

# **Syneron's Vela(TM) Platform Receives FDA Clearance for Temporary Reduction of Thigh Circumference**

Syneron First to Receive FDA Clearance and CE Mark for Circumferential Reduction

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Syneron Medical Ltd. (NASDAQ: ELOS), an innovator in the development, marketing and sales of elos™ combined-energy medical aesthetic devices, today announces its Vela™ platform has received the US Food and Drug Administration (FDA) 510(k) pre-marketing clearance and CE Mark certification in the European Union for the temporary reduction of thigh circumference. This announcement marks the first FDA clearance and CE Mark certification for a product designed to reduce circumferences in the body.

The Syneron Vela platform previously received clearance by the FDA for cellulite treatment. This new clearance enhances Syneron's leading position in the fast-growing global market of non-invasive body shaping and contouring.

The clearance is based on a multi-center, blinded and randomized clinical study performed in the US and Canada. The study included 66 patients. Each patient in the study was treated on only one thigh, while the other thigh was used as a control. The choice of the thigh to be treated was randomized at each site and the person who performed the circumferential measurements did not know which thigh was treated. All study participants were women between the ages of 21 to 62, with a wide range of body mass indexes (BMIs) corresponding to underweight, normal, overweight and obese. Seventy-three percent of the participants had normal BMIs.

The average circumferential reduction in the treated thigh was 1.9 cm (0.75 inch) with a range of 0.3 to 7.2 cm (0.12 to 2.8 inches). The average circumferential reduction in the untreated thigh was 0.3 cm (0.12 inch) with a range of -2 cm (-0.78 inch), an increase in circumference, to 1.7 cm (0.67 inch). Measurements were taken three to four weeks post final treatment. The differences in the circumference change levels of the treated and control thighs were found statistically significant ( $p < 0.001$ , t-test for unpaired data). The study demonstrated the effectiveness of the Vela platform devices in thigh circumferential reduction.

"The clearance by the FDA and receipt of the CE Mark are key milestones in Syneron's continuing progress toward development of non-invasive technology for body shaping," said Syneron Chairman, Dr. Shimon Eckhouse. "Syneron invested significant resources in this study, developing unique tools which enabled us to reliably prove in a blinded and controlled study the effectiveness of the Vela in thigh circumferential reduction. The choice of thighs for this study, rather than other parts of the body, gave us a natural control which is a critical element for such a study.

"We are delighted to be the first company to receive FDA clearance for this indication," said Doron Gerstel, CEO of Syneron. "With the Vela, we were the first to achieve FDA clearance for the temporary reduction in the appearance of cellulite under a new product class that was created by the FDA and now are proud to announce another first in the circumferential reduction market."

Syneron's Vela devices are safe and powerful tools for non-invasive treatment of cellulite and circumferential reduction. The Vela simultaneously applies light energy to the tissue at a controlled infrared wavelength, conducted RF energy, and mechanical manipulations of the skin and fat layer to focus energies precisely on target treatment areas.

## About Syneron

Syneron Medical Ltd. (NASDAQ: ELOS) manufactures and distributes medical aesthetic devices that are powered by the proprietary, patented elos combined-energy technology of Bi-Polar Radio Frequency and Light. The Company's innovative elos technology provides the foundation for highly effective, safe and cost-effective systems that enable physicians to provide advanced solutions for a broad range of medical-aesthetic applications including hair removal, wrinkle reduction, rejuvenating the skin's appearance through the treatment of superficial benign vascular and pigmented lesions, and the treatment of acne, leg veins and cellulite. Founded in 2000, the corporate, R&D, and manufacturing headquarters for Syneron Medical Ltd. is located in Israel. Syneron has offices and distributors throughout the world, including North American Headquarters in Canada, North American Logistics Support Center in Irvine, CA, European Headquarters in Germany, and Asia-Pacific Headquarters in Hong Kong, which provide sales, service and support. Additional information can be found at [www.syneron.com](http://www.syneron.com).