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For Immediate Release

Latest Study Demonstrates 79% Reduction in Re-Excisions Without Additional Tissue Loss Using MarginProbe® in Conjunction with Clear Margins Guidelines

Only FDA-approved breast cancer surgical device redefining clear margins in era of "no ink on tumor" assessment

Paoli, Pa., April 26, 2016 – A recent study conducted by Dr. James Pellicane, MD FACS and the breast surgeons at the Bon Secours Virginia Breast Center demonstrated a 79% reduction in the rate of re-excisions for breast cancer patients when MarginProbe® was used in conjunction with the SSO/ASTRO clear margins "no ink on tumor" assessment guidelines. The study also found no significant difference in the volume of tissue removed or changes in expected cosmetic outcomes when using the MarginProbe device.

Presented earlier this month during the 2016 American Society of Breast Cancer Surgeons Annual Meeting, the study, entitled "*The Effects of MarginProbe in the Era of 'No Ink on Tumor' Clear Margins Definition,*" is a retrospective review from sets of consecutive patients who underwent lumpectomy surgery between April 2014 and August 2015.

The research looked at the impact MarginProbe had on the rate of re-excision and the total volume of tissue removal for patients compared to procedures performed before Dr. Pellicane began using the non-invasive MarginProbe assessment technology during surgeries.

Key findings from the study include:
MarginProbe was used in 89 consecutive lumpectomy cases between November 2014 and August 2015 compared to 99 similar cases performed without the device between April 2014 and November 2014. (**Table 1**)

Table 1 - Subjects baseline characteristics

	MarginProbe set (N=89)	Historical set (N=99)
Age		
Mean (STD)	62.5 (12.6)	62.3 (11.0)
Tumor type		
Invasive Ductal	75%	58%
Invasive Lobular	5%	13%
DCIS	20%	29%
Receptor status		
ER+	67%	93%
PR+	58%	75%
HER2+	11%	17%

In more than 55% of the cases there was DCIS present in the tumor and more than 70% of the tumors were smaller than 2 cm. (**Table 2**)

Table 2 - Tumor characteristics, based on final pathology

Tumor composition		
IDC	37%	19%
DCIS	20%	29%
IDC + DCIS	38%	40%
ILC	5%	13%
Tumor/lesion size		
Mean (STD) [cm]	1.5 (1)	1.5 (1.5)
<1cm	30%	37%
1 cm to 2 cm	41%	42%
>2 cm	29%	21%

The re-excision rate in the device set was 3.4% compared to 16.2% re-excisions in the comparison set. (**Table 3**)

	MarginProbe cases	Historical set	Absolute Reduction (% points)	Relative reduction	P-value
Lumpectomy procedures	89	99			
Re-excision procedures	3	16			
Re-excision rate	3.4%	16.2%	12.6%	79%	P<0.01

Table 3 – Comparison of re-excision procedures between the sets

The total volume of tissue removed during the initial lumpectomy was 91cc in the device set and 92cc in the comparison set. (**Table 4**)

	MarginProbe cases	Historical set
Shavings with no clinical benefit, per case; Mean (STD)	1.8 (1.4)	0.9 (1.6)
Main Specimen volume; Mean (STD)	78 (62) cc	87 (72) cc
Shaving volume; Mean (STD)	7.5 (6.9) cc	5.8 (5.2) cc
Total volume removed in the lumpectomy procedure; Mean (STD)	91 (63) cc	92 (72) cc

Table 4 – Comparison of additional margins taken and tissue volume removed between the sets

While the SSO/ASTRO assessment guidelines have led to an overall reduction in re-excision rates, the percentages are even greater when combined with MarginProbe.

"Even in the era of 'no ink on tumor' margin assessment where some reports suggest that re-excision rates are falling, utilizing MarginProbe further reduces the need for additional surgeries," said Dr. Pellicane. "The study also found a slightly lower volume of tissue removed. The combination of these factors gives patients the best chance for a successful surgery with good cosmetic results."

Traditionally, one-in-four women who undergo a lumpectomy require additional surgery to remove cancer missed during the initial procedure. The Pellicane study is just the latest research to show how MarginProbe, the first and only FDA-approved technology, offers surgeons a non-invasive, real-time detection of cancer at the surface of excised tissue specimens during surgery.

"Using MarginProbe in every lumpectomy gives patients the best chance of getting all the cancer in their first and only surgery," said Lori Chmura, President of Dune, Inc. "Getting clean margins in one surgery moves a patient through to radiation and recovery more quickly giving them the best possible surgical and cosmetic outcomes and ultimately improving their level of satisfaction."

About Dune Medical Devices

Dune Medical Devices was founded in 2002 by Dr. Dan Hashimshony, CEO, to realize the extraordinary medical potential of its proprietary tissue characterization technology. Offering surgeons and radiologists the real-time ability to identify cancerous tissues and react immediately, this technology holds the potential for a broad range of surgical and diagnostic applications. Dune Medical Devices is a privately held company with offices in the U.S. and Israel. For more information, please visit www.dunemedical.com and www.marginprobe.com.