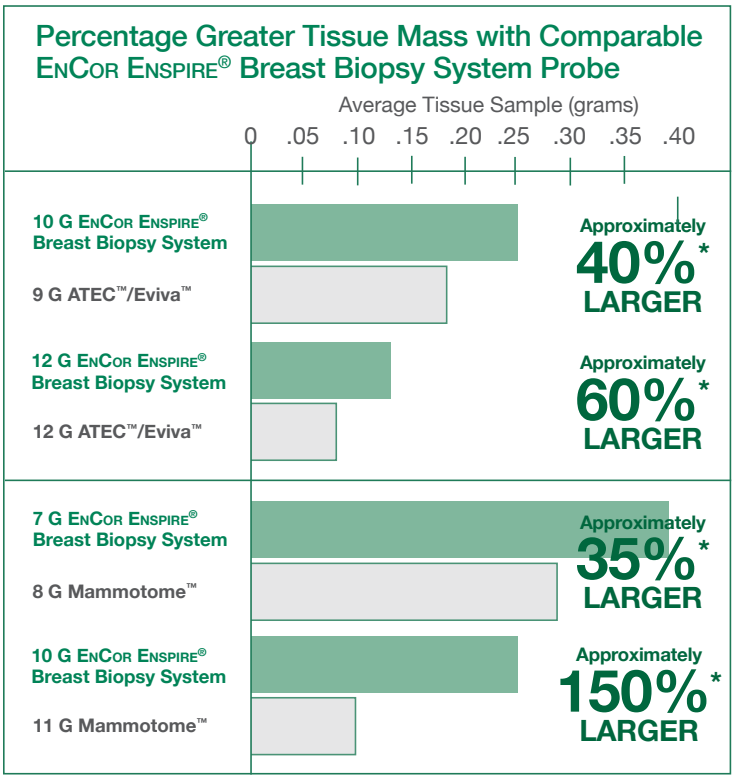
Vacuum-Assisted Breast Biopsy Devices

Comparison of Tissue Sample Mass and the Potential Advantages of Larger Samples

There are many devices on the market for obtaining breast biopsy tissue samples. Each device produces tissue samples that have a range in appearance. Larger, less fragmented tissue samples can contribute to a pathologist making a more accurate diagnosis. For a pathologist, working with smaller fragmented samples can be like working with a disassembled jigsaw puzzle. Larger cores, with more intact histologic patterns, "require less mental reassembly of the histologic jigsaw puzzle, thus facilitating a more rapid specific diagnosis."[1]

The EnCor Enspire® Breast Biopsy System Obtained Samples Up to 150% Larger Than Other Systems In Simulated Use Testing†



*Tolerances percentage 17% calculated from data collected on "medium" gauge devices. Data on file.
†See Study Description and Disclosures on side 2.

Device	Large Gauge	Medium Gauge	Small Gauge
Bard Biopsy EnCor Enspire® System[2]	0.39	0.25	0.13
Hologic™ ATEC™/Eviva™ Systems[3]		0.18	0.08
Devicor™ Mammotome™ System[4]	0.28	0.10	
	Average Sample Size (grams)		

"EnCor Enspire® Breast Biopsy System definitely produces a more solid specimen that is not fragmented as much as the other biopsy devices that I have used… My pathologist stated that he can not only see the histology of the cell more clearly, but also the maintenance of the original tissue helps in assessing the extent of spread better."

Jason Hechtman, M.D., F.A.C.S., Medical Director, The Breast Institute at Brandon Regional Hospital, 15 breast biopsies weekly.

"Increased size of individual biopsy fragment fosters accuracy of histopathologic assessment and can reduce number of procedures required for diagnosis and definitive treatment."[1]

"Our samples are of such high quality that our pathologists have told me that they are similar in quality to specimens obtained from an excisional biopsy."

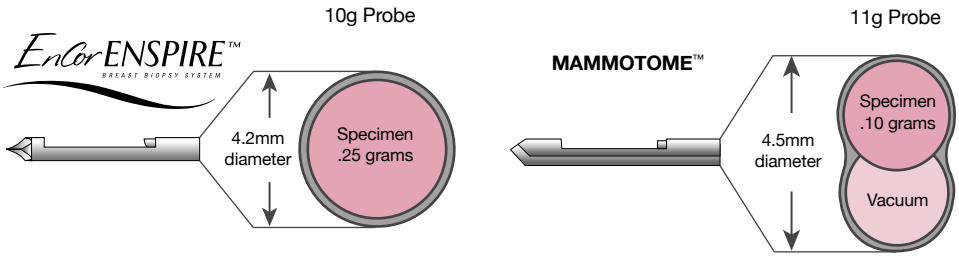
Linda B. Griska, M.D., Director of Breast Health Services, Abington Health Medical Director, Mary T. Sachs Breast Center, 30 breast biopsies weekly.

"When we first switched over to EnCor Enspire® Breast Biopsy System, the pathologists commented on how large and intact the specimens were—great for diagnosis and obtaining prognostic panels"

S. Chace Lottich, M.D., Community Breast South Hospital, Indiana Surgeon, 10 breast biopsies weekly.

Variations in Gauge Measurement Methods

The manufacturer stated gauge of the probes included in the study was not always indicative of the actual outer diameter of the needles. The probe size is much larger than comparable EnCor Enspire® Breast Biopsy System probes due to the Mammotome™ probe's design, which holds the sample collection area above the vacuum.



† **STUDY DESCRIPTION:** Conducted by Bard Biopsy Systems, the study included the EnCor Enspire® Breast Biopsy System, Hologic ATEC™ System, Hologic EVIVA™ System, and Devicor Mammotome™ System.

Five (5) probes for each probe type/gauge size were used to acquire 12 samples each (for a total of 60 samples) in chicken breast. To measure the inner diameter of the probes, needles were disassembled to access the cannula containing the sample notch. The inner diameter of the sample notch was measured using pin gages.

STUDY DISCLOSURES: Please note that these values are representative for comparison purposes. Performance in human breast tissue will vary. Different patients/densities and consistency of breast tissue will have a different yield in tissue sample mass. Gauge sizes listed are manufacturer-stated gauge sizes and do not necessarily represent the actual measured gauge size.

Jason Hechtman, M.D., F.A.C.S., Linda B. Griska, M.D. and S. Chace Lottich, M.D. are currently consultants for Bard Biopsy Systems.

Multiple Features Contribute to Higher Quality Samples

According to S. Chace Lottich, M.D., a number of system features combine to enable her to get larger samples with the EnCor Enspire® Breast Biopsy System:

- **Driver with built-in headlights**
- **Half-Sample Mode**
- **Dense Tissue Mode**
- **Sharp TriConcave™ Cutting Tip**
- **Automated sampling**

"It's all about targeting, efficiency, and getting adequate samples as painlessly as possible," she explains. She credits the above as to all contributing to targeting and patient comfort. "Overall," she says, the samples are "bigger and just easier to get."

1. Rogers RW: Breast Biopsy: A Pathologist's Perspective on Biopsy Acquisition Techniques and Devices with Mammographic-Pathologic Correlation. Seminars in Breast Disease: Radiologic, Pathologic and Surgical Considerations, Volume 8, issue 3 (September, 2005), p. 127-137.
2. EnCor® probes sizes: large gauge - 7g; medium gauge - 10g; small gauge - 12g.
3. ATEC™ and Eviva™ probe sizes: large gauge - n/a; medium gauge - 9g; small gauge - 12g.
4. Mammotome™ probe sizes: large gauge - 8g; medium gauge - 11g; small gauge - n/a.

EnCor Enspire® Breast Biopsy System
INDICATIONS: The EnCor Enspire® Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. **CONTRAINDICATIONS:** EnCor Enspire® Breast Biopsy System is contraindicated for those patients where there is an increased risk of complications associated with percutaneous removal of tissue samples. **WARNINGS:** The EnCor Enspire® Breast Biopsy System must be properly grounded to ensure patient safety. • Use of accessories not compatible with the EnCor Enspire® Breast Biopsy System may create potentially hazardous conditions. **PRECAUTIONS:** This equipment should only be used by a physician trained in its indicated use, limitations, and possible complications of percutaneous needle techniques. • Patients who may have a bleeding disorder or who are receiving anticoagulant therapy may be at increased risk of complications. • As with any biopsy instrument, there is a potential for infection. **POTENTIAL COMPLICATIONS:** Potential complications are those associated with any percutaneous removal/biopsy technique for tissue collection. Potential complications are limited to the region surrounding the biopsy site and include hematoma, hemorrhage, infection, a non-healing wound, pain and tissue adherence to the biopsy probe while removing it from the breast. **Please consult package insert for more detailed safety information and instructions for use.**

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