StarchMark® Clinical Case Study

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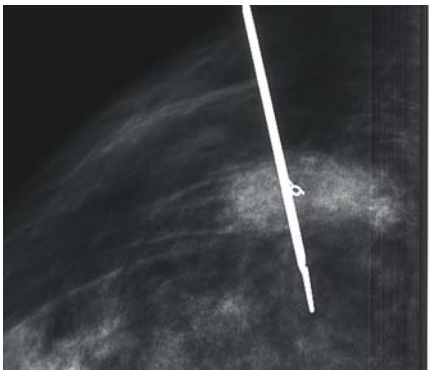
Case Study – Marker Migration

Twelve patients underwent stereotactic biopsy using the EnCor® 10-gauge probe and received the StarchMark™ biopsy site marker*. Prior to each lumpectomy, needle localization was completed. The StarchMark was in the center of each lesion in 11/12 patients; in the last case the marker was in the biopsy cavity but 7 mm from the center of the lesion.

In addition to these 12 patients with positive biopsy, 5 patients were reviewed who had negative biopsies and had returned for a 3-4 months post-biopsy follow-up mammogram. In all 5 of these cases, the StarchMark was in the center of the biopsy site.

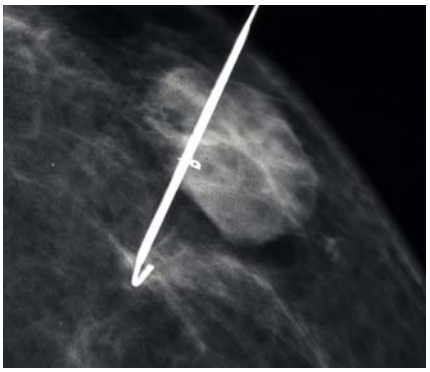
All biopsy markers have the potential for migration. There is no reason why the StarchMark would migrate more than any other marker on the market. In fact, it should migrate less because of the starch component with its known properties for controlling bleeding. If marker migration is observed (with any marker), it may be due to making the biopsy cavity too large, but it should still be in an acceptable range within the site. If a large blood vessel is cut it may wash the marker out through the biopsy tract. Tips to minimize marker migration following stereotactic biopsy include:

- Fully seat the marker applicator before releasing the marker and rotate the probe before removal.
- Release the compression slowly in order to minimize the accordion effect of the breast.
- If the z-value is such that only half of the chamber is used, apply finger pressure to the superficial biopsy site when releasing the compression thus holding the marker in place.



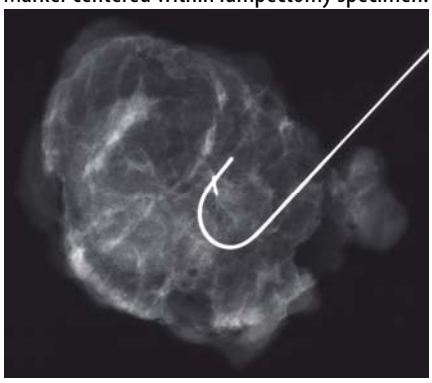
Patient A

Two representative radiographs of the StarchMark clearly visible within the biopsy cavity for accurate needle localization.



Patient B

Marker centered within lumpectomy specimen.



*StarchMark® has been commercially available since December 2008.

Rx Only. Please consult the Instructions for Use for indications, contraindications, hazards, warnings, cautions and directions for use.

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