

New Ultrasound and Mammographically Visible Breast Biopsy Marking Device For Use in Core Needle Biopsy Procedures.

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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: Eleven physicians at five centers utilized the new device to place biopsy markers in 43 biopsy sites in 39 patients after an ultrasound-guided core needle biopsy. The device, (UltraCor™, SenoRx, Aliso Viejo, CA) consists of a beveled needle applicator containing a biopsy site marker consisting of 5 resorbable pellets, which are delivered to the biopsy site by depressing a syringe-type plunger. CO₂ within each pellet provides marker ultrasound visibility. A stainless steel wire form embedded in the first pellet provides long-term mammographic visibility. Study parameters included functional characteristics and marker visibility. Ultrasound images were obtained at deployment (time 0) and at a follow-up examination up to 5 weeks after biopsy. A 3 point scale (0= not visible, 1= adequately visible, 2= highly visible) was used to score overall visibility of the marker with ultrasound.

Results: Physicians placed the new biopsy marker in 43 biopsy sites in 39 patients between 8/6/02 and 9/11/02, recording data on a standardized form. The marker was placed after 14G biopsy in 41 cases, after 1 FNA, and after 1 directional vacuum assisted biopsy case. An average of 5 samples was collected per case (range 1-15). The applicator was placed independently in 88% of cases and through a co-axial needle guide in 12%. Directing the beveled needle to the biopsy site was rated "easy" or "satisfactory" in 98% of cases. Pellet deployment force was rated "easy" or "satisfactory" in all cases, with no difficult or failed deployments reported. The marker was visible by ultrasound in 95% of cases at time 0 and in 90% of patients with completed follow-up ultrasound imaging to date (30 patients).

Conclusion: A new biopsy marking device with a beveled needle applicator containing mammographic and ultrasound visible markers allows successful marking of biopsy sites following standard 14 G core needle procedures. In addition to long term mammographic visibility, the marker allows for ultrasound visualization of the biopsy site for up to 5 weeks following biopsy.