

# A Prospective Clinical Study to Evaluate the Safety and Performance of Wireless Localization of Nonpalpable Breast Lesions Using Radiofrequency Identification Technology.

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## Introduction

Hook wires are the most common method with which to localize nonpalpable breast lesions. However, there are numerous limitations with this approach, including logistical difficulties due to necessity for same-day surgeon-radiology department case coordination; patient anxiety due to wire visibility; potential for bacterial infection; and possibility for wire migration or dislodgement. Radiofrequency identification tags are an alternative method to localize breast lesions.

**Objective:** To assess the safety and performance of a radiofrequency identification tag to localize nonpalpable breast lesions for surgical excision.

## Methods

- Eligible patients (women requiring breast lesion localization prior to surgical excision) had previous metallic clip placement to serve as a discrete target.
- Patients with cardiac pacemakers, defibrillators, palpable lesions, or lesions located  $\geq 6$  cm deeper from the skin were excluded.
- Enrolled subjects were implanted with both the radiofrequency identification tag and a hook wire under ultrasound or stereotactic guidance.
- The primary outcome measure was successful target lesion localization and removal using solely the radiofrequency identification tag system.
- Safety measures assessed included tag migration prior to surgical removal and 30-day postoperative infection.

## Results

Twenty women were enrolled in the study: all 20 lesions were successfully removed using the radiofrequency identification tag system as guidance. No localization failures or tag migration (prior to incision) occurred. In 3 subjects, migration occurred along the insertion track during lesion retraction and manual compression of the specimen. Four subjects required re-excision for positive margins. No infections occurred within 30 days of surgical procedure.

## Conclusions

Since this study, antimigration tags have been added to the system to address the possibility of tag slippage, which occurred in 3 cases. Nonpalpable breast lesion localization was successfully performed with a radiofrequency identification tag system in 20 patients, with no safety concerns observed. Further study and development are warranted for this promising technology.

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