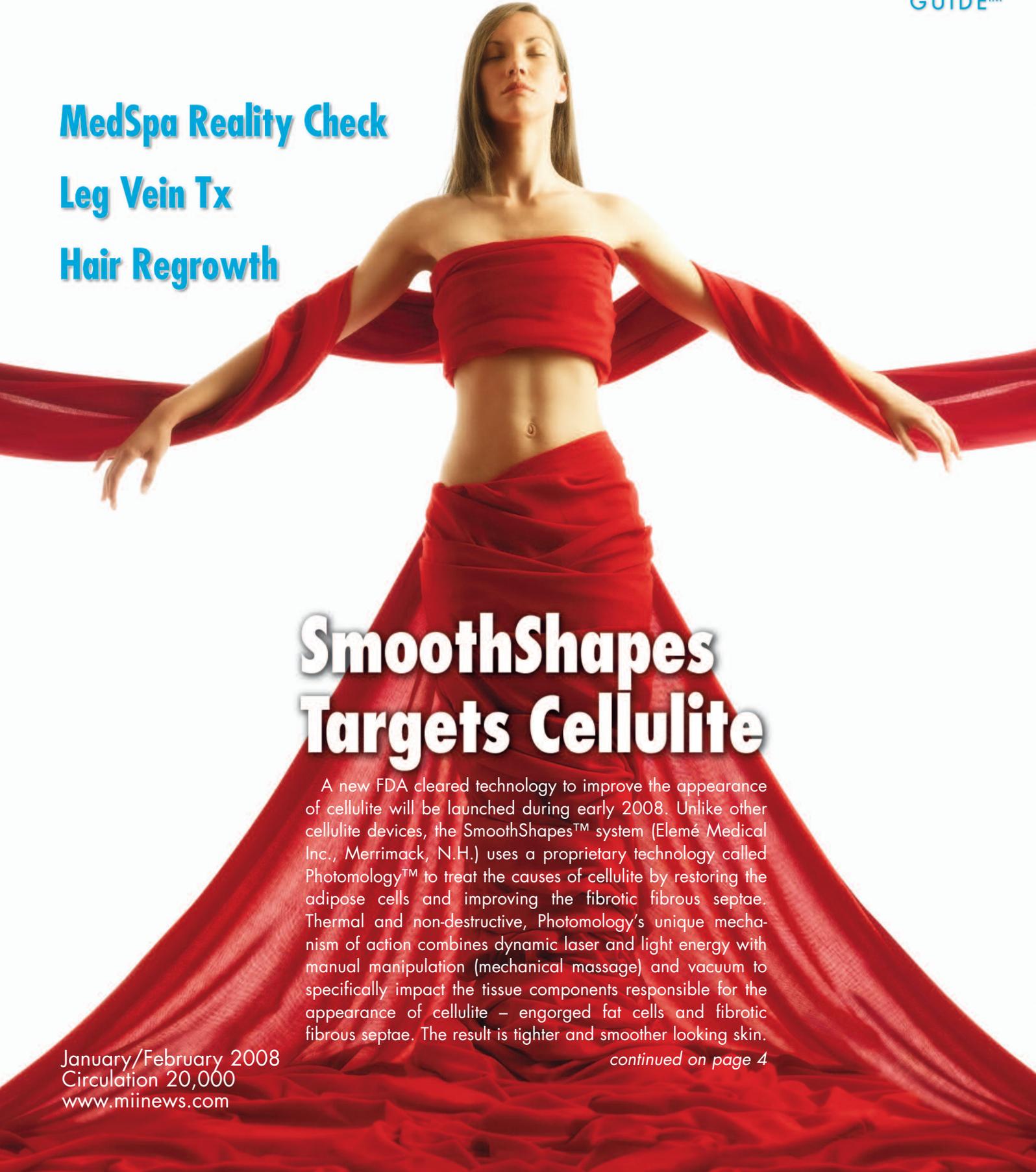


**MedSpa Reality Check**

**Leg Vein Tx**

**Hair Regrowth**



# SmoothShapes Targets Cellulite

A new FDA cleared technology to improve the appearance of cellulite will be launched during early 2008. Unlike other cellulite devices, the SmoothShapes™ system (Elemé Medical Inc., Merrimack, N.H.) uses a proprietary technology called Photomology™ to treat the causes of cellulite by restoring the adipose cells and improving the fibrotic fibrous septae. Thermal and non-destructive, Photomology's unique mechanism of action combines dynamic laser and light energy with manual manipulation (mechanical massage) and vacuum to specifically impact the tissue components responsible for the appearance of cellulite – engorged fat cells and fibrotic fibrous septae. The result is tighter and smoother looking skin.

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# Elemé Focuses on Science of Cellulite

“The SmoothShapes system makes more sense than the other devices out there for cellulite because it addresses the subcutaneous fat layer non-invasively and the treatment is pleasant for patients.”

By Fred Wilson, Contributing Editor

“The SmoothShapes system makes more sense than other devices out there for cellulite. It addresses the subcutaneous fat layer non-invasively and the treatment is pleasant for patients,” reported Miles Graivier, M.D., who is evaluating the SmoothShapes system as a stand-alone device for treating cellulite, and as an adjunctive treatment in patients undergoing liposuction. “We have begun work with a prototype and look forward to the new version, which features a more powerful laser and vacuum system plus improved ergonomics,” said Dr. Graivier, who practices plastic surgery in Roswell, Ga.



**Miles Graivier, M.D.**  
Plastic Surgeon  
Roswell, GA

Elliot Lach, M.D., a plastic surgeon in Boston, Mass., has been developing and evaluating the SmoothShapes system since 2002 and has treated the thighs, buttocks and abdomen. His experience in liposuction played a role in the decision to combine dermal and sub-dermal massage with low-energy, dual-wavelength laser treatment in the SmoothShapes system design. “A thin person who exercises and has a persistent fold in the hips or thigh is an ideal candidate for liposuction,” he said. “But removing the fat in this fold may not improve cellulite and may even make it worse. So with the SmoothShapes system, we combined a known method of cellulite improvement (massage) with a known way to target subcutaneous fat and stimulate collagen to restore the health of the hypodermis.”

“Using a patient as his or her own control, a study revealed that massage alone could produce a very short-term improvement in

skin appearance but did not reduce fat; laser treatment alone had little effect on cellulite or subcutaneous fat; but combining both reduced fat and improved the appearance of cellulite,” Dr. Lach reported. “Once research pointed to the effectiveness of dual modalities (dynamic laser and light energy with mechanical methods), we began work to develop the best performing combinations of laser, light and mechanical methods. The result was Photomology.”

SmoothShape’s Photomology technology uses laser and light energy combined with vacuum and contoured rollers for mechanical manipulation. A 915 nm laser liquefies fat whereas a 650 nm light increases cell membrane permeability to allow movement of liquid fat into the interstitial fluid; stimulate collagen production; and restore circulation. A vacuum component enables consistent light penetration, while the actions of mechanical contoured rollers move liquids from the interstitial fluid into the lymphatic system. A 2006 study by R. Rox Anderson, M.D., and colleagues described the absorption spectra of human fat and identified the 915 nm wavelength as one of the four absorption peaks for lipids.

“The light combination allows the SmoothShapes system to target lipids selectively,” explained Dr. Lach. “Additionally, we know that low-energy, 650 nm light delivered to the proper depth in skin can loosen the chemical bonds of fat molecules so these molecules can migrate from adipose cells to the interstitial fluid without destroying the adipose cell membrane. Subsequently, the released fat molecules absorb at longer wavelengths such as 915 nm and the amount of heat generated is enough to allow the fat to be eliminated through normal metabolic channels rather than to re-enter the adipocytes.”

"Our strategy with the SmoothShapes system was to mobilize the by-products of the subcutaneous fat as well as the fat itself," Dr. Lach said. "The vacuum component of the SmoothShapes system positions the skin up into the rollers for the most effective modality performance, while the mechanical rollers assure dynamic lymphatic drainage."



**Elliot Lach, M.D.**  
Plastic Surgeon  
Boston, MA

Unlike other cellulite devices, the SmoothShapes device maintains the integrity of the adipocytes during treatment. "The procedure does not damage these cells because the cellular temperatures are always below 41° C," Dr. Lach explained. "SmoothShapes treatments also cause organized collagen to be deposited in the fibrous septae in a more predictable fashion, which makes the patient's skin and underlying adipose tissue appear more youthful."

Neither Dr. Lach nor Dr. Graivier, who has treated patients with the SmoothShapes system for six months, have seen any adverse effects during or after SmoothShapes treatment and they have not used pain medications or topical anesthetic.

### Treatment Protocol

Although Dr. Lach developed his SmoothShapes protocols on patients with moderate cellulite, he has found that the device is also effective in large sized patients with more cellulite and fat. "These patients simply need longer courses of treatment," he said. "People within 20% of their ideal body weight are better candidates, but personal anatomy is also

a factor. A fit person with fat around the thighs may be just as good of a candidate as a person who is a little heavy everywhere."

Depending upon the patient's class of cellulite, the initial treatment protocol calls for six to ten treatments. Treatment times range from 10 to 40 minutes depending on the area being treated, and patients may choose to treat more than one problem area. The SmoothShapes system software allows the technician to select treatment areas and assures accurate timing of procedures.

While some other cellulite devices may require maintenance treatments ranging from every six weeks to three months, SmoothShapes' maintenance is once a year, after the initial course of treatments. "Although not part of the protocol, five of the initial study patients came back for an elective 13 month post treatment evaluation and four of five patients maintained 80% of their result," reported Dr. Lach.



**Klaus Fritz, M.D.**  
Dermatologist  
Landau, Germany

### Clinical Studies

Klaus Fritz, M.D., a dermatologist in private practice in Landau, Germany, has been evaluating the SmoothShapes system over the last six months. "We are seeing consistent, lasting results from the SmoothShapes treatments," he said. "The early results indicate that patients may not need follow-up maintenance treatments for quite some time." Dr. Fritz is vice president of the *European Society of Laser Dermatology* and secretary general of the *German Dermatology Association*.

"The vacuum component of the SmoothShapes system positions the skin up into the rollers for the most effective modality performance, while the mechanical rollers assure dynamic lymphatic drainage."

“Patients tell us they love the appearance of their skin and that their clothes fit better.”

Dr. Lach also reported very positive patient responses. “Patients tell us they love the appearance of their skin and that their clothes fit better,” he said. “One patient planned for ten visits, but after visit five, she asked us to treat another area because she was losing too much fat in the area we had treated.” Although the results have been very gratifying, Dr. Lach and his colleagues are still learning and predict that even patients with severe cellulite (excluded so far) may also be improved with SmoothShapes treatment.

Kathy Nagel, R.N., has treated approximately 25 patients with the SmoothShapes system device under the direction of Dr. Lach. “Some of my female patients have dropped one or two pants sizes,” she reported. “These are the ones who also maintain a healthy life style, which I advise all my patients to do.” Ms. Nagel added that patients notice improvement immediately after each treatment, but the change is much greater the next morning. “Women

are particularly thrilled that their husbands also notice their improvement.”

According to Ms. Nagel, patients have no downtime and pain medication is not necessary. “Although rare, bruising can occur if settings are not followed per protocol. None of my current patients are bruised.” Ms. Nagel added that the SmoothShapes treatment technique can be learned in one afternoon, but the ability to recognize areas with the most cellulite and to adjust the treatment procedure accordingly requires more time. “I spend more time on the troubled areas.”

#### Liposuction Adjunctive Treatment

As indicated earlier, Dr. Graivier is also evaluating the SmoothShapes system as an adjunctive treatment in patients undergoing liposuction. In his liposuction study, he pre-treats with SmoothShapes one week before surgery, just before surgery, as well as one and two weeks after surgery. He has found that when he pre-treats his liposuction patients with the SmoothShapes device, patients experience less pain, bruising and bleeding during and after liposuction.

“My patients find the treated areas comfortable a week after surgery, which is not the case when liposuction is done without the SmoothShapes system,” Dr. Graivier reported. “It’s like you are deflating the fat cells, and then liquefying the released fat before you do the evacuation with the liposuction. The adipose cells experience less trauma and the physician removes more aspirant, so the liposuction procedure is less traumatic, which most likely explains why I get reduced bruising and bleeding. The SmoothShapes system has been a very nice addition to the liposuction technique. When we get the final commercial unit, I’m sure our liposuction results will improve even more.”



Thigh before Tx



Thigh one month after tenth SmoothShapes Tx

Like Dr. Graivier, Dr. Lach has treated his liposuction patients with the SmoothShapes system. "We try to make their skin smoother and clear the lymphatic drainage in patients with swollen legs," he said. "We hope in the future to treat the face, arms, neck and other areas with the SmoothShapes system."

### Market Potential

Although the SmoothShapes system received FDA approval in July 2006, president and chief executive officer Nancy Briefs elected to obtain more clinical experience before making the device commercially available. The second half of 2007 has been spent refining protocols and design through feedback from physicians at 16 centers in the U.S. and around the world. "At Elemé Medical we are serious about the science of cellulite and we're dedicated to providing market leading technology in all areas of body contouring. This additional time for research has assured us that our first users will achieve significant and long lasting results for their patients," explained Ms. Briefs.

Dr. Graivier envisions a dual role for the SmoothShapes system device in his practice. One is for cellulite treatment and the other is for reducing pain and bruising associated with liposuction. "I expect my cellulite volume to go up because the SmoothShapes procedure is more effective and more comfortable for patients than the other cellulite procedures out there." Dr. Graivier added that Elemé Medical has used data from test sites to improve their technology prior to commercial launch. They have modified the technology, ergonomics, laser energy levels, suction and rollers that help to break up the fibrous adhesion in cellulite. "With a more powerful laser we may be able to achieve the same results with fewer treatments and still maintain the comfort."

According to a 2004 study, "85% to 98% of post-pubescent women have cellulite, therefore the cellulite treatment market will have a significant impact on any aesthetic practice," added Dr. Lach.

"At Elemé Medical we are serious about the science of cellulite and we're dedicated to providing market leading technology in all areas of body contouring."



SmoothShapes Treatment