

## **14 G Sonographic and Mammographic Breast Biopsy Marker For Ultrasound Guided Large Core Needle Biopsies**

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**Purpose:** To evaluate the visibility, performance and ease of use of a new 14 gauge breast biopsy marking device designed for use in ultrasound-guided core needle biopsies.

**Material & Methods:** Physicians at 16 centers utilized the new device to place a marker after an ultrasound-guided core needle biopsy. The biopsy site marker, a 14 gauge beveled needle applicator, delivers 5 bioresorbable pellets to the biopsy site by depressing a syringe-type plunger. These CO<sub>2</sub> embedded pellets provide sonographic visibility. A stainless steel wire form molded into the first pellet provides long-term mammographic visibility. Study parameters included functional characteristics and marker visibility by ultrasound at the time of deployment and up to 5 weeks following biopsy. Ultrasound images were obtained on a subset of patients at a follow-up examination up to 5 weeks after biopsy. Functional characteristics and ultrasound visibility of the marker were scored on a 3 point scale.

**Results:** Physicians placed the new biopsy marker in 127 biopsy sites in 114 patients between 8/6/02 and 10/02/02, recording data on a standardized form. The marker was placed after ultrasound-guided core biopsies performed with large core needles (n=120), FNA (n=2) or vacuum-assisted biopsy (VAB, n=5). An average of 5 core samples was collected per core needle or VAB biopsy (range 1-30). The applicator was placed directly through the breast in 101 (80%) cases and through a standard co-axial needle guide in 25 (20%). Directing the beveled needle to the biopsy site was rated "easy" or "satisfactory" in 94% of cases. Pellet deployment force was rated "easy" or "satisfactory" in 94% of cases. Immediately after deployment, the marker was scored highly or adequately visible by ultrasound in 92% of cases. Follow-up sonography within 5 weeks was obtained in 35 patients. The marker was scored highly or adequately visible in 89% of cases.

**Conclusion:** A new biopsy marking device with a 14G beveled needle applicator containing mammographic and ultrasound visible markers allows successful marking of biopsy sites following standard large core needle procedures. The device is easy to position and deploy. The marker allows for sonographic visualization of the biopsy site for up to 5 weeks following biopsy in addition to long term mammographic visibility of a wireform.