MarginProbe®

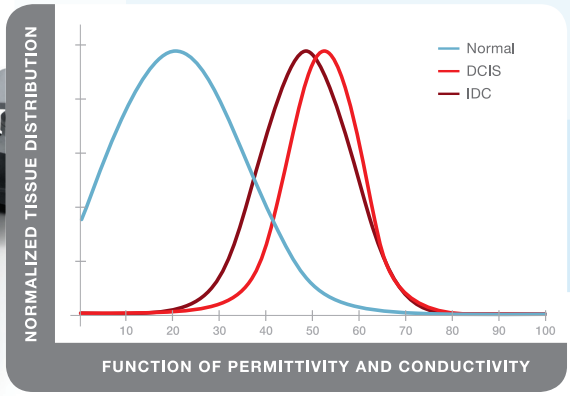
The Science Behind Your Peace of Mind

The MarginProbe System

The MarginProbe® System is the first and only FDA approved technology that provides surgeons the ability to perform real-time intraoperative margin assessment during lumpectomy procedures. In under five minutes, in the operating room, surgeons using the MarginProbe®, get an immediate indication about positive margins of a freshly excised lumpectomy specimen.

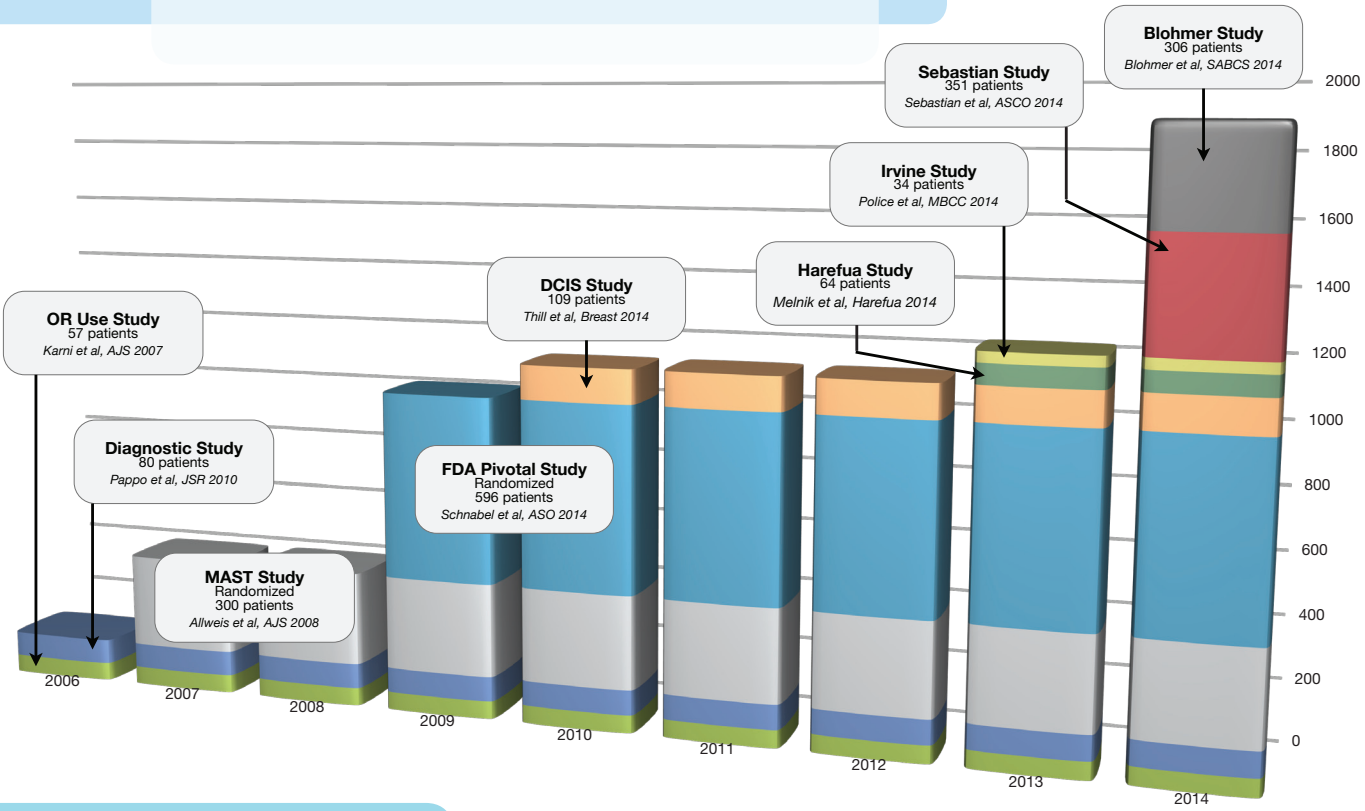
The Science

The MarginProbe® system utilizes non-destructive RF Spectroscopy to analyze the outer layer of tissue as either normal or containing clusters of cancer cells. The probe's sensor was designed to detect the minute differences in electromagnetic properties as they are analyzed for each measurement in less than a second. The MarginProbe® is sensitive enough to detect pure DCIS, as well as invasive cancer.[1] Depending on the specimen's size dozens of measurements are accumulated on the screen, and per each of the six margins they are grouped together for optimal orientation of a possible additional small excision, when a positive margin is detected.[2]



The Proof

The MarginProbe has over eighteen hundred patients in clinical studies and thousands of cases performed routinely in commercial use. The studies showed reduction in re-excision procedures that ranged between 25 and 56%. The studies included invasive as well as DCIS patients.[2] [3]



MarginProbe Growing Body of Clinical Studies

The Patient

Adding routine use of MarginProbe into your practice will give you the peace of mind of knowing your patients have the best chance possible of achieving clean margins in their first and only lumpectomy. The MarginProbe is designed for use in every initial lumpectomy procedure regardless of the patient's cancer type, including pure DCIS patients. With new therapeutic techniques such as IORT and oncoplastic surgery, it is more important than ever to achieve clean margins in a single procedure.

Contraindications

The MarginProbe should not be used:

- To replace standard permanent tissue histopathology assessment.
- On removed tissue that have been exposed to saline, ultrasound gel, or local anesthetic solutions.
- Within the lumpectomy cavity.
- On tissues other than breast tissue (that is, it should not be used on Sentinel Lymph Nodes).
- Closer than 1.5 mm to a fine needle localization guidewire.

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[1] *Pappo et al, J SurgRes. 2010; 160(2):277-81* [2] *Summary of Safety and Effectiveness Data. (2012). 46-46.* [3] *Allweis et al, AM J Surg (2008) 196, 483-489*