very fine, light brown hair*. Therefore, the hair should be targeted as such. Naturally, when attempting to treat lighter shades of hair, stronger laser settings are usually necessary. If this point is not strongly and clearly relayed to the physician or laser technician, they may target the hair with parameters too low to achieve effective results. *For more detail on technical laser issues and laser use, please refer to 2.2 and 3.1.*

1.2.3 Key #3: Realistic Expectations
Since its introduction, Meladine has been helping thousands of patients to achieve the hair removal results they are looking for. However, it is extremely important to communicate to the patient that while the success rate is very high, there is no guarantee Meladine will work the same for everyone.

As with many topical applications and procedures, there are variables that may exist that are beyond the control of manufacturer, the doctor and the patient. Other than patient compliance, and proper laser usage, additional variables may include *hormonal or body chemistry changes, age, weight gain, medication usage, etc.*

Historical results show that vellus haired patients receive higher rates of success than patients with coarse hair. This may be the case for any number of reasons, however it is believed that this difference is mainly due to the variables listed above.
SECTION 2: SELLING MELADINE

2.1 COMMUNICATING WITH YOUR CLIENTS

The information and support that you give your clients may ultimately determine the success of Meladine for your company. Your clients should have the most correct and relevant information available in order for them to achieve higher rates of success. The following paragraphs are techniques that Creative Technologies has developed to sell Meladine effectively.

2.1.1 The Meladine Client
Creative Technologies chooses to sell Meladine only to laser hair removal clinics, and not to individual patients, for several reasons. Patients experience higher rates of success when doctors are informed and have direct contact with the company.

2.1.2 First Purchase
When talking to first time purchasers either on the phone or in person, it is absolutely critical that you instruct your client on use of Meladine.

The points that must be communicated to your new clients includes:

- *Proper Use of Product*: Do your clients understand the time commitment involved in the application of Meladine? Do they understand the difference between treating vellus hair versus coarse hair? Do they understand that it is critical to keep the hair as short as possible? *Do they understand “more is better”?* Etc.

- *Keys to Success*: Do your clients have proper expectations? Do they understand the “3 Keys to Success”?

2.1.3 Frequently Asked Questions
This section lists the most frequently asked questions and their answers. If a patient presents a question you cannot answer, please contact Creative Technologies, we welcome your inquiries. Remember that you may also direct clients to [www.meladine.com](http://www.meladine.com) for more information.

**Who owns Meladine?**
Creative Technologies, Inc. owns, manufactures and distributes Meladine.

**Is Meladine a drug? Does it require a prescription?**
No. Meladine is considered a topical cosmetic/preparation. Meladine’s ingredients are natural, non-toxic and non-irritating to the skin.
Has Meladine been approved by the FDA?
Meladine has received 510(k) clearance from the FDA as an “Accessory to a Surgical Laser Instruments used for Hair Removal” to enhance the effects of lasers in the treatment of non-pigmented hair.

What is Meladine and how does it work?
Meladine is the only product in the world that has proven to enhance the effects of hair removal lasers on non-pigmented hair. Meladine simply deposits natural pigmentation in the hair follicle which aids the laser in targeting the hair follicle for removal.

Meladine’s “active ingredient” is a liposome delivery system composed of natural melanin and natural soy lecithin. The liposomes absorb into the hair follicle, depositing natural melanin and creating a target for the laser.

How long will one bottle last?
This will be determined by 3 factors:

a) Size of the area to be treated: Obviously smaller areas will require less product. A lip may require 1 spray to sufficiently cover the area, while a back may require 6-8 sprays.
b) Type of hair to be treated: Patients treating for fine, vellus hair will use less product than patients treating coarse hair because of the different application lengths.
c) Patient preference: Some patients may feel that “more is better” and may use Meladine more liberally when applying.

One bottle contains approximately 720 sprays, which may be enough to cover several pre-treatment regimens for a lip, but may only cover one pre-treatment regimen for a full face.

Must Meladine be applied before EACH laser treatment or just before the first laser treatment?
Meladine must be applied prior to each laser treatment because the melanin deposit in the hair follicle is only temporary.

How long must Meladine be applied before each laser treatment?
Please refer to the enclosed sheets entitled “Suggested Use for Fine, Soft Vellus Hair” and “Suggested Use for Coarse Hair” for details. Vellus hair will require a minimum of 2 weeks of application prior to each laser treatment and coarse hair will require 6 weeks of application prior to each laser treatment.

Why is the application regimen so different when treating vellus versus coarse hair? Is 6 weeks really necessary to treat coarse hair?
The different regimens exist due to the nature of the hair. While the vellus hair seems to easily absorb the melanin liposomes, the coarser, thicker hair seems to absorb the liposomes at a lower rate. Creative Technologies found that patients with coarse hair have seen higher rates of success when they use Meladine for the suggested 6 week regimen.
Keep in mind that patients should always aim to do as many applications as possible to increase the melanin deposit (and their chances for success).

**Can Meladine be used on red hair?**
Yes. Meladine may be used to treat any type of hair that does not respond to laser treatment alone, including light brown, vellus dark hair, coarse red hair, vellus “strawberry” blonde hair, etc. Remember that Meladine increases the pigment in any hair that it is applied to. For optimal results, assess the type of hair (coarse or vellus) and chose the application regimen based on the thickness of the hair. For example, coarse red hair will require a 4-6 week regimen, etc.

**Does Meladine stain the skin or change the appearance of hair above the surface of the skin?**
No. Meladine penetrates into the hair follicle itself and therefore does not color the skin or hair. Remember that topical hair should be removed (preferably by shaving) prior to Meladine application.

**If a patient stops using Meladine and never receives a laser treatment, will their hair follicle retain the melanin deposit?**
No. If a patient were to never receive a laser treatment, the melanin deposit would naturally dissipate as the hair grows and falls out.

**Can the patient shave immediately before applying Meladine or must there be some hair above the skin?**
Meladine is best absorbed into the hair when it has been shaved. If there is long topical hair in the area where Meladine is applied, the liposomes have less of a chance to reach the hair follicle.

**Is daily shaving absolutely necessary?**
Remember, the goal is to keep the hair as short as possible so that the liposome carrying the melanin has the best chance to reach the follicle. Therefore, it is recommended that the area be shaved daily. If the hair grows very slowly, daily shaving may not be necessary. If a patient is very hesitant to shave, an alternative is closely clipping the hair each day.

**Will shaving change the color and the texture of the hair?**
No. It has been shown that shaving does not change the nature of the hair. Shaving removes the topical hair from the surface of the skin—it does not affect the follicle or the bodily functions that dictate the nature of the hair. Variables that contribute to the change in color and texture of hair include, hormones, excessive weight gain, age, etc.

**Can patients use a cotton ball to apply Meladine?**
The patient must absolutely avoid applying Meladine with an applicator (cotton balls, makeup sponges, makeup brushes, Q-tips, etc). If the patient uses an applicator, the liposomes will be absorbed by the applicator and will not be applied, or absorbed, into
the hair shaft. If desired, the patient may use his finger tips to spread or gently pat Meladine onto the area to be treated.

Can a hairdryer be used to help dry the Meladine?
Although it is highly recommended that Meladine be allowed to air dry, a hair dryer set on a low, cool setting and held at arms length from the skin may be used to aid in drying. It is important that the Meladine not evaporate too quickly so patients must take care when using a hairdryer. Keep in mind that a dryer used on a heat setting may melt the liposomes, in which case the melanin will not be absorbed.

What if the patient forgets or misses an application? Must they start over?
It is important that the patient faithfully apply Meladine for optimal results. Melanin that has been deposited into the hair follicle will naturally dissipate as the hair grows and falls out. If several applications are missed, the patient may have lost some valuable melanin deposit and may consider extending the application regimen for a number of days. Keep in mind that the goal of using Meladine is to create a melanin deposit that is dark enough to be effectively targeted by the laser. If the patient does not apply a sufficient number of applications he may cheat himself of an effective treatment.

How long after the application of Meladine must the patient wait before showering/Getting in a pool?
It is recommended to wait 1 hour after applying Meladine before showering, however Meladine can be applied immediately after showering. Meladine is colorless and dries without any lingering odor.

Can the patient use other creams or lotions in conjunction with Meladine?
A patient may continue to use her/his normal moisturizing lotions/creams, cleansers and/or make-up while applying Meladine. However, it is recommended that after applying Meladine the patient wait 1 hour to apply other topical cosmetics.

Are there any products that contraindicate Meladine?
The only topical applications that may contraindicate Meladine are creams that contain bleaching agents designed to lighten hair or skin. Since the effect of topical bleaches on Meladine has not been verified, Creative Technologies cannot guarantee that skin bleaching products will not affect the melanin deposit. Because of this we recommend that patients avoid skin bleaching agents while using Meladine. Remember, when applying Meladine in the morning and evening, it is important the skin be clean and free of substances that may inhibit absorption.

Does Meladine work the same for everyone?
Although hundreds of doctors are reporting exciting results, there is no guarantee that Meladine will obtain the same results for everyone. Results may vary depending on the patient’s adherence to the application and treatment regimen. Other variables may include density and coarseness of hair, hormonal changes, etc.
Can pregnant women use Meladine? Can nursing mothers use Meladine?
Meladine is considered a topical cosmetic, similar to moisturizing lotions or makeup. Although Meladine’s all natural ingredients do not penetrate into the bloodstream, Creative Technologies recommends that any patient who feels uncomfortable, should consult her regular physician.

As a laser technician, what are the best laser parameters to use when treating patients using Meladine?
Clinical biopsies have shown that a hair follicle treated with Meladine is equivalent to that of a fine, light brown hair. Therefore, doctors have had the greatest success when they treat Meladine treated hair with laser settings that are indicated for treatment of fine, light brown hair. Of course parameters used for each patient should be determined entirely by the doctor or laser technician.

2.1.4 Trouble Shooting
Occasionally it will be necessary to trouble shoot customer complaints and, if possible, advise the client of measures to take. In ninety percent of the cases where the client claims to see no results, the underlying issue is directly related to patient compliance, proper laser usage, and sometimes realistic expectations. See 1.2 for Keys to Success.

Your first step should be to gather the facts:
- What type of hair is being treated?
- Which area of the body is being treated?
- What is the patient’s age?
- How many treatments has the patient received while using Meladine?
- What laser are you using to treat the patient?

The next step is to find out if the product is being used correctly. The best way to do this is by asking questions related to the Keys to Success.

- Check for Patient Compliance: (How is the patient applying Meladine?)
  - Regimen
    - Following correct regimen for hair type (texture)?
    - Shaving/clipping the hair? Not using depilatories?
  - Daily applications
    - Spraying and drying a minimum of 6 applications?
    - Applying Meladine in the morning and evening?
  - Other variables to watch for:
    - Using applicator tools (other than fingers) to apply Meladine
    - Transferring Meladine into alternate container (i.e. regular plastic)
    - Storing the product in a cool, dry place?

- Check for Proper Laser Usage: (How is the laser technician treating the patient?)
Type of laser
  - Is the laser flexible enough to achieve the necessary parameters?

Settings or parameters used
  - Using high enough fluence (J/cm²)?
  - Using short enough pulse width (ms)?
  - Using smaller spot size (mm) if applicable?
  - If IPL: wavelength indicated for hair removal? (655-1200nm)?

Treatment intervals
  - Does the patient have enough time between treatments to achieve a sufficient melanin deposit?
  - Is the patient applying Meladine to hair that has grown through the surface of the skin?

If all other possibilities have been eliminated, (patient compliance and laser/technical issues appear to be satisfactory), this may be a case where the expectations have been unrealistic.

- Check for Realistic Expectations:
  - Results
    - Does the patient expect all the hair will be removed at once?
    - Is the patient not seeing ANY results? Or have they seen some, (but are expecting a miracle)?
  - Other variables
    - Is the patient experiencing any changes in her body?
    - Is the patient older?
    - Is the patient taking medications?

If it is determined that the patient is not experiencing results due to an uncontrollable variable, you may recommend that:

- The patient try one more treatment, using more applications each day to determine if that will help.

## 2.2 Introduction to Laser Use

Meladine has the potential to work with lasers that are designed to target melanin in the hair follicle. However, a laser’s ability to effectively target Meladine pre-treated hair will vary depending on its individual capabilities. Some lasers are inherently capable of treating lighter hair, while other lasers have less success. This concept is discussed in greater detail in Section 3.1.

When a compliant patient has used Meladine for several weeks, his/her hair follicle will become the equivalent of a light-brown, finely textured hair follicle. The hair will not be visibly colored after using Meladine, but will react like light brown hair; and although the hair may actually be coarse in texture, it will react like finely textured hair.
Therefore, the bottom line in determining efficacy of the laser with Meladine is: *If the laser typically has success with light-to-medium shades of fine brown hair, it should see success with Meladine in compliant patients.*

Remember, because specifications vary from laser to laser, and patient to patient, it is not possible to give you exact settings to use with their lasers when treating with Meladine. All we can do is advise you of how others have experienced success.

### 2.2.1 Laser Usage for Successful Treatments

<table>
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<tr>
<th>AN ABSOLUTE MUST USE EQUATION:</th>
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<tr>
<td>Smaller mm + higher j/cm² + shorter ms = better results on fine, light hair</td>
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As you may know, in order to effectively treat light, fine hair, *any* laser will need to use this basic equation. Smaller spot size (mm) allows higher fluence (j/cm²) to be used. Using shorter pulse durations (ms) heats up the follicle quickly which is necessary when treating a finely textured follicle (quick thermal relaxation time). Since hair follicles that have been treated with Meladine will become the equivalent of a light, fine brown hair follicle, best results have been shown when the laser is set to treat this type of hair.

The above equation has been repeatedly confirmed by the feedback from hundreds of laser technicians who have treated their patients with Meladine. Laser technicians who are mindful of the above equation tend to have the best results in compliant patients.

**Remember that higher settings may not always be safe for use on all patients (darker skinned patients in particular), so it is important to remember that the physician or laser technician is the “laser expert” and that they must ultimately determine the settings with which to treat each individual patient.**
SECTION 3: TECHNICAL ISSUES

3.1 LASER TREATMENT PROTOCOL

Treating patients with Meladine will take some care, understanding and experimentation on the part of the laser technician. Although there can be no specific recommendations for how to treat patients using Meladine, there are some very important points that may affect the doctors’ decision on how to treat their patients and how to counsel each patient.

3.1.1 Laser Treatment Intervals
Creative Technologies does not recommend specific treatment intervals, but encourages doctors to treat their patients at intervals they feel comfortable with. However, it is extremely important that the doctor be aware of (and if they chose, make adjustments for) Meladine application regimens.

For example, in the case of coarse hair, patients will be required to follow the 6 week application regimen. If the doctor is treating the patient every 4 weeks, this will have a significant impact on the patient’s Meladine regimen. (i.e. if the patient is only able to apply Meladine for 4 weeks prior to his laser treatment, it is imperative that they follow the “alternate directions”—a minimum of 8 applications in the morning and evening for 4 weeks prior to laser treatment). When choosing laser treatment intervals for patients using Meladine, an important piece of information that may have an affect on the treatment intervals has to do with Meladine absorption as discussed next in 3.1.2.

3.1.2 Meladine Absorption
Meladine will only be effective to hair that is in the anagen stage (i.e. is growing and has reached the surface of the skin). If Meladine is applied to skin that has no hair growth, the absorption into the hair follicle is severely restricted. Once the hair has grown through the surface of the skin, it is best to keep the hair short for optimum results (see 1.1.3).

3.1.3 Lasers and Meladine
Meladine has the potential to work with any laser that targets melanin in the hair follicle. However, not all lasers are equal in their ability to target Meladine pretreated hair. The difference in ability may be due to the individual laser’s range of specifications.

The more “flexible” the laser is in reaching the upper/lower limits of the settings (mm, j/cm², and ms), the more likely the laser is to achieve success with Meladine. For instance a laser that has only one spot size (especially if it is a very large spot size) may prevent the laser technician from using fluences that will effectively disable a lightly colored follicle.

A simple way to determine the efficacy of a laser with Meladine is by determining the laser’s success in treating fine, light brown hair (This concept is discussed in more detail
in section 3.1.4). Of course, the even if the laser has the specifications to treat fine, light brown hair, ultimately it us up to the laser technician to use the parameters that will treat such a hair.

3.1.4 Laser Settings
As a patient applies Meladine during his/her suggested regimen, microscopic amounts of melanin are deposited into the hair follicle. Over time, the melanin deposit will darken to the equivalent of a light brown hair. Therefore, it will be necessary to use laser parameters that will target a light brown hair. Additionally, because the melanin deposit will be relatively small, it will be just as important to use laser parameters that will target a finely textured hair, even if the hair is actually thick and coarse in nature.

The parameters that are required to treat light, fine hair will differ greatly from parameters that will treat a dark, coarse hair. Therefore, the equation below is absolutely critical to successful laser treatments with Meladine (as mentioned in 2.2.1) and is the same combination of parameters that would treat a light, finely textured hair: Smaller mm + higher j/cm² + shorter ms.

Smaller millimeters (mm) are recommended because they will allow higher fluences to be used. Additionally, many lasers have a “cut off” point where fluence is limited by the size of the handpiece used.

Milliseconds (ms) are as critical to the equation as fluence. Longer ms heat the hair follicle slowly, and although this technique may be effective on dark, thick hair—very fine, light brown hair has a quick thermal relaxation time and simply will not respond well to slow heating. A fine, light brown follicle must be heated quickly in order for the follicle to be effectively cauterized.

Remember that it is important to relay this information to the doctor, but it is equally important to remind the doctor that he/she is solely responsible for the treatment of the patient.

3.1.5 Meladine and Skin Type
No matter what skin type is being treated, the basic concept remains the same: the hair follicle will react to laser treatment like a finely textured, light brown hair.

It goes without saying that the easiest skin types to treat using the above equation are types I, II and III. When treating skin types IV, V and VI, the parameters may change, but the basic idea remains the same. Our clients who have had success with Meladine in darker skin types report that they use much more aggressive settings on their patients than they would normally use. For instance, one client reports treating a skin type VI patient with parameters she would normally use on a skin type IV.
Additionally, feedback from our clients has revealed that an excellent cooling mechanism is critical to treating darker skin types in light of the “aggressive” treatments necessary to treat lighter hair in darker skin.

Remember that the more applications a patient applies the darker melanin deposit they are likely to form in their hair follicle. While this is important for any patient, it is especially important for darker skinned patients as they often hover between having enough melanin in the follicle and too much melanin in the skin.

### 3.2 Product Specs

#### 3.2.1 Manufacturing & Distribution of Meladine
Meladine is both manufactured and distributed in the United States. At the time of the writing of this manual, exclusive distributorships supported by Creative Technologies exist in Canada, Australia, Brazil and Israel.

#### 3.2.2 FDA Clearance
Meladine received FDA 510(k) marketing clearance on January 29, 2003. Meladine is classified with the FDA as an “Accessory to Surgical Laser Instruments used for Hair Removal”. Clearance was granted based on data from a two year clinical study.

#### 3.2.3 Ingredients
- Water
- Melanin (derived from squid ink)
- Glycerol
- Natural Soy Lecithin (forms shell of the liposome)
- 2-Phenoxyethanol (0.55% as preserving agent)

#### 3.2.4 Delivery
The “active ingredient” in Meladine is melanin encased in microscopic spheres of soy lecithin called liposomes. When applied to the hair, the liposome carries the natural melanin to the hair follicle where it is deposited. Each time Meladine is applied, more melanin is deposited in the follicle which eventually will form a dark enough target for the laser to pick up.

#### 3.2.5 Bottle
- 4 fl.oz. / 120ml per bottle: Approximately 720 sprays/bottle
- Cobalt blue color: necessary to protect Meladine from direct light. Direct light or heat causes the liposomes to melt and clump together and become too large to penetrate the hair follicle.
- PET plastic bottle: necessary to protect product from breaking down. Liposomes will readily adhere and absorb into normal plastic, but not into PET plastic.
Meladine must not be transferred into regular plastic containers to maintain product integrity.

- Label: Waterproof.
- Plastic seal: Provided for patient safety and to provide additional protection from possible air exposure.

### 3.2.6 Product Characteristics

Scent: Meladine has a very mild scent and has been described by clients as “earthy”. Any residual scent from the product will dissipate when the product has dried completely.

Color: Should be translucent amber or light brown in color when in concentrated liquid form. Meladine will spray on without color and will not stain the skin or hair.

Texture: Meladine is water based and is non-oily in nature.

### 3.2.7 Reactions

Meladine is a natural melanin enhancer that contains natural ingredients. Users with a known sensitivity to 2-phenoxyethanol (alcohol used as preserving agent) should not use Meladine. This is an extremely rare sensitivity, but has been known to exist. If a patient believes he is reacting to Meladine he may decide perform a spot test on a separate area of the body or consult his physician.

### 3.2.8 Contraindications

The only products known to contraindicate Meladine are products containing bleaching agents designed to lighten hair or skin. While topical bleaching products that are designed to lighten skin do not claim to penetrate to the hair follicle (thereby contraindicating Meladine) it has not been proven that they have no definite effect.

Since the effect of topical bleaches on Meladine has not been scientifically verified, we recommend that patients avoid using bleaching agents if possible while using Meladine. Patients may continue to use other lotions, creams and makeup in conjunction with Meladine, however, we recommend patients wait 1 hour before applying other topical applications.

### 3.2.9 Storage & Transportation

Meladine has a shelf life of approximately 24 months.

Meladine (in its case as well as individual bottles) must be stored at reasonable temperatures. Room temperature (approximately 60-85 degrees F) is acceptable, and normal refrigeration is ideal.

Heat: Care must be taken that Meladine does not reach extreme temperatures for long periods of time (i.e. do not leave it in a hot car). Avoid temperatures above 85 degrees F for long periods of time, and Meladine should never reach boiling point (100—212 degrees F and above).
Cold: Although freezing Meladine has not been proven to harm the product, avoiding this is advised. Other problems besides product damage may occur such as cracked bottles, leaking caps and sprayers, etc.

Light: Due to the fragile nature of the liposomes, care must be taken not to expose Meladine to direct, bright light.

Air: Air exposure should be avoided mainly because of the susceptible nature of the product to microbiological contamination. (The pump system that dispenses Meladine is designed to limit air exposure).

3.2.10 Product Degradation
If Meladine has been exposed to unfavorable conditions (light, heat, age) for long periods of time, the product may to begin to break down, which is typical with any topical cosmetic product.

To test for product break down: pour several drops of Meladine into the bottom of a clear glass or onto a mirror. The liquid should appear to be translucent amber or light brown in color. If the integrity of the product has been compromised, the liquid will appear milky or cloudy—similar to the appearance of chocolate milk. The milky appearance indicates that the liposomes have separated from the melanin, have melted together and are no longer effective in absorbing into the hair follicle.