



**Roundtable with the Experts:
 Localization Techniques**

**Thursday, November 5, 2020
 7:00PM-8:30PM ET**

AGENDA

ASBrS is hosting a *Roundtable with the Experts*, a new series of webinars designed to provide members opportunities to hear from industry experts on technologies available for specific procedures and techniques. The first webinar in this series will focus on surgical localization techniques, featuring presentations from Elucent Medical, Endomag, Hologic, Mammotome, and Merit Medical. Each company will provide a brief presentation on their product(s) followed by an interactive and objective panel discussion led by society leaders. *Note: No CME will be provided.*

This webinar will focus on localization techniques and the different devices available.

Moderators: Susan K. Boolbol, MD, Eric R. Manahan, MD, Shawna C. Willey, MD

Speakers: Ralph L. Corsetti, MD, David Gilstrap, Valerie Gorman, MD, Jodi Hafemeister, Daniel A. Howard, MD, Sarah Megna, Jane Perry, Mathew Stephens, Lee G. Wilke, MD

Panelists: Stephanie Bernik, MD, Scott R. Karlan, MD, Jaime D. Lewis, MD, Andrea Madrigano, MD, Ashley B. Simpson, DO

7:00 PM-7:10 PM	Welcome and Company Introductions Introduction of Panelists	Eric R. Manahan, MD Shawna C. Willey, MD
7:10 PM-7:20PM	Company Presentation: Elucent Medical	Lee G. Wilke, MD
7:20 PM-7:30 PM	Company Presentation: Endomag	Mathew Stephens, CMO
7:30 PM-7:40 PM	Company Presentation: Hologic	Valerie Gorman, MD, Sarah Megna
7:40 PM-7:50 PM	Company Presentation: Mammotome	Jodi Hafemeister, Daniel A. Howard, MD
7:50 PM-8:00 PM	Company Presentation: Merit Medical	Ralph L. Corsetti, MD, David Gilstrap, Jane Perry
8:00 PM-8:30 PM	Panel Discussion/Q&A	Moderated by Susan K. Boolbol, MD All Speakers and Panelists
8:30 PM	Wrap Up	Eric R. Manahan, MD

**ASBrS ROUNDTABLE WITH THE EXPERTS:
LOCALIZATION TECHNIQUES
NOVEMBER 5, 2020 7:00PM – 8:30PM ET**

Company Name: Elucent Medical
Product Name: EnVisio™ Surgical Navigation System
Website Address: www.elucent.com
Contact Name: Ginger Sands
Contact Email/Phone: ginger.sands@elucent.com

Company/Product Description

Elucent Medical seeks to solve the overarching need for a physician/surgeon to be able to return to the precise location where targeted excision or therapy is needed. Elucent Medical has designed the EnVisio™ Navigation system; a novel device that utilizes an innovative electromagnetic field and SmartClip™ to enable precise navigation within a wide field of view to a target of interest. The integration of the navigation tool on to the electrocautery device provides real-time guidance in the surgical field to deliver visual and audible indicators that provide depth, distance, and direction to the SmartClip™. This integrated system enables increased speed because of the ability to have the EnVisio pad providing localization of SmartClips, in addition to the Real-Time Navigation is within the surgeon's hand. The system provides guided navigation on both a heads-up monitor as well as an integrated IWatch size screen on the navigation tool. The guidance and localization updates as the tissue is manipulated during the surgery. The generation of an unprecedented large field of the electromagnetic field for navigation, the EnVisio™ System, and SmartClip™ Technology broaden the treatable patient population expanding SmartClip™ localization from the breast, and lymph nodes to the head & neck, abdominal soft tissue as well as the lung in the future.

The EnVisio™ Navigation system addresses the clinical need to meet the broadest patient demographics from simple (single site) to complex (several sites in the breast and axilla) cases allowing individualized treatment. Elucent Medical is founded on the continued collaboration of multi-disciplinary physicians who seek to improve patient outcomes. This belief and drive were made even more evident during the early months of COVID 19. The Elucent Medical team implemented a comprehensive remote support and education platform to reach physicians who welcomed the opportunity to provide breast-conserving surgeries without exposing others unnecessarily during this pandemic.

CAPABILITIES	LIMITATIONS
SmartClip™ markers are permanently implantable for soft tissue and solid organ (current - breast, lymph nodes; head and neck, abdominal).	As a surgical navigation device, the EnVisio™ system requires a capital component/mattress pad be placed on the operative table to generate the electromagnetic field used for guided navigation.
Next Platform lung, colorectal. They can be placed at time of a biopsy or as localization device.	
Unique SmartClip™ signatures (different colored clips) provide surgical navigation differentiation for simple to complex bracketing in the breast.	Currently the EnVisio™ system is attached to a standard electrosurgical device. If a surgeon is using a knife for their breast conservation surgery the EnVisio™ Navigator attached to a standard bovie would act as an independent secondary device. This would eliminate the integration ergonomics requiring switching off tools in the surgical field.
The foot pedal provides the surgeon control in managing the standard workflow during navigation and excision eliminating the need for circulating nurse to interact after system is set up and case is initiated.	The surgeons must use a foot pedal or sterile drape over the heads up monitor to toggle between multiple SmartClips.

<p>The intraoperative EnVisio™ guided surgical navigation is attached to an electrocautery device and does not require the surgeon to put down or pick up a separate localization device; the “localization” of the SmartClip™ is done through the patient pad, while the “Navigation” is within the surgeon’s hand during the procedure.</p>	<p>Currently, due to the imaging under fluoroscopy, the EnVisio™ patient pad that sits on the operative table must be removed if you are combining port placement post lumpectomy.</p>
<p>SmartClip™s do not require a signal verification at the time of placement, thus there are no equipment needs for Radiology. The SmartClip™ is active when the patient is positioned on the capital component mattress on the OR bed.</p>	
<p>The EnVisio™ 3D guided surgical navigation system enables surgeons to identify a PRECISE PATHWAY for the best oncological and oncoplastic outcome. The navigation provides X/Y/Z coordinates to the clip and lesion of interest. The 3D guided “flight plan” heads up or electrocautery attached display is active from the time patient is positioned on the OR table until the “target clip is removed”.</p>	
<p>Depth of Navigation from the electrocautery tool to the SmartClip™ is 20cm.</p>	
<p>The SmartClip™ is agnostic to electrocautery energy and will continue to deliver unique signature “signal” allowing tissue excision planes on or near the SmartClip™(s). The display continually updates the position of the SmartClip™(s) during surgery as the tissue is moved.</p>	
<p>SmartClip™ signal detection for navigation is not impacted by a fluid such as hematoma.</p>	
<p>The EnVisio™ Navigation System enables identification to take place in the OR simply by having the patient lay on the specialized mattress bed which is placed on the OR bed. The EM field of 50cm x 50cm x 35cm created by the patient pad provides the surgical team confidence in location of the SmartClip™(s) in large or small patients.</p>	
<p>Early review of clinical data indicates a low re-excision rate for radiologic SmartClip™ cases as well as ease of pathologic review and processing due to the lack of a need to remove a radioactive seed or wire.</p>	

Company Name: Endomag

Product Name: Sentimag® Surgical Guidance System

Website Address: www.endomag.com

Contact Name: Mathew Stephens

Contact Email/Phone: mstephens@endomag.com / +44 1223 652540

Company/Product Description

Endomag is the global technology company that believes everyone deserves a better standard of cancer care. Many of the world’s leading physicians and hospitals use the company’s technologies to help women with breast cancer avoid surgery when it isn’t needed, and experience better outcomes when it is.

The company was founded in 2007 when two professors based at University College London (UCL) and the University of Houston realised that magnetics might be able to improve the existing standard of cancer care. Years of research led them to successfully develop a magnetic sensor capable of detecting one millionth of the Earth’s magnetic field, the Sentimag® probe.

The Sentimag® probe works like a metal detector, which when placed near the skin’s surface can detect Endomag’s magnetic seed (Magseed®) or liquid tracer (Magtrace®), used in tissue localisation and sentinel node biopsy procedures, respectively. To this day the Sentimag® system has been used in over 90,000 breast cancer procedures at over 450 hospitals in more than 35 countries. Endomag is a global company headquartered in Cambridge, UK, with an office in Austin, Texas.

To date, the company has helped tens of thousands of women around the world access more precise and less invasive breast cancer care. To learn more visit: <https://www.endomag.com/>

Visit Website: www.endomag.com

Contact by Phone: +44 1223 652540

CAPABILITIES	LIMITATIONS
Simple seed that is easy to accurately place	Magseed creates an artefact on MRI (Magseed Biopsy resolves this)
Reliable - can't break or move during placement	Don't currently offer millimetre measurement
Very easy to find in any tissue type, any depth and from any angle to remove smaller specimens with low positive margins	Metal tools interfere with signal during sensing
Cannot be deactivated with electrocautery	
Most studied non-radioactive seed	
Used in more countries than any other	
Signal not interfered with OR lights Magtrace for SLNB and Delayed SLNB in same system	

Company Name: Hologic

Product Name: LOCALIZER™ Wire-Free Guidance System

Website Address: www.hologicbreastsurgery.com

Contact Name: Sarah Megna

Contact Email/Phone: Sarah.Megna@hologic.com / 508-951-8793

Company/Product Description

Hologic is a global medical technology company specializing in women’s health—offering innovative solutions for screening, detecting and treating conditions affecting women throughout their lives, including breast and cervical cancer testing, gynecological and skeletal issues; and sexually transmitted diseases.

CAPABILITIES	LIMITATIONS
Pencil like probe	12G needle applicator
Handheld reader that can be used inside or outside the sterile field	MRI Artifact
Each tag has a unique ID	
Integrated loop probe in reader to confirm placement (No need for separate capital to confirm placement)	
Provides real-time distance measurement	

Company Name: Mammotome

Product Name: HydroMARK

Website Address: www.mammotome.com

Contact Name: Jodi Hafemeister

Contact Email/Phone: jodi.hafemeister@mammotome.com

Company/Product Description

At Mammotome, we are committed to providing best-in-class technology to help clinicians accurately diagnose breast cancer. Never forgetting that at the heart of each breast cancer diagnosis is the patient.

CAPABILITIES	LIMITATIONS
Excellent U/S long-term visibility even with NACT	Requires surgeon to learn ultrasound
Dependable visibility even with different types of breast tissue	Must find access to use ultrasound in OR (borrow from other departments)
Compatibility with the patient (no nickel)	
De-couple the localization from radiology without the high cost of a wire-free seed	

Company Name: Merit Medical

Product Name: SCOUT® Radar Localization System

Website Address: www.meritmedical.com

Contact Name: Jane Perry

Contact Email/Phone: jperry@meritmedical.com

Company/Product Description

Merit Medical Systems, Inc. is engaged in the development, manufacturing and distribution of proprietary disposable medical devices used in interventional, diagnostic, and therapeutic procedures, particularly in cardiology, radiology, oncology, critical care and endoscopy.

Merit Oncology, a division of Merit Medical, is a provider of world-class solutions for the diagnosis, localization, and treatment of cancer and is focused on expanding applications that continually advance patient care, reduce costs and ease the burden of cancer for patients and their loved ones.

The SCOUT® Radar Localization System is the preferred localization solution *from biopsy to surgery*. *The system* is FDA cleared and been clinically demonstrated to drive value and improve patient outcomes, radiology workflow and significantly reduces OR delays. Using SCOUT, surgeons can precisely target the affected tissue to pinpoint its location within 1mm, which can mean more successful surgeries, optimized breast conservation strategies, and enhanced outcomes for women.

SAVI® Brachy, for accelerated partial breast irradiation (ABPI), combines the precise dosimetry of interstitial brachytherapy with the ease and convenience of single-entry devices. With SAVI Brachy, patients receive customized radiation therapy based on their specific anatomy in as little as 2 days.

In addition, the division offers soft tissue biopsy brands, such as Achieve®, Temno®, Tru-Cut® and CorVocet®, that offer advanced features to obtain top-quality tissue samples with ease and efficiency for precise samples every time.

All our technologies address unmet needs in the delivery of radiation therapy, biopsy, tumor and soft tissue localization and surgical guidance to treat more patients.

Please visit www.merit.com/merit-oncology/ for more information.

CAPABILITIES	LIMITATIONS
Indicated for placement in soft tissue	60mm max depth detection
>30day long term implant status	Not for use in eye, heart, brain or spinal cord
+/- 1mm accuracy detecting reflector location	Not to be placed in tissue site with clinical evidence of infection
Depth detection up to 60mm	
Spherical 360-degree detection capability	
Can be placed at time of biopsy or pre neoadjuvant therapy	
Does not interfere with imaging modalities	