

Silk'n™ Home Pulsed Light™ Hair Removal

INFORMED CONSENT BOOKLET

INSTRUCTIONS

Silk'n™ is a medical device used for at-home hair removal using Home Pulsed Light™. Home Pulsed Light™ hair removal is a procedure that does have both benefits and risks that need to be weighed. This booklet was prepared for you by the California Ear Institute, dba California Face and Laser Institute (CFI) to help you make an informed decision. During your consultation, we will review with you the potential benefits, the alternatives and the few risks associated. It is important that you read this booklet carefully and completely. Only when you have no questions or concerns should you initial each page, indicating that you have read and fully understand all the items it discusses. When you arrive at the end of the booklet, please sign the consent for the procedure. If you have any remaining questions or concerns, do not sign the consent form until getting these questions answered by a CFI medical representative

In addition, it is necessary to read the Silk'n™ User Manual in its entirety prior to operating the device. Pay particular attention to sections on device procedures, device operation and after-use procedures. We recommend you re-familiarize yourself with the Silk'n™ User Manual before each use of the Silk'n™.

The following is a list of questions and answers that we have found addresses the majority of most people's concerns.

INTRODUCTION

Lasers are machines that produce a beam of light that has a specific biological target. Some lasers target blood vessels and are absorbed by these. Some lasers target pigment, so hair follicles or "age spots" absorb these. The target that absorbs the light converts it to heat and is modified or removed.

Silk'n™ is a light-based device for long-term hair removal designed for home-use. Silk'n™ is intended for removal of unwanted hair by using a highly sophisticated technology called Home Pulsed Light™ (HPL™). HPL™ technology uses lower light energy to target melanin pigment in the hair, thus destroying the hair follicle and disabling hair growth. Therefore the more melanin present in the hair (i.e. the darker the hair) the more light that can be absorbed and the more effective light can be at removing hair. Over a couple weeks post treatment, the treated hair will gradually fall out. Because HPL™ technology relies solely on the pigment of the hair follicle as its target, the Silk'n™ is not recommended for use on light hair, as it will not respond well.

The device is specifically indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician, after training by a healthcare professional. Silk'n™ may be used to remove unwanted body hair. Ideal body areas for Silk'n™ use include the underarms, bikini line, arms and legs.

ALTERNATIVE TREATMENT

Alternatives to Silk'n™ Hair Removal include in-office Laser Hair Removal, shaving, plucking, waxing, depilatories, and electrolysis. At CFI, we currently are using all of these techniques. All in-office laser treatments provide a series of gentle, no "down time" treatments that can yield 30%-90% permanent hair reduction.

BENEFITS OF SILK'N™ USING HOME PULSED LIGHT™ TECHNOLOGY

Silk'n™ Home Pulsed Light™ (HPL™) technology is able to achieve long-term hair removal results at a fraction of the energy level used in other light-based hair removal equipment.

Light-based hair removal is much faster than electrolysis. Because of this, many more sessions are required with electrolysis than with laser treatment. Light-based hair removal also eliminates ingrown hairs and can help people who suffer from folliculitis.

WHO IS A GOOD CANDIDATE FOR SILK'N™ USING HOME PULSED LIGHT™ TECHNOLOGY

Anyone who is looking for permanent hair reduction who understands the risks, costs and time necessary to achieve the full benefit of the at-home treatment and who has realistic expectations of the ultimate outcome. We encourage the use of the Silk'n™ for maintenance post laser hair removal treatments on the body.

WHO IS NOT A GOOD CANDIDATE FOR SILK'N™ USING HOME PULSED LIGHT™ TECHNOLOGY

Silk'n™ is not designed for everyone. Please read the Silk'n™ User Manual for more detailed information on this section.

PIGMENTED SKIN OR TANNED SKIN: Silk'n™ is NOT designed for use on naturally dark skin. Treating dark skin with Silk'n™ can result in adverse effects such as burns, blisters and skin color changes (hyper- or hypo-pigmentation). Silk'n™ is also NOT recommended for use on tanned skin or after recent sun exposure, tanning booth exposure, or self-tan applications. If you are tanned or have recently been exposed to the sun in the area you are having treated, you may be more susceptible to potential side effects such as blisters or crusts and/or your treatment may need to be reduced in intensity or postponed until the tan fades. You must let the tan fade completely before using the Silk'n™. Do NOT use the Silk'n™ on areas of skin that have tattoos, permanent makeup, dark brown patches or black spots, such as large freckles, birthmarks, moles or warts.

FACE OR NECK: Silk'n™ is NOT recommended for use on the face or neck. Using Silk'n™ to remove facial hair may cause serious eye injury and may stimulate facial hair growth.

LIGHT HAIR: Silk'n™ is NOT effective on light hair. Naturally white, grey, blond and red body hair will not respond to this device.

OTHER: DO NOT USE THIS DEVICE IF:

- you are under 18 years of age
- you are pregnant or nursing (lactating)
- you have been on Accutane within 6 months
- you have been on a steroid medication within the past 3 months
- you have a history of keloid scarring
- you have a known photosensitivity to light or are taking medication that makes the skin more sensitive to light
- you are taking aspirin or blood thinners, you may experience some bruising that can take up to 2 weeks to resolve.
- you have abnormal skin conditions caused by diabetes or other systemic or metabolic diseases
- you have recently been on Alpha hydroxyl-acids (AHAs), Beta-Hydroxy Acids (BHAs), topical retinoids or azelaic acid in the area to be treated.
- you have eczema, psoriasis, lesions, open wounds or active infection, such as a cold sore in the areas to be treated. Wait for the effected area to heal before using Silk'n™.
- you suffer from epilepsy
- you have an active implant, such as a pacemaker, incontinence device, insulin pump, etc.

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- you have a disease related to photosensitivity, such as porphyria, polymorphic light eruption, solar urticaria, lupus, etc.
- you have a history of skin cancer or areas of potential skin malignancies
- you have received radiation therapy or chemotherapy treatments within the past 3 months
- you have any other condition which in your physician's opinion would make it unsafe for you to be treated.

If you are unsure whether you have a condition which would make it unsafe for you to be treated by the Silk'n™ device, or whether a drug that you are on or have been on is on the prohibited list, seek the opinion of your primary care physician before using the device.

Visible hair is necessary in order to effectively remove it. Therefore, you should not wax or pluck before a treatment.

RISKS OF SILK'N™ USING HOME PULSED LIGHT™ TECHNOLOGY

Every procedure involves a certain amount of risk and it is important that you understand the risks involved with the Silk'n™ device. Although the majority of clients do not experience these complications, it is important that your decision to proceed with the Silk'n™ treatments is based upon a consideration of the alternatives to treatment as well as the risks, benefits, and costs of the proposed plan. CFI medical personnel will make sure that you fully understand the alternatives, benefits, risks, potential complications, and expected outcomes of this treatment device.

DISCOMFORT

Some discomfort during the procedure likened to the snapping of a rubber band occurs. Most people find this to be mild and tolerable. A cold compress can be applied to minimize any discomfort. Anything beyond this minor discomfort is abnormal and means that either you should not continue to use the Silk'n™ because you are unable to tolerate the hair removal application, or that the energy level setting is too high, in which case you need to lower the setting.

REDNESS AND SWELLING

Short-term immediate risks include prolonged redness and swelling at the area being treated.

BRUISING

Bruising is very uncommon, although the risk increases if you take aspirin products or are on blood thinners.

SKIN WOUND, INFECTION, AND SCARRING

Uncommonly, skin wounds such as superficial blisters and scabs can occur, which heal within 2 days to 14 days. Use of antibiotic ointment such as Bacitracin or Polysporin on a regular basis subsequent to this occurrence usually results in uneventful healing. There is a <0.5% possibility of a skin wound leaving behind a permanent scar. It is also rare for an infection to occur since the skin is usually not broken. Subsequent aesthetic treatments may be required to improve the appearance of the scar. All such occurrences must be reported to CFI. Do not use the Silk'n™ device again in this area for at least 3 months, or until cleared by CFI medical personnel.

HYPOPIGMENTATION AND HYPERPIGMENTATION

Another risk is a possibility of hypo (too little) or hyper (too much) pigmentation that is very uncommon. Usually treatable with prescriptions creams, chemical peels or further laser treatments, there is a <1% possibility that this could be permanent. There is an increased risk of

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this with tanned or naturally dark skin and can result in adverse effects such as burns, blisters, and skin color changes. For this reason, the Silk'n™ device is **NOT** recommended and **NOT** safe to be used on naturally dark skin or skin that is tan. If you are tan, you must wait for your tan to completely fade prior to using this device. We also do not recommend that you artificially tan (with self-tanners, spray tanners, or tanning beds) for 3-4 weeks prior to this procedure. If you have naturally dark skin, we recommend that you consult with CFI regarding our in-office Laser Hair Removal or other non-laser hair removal treatment options as there are treatments that are safe to be used on dark skin types.

MULTIPLE TREATMENTS AND MAINTENANCE TREATMENTS

Specific areas of hair growth are easier to remove than others. Underarms, bikini lines, and legs are the easiest areas to treat **The Silk'n™ device is NOT recommended for use on the face or neck, only for the body.**

The average number of treatments ranges because at any given time, only a fraction of hairs are in the "growing phase" (anagen cycle). Only anagen hairs can be effectively removed with laser because the "resting phase" (telogen) hairs do not have mature pigment at their follicle bulb that is the target for the light. Thus, one treatment will sometimes only get 30% of the hairs because only those hairs have enough pigment to be destroyed.

The first 3-4 hair removal sessions with Silk'n™ will be approximately two weeks apart. Hair removal sessions 5-7 with Silk'n™ will be approximately four weeks apart. After that you will typically use Silk'n™ again from time to time if and when needed, until long-term results are achieved. Maintenance hair removal sessions with Silk'n™ may be required from time to time due to hormonal or other physiological changes affecting the activity of dormant hair follicles.

For more advanced results, we recommend that you inquire about in-office laser hair removal procedures. Data has shown that about 30-90% of the hair does not grow back for one year after the end of the treatment cycle. Of course, this assumes the appropriate treatment and the correct number of treatments for each individual, all of which can be variable. We cannot guarantee 100% permanent hair removal, as people do need occasional maintenance or touch-up treatments.

PATIENT SATISFACTION

A typical full hair growth cycle may take 18-24 months. During this time multiple Silk'n™ sessions may be required in order to achieve long term hair removal. The efficiency of hair removal varies from person to person according to body area, hair color and how Silk'n™ is used. In general there is a 30-90% improvement that can be expected, yet we cannot provide you with any guarantee of your final results.

POST TREATMENT CARE

It will take 2-4 weeks following each treatment for the hair to fall out. Between treatments you may shave or clip the hair, but do not pluck or wax. If you pluck or wax it completely removes the hair from the follicle and therefore will not be treated at the following visit. It is important that you use a daily, reliable sunscreen during the entire time that you are undergoing these procedures and try to avoid prolonged sun exposure. You may not go in a tanning booth at any time either before or during these treatments. Doing so will greatly increase your risks of a side effect. If there is any blistering or breakage of the skin after the procedure, you should use an antibiotic ointment such as Bacitracin or Polysporin at least 2 times per day to keep the area moist and call the office as soon as possible. Do not use the Silk'n™ device again in this area until cleared to do so by CFI medical personnel.

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FINANCIAL RESPONSIBILITY

The Silk'n™ and the Silk'n™ Disposable Lamp Cartridges are available for purchase through CFI with a prescription. All sales are final for the Silk'n™. Returns are not accepted on the Silk'n™ or the Disposable Lamp Cartridges. The Silk'n™ Disposable Lamp Cartridges can fire 750 light pulses that would typically cover 2 Legs, Arms, Under arms, and Bikini line. Pulse density is determined only according to the energy level setting of the device. There is no decrease of energy during the usable lifetime of the Lamp Cartridge. The number of cartridges required varies from patient to patient depending on the number of pulses required to complete the level of desired hair removal and cannot be predicted in advance.

THE SILK'N™ USING HOME PULSED LIGHT™ TECHNOLOGY TRAINING

CFI medical personnel will train you on how to use this device. Dr. Mingrone reviewed and approved of the sale of the Silk'n™ device through CFI for your personal use. You can read about Dr. Mingrone's educational background and experience at <http://www.calface.com>. We attend national meetings frequently to keep updated on the latest, best and safest techniques and remain at the forefront of cosmetic dermatology. There is an instruction manual in the Silk'n™ box that we recommend that you read through carefully prior to use and refer to as needed for the Silk'n™ device.

Only the person who is prescribed and purchasing the Silk'n™ device, who is consented and trained by CFI may use this device. Do not, under any circumstances, loan it to friends or family members who have not had their skin questionnaires or medical backgrounds reviewed by qualified and trained medical personnel. If you have any further questions regarding your device once purchased, you are required to contact Home Skinovations for Silk'n™ Customer Service at 1-877-DO SILKN (1-877-367-4556) or email them at contact@silkn.com.

DISCLAIMER

Informed-consent documents are used to communicate information about treatments, along with disclosure of risk and alternative treatments(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most cases. What your physician, Cosmetic Coordinator, and/or Laser Provider have discussed with you and included again in this booklet are the material risks, both common and uncommon, that they feel a reasonable person would want to know, understand, and consider in trying to decide if this treatment is something they would like to proceed with. It is important that you read the above information contained on this and all proceeding pages carefully and have all your questions answered before signing the consent on the next page. Additional questions can be answered by calling CFI at 650 462-3161 or by e-mail at facemd@calface.com or Home Skinovations Silk'n™ Customer Service at 1-877-DO SILKN (1-877-367-4556).

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Consent for Procedure

1. I have read all pages contained in this booklet and hereby authorize CFI to sell me the **Silk'n™** for home-use.
2. I recognize that during the course of the procedure unforeseen conditions may necessitate different procedures than those described in this booklet. I therefore understand that CFI is not held responsible for any Silk'n™ units that are broken, damaged, or in need of repair, or for any complications that may develop with the at-home use of this device.
3. I acknowledge that no guarantee has been given by anyone at CFI as to the results that may be obtained with the use of the Silk'n™.
4. I have watched the Silk'n™ DVD "Instructions For Use" and have been properly consented on the use of this device.
5. **IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:**
 - a. THE ABOVE PROCEDURE TO BE UNDERTAKEN
 - b. THERE ARE ALTERNATIVE PROCEDURES AND METHODS OF TREATMENT INCLUDING DOING NOTHING
 - c. THERE ARE RISKS TO THE PROCEDURE PROPOSED
 - d. ANY QUESTIONS I MAY HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION

I consent to the procedure and the above listed items (1-6). I am satisfied with the explanation.

print name

signature

today's date

date of birth

witness

MD or provider



PATIENT INFORMATION FORM

APPOINTMENT DATE: _____

Name: _____
Last First Middle

Date of Birth: _____ Age: _____ Sex: _____

Please check next to the procedures or treatments that you are interested in-

- | | |
|---|--|
| <input type="checkbox"/> BOTOX Cosmetic | <input type="checkbox"/> Injectable Fillers (Juvederm/Restylane) |
| <input type="checkbox"/> Eyelid surgery | <input type="checkbox"/> Laser hair removal |
| <input type="checkbox"/> Facelift/Necklift/Minilift | <input type="checkbox"/> Spider veins / leg vein treatment |
| <input type="checkbox"/> Endoscopic browlift | <input type="checkbox"/> Photo facial |
| <input type="checkbox"/> Cheek lift | <input type="checkbox"/> Broken capillaries on the face |
| <input type="checkbox"/> Skin care | <input type="checkbox"/> Skin resurfacing/Active FX |
| <input type="checkbox"/> Scar revision | <input type="checkbox"/> Acne scar treatment |
| <input type="checkbox"/> Facial liposuction | <input type="checkbox"/> Chemical peel |
| <input type="checkbox"/> MicroLaserPeel/Microdermabrasion | <input type="checkbox"/> Ear correction |
| <input type="checkbox"/> Nasal surgery | |

Other interests not listed: _____

Which of the above have you already had performed? _____

MEDICAL HISTORY

Are you taking any drugs, medications or vitamins? YES NO If yes, list:
1. _____ 2. _____
3. _____ 4. _____

Are you allergic to any medications? YES NO If yes, list:
1. _____ 2. _____

Please list all previous surgeries (including cosmetic) and dates?
1. _____ 2. _____
3. _____ 4. _____

Have you ever received local anesthesia (Novocaine or Xylocaine) by a dentist or doctor?
 YES NO If bad reaction. describe:

Do you have now, or have ever had diseases or conditions of: (Please check YES or NO)

Lungs:	YES	NO	Gastrointestinal:	YES	NO
Asthma or Emphysema	<input type="checkbox"/>	<input type="checkbox"/>	Ulcers	<input type="checkbox"/>	<input type="checkbox"/>
Tuberculosis	<input type="checkbox"/>	<input type="checkbox"/>	Gastritis	<input type="checkbox"/>	<input type="checkbox"/>
Abnormal chest x-rays	<input type="checkbox"/>	<input type="checkbox"/>	Colitis	<input type="checkbox"/>	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>	<input type="checkbox"/>	Diverticulitis	<input type="checkbox"/>	<input type="checkbox"/>
Bronchitis/Pneumonia	<input type="checkbox"/>	<input type="checkbox"/>	Musculoskeletal/neurological:		
Cardiovascular:			Convulsions	<input type="checkbox"/>	<input type="checkbox"/>
High/low blood pressure	<input type="checkbox"/>	<input type="checkbox"/>	Epilepsy	<input type="checkbox"/>	<input type="checkbox"/>
Blood clots in legs or lungs	<input type="checkbox"/>	<input type="checkbox"/>	Headaches	<input type="checkbox"/>	<input type="checkbox"/>
Heart Attack	<input type="checkbox"/>	<input type="checkbox"/>	Arthritis	<input type="checkbox"/>	<input type="checkbox"/>
History of leg swelling	<input type="checkbox"/>	<input type="checkbox"/>			
Abnormal electrocardiogram	<input type="checkbox"/>	<input type="checkbox"/>			
Chest pain	<input type="checkbox"/>	<input type="checkbox"/>			
PACEMAKER/Defibrillator	<input type="checkbox"/>	<input type="checkbox"/>			

Hematologic/metabolic:	YES	NO	Other systemic:	YES	NO
Anemia	<input type="checkbox"/>	<input type="checkbox"/>	Dry eyes	<input type="checkbox"/>	<input type="checkbox"/>
Bleeding problems	<input type="checkbox"/>	<input type="checkbox"/>	Blurred vision	<input type="checkbox"/>	<input type="checkbox"/>
Blood transfusions	<input type="checkbox"/>	<input type="checkbox"/>	Glaucoma	<input type="checkbox"/>	<input type="checkbox"/>
Autoimmune disease	<input type="checkbox"/>	<input type="checkbox"/>	Corrective lenses	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes	<input type="checkbox"/>	<input type="checkbox"/>	Ear disease	<input type="checkbox"/>	<input type="checkbox"/>
Thyroid disease	<input type="checkbox"/>	<input type="checkbox"/>	Nosebleeds	<input type="checkbox"/>	<input type="checkbox"/>
Hepatitis	<input type="checkbox"/>	<input type="checkbox"/>	Nasal/sinus disease	<input type="checkbox"/>	<input type="checkbox"/>
Bleeding problems	<input type="checkbox"/>	<input type="checkbox"/>	Other: _____		

List any other diseases or conditions not covered above:

Social History:

Do you drink alcohol? YES NO If YES _____ drinks per week.
 Do you smoke? YES NO If YES, how much: _____
 Have you had or have you been exposed to HIV (AIDS)? YES NO
 (Women) Are you pregnant? YES NO Due Date: _____

Skin: One of the important parameters for the success of your treatment is the correct typing of your skin. Your doctor will consider your skin type when planning your treatment program for many aesthetic medical procedures. Skin type is often categorized according to the Fitzpatrick skin type scale which ranges from very fair (skin type I) to very dark (skin type VI). The two main factors that influence skin type and the treatment program devised by your doctor are genetic disposition and reaction to sun exposure and tanning beds.

Skin type is determined genetically and is one of the many aspects of your overall appearance, which also includes color of eyes, hair, etc. The way your skin reacts to sun exposure is another important factor in correctly assessing your skin type. Recent tanning (sun bathing, artificial tanning or tanning creams) have a major impact on the evaluation of your skin color.

Please take a few minutes and complete this questionnaire to help us determine your skin type and treat you the right way.

GENETIC DISPOSITION:

Score	0	1	2	3	4
What is the color of your eyes?	Light blue, Gray, Green	Blue, Gray or Green	Blue	Dark Brown	Brownish Black
What is the natural color of your hair?	Sandy Red	Blond	Chestnut/Dark Blond	Dark Brown	Black
What is the color of your skin (non-exposed areas)?	Reddish	Very pale	Pale with Beige tint	Light Brown	Dark Brown
Do you have freckles on unexposed areas?	Many	Several	Few	Incidental	None
	< Total score for Genetic Disposition				

REACTION TO SUN EXPOSURE:

Score	0	1	2	3	4
What happens when you stay too long in the sun?	Painful redness, blistering, peeling	Blistering followed by peeling	Burns sometimes followed by peeling	Rarely burns	Never had burns
To what degree do you turn brown?	Hardly or not at all	Light color tan	Reasonable tan	Tan very easy	Turn dark, brown quickly
Do you turn brown within several hours after sun exposure?	Never	Seldom	Sometimes	Often	Always
How does your face react to the sun?	Very sensitive	Sensitive	Normal	Very resistant	Never had a problem
	< Total score for Reaction to Sun Exposure				

TANNING HABITS:

Score	0	1	2	3	4
When did you last expose your body to sun (or artificial sunlamp/tanning cream)?	More than 3 months ago	2-3 months ago	1-2 months ago	Less than a month ago	Less than 2 weeks ago
Did you expose the area to be treated to the sun?	Never	Hardly ever	Sometimes	Often	Always
	< Total score for Tanning Habits				

	< Total score for Genetic Disposition
	< Total score for Reaction to Sun Exposure
	< Total score for Tanning Habits

	< SKIN TYPE SCORE
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FITZPATRICK SKIN TYPE

Skin Type Score	Fitzpatrick Skin Type
0-7	I
8-16	II
17-25	III
25-30	IV
Over 30	V-VI

The above information is strictly confidential

Completed by: Patient

Medical Assistant/RN _____
Initials

Signed by Patient Date

Reviewed by Date