

Viveve System Spotlights

Monopolar RF-Based Feminine Rejuvenation



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“When I first heard about the Viveve system, I thought it sounded too good to be true. The response I got from patients was much better than expected.”

By Jeffrey Frentzen, Executive Editor

Of the new energy-based vaginal rejuvenation systems currently entering the marketplace, the Viveve® System from Viveve, Inc. (Sunnyvale, California, U.S.) represents a notable difference from existing solutions that deal with vaginal laxity.

While other products merely treat the vagina’s superficial tissue layer, the Viveve procedure uses proprietary monopolar radiofrequency (RF)-based energy to restore collagen at a deeper level to provide optimal structural support. Its patented, controlled cooling protects the surface tissue to allow deep penetration of energy, maintain patient comfort and avoid any surface irritation or post treatment issues.

The platform has received a CE mark in Europe and has been approved for sale in Canada and locales throughout Asia. Currently, the system has U.S. FDA clearance for general use, but specific indications, as well as a range of hand-piece tips for expanded applications, are being pursued by this women’s health company.

“Post-partum vaginal laxity is a symptom that affects quality of life, and I thought this new therapeutic weapon was quite promising,” stated Santiago Palacios, M.D., a gynecologist and researcher in Madrid, Spain, adding that RF-based energy provides an effective modality for treating vaginal laxity and related indications. “Among the different medical specialties, RF has already shown to improve tissue quality by neocollagenesis and angiogenesis. Genital RF uses the same mechanism of action,” he said.

Bruce Allan, M.D., Ph.D., F.R.C.S.(C), a gynecologist in Calgary, Alberta, Canada, has specialized in surgical vaginal tightening procedures for decades, but also knew some

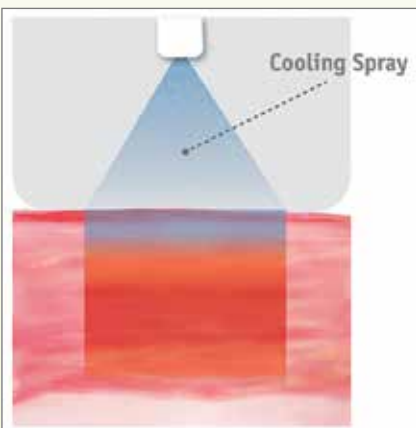
of his patients did not want surgery. “When I first heard about the Viveve system, I thought it sounded too good to be true. It is a half hour procedure with no downtime, purported to increase sexual response and tightness of the vagina,” he expressed. “The response I got from patients was much better than expected.”

Vaginal childbirth can often lead to trauma to the pelvic floor with ensuing laxity of the vaginal tissue and introitus, Dr. Allan added. “Viveve treats that first 2 to 3 centimeters of the opening of the vagina. Patients reported the sensation of tightness, but more than that, the treatment was actually changing the integrity of the vaginal wall, stimulating new collagen growth.”

Dr. Allan’s skepticism was further eroded after finding published studies on the Viveve system, including clinical trials in the U.S. and Japan that specified an exceptional safety profile with 90% of patients reporting significant improvement at 12 months. Later he joined an international, multi-center clinical trial conducting a first-of-its-kind placebo-controlled study of the product that should be published this year.

Patients love this treatment, expressed Dr. Palacios. “My patients are greatly satisfied, first because they are so pleased that a non-surgical solution is possible; and second, they really feel the vaginal contraction and improvement one month after treatment.”

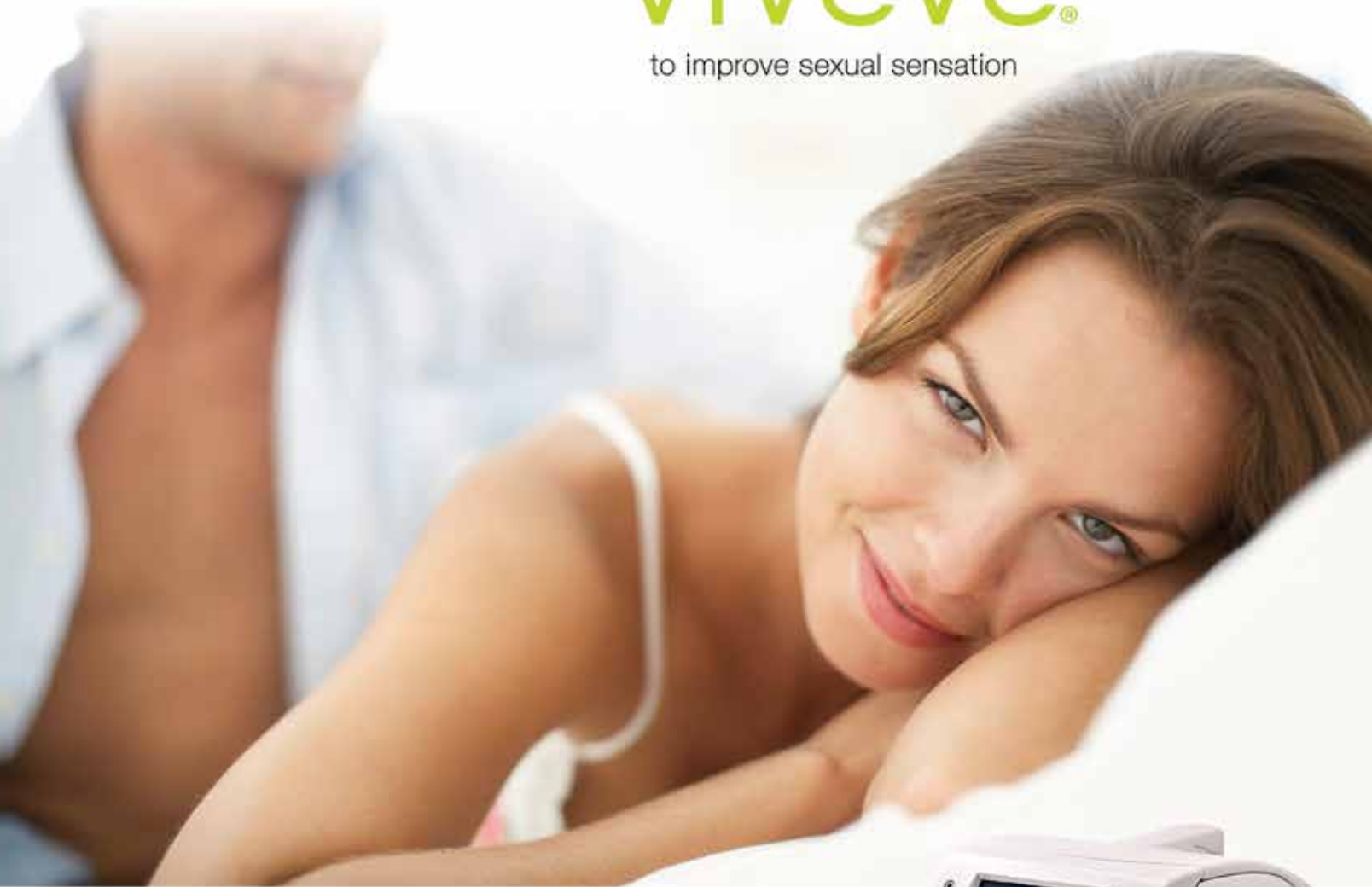
After two-and-a-half years of using the Viveve System, Dr. Allan regrets nothing. “I have been very pleased to be able to offer patients a non-surgical option that I can use as an outpatient treatment. It is far less expensive than surgery and very safe,” he said.



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