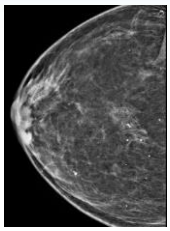
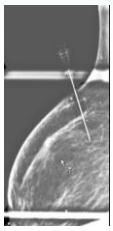
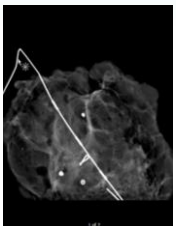
Conflict of Interest

Titanium Clip Detectors and Methods of Detection, Delphine Dean, Cody Jordan, Melissa McCullough, **Nancy DeMore**, Scott Slaney, Joseph Wilson, Provisional patent filed 8/30/2016

Will discuss off-label use of titanium clip detector for breast localization surgery

Wire Localized Breast Excision

Problems with Wire Localization

- Long wait times between when radiology places wire and coordination with OR for surgery
- Limited number of OR procedures performed during the day because dependent on number of available radiology procedure slots
- Patient dissatisfaction from having wire placed
- OR time costs $177/minute or $10,620/hr
- **Operating room lost opportunity cost**
  - Avg time delay with wire loc 0.5 hr
  - % lumpectomies delayed by wire loc 30%
  - # lumpectomies/ week 10
  - Total OR loss per week apx $15,000, or **$780,000 / year**

Alternatives to Wire Localization

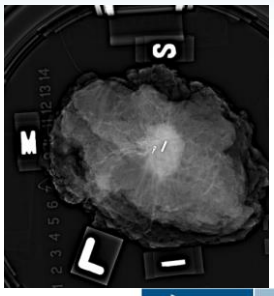
- Radioactive seed localization
  - I^{125} seed placed next to titanium clip 1-5 days before surgery
  - Advantage: Increases OR utilization, can have a first case, OR schedule not dependent on radiology schedule
  - Disadvantage: If seed breaks, radiation disaster
  - **Disadvantage: Requires invasive procedure to place seed**
- Savi Scout
  - Reflector chip placed next to titanium clip 1-30 days before surgery. Uses electromagnetic waves to detect clip
  - Advantage: Increases OR utilization, no radiation
  - **Disadvantage: Requires invasive procedure to place chip**
  - **Expensive: $75K surgical console, $15k radiology console, each chip $450**
- Sentimag Magnetic Seed Localization
  - Magnetic seed inserted next to titanium clip
  - Probe detects magnetic
  - **Disadvantage: Requires invasive procedure to place seed**
  - **Expensive: $105k surgical console and probe and each seed $625**

I-125 Breast Seed Localization

- Low energy
- Half life 59.4 days
- Implanted in suspected cancer site
- Days later the surgeon uses the gamma probe in a similar manner to a breast sentinel lymph node procedure to locate the seed
- Can be used in conjunction with Tc-99m sulfur colloid

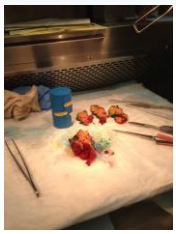
Daus, Alan, Gundersen Health Imaging Dept.

Results of Surgical Procedure



Daus, Alan, Gundersen Health Imaging Dept.

Histology Seed Extraction Procedure



Daus, Alan, Gundersen Health Imaging Dept.

Potential Hazards

- Broken seed can contaminate personnel and immediate area. I-125 cab be taken up by thyroid tissue of the patient.
- Lost seeds means a lockdown in the area until the seed is found
- If a seed is lost, ruptured, or patient doesn't return, need to report to NRC

SCOUT Radar Localization System

Non-Radioactive
Micro-Impulse RADAR
Infra-red Activated

- Inert (Passive) Reflector
- Ultrasound visible
- MRI compatible

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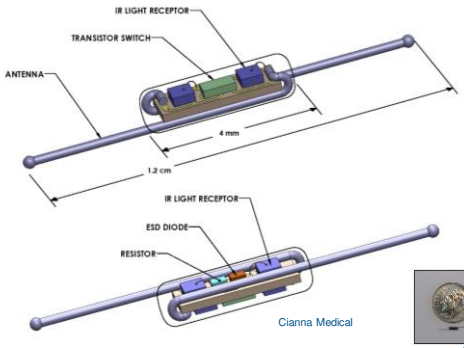
SCOUT Reflector



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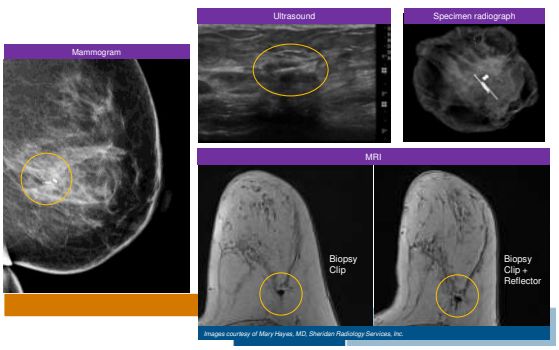
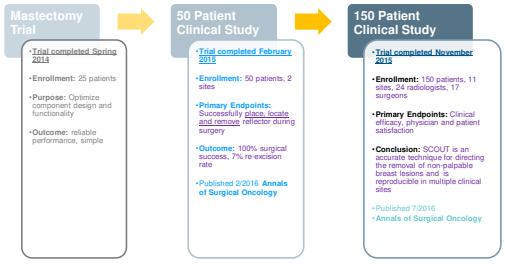
Clinical Views – Reflector



SCOUT Clinical Research



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150 Patient Clinical Study Sites

Site	City, State
University of South Florida*	Tampa, FL
Nashville Breast Center*	Nashville, TN
Morton Plant Mease Health Care	Clearwater, FL
University of California, Irvine	Orange, CA
Pink Lotus Breast Center	Beverly Hills, CA
St. Joseph Hospital	Denver, CO
New York University	New York, NY
Medical Center Plano	Plano, TX
Baylor University	Plano, TX
Medical City Dallas	Dallas, TX
Hackensack University	Hackensack, NJ

* 50 Patient Pilot Study Sites

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SCOUT 150 Patient Study

Breast Lesion Localization 4.0
Eliminating Wire Localization
(for good this time)

Prospective, Single-arm, Multi-site, Clinical Evaluation
of a Non-radioactive Surgical Guidance Technology
for the Location of
Non-palpable Breast Lesions during Excision

Presented by: Pat Whitworth, MD, FACS, Nashville Breast Center
American Society Of Breast Surgeons 2016

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Radiologist Experience with Radar Loc

99.4% Successful Reflector Placement
2.6 mm reflector distance from target
No observed reflector migration
58% mammography and 42% ultrasound placements

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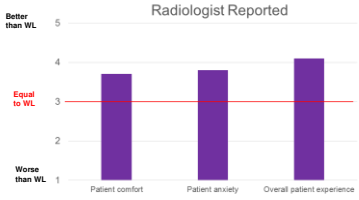
Radiologist Reported Patient Experience



- 67% of reflectors were placed on a day other than surgery
- 70% of patients returned to work on the same day or day after procedures
- 97% of patients would recommend SCOUT

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Surgical Experience with Radar Localization

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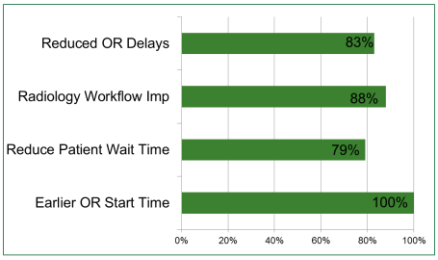
Physician Reported Efficiency Improvement



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Summary of Savi Scout

The SAVI SCOUT radar localization system is an FDA-cleared medical device that utilizes radar technology to provide real-time guidance during lumpectomies

SCOUT has the potential to reduce surgical delays, improve patient satisfaction, and optimize surgical scheduling – all without radioactive components

With SCOUT, surgery and radiology schedules do not need to be coordinated on the day of surgery

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Sentimag magseed®

- Seed size 1mm x 5mm
- Implant up to 30 days prior
- Sensing depth 3 cm
- Detectable from any orientation
- Can bracket seeds 2cm apart or greater
- Uses a handheld magnetic probe
- FDA approved 2016

Magseed ® Open Label Trial

- Two centers in UK to assess feasibility and safety
- Magseeds placed into 28 women undergoing mastectomy
- Primary outcome seed migration distance
- Secondary outcomes
  - accuracy of placement
  - ease of transcutaneous detection
  - seed integrity and safety
- Results
  - No migration of seeds between placement and surgery
  - Twenty-seven seeds were placed directly in the target lesion with the other seeds being 2 and 3 mm away
  - All seeds were detectable transcutaneously in all breast sizes and at all depths
  - There were no complications or safety issues

Harvey, J. et al *Breast Cancer Res Treat.* 2018; 169(3): 531–536.

Initial Clinical Experience With an Inducible Magnetic Seed System for Preoperative Breast Lesion Localization.

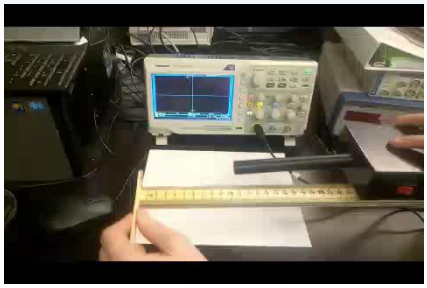
- 64 patients (73 seeds) underwent preoperative localization using Magseed
- All seeds (73/73) were placed successfully, defined as positioning within 1 cm of the target. Fifty-one seeds (70%) were located within 1 mm of the target (either directly contacting the target or immediately adjacent to it).
- Margin positivity rate 12%
- One pneumothorax related to Magseed

Price, ER, et al *AJR Am J Roentgenol.* 2018 Apr;210(4):913-917

Product-Titanium Clip Detector

- We are developing a specialized metal detector that is sensitive enough to directly detect the titanium clip
- Provisional Patent filed August, 2016
- Stage of development: Prototypes of large and small diameter coils that detect titanium at 5cm away.

Functional Prototype



Summary of Breast Localization Devices

	FDA Approved	OR Inefficiency	Expensive	Radiation	Insertion of Device into breast	Patient lost time from work/ family	Detected from any direction
Wire localization	X	X			X	X	X
Radioactive Seed	X			X	X	X	X
Savi Scout®	X		X		X	X	
Sentimag® magnetic seed	X		X		X	X	X
Titanium Clip Detector							X