

NEW MINIMALLY INVASIVE LAPAROSCOPIC PROCEDURE FOR TREATMENT OF FIBROID TUMORS

HALT MEDICAL, INC., BRUCE B. LEE, MD

Uterine fibroids are muscle cell tumors that occur in 80% of all women and may cause heavy and painful menstrual bleeding, pelvic and abdominal pain, and urinary frequency. Uterine fibroids are the most common type of pelvic tumor found during the reproductive years, and are most often treated by removal of the uterus (hysterectomy). Approximately 235,000 hysterectomies per year are performed in the United States to treat fibroids.

In 1999, Dr. Bruce B. Lee, a gynecologist in Monterey, California, devised a new, minimally invasive, out-patient, laparoscopic procedure using a technology called radiof-

needle probe into the fibroid, causing destruction of the tumor by heat. The spread of the heat is controlled and limited to the fibroid itself, leaving surrounding tissue unharmed. The treated fibroid is partially or completely resorbed by the muscle tissue around it, causing the overall size of the uterus to shrink. Recovery and return to most normal activities occurs in two to seven days.

Dr. Lee conducted a pilot study of 58 patients and subsequently a prospective study of 110 patients. The procedure was very effective in producing resolution of patients' symptoms, reduction in uterine size, and in allowing rapid return to normal activity.

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requency ablation. The procedure requires two small, 1 cm incisions, one in the umbilicus for a scope (laparoscope), and one in the bikini line for an intra-abdominal ultrasound transducer. The thin needle probe is inserted through small skin puncture sites (which do not require sutures) and is guided with laparoscopic visualization and ultrasound imaging into each fibroid. Low-energy radiofrequency current is directed through the

In 2004 HALT Medical, Inc. was founded to develop and manufacture the medical device, The HALT 2000 System™, designed specifically to ablate uterine fibroids. In three ongoing studies outside the United States, it has been successfully used to ablate 235 fibroid tumors in 70 patients. Heavy menstrual bleeding and fibroid symptoms have significantly declined, and quality of life has sharply improved.

According to HALT Medical co-founder and CEO Jeffrey M. Cohen, “We are very pleased with our clinical results and the potential to improve the lives of millions of women suffering with symptomatic uterine fibroids. Dr. Lee developed a wonderful, new surgical procedure and my longtime business partner, Dr. Gordon Epstein, designed a fabulous surgical device to easily perform it. A great team and a great product that may prevent major surgery and change women's healthcare. It doesn't get much better than that”!



Jeffrey M. Cohen CEO and Bruce B. Lee, M.D.

A pivotal FDA multi-center trial is currently underway in six cities across the U.S. and in Monterrey, Mexico. More information is available at www.clinicaltrials.gov, study #00874029 and at the HALT Medical website www.haltmedical.com.

CAUTION: INVESTIGATIONAL DEVICE, LIMITED BY FEDERAL (OR UNITED STATES) LAW TO INVESTIGATIONAL USE.



The Halt 2000 System™ is a Radiofrequency Generator that may offer women who suffer with symptomatic uterine fibroids, a minimally invasive alternative to conventional surgery.