ExAblate® Receives European CE Mark for Treatment of Adenomyosis

RealWire

Non-invasive procedure now available where options were limited; InSightec innovation continues to expand treatment choice in Women’s Health

TIRAT CARMEL, Israel (June 23, 2010) -- InSightec Ltd. announced today that its ExAblate® system has received an expanded CE Mark certification for “ablation of soft tissue for treatment of benign tumors, including uterine fibroids **and adenomyosis**” using Magnetic Resonance guided Focused Ultrasound (MRgFUS) technology. The certification was granted on the basis of clinical evidence showing that focused ultrasound is safe and effective in treating symptomatic adenomyosis, which included published data of patients with the condition. The certification body KEMA Quality agreed that treatment with InSightec’s system resulted in statistically significant improvement in subjective symptoms, and significant volume reduction of the treated mass.

Adenomyosis is a benign gynecologic growth characterised by the presence of ectopic endometrial glands and stroma in the myometrium and hyperplasia (excessive cell reproduction) of adjacent smooth muscles. It manifests with uterine myoma-mimicking symptoms such as heavy menstrual bleeding, pain, and diffuse uterine enlargement. Women with this condition are unlikely to conceive.

“Patients who suffer from Adenomyosis and want to preserve their uterus have had few viable options in the past,” said Dr. Jaron Rabinovici, Vice-Chair, Department of Obstetrics and Gynecology, Sheba Medical Center. “Adenomyosis may have a grave impact on a woman’s health and quality of life and until recently hysterectomy was the only accepted treatment involving adverse effects and hospitalization. Another treatment option is medication, which offered only temporary relief of symptoms and had its own set of side effects.

The availability of this procedure is a welcome development for women living with this condition, because it means they now have a treatment choice that is non-invasive, safe and effective. More importantly, women who underwent this non-invasive option for adenomyosis conceived and delivered subsequently healthy children.”

“ExAblate® has been used to treat uterine fibroids non-invasively with great success since 2004, and this expanded CE Mark represents a significant milestone in our commitment to continually broaden the applications of this non-invasive, innovative therapy in addressing women’s health ” said Dr. Kobi Vortman, President and CEO of InSightec. “This procedure is done on an outpatient basis, patients can return to work the next day, and complications are

rare. The clinical and economic advantages of ExAblate® allow for enhanced access to treatment – and improved quality of life - for more women.”

While fibroids and adenomyosis are both non-cancerous tumours of the uterus, fibroids grow out from the uterine wall, and adenomyosis originates from swelling of the uterine wall as a result of the penetration of endometrial tissue. While a fibroid is distinct from the uterine wall and can be removed, adenomyoma cannot be removed without actually removing the involved uterine muscle. Clear-cut surgical excision of the whole adenomyosis lesion is difficult because of its ambiguous boundary.

About InSightec
InSightec Ltd. is a privately-held company owned by Elbit Imaging, General Electric, MediTech Advisors, LLC and employees. It was founded in 1999 to develop the breakthrough MR guided Focused Ultrasound technology and transform it into the next generation operating room. Headquartered near Haifa, Israel, the company has over 160 employees and has invested more than $130 million in research, development, and clinical investigations. Its U.S. headquarters are located in Dallas, Texas. For more information, please go to: http://www.insightec.com/ [1]

About ExAblate®
ExAblate is the first system to use the MR guided focused ultrasound technology that combines MRI – to visualize the body anatomy, plan the treatment and monitor treatment outcome in real time – and high intensity focused ultrasound to thermally ablate tumors inside the body non-invasively. MR thermometry, provided uniquely by the system, allows the physician to control and adjust the treatment in real time to ensure that the targeted tumor is fully treated and surrounding tissue is spared. The ExAblate system was approved by the U.S. Food and Drug Administration in 2004 as a treatment for symptomatic uterine fibroids. Over 6,000 women have been treated worldwide to date. ExAblate® 2000 received the European CE Mark for pain palliation of bone metastases in June 2007.

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