

Dune Medical Launches US FDA Cleared Clinical Trial For Use Of MarginProbe In Breast Cancer Surgery

Dune Medical Devices, Ltd. today announced the launch of a pivotal clinical trial of the MarginProbe™ intraoperative, real-time, positive margin detection system, following U.S. Food and Drug Administration (FDA) investigational device exemption (IDE) approval of its protocol during breast cancer surgery.

With the FDA IDE approval in place, Dune is launching a nationwide U.S. clinical trial of MarginProbe, which uses Radio Frequency Spectroscopy to characterize breast tissue during surgery to determine the malignancy status of tumor margins. The study will involve more than 600 women in more than a dozen leading medical centers in New York City, Baltimore, Washington DC, Allentown PA and Los Angeles.

Underscoring the benefits of MarginProbe technology, the American Journal of Surgery published in its October issue results of an earlier 300-patient, prospective, randomized, controlled clinical trial that found a 56 percent reduction in repeat lumpectomies with use of MarginProbe. The double-arm study compared surgeons' ability to detect and remove positive margins during an initial lumpectomy and the resulting reduced rate of repeat procedures. In the MarginProbe group, surgeons applied the probe to the excised lumpectomy specimen and shaved additional tissue according to the device's readings, which resulted in a 56 percent reduction in the need for repeat surgeries.

Dune recently closed a \$15 million Series C investment led by Apax Partners. Apax also led Dune's two previous financing rounds in 2004 and 2006.

"With its recent IDE, the opening of its European office, the readiness of production, and the recent funding, Dune Medical Devices is well positioned for introduction of MarginProbe, following our clinical trials and FDA clearance. We are gratified to have received funding given the current world financial situation and believe this underscores the importance of what our technology is bringing to healthcare," said Dr. Dan Hashimshony, founder and CEO of Dune Medical Devices, Ltd. "Based on the strength of our ongoing studies and their validation of the benefits of MarginProbe, we look forward to the device's acceptance within the surgical community. Soon thereafter, we hope to help ease the difficulties experienced by women who receive multiple surgeries for breast cancer."

Current statistics indicate that between 20 and 60 percent of breast-conserving lumpectomies performed each year in the U.S. necessitate re-excision because clean margins were not obtained in the initial procedures.

The Dune MarginProbe system comprises a sterile hand-held probe and portable console. When the probe tip is applied to an excised lumpectomy segment, radio frequency signals are transmitted into the tissue and reflected back to the console, where they are analyzed using a specialized algorithm to determine tissue status. With streamlined operation and instantaneous results, the technology is designed for easy integration into existing surgical workflow.

About Dune Medical Devices, Ltd.

Founded in 2002 and headquartered in Caesarea, Israel, Dune Medical Devices, Ltd. is a privately owned, venture-funded medical device company, backed by Apax Partners. Dune is engaged in the development and commercialization of devices for real-time tissue characterization. Dune Medical's devices facilitate complete, therapeutic excisions in surgical oncology procedures. The MarginProbe™

described above is undergoing clinical trials in Israel and the U.S. <http://www.dunemedical.com>

Source

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