

Injected Lipolysis
Aesthetic Market Recession
Neurotoxin Safety

Silk'n Enhances In-Office Hair Removal

Silk'n from Home Skinovations (Yokneam, Israel) brings safe, effective hair reduction to the privacy of the home by harnessing a novel technology similar to intense pulsed light (IPL), in a small home-use device. Available only through physicians, the FDA cleared Silk'n serves as both a post treatment maintenance solution for some practitioners and an economical entry into the light-based hair reduction market for others.

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Silk'n Home Hair Removal Device Provides Opportunity for Physician Profits

By Kevin A. Wilson, Contributing Editor

"The broad spectrum light and low energies involved limit potential complications. When used as directed by a physician, treatment is virtually painless."

"Silk'n is simply a less expensive, hand-held version of what we perform in-office, with a lower energy setting," explained Tina S. Alster, M.D., director of the Washington Institute of Dermatologic Laser Surgery (Washington, D.C.). "With in-office hair reduction a 50% to 80% improvement in the treated area is typically achieved, but that means there is still 20% to 50% of hair left. On-going maintenance may be cost prohibitive for some individuals. There's also a huge population who, for lack of money or want of privacy, won't undergo hair removal in an office or spa setting. Silk'n will reach these two viable segments of the market. We're just seeing the tip of the iceberg on this, especially when one considers the relative cost of Silk'n versus in-office hair treatment."



Tina Alster, M.D.
Washington Institute of
Dermatologic Laser Surgery
Washington, D.C.

According to Amir Waldman, Ph.D., vice president of clinical affairs at Home Skinovations, efficacy of the Silk'n device rests on a proprietary combination of broad spectrum light (475 nm to 1200 nm) and acoustic energy in a pulse structure that produces a high peak power with approximately 3.5 J/cm² of energy density known as Home Pulsed Light (HPL).

Before treating themselves with Silk'n, users must shave the hair at the treatment site. "Untrimmed hair will burn, have an unpleasant odor and leave debris on the optical window which will reduce its effectiveness," noted Dr. Waldman. The device is used directly on the skin without any lotion or cream of any kind. To prevent non-treatment pulsing of the Silk'n

device, the applicator must be fully pressed against the skin, activating a switch that allows the unit to function. "The broad spectrum light and low energies involved limit potential complications. When used as directed by a physician, treatment is virtually painless. Most users have reported nothing more than a minor itching sensation." Similar to other light-based hair removal technologies, Silk'n is not effective on light-colored hair and cannot be used on darker skin types.

"One major advantage of Silk'n is relatively rapid treatment," said Dr. Waldman. "The large spot size of 2 cm x 3 cm, which equals about one square inch, allows users to cover more area in less time. Another factor in treatment speed is the interval between pulses – 3.5 seconds, therefore two lower legs can be treated in less than 30 minutes on average."

Silk'n comes with two cartridges. The treatment lamp and optical window are housed in the cartridge, which is capable of delivering 750 treatment pulses. Additional cartridges are available for purchase. "We anticipate a single user needing three to four cartridges per year on average," said Dr. Waldman. "How long a cartridge lasts depends on the size of the treatment area. Someone doing a large area like legs, underarms and bikini line will probably expend a cartridge in two or three sessions. But if you're just treating the underarms, for example, it could last years."

Silk'n uses a proprietary combination of photo and acoustic energies to harness the principle of selective photothermolysis and remove unwanted hair. "Silk'n utilizes broadband wavelength light which targets melanin in the hair, predominately at the shaft," explained Michael H. Gold, M.D., director of the Gold Skin



Silk'n by Home Skinovations

Care Center and the Tennessee Clinical Research Center in Nashville, Tenn. "Once the shaft is destroyed you can access the follicle, which is deeper in the skin, to achieve more permanent hair reduction. That's how all laser and light-based hair removal treatments work." Since melanin is the target chromophore, efficacy is somewhat dependent on the amount of pigment present, which is why such devices are much less effective on light-colored hair and shouldn't be used over pigmented lesions or tattooed skin. "The HPL technology of Silk'n is similar to IPL – the standard for hair removal. There are probably more IPL devices in the world for hair removal than any other technology."



Michael H. Gold, M.D.
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Dr. Alster recently completed a study of 20 women with varying skin types (up to type IV) exhibiting unwanted black or brown hair in four non-facial sites: axilla, forearms, bikini and lower legs. In a clinical office setting, patients self-administered a series of three Silk'n treatments at two week intervals with follow-up six months post treatment after being professionally instructed. Results were measured by hair count as well as clinical photography. "After the course of three consecutive treatments, significant hair reduction was observed in all patients and hair counts were reduced by 40% to 50%, with the lower legs displaying the best result," she reported. Findings from Dr. Alster's study will soon be published. "Initial hair removal studies using high-powered lasers in an office setting, saw reductions of 50% to 80%. Silk'n showed

results on the lower end of those early trials, but given its home-use application, the clinical outcome is very promising."

Dr. Gold is currently in clinical trials studying the safety and efficacy of Silk'n as well. Patients receive three to four treatments, approximately two weeks apart. "Results are preliminary, but so far patient acceptance is high. It's still early but at this point the device appears to be safe and effective, however we don't have any hard numbers yet."

"We have used various light sources to successfully decrease hair growth for more than a decade," noted Dr. Alster. "A home-use device makes sense and hair removal is a much safer, easier and clinically effective entry into the market than other modalities may have been."

Experts agree that the home-use market's strength is burgeoning. In August 2008, E. Victor Ross, M.D., director of the laser and cosmetic dermatology unit at the Scripps Clinic in San Diego, Calif. commented on the subject of home-use devices at the Controversies and Conversations in Laser and Cosmetic Surgery symposium in Whistler, B.C., Canada. "The bottom line is that these devices will become more commonplace, especially as efficacy and safety go up while prices come down."



E. Victor Ross, M.D.
Director
Cosmetic and Laser Dermatology Unit
Scripps Clinic
San Diego, CA

"Technological advancements have made these devices less expensive and more compact, therefore some treatments that previously could only be done in-office

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“There are also some physicians who cannot afford expensive professional hair removal devices, so Silk’n represents an opportunity to enter the hair removal business.”

are now within reach of the consumer,” Dr. Ross continued. “However, the high-energy required for some cosmetic applications will inhibit replacement of many professional caliber devices. Hair reduction represents a good opportunity for home-use devices because it’s a large market, and provided that great care is taken in design, education and operation, these devices can be deployed safely by the consumer.” Dr. Ross also suggested that home-use devices might play a complementary role to in-office procedures by maintaining some of the cosmetic enhancement achieved in a clinical setting.

According to Deborah S. Sarnoff, M.D., F.A.A.D., F.A.C.P., associate clinical professor of dermatology at New York University Medical School (New York, N.Y.), media interest in home-use hair reduction is extraordinary. Home-use devices have recently been featured on *The Today Show* as well as in *Allure* magazine and *The Wall Street Journal*. “I’m on Park Avenue in New York City and I have many beauty editors as patients. These people are young, professional women. When you talk about deep wrinkle reduction and other sorts of anti-aging treatments, they cannot relate, but managing unwanted hair is a problem women of all ages relate to.”

Stephen Mulholland, M.D., a cosmetic plastic surgeon in private practice in Toronto, Canada and Los Angeles, Calif., recently conducted a workshop at THE Aesthetic Show (TAS) 2008 in Las Vegas demonstrating the use of Silk’n. He considers the device to be a perfect complement to in-office hair reduction. “Regardless of which wavelength or system we use, you generally have a fair number of patients who do not achieve 100% permanent hair reduction in-office. Even after five sessions about 25% to 30% of hair remains. Silk’n may provide slightly more reduction as well as maintenance and management. This protects the patient’s investment and/or extends it by providing longer hair-free intervals.”



Stephen Mulholland, M.D.
Cosmetic Plastic Surgeon
Toronto, Canada
Los Angeles, CA

Dr. Mulholland offers Silk’n to patients as part of his in-office hair reduction package. “There are also some physicians who cannot afford expensive professional hair removal devices, so Silk’n represents an opportunity to enter the hair removal business.”



Underarm before Tx



Underarm after Silk'n treatments

"I think the device is best used as an adjunct to in-office hair reduction," explained Dr. Sarnoff, who operates private practices in Manhattan and Long Island, N.Y. "However, many women today work and don't want to make time for in-office treatments. They love the convenience of using a safe, effective device in the privacy of their home with minimal discomfort. Results are easy to see because you either still have hair or you don't, so there's no gray area."



**Deborah Sarnoff, M.D.,
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"In my practice, at-home patient experience with Silk'n has been very positive," said Dr. Alster. "It's probably due to a combination of easy-to-use teaching aids, physician consultation and the results." Silk'n comes with a quick reference card and a DVD to guide users to safe, effective hair reduction.

"Patient satisfaction with Silk'n is extraordinary," reported Anthony Bennett, managing director of Red Sky Insights, an independent marketing consulting firm based in New York City, N.Y. Mr. Bennett oversaw a beta test of the Silk'n prototype devices for about 100 Toronto women. After receiving instruction, participants were asked to use the device at home once every two weeks. Various measures of satisfaction and patient perceived results were evaluated after six weeks (two to three treatments), at about 12 weeks (five or six treatments) and after nine months (at least seven or eight treatments).

"It was interesting to see the results between the first and second evaluations," noted Mr. Bennett. "After about

two to three treatments approximately 60% of people said they saw slight to significant hair reduction. But at the three month mark, that number was 93%, and 88% said they would recommend the device to a friend. In this business those are great numbers."

According to Mr. Bennett, reaction to the device was consistent as well. "Participants would use the device, then return to their daily activities immediately. It was obvious that the convenience and privacy factors were important, and patients expressed a high level of comfort using the device."

One beta test group participant, Patricia Geoffrey, R.N., a clinical nurse specialist in occupational medicine in Toronto, Canada explained, "My grapevine experience was that hair removal was painful, so I was interested in this new home-use device but unsure. You can never be sure about what you're getting at a spa. Plus it costs so much."

Like her fellow participants, Ms. Geoffrey was pleasantly surprised at how easy, effective, safe and comfortable Silk'n treatment was to perform and has since become a regular user. "I use this in the privacy of my own home, when I want to. I've made it part of my self-pampering regimen and now there are parts of my body I don't have to shave as often." Ms. Geoffrey participated in Dr. Mulholland's TAS workshop as well. "I think any woman would enjoy Silk'n the way I do."

Backed by a team of experienced industry veterans, many formerly with Syneron Medical, Ltd., Home Skinovations is committed to the home-use market, according to CEO Moshe Mizrahy. "This is the next big trend in the industry, and we have the best technology and strategy to successfully

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“We’re working toward providing a full range of these devices for rejuvenation, acne treatment, skin tightening, cellulite and other applications. We believe the home-use market possesses huge potential.”

reach this market,” he stated. “The rationale for this commitment is simple: most people in the marketplace cannot afford expensive treatments but will pay for an effective alternative, and for any number of reasons many never seek in-office treatments in the first place.”

There are no plans for Silk’n to go retail. “We will not cut out the physician,” explained Mr. Mizrahy. “The pathway we have chosen is the best. We are developing ways to help doctors market Silk’n and use it to increase their hair removal business.”

“Making Silk’n available only through physicians is a brilliant strategy,” said Dr. Sarnoff. “It forces patients to become educated and provide informed consent before they can obtain the device. Patients need to be aware that they cannot use it over tattoos or pigmented lesions, and that it isn’t for dark skin types or if you’re tan. Average results will be enhanced by reducing the chance for errors. Silk’n is also a great practice builder in the sense that patients may inquire about other cosmetic services offered in your facility.”

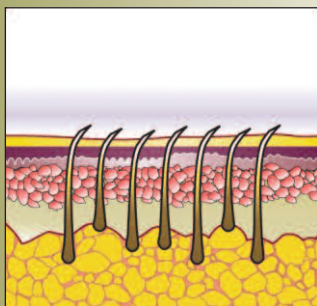
According to Dr. Alster, physician-only distribution may be the key to the successful entry of Silk’n into the marketplace. “By allowing the aesthetic medicine community

to control how rapidly this new technology eases into the public consciousness, the market — including physicians and end users — will have more time to adjust. It’s going to take some time for the community to reach the optimum comfort level with this and other home-use devices. Otherwise products appear fly-by-night. It’s similar with prescription medications that became available over-the-counter after a certain amount of time.”

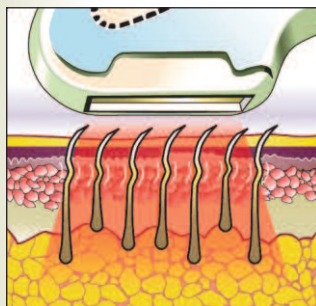
The future of Home Skinovations is expansion of their home-use device product offering. “We’re working toward providing a full range of these devices for rejuvenation, acne treatment, skin tightening, cellulite and other applications,” said Mr. Mizrahy. “We believe the home-use market possesses huge potential.”

Industry experts agree, “This is only the beginning,” noted Dr. Alster. “It may seem to go against what we’ve traditionally been taught about laser and light-based devices and how dangerous they can be when not properly used, but once everyone is up to speed on how safe and effective these devices can be, people will rapidly accept the idea. This will pave the way for other home-use devices.”

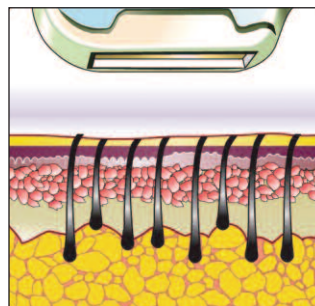
Amid concerns that devices such as Silk’n might have a negative effect on hair removal business, Dr. Ross does not see a threat. “If anything, home-use devices will bring in more business by raising awareness,” he said. “These devices are not as effective as what we can achieve in-office, and patients will need physician guidance on how to safely and effectively use them, so we’ll still be in the game. The market is huge.”



Before Silk’n HPL pulse



Effect during Silk’n HPL pulse



After Silk’n pulse