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VelaShape Gains FDA Approval

Syneron's (Irvine, Calif.) newest body contouring device, the VelaShape, has received 510k clearance for the temporary reduction of thigh circumference, according to James Bartholomeusz, Syneron's director of product development. "Syneron's current device for the body shaping market, the VelaSmooth, though used primarily to reduce the appearance of cellulite in numerous laser, surgery and primary care centers, also showed nice circumferential reduction, but 10 to 12 treatments were required. With the VelaShape, the same results can be obtained with just four treatments and no increase in downtime." The VelaShape also has 510k clearance for the reduction in the appearance of cellulite.

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VelaShape Offers Greater Efficacy for Body Contouring with Fewer Treatments

By Lara G. Owens, Contributing Editor

Photos courtesy of Gerald Boey, M.D.



Cellulite before Tx



After four VelaShape treatments

VelaSmooth user, and family practitioner, Cheresse LaPorta, D.O., is thrilled with the VelaShape. "Treatment time is dramatically reduced from 45 minutes to 20 minutes and treatment frequency is reduced from 8 to 12 treatment sessions to four treatment sessions once a week," she said. "The handpiece is almost foolproof. If you break suction you hear it immediately and the device stops functioning. You cannot harm anyone. I've also not seen adverse effects beyond erythema, and that resolves on its own within a few hours."



Cheresse LaPorta, D.O.
Family Physician
Patchogue, NY

According to Mr. Bartholomeusz, the new VelaShape was designed with body contouring in mind. "We've developed the V-Contour applicator specifically for circumferential reduction. The V-Contour's electrodes were designed to deliver high levels of RF current through the fat." In addition to the V-Contour head, the VelaShape also features a new and improved handpiece for cellulite, called the V-Smooth. "The V-Smooth applicator has also reduced cellulite treatment from 10 to 12 treatments down to four," Mr. Bartholomeusz noted. "The inclusion of this second treatment head will most likely replace VelaSmooth as a stand-alone device."

Like the VelaSmooth, the VelaShape features e $\dot{\text{L}}$ os (Electro-Optical Synergy) technology, Syneron's combination of bipolar radiofrequency (RF) and infrared light energies, combined with light suction and massage, according to Mr. Bartholomeusz. "The RF and optical energies heat the skin while the body-optimized negative pressure and tissue manipulation facilitate the efficient delivery of that energy." Mr. Bartholomeusz added that the VelaShape offers the same

"More RF current reaches the fat, resulting in fewer treatments and reduced treatment time to achieve the desired result."

safety profile as the VelaSmooth. "The patient doesn't feel an increased heat sensation or experience more downtime."

One difference, however, is the greater power of the VelaShape. "The VelaShape's RF current, which reaches the fat, offers 50 watts of power, whereas the VelaSmooth's RF current offers only 20 watts," Mr. Bartholomeusz explained. "The VelaShape's energy is also more focused due to its new electrode design and optimized tissue manipulation. More RF current reaches the fat, resulting in fewer treatments and reduced treatment time to achieve the desired result. In other words, VelaShape, although it heats the skin surface by the same amount, creates more heat in the fat because it delivers more RF current to the deeper layers where the fat resides."

In summary, the amount of RF current delivered to the fat layer is increased by three improvements: the increased power, body-specific vacuum optimization and the new electrode design. The VelaShape is also significantly quieter during operation than the VelaSmooth.

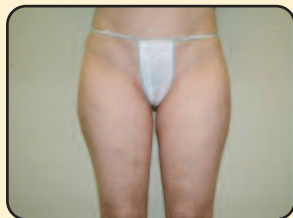
Until now, according to Dr. LaPorta, who practices in Patchogue, N.Y., surgery and other invasive procedures have been the only methods guaranteed to achieve good body contouring. "In my practice, patients request cellulite and fat reduction, but they don't want to go under the knife," she said. "VelaShape allows us to treat cellulite and promise circumferential reduction, which really no other device can achieve so reproducibly. Even people who've had liposuction, mesotherapy, or injectable chemicals don't have the smooth skin or reduced dimpling I've seen in patients treated with the VelaShape. The VelaShape is also a lot less frightening than those other methods."

Dr. LaPorta cautioned that it's important to pick the right candidate for treatment because the VelaShape isn't designed for

Photos courtesy of Gerald Boey, M.D.



Circumferential reduction before Tx



After five VelaShape treatments

excessively heavy patients. "A good candidate is a person with protruding areas of fat or who is no more than 50 pounds overweight," she noted. "For large patients, we might put them on a diet and exercise regime before introducing them to VelaShape." Dr. LaPorta has found that with the VelaShape she achieves both fat reduction and skin smoothing by combining the V-Smooth and V-Contour applicators.

As the demand for aesthetic procedures grows, so does the number of primary care physicians entering the aesthetic market, according to Mr. Bartholomeusz. "People are comfortable with their physicians and want them to take care of their aesthetic concerns," he said. "Body contouring is the fastest growing segment of the aesthetic market. Since VelaShape is the only real contouring solution cleared by the FDA, it's going to be big."

Dr. LaPorta agrees, "Patients come to their family doctors for many reasons. They trust them and feel comfortable coming to them for treatment, which certainly helped me to integrate the VelaSmooth into my practice. It was an instant success, a real step up for primary care. Now I'm excited about the VelaShape."

VelaSmooth user John Shieh, M.D., also looks forward to adding VelaShape to his primary care practice. "Ten or more treatments with the VelaSmooth will turn into four treatments with the VelaShape, with treatment times dropping down to less than 30 minutes. These changes make a big difference to both patients and staff." In the past Dr. Shieh combined VelaSmooth with other treatments to achieve results more rapidly. "VelaShape allows me to get the same result as I would get when using VelaSmooth and



John Shieh, M.D.
Medical Director
RejuvaYou Medical Spas
Pasadena, CA

"A number of devices purport to do body contouring, but the VelaShape is the only FDA cleared circumference reducer."

Lipodissolve together, but with only four treatments and no injection," he said. "Patients will love that, although some may still opt for the combination therapy."

Dr. Shieh, who practices in Pasadena, Calif., believes the emergence of VelaShape and other body contouring devices and procedures will cause serious competition not only within the non-invasive market, but in surgery as well. "Approximately 14 million body shaping procedures were performed in 2005 and we're looking at 30 to 32 million in 2010," he explained. "Many patients are relieved that they now have a viable non-invasive option."

Despite the competition, Dr. Shieh believes that VelaShape has an edge on other body shaping modalities. "One major advantage is that the VelaShape is the first device actually cleared by the FDA for this application," he said. "Laser and light only devices are limited in how they deliver their energy. VelaShape is unique in that it focuses its energy by isolating the treatment area from the rest of the body."

Dr. Shieh added that primary care salaries have not kept up with inflation during the past ten years and this is driving more physicians toward cash pay procedures. "The primary care office then becomes truly the front gatekeeper, a one-stop shop for patients who want a safe, non-invasive option to address their body contouring concerns," he said.

Plastic surgeon R. Stephen Mulholland, M.D., FRCS (C) (Toronto, Ontario, Canada), agrees that VelaShape's on-label claim is important. "A number of devices purport to do body contouring, but the VelaShape is the only FDA cleared circumference reducer," he said. "In my experience, VelaShape results have been more predictable than those of the VelaSmooth and reduction in circumference is achieved much quicker. Patients also don't want to come in

Photos courtesy of R. Stephen Mulholland, M.D., FRCS (C)



Abdomen before Tx



Abdomen after VelaShape treatments

"Some patients see results after just a couple treatments, and VelaShape promises results in four, which is amazing. Patients also seem very happy."

8 to 16 times for treatments. With the VelaShape, we see a 4 cm reduction after four treatments, a nice difference in patients frustrated with localized fat in their tummy, hips or thighs."

While Dr. Mulholland doesn't believe that VelaShape treatment will replace liposuction anytime soon, he has found that applying VelaShape after liposuction provides smoother overall results. "The V-Contour head decreases my surgical touch-up rate by at least 75%," he said. "I can also smooth out lumps and irregularities that appear after surgery."



R. Stephen Mulholland, M.D., FRCS (C)
Plastic Surgeon
Toronto, Ontario, Canada

Dr. Mulholland projected that in the next year or two, the number of body contouring procedures could equal the number of cellulite treatments. "Although a 4 cm reduction is not liposuction, it's certainly a liposuction-like result. And as long as patient expectations of outcomes are conveyed intelligently, VelaShape will be a very popular treatment."

Regarding pain, Dr. Mulholland's patients understand that no aesthetic treatment is painless. "We use the VelaShape without topical anesthesia," he said. "Patients might have erythema and swelling or, if they are taking high-dose aspirin or an anti-coagulant, the risk of bruising is increased."

Gerald Boey, M.D., a dermatologist in Vancouver, B.C., Canada, participated in the 16 patient study of VelaShape and is most impressed by how few treatments are required to achieve a good result. "Some patients see results after just a couple treatments, and VelaShape promises results in four, which is amazing. Patients also seem very happy."

According to Dr. Boey, physicians experienced with VelaSmooth must remember that VelaShape has much higher power. "However, you'd have to try hard to hurt a patient and no topical anesthetics are needed. Patients just sense heat or have erythema for an hour or two after treatment."



Gerald Boey, M.D.
Dermatologist
Arbutus Laser Centre
Vancouver, B.C., Canada

Dr. Boey believes that the VelaShape would easily fit into primary care. "Primary care physicians are often the first physicians that patients confide in for their cellulite and shaping concerns," he said. "VelaShape is not a cure for obesity, but it's enough motivation for some patients to change their lifestyle."

Dr. Mulholland agreed, "I think body contouring will become a staple of primary care just as hair removal, Botox injections and fillers have. The VelaShape offers an alternative to liposuction that works. It's hard to create injury, and treatment is far safer than even hair removal or photorejuvenation, which many primary care physicians already do. Although surgery is still the gold standard, patients should be informed about new procedures."

Dr. LaPorta added that VelaShape is the next step to popularizing lasers in a primary care office setting. "VelaShape is easy to integrate into a practice because it doesn't require a lot of learning and memorizing. It's non-invasive, painless, causes no downtime or adverse effects, and patients are happy with the way they look after treatment. It makes me feel good to see people so happy with what I've done. I think other physicians will catch on."