



## Frequently Asked Questions

### **Q: What is the MarginProbe™?**

A: Currently in clinical studies, for investigational use only, the MarginProbe™ uses patent-protected, proprietary radio frequency (RF) spectroscopy, and is designed to help physicians intraoperatively distinguish in “real time” cancerous tissue from healthy tissue. The system consists of a hand-held disposable probe and a console unit that provides control, data input, data processing and display.

### **Q: What is the MarginProbe™ potential application in breast cancer treatment and what problem will it likely address?**

A: MarginProbe™ is currently being investigated as a method to improve the outcomes of breast conserving lumpectomy, a procedure in which a surgeon removes a tumor from the breast along with a layer of normal tissue surrounding the main tumor to ensure all cancerous tissue has been removed. Currently, removed specimens are sent for post-surgical pathological analysis where a pathologist determines whether the margins of the excised specimen are free of cancerous tissue or not. Tumor free margins are essential to the success of the operation.

When post-surgical pathology reports show cancer cells are too close to the edge of the excised specimen following a lumpectomy, patients usually undergo a re-excision, an additional surgical procedure. During this procedure the surgeon goes back into the area of the original lumpectomy and removes an additional layer of tissue that surrounded the initial tumor. Investigators hope that the MarginProbe™ can help surgeons detect cancer in the additional rim of normal tissue more frequently than they do today, during the initial lumpectomy procedure, thereby reducing the need to perform repeat surgical procedures.

A re-excision procedure can cause emotional distress for the patient, increase the cost of treatment and contribute to poorer cosmetic results. Additionally, patients who could benefit from new intraoperative technologies and methods such as local radiation therapy or oncoplastic surgery may be considered less likely to receive these options when there are concerns that cancer cells may remain near the original tumor site.

### **Q: How common is the need for a re-excision?**

A: It is estimated that anywhere from 20% up to 60% of all lumpectomy procedures performed in the U.S. each year result in the need for a re-excision. A re-excision procedure typically occurs within days to weeks of the initial surgery.

**Q: What is the primary reason for the need to perform so many re-excisions?**

A: Re-excisions are needed in most cases where there is a positive margin. This is caused by the inability of current practice and commercially available technology to definitively detect tumor margins and facilitate complete excision during the original lumpectomy

**Q: What methods are currently employed to detect tumor margins?**

A: The current “gold standard” for detecting tumor margins is post-surgical pathology tissue analysis. While post-procedural pathology results are definitive, they do not address the unmet need of enabling accurate tumor margins detection during the original lumpectomy. Current techniques employed during surgery (intraoperatively) include wire localization, touch-prep cytology, frozen section analysis and specimen imaging.

**Q: What is the potential significance of the Dune's MarginProbe™ in breast cancer treatment?**

A: Depending on the results of clinical trials, the MarginProbe™ could be the first technology that enables surgeons to intraoperatively determine, in real time, whether the entire malignant tumor was removed. It is hoped that this technology will reduce the need for repeat surgeries.

**Q: How does the MarginProbe™ work?**

A: Applied by hand to the surface of breast tissue, the MarginProbe™ is designed to capture the unique RF spectroscopy “signature” of cancerous vs. non-cancerous cell clusters. Using the MarginProbe™ in investigational studies, surgeons can react to the information it yields before the procedure is over and, where appropriate, remove suspected residuals.

**Q: When will the MarginProbe™ be commercially available for clinical use in the United States?**

A: Currently, the MarginProbe™ is CE marked in Europe and is in clinical trials in the US.