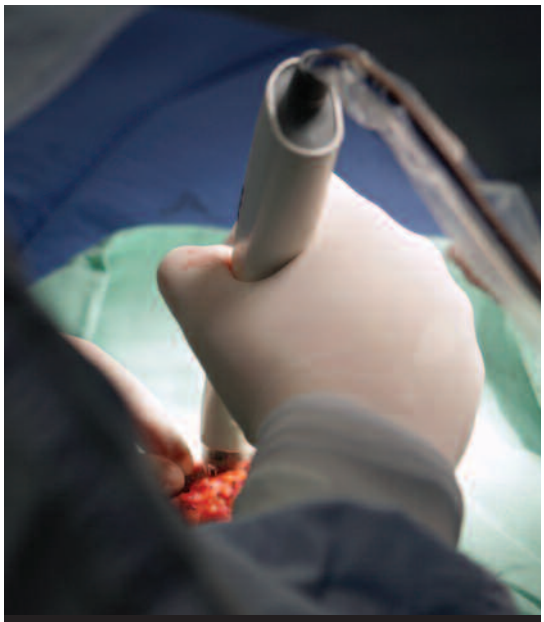
Clinical Trial Aims to REDUCE RE-EXCISION RATE AFTER LUMPECTOMY

SUSAN K. BOOLBOL, MD
Chief of Breast Surgery at The Appel-Venet Comprehensive Breast Service
Specialties: Breast Surgery

Approximately 80 percent of women diagnosed with breast cancer choose breast conservation surgery (BCS), or lumpectomy, and of these, as many as half may need further surgery when final histology results are reported. But a new clinical trial underway at Beth Israel Medical Center, one of only 12 sites nationwide, holds great promise to improve these odds.



The surgeon applies the probe to removed tissue during lumpectomy to check for clear margins.

© Dune Medical Devices

The randomized, controlled clinical study is collecting data on the performance of an intraoperative probe for positive margin detection in lumpectomy. **Using radio-frequency spectroscopy,** the device detects minute differences in electromagnetic properties of tissue with and without cancer, and provides this key information to breast surgeons during surgery.

Susan K. Boolbol, MD, Chief of Breast Surgery at The Appel-Venet Comprehensive Breast Service, and her colleagues are currently enrolling patients in this institutional review board-approved study, selecting those already scheduled for BCS for invasive or pre-invasive breast cancer. Patients with prior breast surgery or those who have had neoadjuvant chemotherapy are excluded.

Enrolled patients undergo lumpectomy and are then randomized into two arms—with and without use of the intraoperative MarginProbe. The device is applied to the lumpectomy specimen at five to eight points along each of six margins—medial, lateral, superior, inferior, deep and anterior. **A margin is considered positive** if one reading registers a positive result. Standard intraoperative margin assessment, including palpation, imaging, and both gross and microscopic pathological assessment, are used at the surgeon's discretion in both the device and control groups. The surgeon re-excises tissue from the lumpectomy cavity where positive margins are found. Applying the device a second time to re-excision margins is precluded by the study's protocol. All specimens are labeled and sent for permanent pathological analysis. Excised tissue volume as well as cosmetic outcomes are being tabulated and evaluated as well.

Approximately 300 patients have been enrolled nationwide to date in the study that aims to register 600 by time of completion in Spring 2010. While no preliminary results are available yet, a similar, study previously reported in the *American Journal of Surgery* in October 2008, showed good results. Researchers in Israel, testing the same MarginProbe device, reported the repeat lumpectomy rate dropped by 56 percent in the device group—to 5.6 percent with MarginProbe, versus 12.7 percent in the control arm, while there were no differences in excised tissue volume or cosmetic results.

For further information or to refer a patient for study consideration, contact Susan Boolbol, MD, or one of her credentialed colleagues, at (212) 844-6231.