

Breast Biopsy Solutions

A comprehensive portfolio of clinically proven solutions from the world leader in breast health



Hologic is the **most recommended brand** in women's imaging and breast biopsy¹



Hologic rated #1 for product experience in breast biopsy.¹

Focused on a **Better Biopsy Experience**

At Hologic, it is our mission to transform breast care with compassionate and effective solutions designed to maximize value, while minimizing the negative impacts of interventional procedures. The best technologies should ease patient anxiety and help clinicians focus on what's most important – providing the best possible care. That's why our curated portfolio of interventional products is supported by clinically proven outcomes and optimized for the future of patient care.



Optimize workflows

- Solutions designed to save time by combining and eliminating steps in the biopsy process
- Quick setup times to keep procedures on track and on time



Create a better patient experience

- Fast, efficient procedures that minimize time spent under compression
- Integrated pain management to address discomfort



Deliver the best outcomes possible

- Confidently approach challenging lesions with clinically proven solutions to acquire the tissue you need for diagnosis
- Give more women an alternative to open surgical biopsy so they can **get back to their lives, sooner**

Hologic Solution to Stereotactic Biopsy

DECADES OF CONTINUOUS INNOVATION

Brevera® Breast Biopsy System with CorLumina® Imaging Technology

A breakthrough in biopsy efficiency

The world's **first** and **only** solution to combine tissue acquisition, real-time imaging and verification, and advanced post-biopsy handling – all in one, integrated system. Recipient of the **2018 MedTech Breakthrough Award** and the **2018 Edison Award**.

- Previously, nearly **85% of imaging and confirmation occurred outside of the biopsy room**. With the Brevera system, there is no need to change rooms, no waiting for sample verification, and no interruptions to the screening schedule.
- Redesigned disposable needle for **54% less waste**² and better inventory management

Improve Patient Experience

- Integrated delivery of pain management, quiet operation, and fast access to information help **improve the patient experience**.
- **9/10 patients felt less uncomfortable** with their Brevera breast biopsy procedure than they expected.³

Enhance Workflow

- An **intuitive user interface, real time imaging, and automated specimen collection and separation** work together to save facilities an average of 13 minutes per procedure.⁴
- Brevera core sampling **automatically separates, identifies, and analyzes target samples**, then transfers seamlessly to pathology with minimal handling to help maintain core integrity.

Increase Accuracy

- **Real-time imaging** delivers a wealth of information at the point of care – so you can make informed decisions with confidence.



Affirm® Prone Biopsy System



Affirm® Upright Breast Biopsy Guidance System



Brevera® Breast Biopsy System



12-Chamber Tissue Filter



Brevera® Needle

Integrated Breast Biopsy Guidance Systems

The Brevera® and Eviva® systems are designed for use with the Affirm® prone and upright breast biopsy guidance systems in both stereotactic 2D and 3D™ biopsy procedures, offering optimized access for faster, more accurate procedures, at a lower dose.⁵⁻⁷

Eviva® Breast Biopsy System

Trusted globally in nearly 3,000 facilities⁸

Proven technology trusted globally to deliver a fast, compassionate, and easy breast biopsy.

Fast

- Remove consistent cores **every 4.5 seconds**.⁹
- **Simple setup** with no software required to program or operate the console.

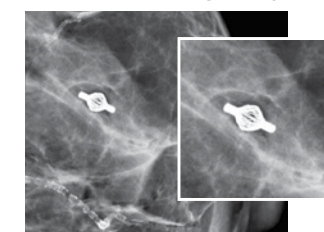
Compassionate

- Manage patient pain with **local anesthetic directly to the biopsy site** automatically with every core.¹⁰
- **9/10 clinicians agree** the Eviva device offers a better patient experience compared to other vacuum assisted breast biopsy devices when it comes to what's important:¹¹
 - Acquires high quality core samples
 - **Minimizes complications** and maximizes patient satisfaction
 - **Reduces false negatives** and minimizes **unnecessary call-backs**
 - **Easy-to-operate**

Easy

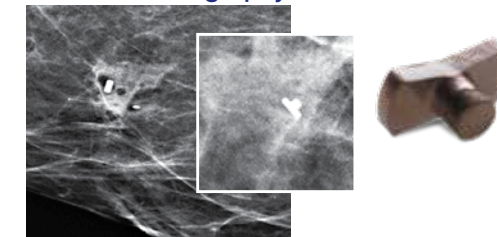
- Optimize access to challenging lesions close to the chest wall using a low-profile needle.
- Simple set up and easy cleanup.
- Manage thin breast compressions as small as 16mm.¹²

Tumark® Marker Under Mammography



Tumark® Vision marker
Image courtesy of Dr. Stoeblen, Essen, Germany

SecurMark® Top Hat Under Mammography



Hologic provides distinct marker shapes with options for great long-term ultrasound visibility. Designed so you can identify sites with confidence.

In-Room Core Biopsy Imaging

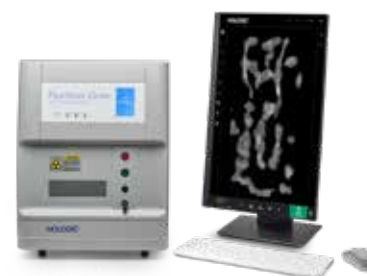
The Eviva® system pairs well with the Faxitron® Core Specimen Radiography System – a small tabletop system that eliminates delays for core sample verifications. With high-resolution imaging right in the biopsy room, you can accelerate procedures and get patients out of compression faster.¹³



Eviva® Needle



ATEC® Sapphire Console



Faxitron® Core Specimen Radiography System

Hologic Solution to Ultrasound Biopsy

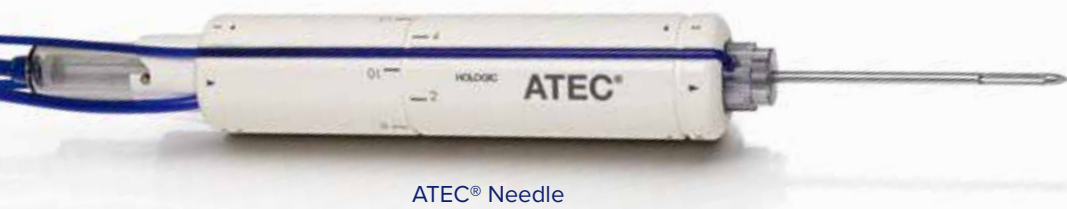
EMPOWERING YOUR CHOICE

ATEC® Breast Biopsy System

Powerful vacuum

Designed for compassionate patient care, the system delivers large, consistent, quality cores with fewer needle insertions.

- Deliver **uninterrupted local anesthetic**. Combination of saline lavage and consistent aspiration helps ensure a core with every cycle.¹⁴
- **Totally closed system**. Setup in less than one minute. No programming required.
- **Tissue acquisition occurs every 4.5 seconds** with a single insertion and clearly visible aperture.¹⁵
- Completely remove the mass without surgery callback.¹⁶



ATEC® Needle



ATEC® Sapphire Console

Pairs with the ATEC® Sapphire 100 system, which can be used in all three modalities – stereotactic, ultrasound and MRI breast biopsy – with specific handpieces for each.

Celero® Breast Biopsy System

Untethered freedom

The industry's first spring-loaded core device with integrated vacuum technology was designed for more control, consistent cores, and better access.

- Make **fewer insertions** for accurate diagnosis with cores more than **two times larger** than other 14G SLC devices.¹⁷
- Ensure large samples and consistent cores with the first spring-loaded core device with **integrated vacuum technology**.¹⁸
- **Confidently approach** challenging lesions:
 - 11° trocar tip for smooth penetration
 - 10mm dead space
 - Option to fire outside of the breast for no throw insertion and clearly visible aperture.



Celero® Needle

Sertera® Breast Biopsy Device

Exceptional control in a simple spring-loaded core device

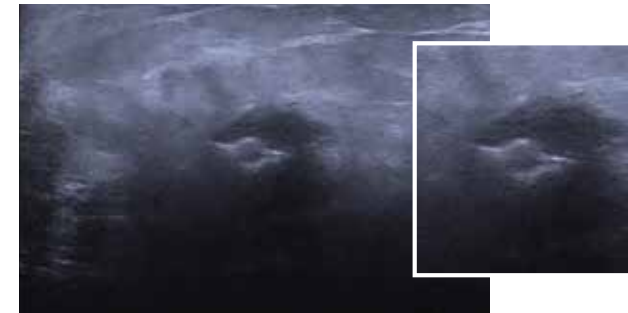
Perfect for accessing difficult lesions, the device was designed to be lightweight and ergonomic thanks to Hologic's patented HandForm™ design.

- Simple, one-handed operation with **patented HandForm™ design**:
 - Lightweight ergonomics comfortable for many hand sizes
 - Two firing modes for extra control when you need it
- Approach challenging lesions with confidence. **7 out of 10 physicians felt the Sertera biopsy device resulted in greater accuracy.**¹⁹
- In an initial survey, 95% of physicians stated that the Sertera biopsy device was **easy to arm & fire and allowed for one-handed operation.**¹⁹
- Nine out of 10 physicians said — **it is easy to use.**¹⁹



Sertera® Needle

Tumark® Marker Under Ultrasound



Tumark® Vision marker
Image courtesy of Dr. Stoebelen, Essen, Germany

Plan your procedure

Localize the biopsy site before surgery and after successful therapy with a marker designed for long term visibility.*²⁰

Ultrasound Imaging

Hologic's ultrasound biopsy solutions are designed for use with the SuperSonic™ MACH™ 20, MACH™ 30 or MACH™ 40 systems, which offer exceptional image quality and innovative modes like Needle PLUS imaging — designed for visibility enhancement during biopsies for improved outcomes and increased patient satisfaction.



SuperSonic™ MACH™ 40 Ultrasound System



Viera® Breast Performance Software with Clarius HD

Hologic's ultrasound biopsy solutions pair well with the Viera® Breast Performance Software with Clarius HD. The industry's first wireless, handheld breast ultrasound system with exceptional breast image quality at the point of care, enabling optimization of your clinical workflow and patient pathway — all at an affordable cost.

* Visibility is dependent on surrounding tissue, experience may vary.

Hologic Solution to MRI Biopsy

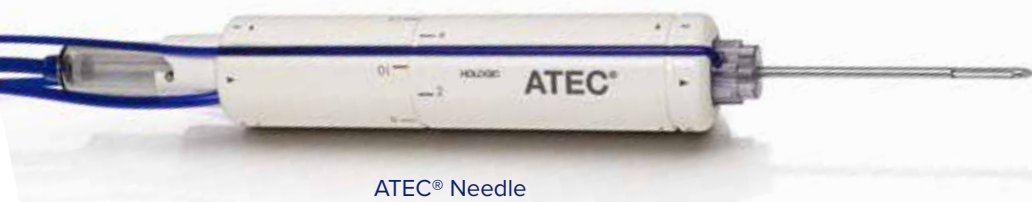
PATIENT FOCUSED, PHYSICIAN INSPIRED

ATEC® MRI Biopsy Device

MRI biopsy pioneer and market leader

The original pioneer in breast MRI biopsy procedures and today's market leader, known for its speed, accuracy, and simplicity.

- The **fastest procedure time** in MRI by 10 minutes.²¹
- MRI access needle allows for the treatment of **thin breasted women**.
- Deliver **uninterrupted local anesthetic**. Combination of saline lavage and consistent aspiration helps ensure a core with every cycle.¹⁵
- **Setup in less than one minute**. Totally closed system. No programming required.



ATEC® Needle



ATEC® Sapphire Console

Pairs with the ATEC® Sapphire 100 system, an all-in-one platform intended for use under ultrasound, MRI, stereotactic and 3D™-image guidance.



ILS Kit

ATEC® Introducer Localization System

- Exclusive to the ATEC® MRI Biopsy System
- Confirm your target prior to completing the biopsy.

Marker Solutions

A SHAPE FOR ANY CASE

Biopsy Site Markers

Options for every modality

An array of biopsy site marking options with distinct shapes to address any case you may encounter.



Tumark® Biopsy Site Markers

Intelligently designed to provide long-term ultrasound visibility, the non-bioabsorbable, biocompatible permanent markers offer excellent visibility under mammography at deployment and are designed to minimize movement.²²

Stereotactic and Ultrasound



SecurMark® Biopsy Site Markers

A bioabsorbable suture-like net carrying a biocompatible permanent marker, designed to minimize migration within the biopsy cavity and enhance ultrasound visualization for three to four weeks post-biopsy.²³

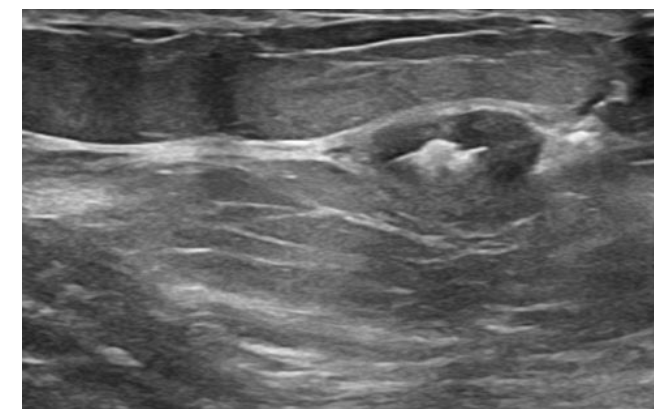
Stereotactic, Ultrasound and MRI



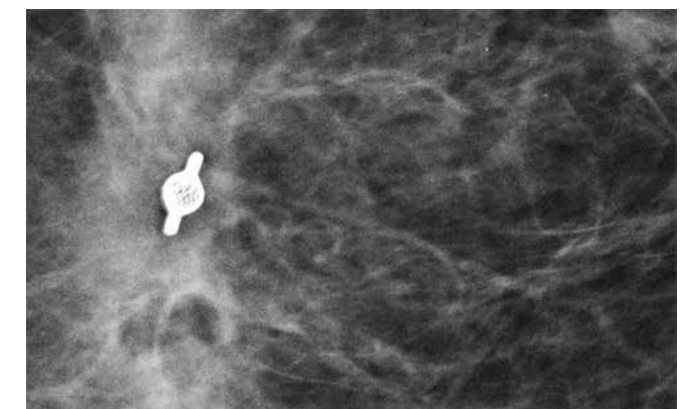
TriMark® Biopsy Site Markers

Reliable and simple bio-compatible Titanium metal markers, optimal for thin-breasted patients and superficial lesions.

Stereotactic, Ultrasound and MRI



Tumark® under Ultrasound
Vision marker
Image courtesy of Dr. Peggy Avagllano

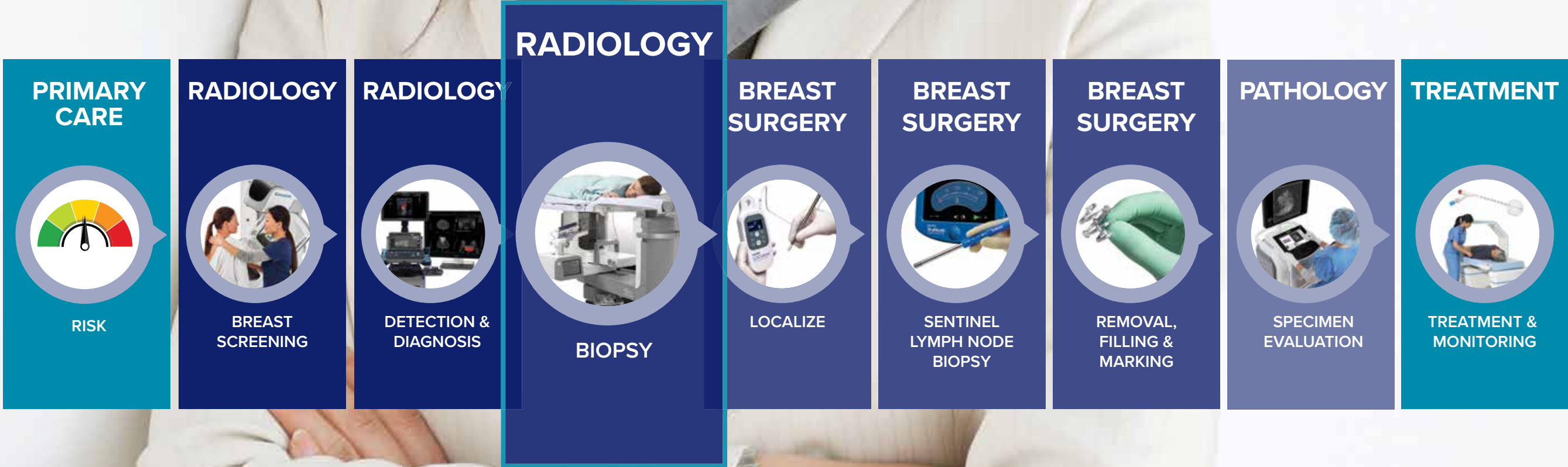


Tumark® under Mammography
Vision marker
Image courtesy of Dr. Lashonda Soma

A Complete Continuum of Care

Best in class, reliable, efficient solutions across the breast health continuum

Hologic's breast health innovations are focused on technologies designed to integrate multiple steps in the patient pathway into a single visit, while also offering speed, comfort and accuracy in outcomes, to ultimately deliver the best possible patient experience. Partner with Hologic to gain access to industry-leading, clinically proven tools to treat your patients at every step along the breast health pathway, while simultaneously reducing costs and creating efficiencies.



At Hologic, our breast health solutions deliver trailblazing technologies to keep you on the forefront of breast care. Our passion drives us in the relentless pursuit of innovative tools that set new paradigms for the early detection, accurate diagnosis, intervention and treatment of breast cancer — technologies to help you protect and preserve the lives of your patients. **With you, we are on a mission to help women live longer, healthier lives.**

For more information on the Hologic family of breast health solutions, please visit hologic.com.

References

1. A representative survey of 159 US radiologists and radiologist administrators conducted Dec 2019/Jan 2020. **2.** Compared to Eviva device. 2017 data on file. **3.** Results from, "A Prospective, Block Stratified Clinical Trial to Evaluate the Performance and Operation of the Brevera® Breast Biopsy System" (NCT03300206) (US) **4.** Brevera Pulse Survey, Quantitative report. Inspired Insights. April 2019. **5.** Hologic data on file, Compared with stereotactic (2D) biopsy. **6.** Schrading S, Martine D, Dirrichs T, et al. "Digital Breast Tomosynthesis-guided Vacuum-assisted Breast Biopsy: Initial Experiences and Comparison with Prone Stereotactic Vacuum-assisted Biopsy." *Radiology*. 2015 274:3, 654-662 E-pub 2014 Nov 12. **7.** Smith A, Sumpkin J, Zuley M, et al. "Comparison of Prone Stereotactic vs. Upright Tomosynthesis Guided Vacuum Assisted Core Breast Biopsies." (paper presented at the annual meeting for the Radiological Society of North America. Chicago, IL, November 2014). **8.** Hologic data on file. **9.** Hologic data on file, Internal testing performed at Hologic and maintained in PLM system **10.** Hologic data on file, AW-02708 - Instructions for use - Eviva - Stereotactic guided breast biopsy system. **11.** Hologic data on file, MISC-06068, Attachment 1 Kadence study, "Eviva Audit – Identifying optimal claims for the Eviva Breast Biopsy device", July 2015. **12.** Hologic data on file, VER-05759, VER-04202, VER-04111, VER-03205, VER-03792, DHM-02115, DHM-02203. **13.** Hologic data on file, Compared to Specimen imaging on mammography unit outside of the biopsy suite, 2015 Kadence International survey of 200 healthcare professionals. **14.** FDA K042290. **15.** K042290. Data on file at Hologic, Inc. **16.** FDA cleared to remove benign fibroadenomas. **17.** Englander, B. White Paper. 2013, Hologic WP-00006. **18.** Data on file at Hologic, Inc. **19.** In an initial survey, 95% of physicians stated that the Sertera biopsy device was easy to arm & fire and allowed for one-handed operation. Data collected from 100 cases performed at various settings using the Sertera biopsy device. **20.** Tumark® Marker Data Collection Study, 2017, DHM-06169, 3 clinicians at 3 hospitals for 90 marker placements, 2017. **21.** M. Scarth, W. Teh; Harrow/UK. MR-guided vacuum-assisted core-needle breast biopsy: Comparison of three vacuum-assisted biopsy devices. ECR Congress 2009. Scientific Paper, e-Poster: B-295. **22.** Tumark® Marker Data Collection Study, 2017, DHM-06169, 3 clinicians at 3 hospitals for 90 marker placements, 2017, In 85% of marker placements, physicians stated that the ultrasound visibility was good to excellent upon deployment. In 56% of marker placements, physicians stated that ultrasound visibility was excellent upon deployment. **23.** Pickney and Shah, 2013, Prospective comparative study to evaluate the sonographic visibility of five commercially available breast biopsy markers. (GelMark, HydroMARK, SecurMark, SENOMARK, and UltraClip by Bard (BioDur® 108 core)). Yen et al. verified that SecurMark and SENOMARK devices show reduced displacement when compared to traditional metal surgical clips (28% and 27% vs 38% displacement, p = 0.001 and p = 0.0001). Visibility is dependent on surrounding tissue, experience may vary.

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