Clinical Brief

Mammotome Breast Biopsy Markers

Mammotome

Retrospective three-center study finds long-term safety and efficacy of Mammotome breast biopsy markers in clinical practice.

Sharon Smith , Clayton R. Taylor , Estella Kanevsky , Stephen P. Povoski & Jeffrey R. Hawley (2020): Long term safety and efficacy of breast biopsy markers in clinical practice, Expert Review of Medical Devices, DOI: 10.1080/17434440.2020.1852928

OBJECTIVE:

Percutaneous breast biopsy followed by marker placement are integral parts of a breast imager's practice benefiting both patients and clinicians. In North America and in many other places in the world, marker placement is the standard to facilitate future care. The purpose of this study was to characterize safety and performance of HydroMARK breast biopsy site marker, MammoMARK biopsy site identifier, and CorMARK biopsy site identifier by evaluating device-related adverse events, device deficiencies, and long-term safety.

METHODS:

- A retrospective review of three radiology practices identified patients who underwent image-guided breast or axillary biopsies followed by marker placement between January 1, 2012 and January 1, 2017.
- Medical records were reviewed with device deficiencies and adverse events related to marker placement and use recorded.

CONCLUSIONS:

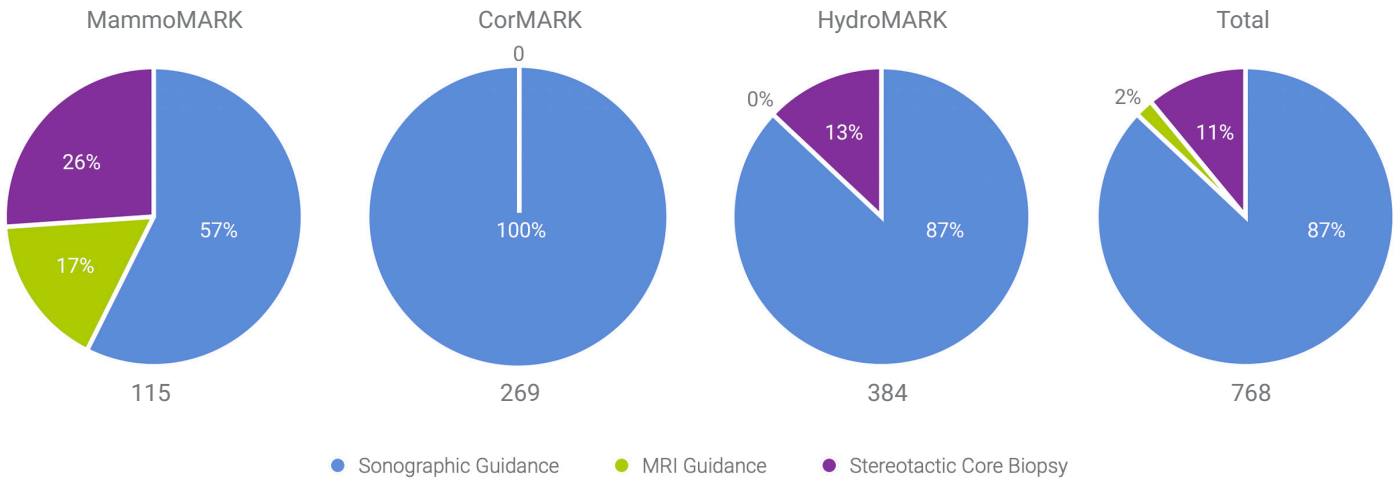
The authors' conclude that breast biopsy markers, specifically, the MammoMARK, CorMARK, and HydroMARK biopsy site markers, are safe with rare occurences of non-serious adverse events or device defiencies. Physicians and their patients should be reassured that such devices are safe and their routie use is justified based upon their safety profile and significant clinical benefits.

RESULTS:

- 768 markers were placed with 3 (0.4%) events recorded in 3 patients. Table 1 below shows the marker type and percentage placed by imaging modality. The majority of placements in this study were during sonographic guidance.

  2 device deficiencies:
  - 1 user error with failure to deploy marker properly per device Instructions for Use (IFU).
  - 1 user error resulting in misplacement of marker relative to target.
- 1 non-serious adverse event involved inability to locate/retain the marker in a surgically resected specimen.
- No serious adverse events were reported.

TABLE 1: BIOPSY MARKER PLACEMENT BY BRAND AND IMAGE-GUIDED BIOPSY MODALITY



Numbers below chart = Total Deployments

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