# **The Science of VAB**

Is ultrasound VAB worth it? The data says yes.

# Mammotome

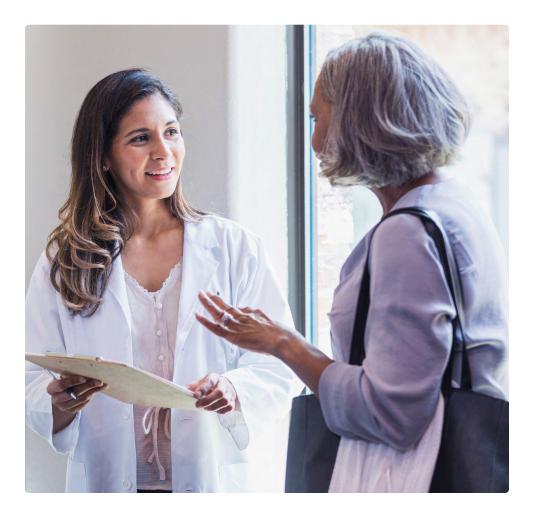


# **The Science of VAB**

# Have you ever been surprised by a histological diagnosis despite getting what you thought was a sufficient sample?

A main reason many clinicians use Vacuum-Assisted Biopsy (VAB) devices in ultrasound-guided breast procedures is for larger cores for diagnostic confidence.<sup>1</sup> These clinicians get the added benefit of improved efficiency from single insertion.<sup>1</sup> However, the benefits don't end there.

Mammotome VAB is engineered to improve outcomes and the biopsy procedure for you and your patients.<sup>1</sup> Learn more about The Science of VAB and the clinical evidence to support it.



# How Tissue Challenges Translate to Mammotome Design Principles

Mammotome VAB devices are engineered to consider challenging breast biopsy cases.

#### Mammotome VAB Design Principles

#### **Scalpel Blade Needle Tip**

The needle tip is designed with an optimized angle and sharpness to reduce force to penetrate in dense breast tissue for easier, more controlled access to the lesion.



3

#### **Single Insertion Design**

Designed to take multiple samples with a single insertion, Mammotome VAB devices ensure that you're in the same spot with each sample you take, eliminating the need to retarget the lesion.



#### Lateral and Axial Vacuum

The lateral vacuum pulls tissue into the aperture, or trough, holding the tissue as it cuts before axial vacuum transports tissue to the cup. This allows for large and more consistent tissue samples across lesion types.

#### Variable Aperture and Adjustable Vacuum

The Mammotome Revolve™ system is designed with multiple aperture size settings and an adjustable vacuum level, providing flexibility to adjust sampling based on preference for size, type and location of the lesion.

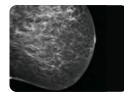








### **Breast Biopsy Challenges**



#### **Dense Breast Tissue**

This can make it difficult to access a lesion in a controlled manner, potentially requiring more force or pressure if the needle isn't sharp enough.

Related VAB Design Principles: 1



#### Challenging Lesions

Lesion properties can vary, presenting challenging sampling scenarios such as small masses, complex cysts, and microcalcifications.

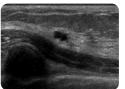
Related VAB Design Principles: 2



#### **Smaller Non-Palpable Lesions**

These lesions can be more difficult to accurately sample, especially after the first sample is taken.

Related VAB Design Principles: 2



#### **Lesions in Challenging Positions**

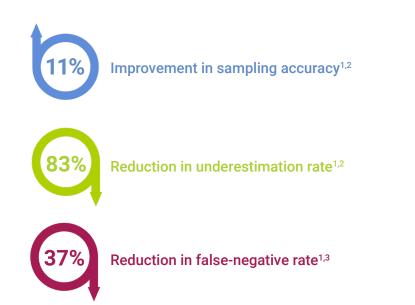
These lesions can be difficult to access and may require a different approach.

Related VAB Design Principles: 2 3 4

# Evidence-Based Benefits<sup>1</sup> of VAB in U/S-Guided Breast Biopsies: Better Outcomes

## Larger Samples For More Confidence In Your Diagnosis

As compared to 14G spring-fired core needle devices



VAB can help get more tissue with each sample even with similar gauge sizes. A case study found that larger tissue samples mean more tissue to send for additional pathology testing from the same location. Additional pathology testing can lead to a more tailored treatment approach.<sup>4,5,6</sup>

Touchless tissue retrieval eliminates the need to touch the sample each time, decreasing risk of crush artifact and fragmentation.<sup>1,4</sup>

Multiple studies show using single insertion VAB devices results in less or equivalent pain during and equivalent pain after procedures as compared to core needles despite larger gauge sizes (10G to 13G).<sup>2,3,7</sup>

 
 Gerarde sample weight
 Mammotome®
 Mammotome®
 Mammotome
 Mammotome

 Core Needle<sup>8</sup>
 Mammotome®
 Mammotome®
 Mammotome
 Mammotome

 14G
 13G
 10G
 8G



View The Science of VAB Clinical Highlights for additional information

View Document

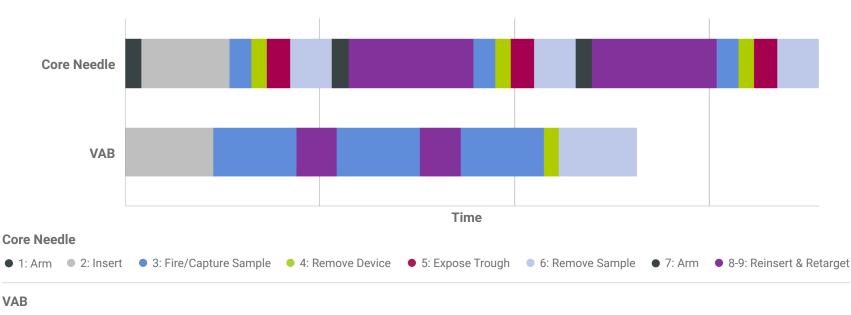
# **Evidence-Based Benefits**<sup>1</sup> of VAB in U/S-Guided Breast Biopsies: Efficiency and Patient Benefits

### Efficiency

- Single insertion VAB devices remove the need to arm the device, spring-fire the needle, remove the needle, handle the tissue, reinsert the needle, relocate the lesion, etc.
- Touchless tissue transfer allows for the transfer of all tissue samples to formalin at the same time.
- There is no pumping or manual arming required.
- Fluid management helps control fluids in the lesion cavity.
- The Mammotome<sup>®</sup> Elite and Mammotome Revolve<sup>™</sup> systems have a short cycle time of less than nine seconds per sample retrieval.

## **Other Patient Benefits**

- An efficient procedure means less procedure time for you and your patient.
- There are no startling snapping noises from the needle throw.
- The single insertion design of Mammotome VAB devices means there is no need to repeatedly move the needle in and out of the breast.



## Example Sampling Steps and Relative Average Cycle Time for 3 Samples<sup>9</sup>

# System Specific Benefits: Mammotome<sup>®</sup> Elite Tetherless Vacuum-Assisted Biopsy System



## System Specific Benefits: Mammotome Revolve<sup>™</sup> U/S Dual Vacuum-Assisted Breast Biopsy System



## Maximize tissue specimen size

- Stronger vacuum and larger gauge sizes than the Mammotome<sup>®</sup> Elite tetherless system
- 8G and 10G options

## Customized control

- · Adjustable vacuum settings with dual vacuum technology
- Variable aperture settings to more closely match the length of the aperture with size and location of the lesion
- Continuous biopsy mode to take samples back-to-back while holding the activation button

## Fluid management

- On-demand vacuum and continuous suction with SteadyVac manages fluid in the biopsy cavity
- Enables fluid insertion through the device, including local anesthetic

## Advanced tissue management

• Automatically collects and organizes specimens in touch-free chambers for tissue verification and easy imaging

## Mark the site with a tissue marker without removing the needle

Multi-modality flexibility; compatible with the Mammotome Revolve<sup>™</sup> ST biopsy system control module

# References

- 1. As compared to 14G spring-fired core needle devices
- 2. Seo, J, et al. Ultrasound-Guided Cable-Free 13-Gauge Vacuum-Assisted Biopsy of Non-Mass Breast Lesions. Vol. 12, no. 6, 19 June 2017, p. e0179182, https://doi.org/10.1371/journal.pone.0179182.
- 3. Zhang, Y., et al. "The comparison of efficacy and safety evaluation of vacuum-assisted Elite 10-G system and the traditional BARD 14-G core needle in breast diagnosis: an open-label, parallel, randomized controlled trial." International Journal of Surgery 109:1180–1187, April 2023, http://dx.doi.org/10.1097/JS9.0000000000257.
- 4. Utility of Adequate Core Biopsy Samples from Ultrasound Biopsies Needed for Today's Breast Pathology (Ozerdem, 2017, MDM 17-0021)
- 5. McVeigh, Terri P, and Michael J Kerin. "Clinical Use of the Oncotype DX Genomic Test to Guide Treatment Decisions for Patients with Invasive Breast Cancer." Breast Cancer: Targets and Therapy, vol. 9, 29 May 2017, pp. 393–400, www.ncbi.nlm.nih.gov/pmc/articles/PMC5459968/, https://doi.org/10.2147/BCTT.S109847.
- 6. Sparano, Joseph A., et al. "Adjuvant Chemotherapy Guided by a 21-Gene Expression Assay in Breast Cancer." New England Journal of Medicine, vol. 379, no. 2, 12 July 2018, pp. 111–121, www.nejm.org/doi/full/10.1056/ NEJMoa1804710.
- 7. Szynglarewicz, B., et al. "Pain Experienced by Patients during Minimal-Invasive Ultrasound-Guided Breast Biopsy: Vacuum-Assisted vs Core-Needle Procedure." European Journal of Surgical Oncology (EJSO), vol. 37, no. 5, May 2011, pp. 398–403, https://doi.org/10.1016/j.ejso.2011.02.002.
- 8. Mammotome DualCore<sup>™</sup> Dual Stage Core Biopsy System per porcine lab study (ES-002753)
- 9. Benchtop Time Savings Study of Single Insertion Device vs Multiple Insertion Devices (ES-002770)
- 10. Mammotome Data on File; Internal Engineering Study

# Mammotome · mammotome.com

