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We have developed a 125I-radiolabeled injectable fiducial tissue marker with the potential to replace current methods used for surgical guidance of non-palpable breast tumors. Methods in routine clinical use today such as radioactive seed localization, radio-guided occult lesion localization and wire-guided localization suffers from limitations that this injectable fiducial tissue marker offers solutions to. The developed 125I-radiolabeled injectable fiducial tissue marker is based on highly viscous sucrose acetate isobutyrate. The marker was readily inserted in NMRI mice and proved to be spatially well-defined and stable over a seven day period with excellent CT contrast (>1500 HU), enabling fluoroscopic visualization of markers during placement. The radioactivity remains strongly associated with the marker during the implantation period, which limits exposure to healthy tissue. Biodistribution studies show that there is negligible radioactivity in all non-tumor tissues sampled, with the exception of the thyroid gland, where limited accumulation was observed (0.06% of injected dose after 7 days). Based on the excellent performance of the marker and the fact that it can be delivered through thin hypodermic needles (≥27G), the marker holds great promise for clinical application, since patient discomfort is reduced significantly compared to current methods. Statement of Significance. A new type of tissue marker for local administration to non-palpable breast tumors has been developed. The surgical guidance marker is based on derivatives of the biomaterial sucrose acetate isobutyrate and unlike currently used markers it is injectable in the tissue using thin needles, reducing the discomfort to the patients significantly. The marker confers CT contrast and has radioactive properties, meaning it also could find use in brachytherapy. The design of the iodine-125 labeled fiducial tissue marker enables control of dosimetry as well as a choice of iodine isotope used. The marker is anticipated to be clinical applicable due to its contrast performance in mice and its potential for enhanced flexibility in surgical procedures, compared to current methods.

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