



The MarginProbe® System: An Innovative Approach to Reduce the Incidence of Positive Margins Found After Lumpectomy

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The goal of lumpectomy surgery for breast cancer is to completely remove the tumor and have clear margins, reducing the rates of local recurrence. The MarginProbe® System is a new device that can detect microscopic tumor cells at or close to the margin of the surgical resection intraoperatively, providing the surgeon with the ability to re-excite tissue at the time of surgery, reducing the need for a second surgery to obtain clear margins.

At a Glance

- Lumpectomy surgery followed by radiation is the recommended treatment for early-stage breast cancer; however, successful lumpectomy is contingent upon cancer-free surgical margins.
- Current standards of intraoperative margin assessments include visual inspection, palpation, and imaging techniques, which are all less than reliable.
- The MarginProbe® System, used during lumpectomy surgery, has been shown to reduce the need for a second surgery because of positive tumor margins.

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Breast cancer is the most common type of cancer affecting women in the United States, with an estimated 246,660 women diagnosed with invasive breast cancer and an additional 61,000 new cases of in situ breast cancer diagnosed in 2016 (American Cancer Society, 2016). About 60%–75% of women in the United States with early-stage breast cancer, defined as stages 0–II, opt for a lumpectomy. A lumpectomy involves removal of the tumor and some of the normal tissue surrounding the tumor, called the margin. Although lumpectomy has

been a standard procedure since the 1990s, no consensus exists on how a negative margin is defined. About 25% of women undergoing a lumpectomy procedure undergo a re-excision, and about half of these procedures are performed to obtain more widely clear margins in women with negative margins, as defined by no ink on tumor (McCahill et al., 2012). Having to add a second surgery increases discomfort and stress for patients, involves possible surgical complications, has cosmetic implications, and increases cost (King et al., 2011).

Because of concerns of having different definitions of a negative margin status by surgeons, a multidisciplinary panel of breast experts reviewed data from a meta-analysis, which included a systematic review of 33 studies with 28,162 patients and a median follow-up time of 6.6 years (Moran et al., 2014). The panel of experts looked at margin width and local tumor recurrence in women with early-stage breast cancer. A positive margin was defined as the presence of ink at the surface of the surgical specimen on either invasive tumor cells or ductal carcinoma in situ (DCIS). A positive margin would signify an incomplete resection and a higher risk of local tumor recurrence. The findings of this meta-analysis revealed that a positive margin was associated with a two-fold increase in local tumor recurrence. A second finding revealed that a more widely clear margin (i.e., 1, 2, and 5 mm margin widths) did not significantly decrease the rate of local tumor recurrence compared with no ink on tumor (Moran et al., 2014). Based on this information, the Society of Surgical Oncology–American Society for Radiation Oncology Consensus Guideline recommends that the standard for an adequate margin in invasive cancer be defined as no ink on tumor (Moran et al., 2014).

During lumpectomy surgery, the goal of clear margins is not always possible. Microscopic involvement of tumor in the margins is not easily assessable through palpation alone. Other methods, such as frozen section and touch preparation cytology, performed during the surgery can be time-consuming and inaccurate.