EnCor Enspire™

Breast Biopsy System

Designed for efficiency and ease in all modalities

BD

Encor Enspire™

Breast Biopsy System

Exclusive advantages in all modalities

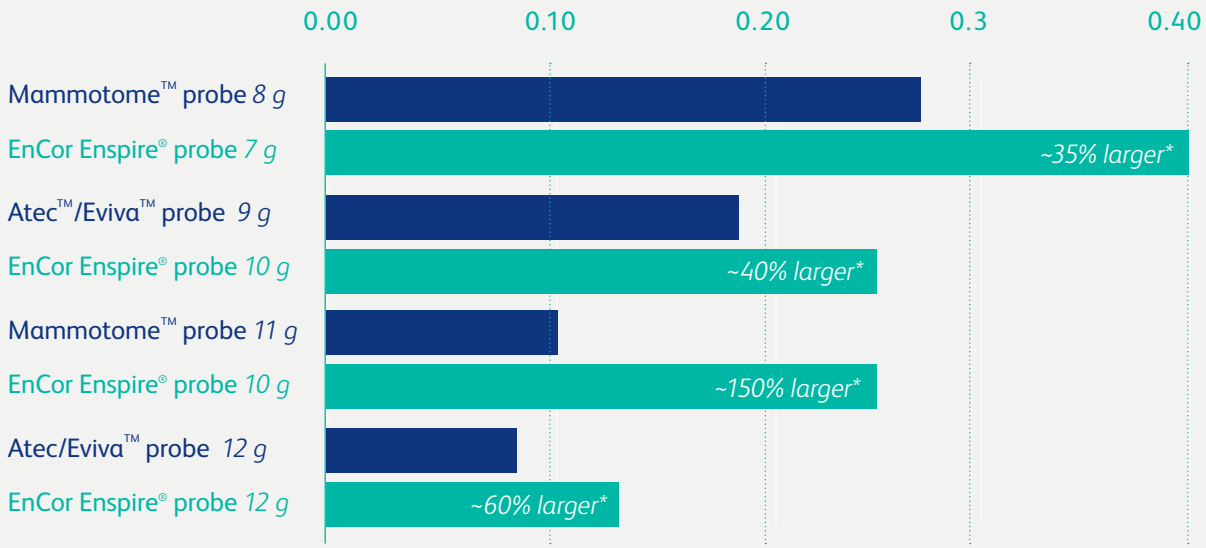
Larger samples

The EnCor Enspire® Breast Biopsy System outperformed all other systems tested[1]

Less frequent noise

With its quiet-run technology and large vacuum capacity, the EnCor Enspire™ System vacuum engages only when necessary to maintain vacuum levels.

Simulated use testing Average tissue sampling *(grams)*

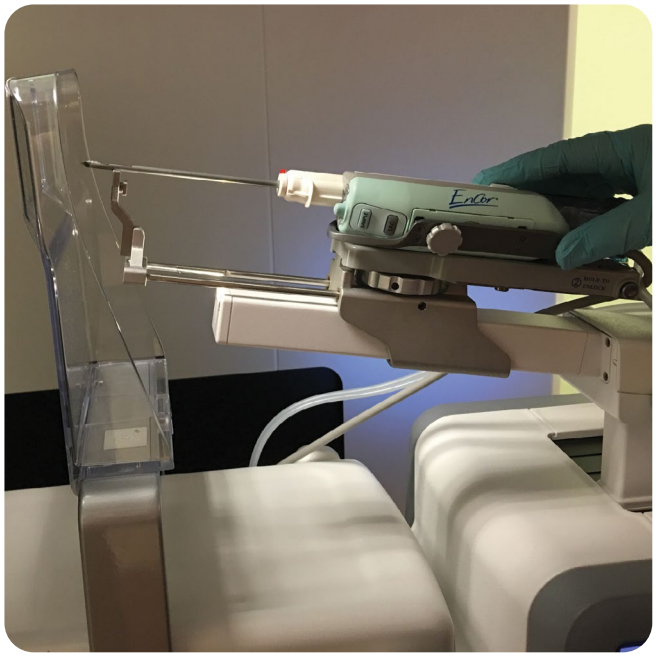


The only system that offers:

- Sharp TriConcave™ Tip
- Three probe sizes: 12 G, 10 G and 7 G
- Sample automation
- VisiLoc® MRI Obturator and Double-Locking Block
- Headlight for visualizing insertion site

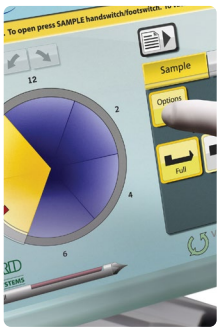
1. **Study description:** Conducted by Bard Peripheral Vascular, Inc. *(Tempe, AZ)*, the study included the EnCor Enspire® ® Breast Biopsy System, Hologic Atec™ System, Hologic Eviva™ System, and Devicor Mammotome™ System. Five *(5)* probes for each probe type/gauge size were used to acquire 12 samples each *(for a total of 60 samples)* in chicken breast. **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.
2. Bench test data on file at Bard Peripheral Vascular, Inc., Tempe, AZ. Bench testing may not be indicative of clinical performance.

All-around inspired performance



Stereotactic/ Tomosynthesis upright

Unique automated sampling, probe versatility



- Automated sampling for a fast biopsy
- 7 G probe to obtain larger tissue samples than any other vacuum-assisted biopsy device
- Vertical probe option designed for a craniocaudal (CC) approach

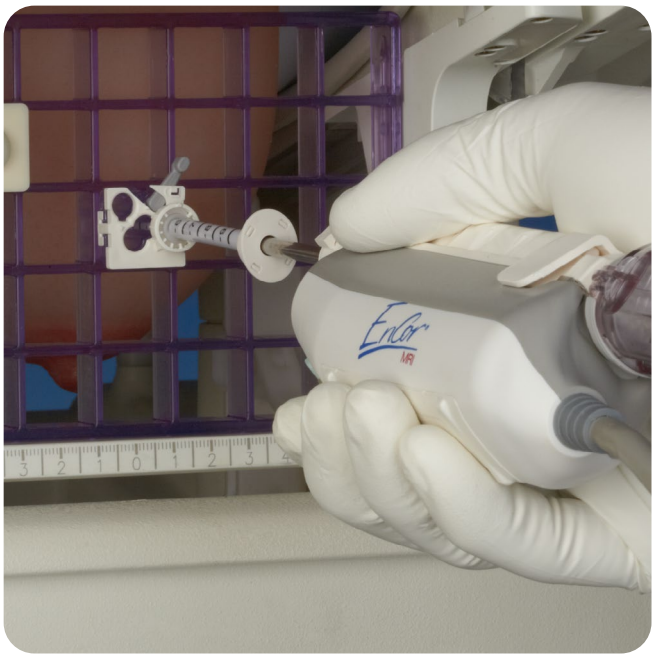
Stereotactic/ Tomosynthesis prone

Half-sample mode, in-breast adaptability

Half

- Half-sample mode at the touch of a button facilitates access to lesions
- Anesthetic mode for efficient delivery of anesthesia
- Intuitive touch screen for fast procedures

Samples **35-150% larger** in simulated testing[1]



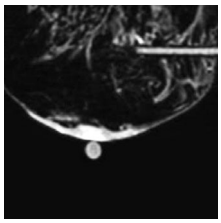
Ultrasound

Ergonomic design, reduced effort

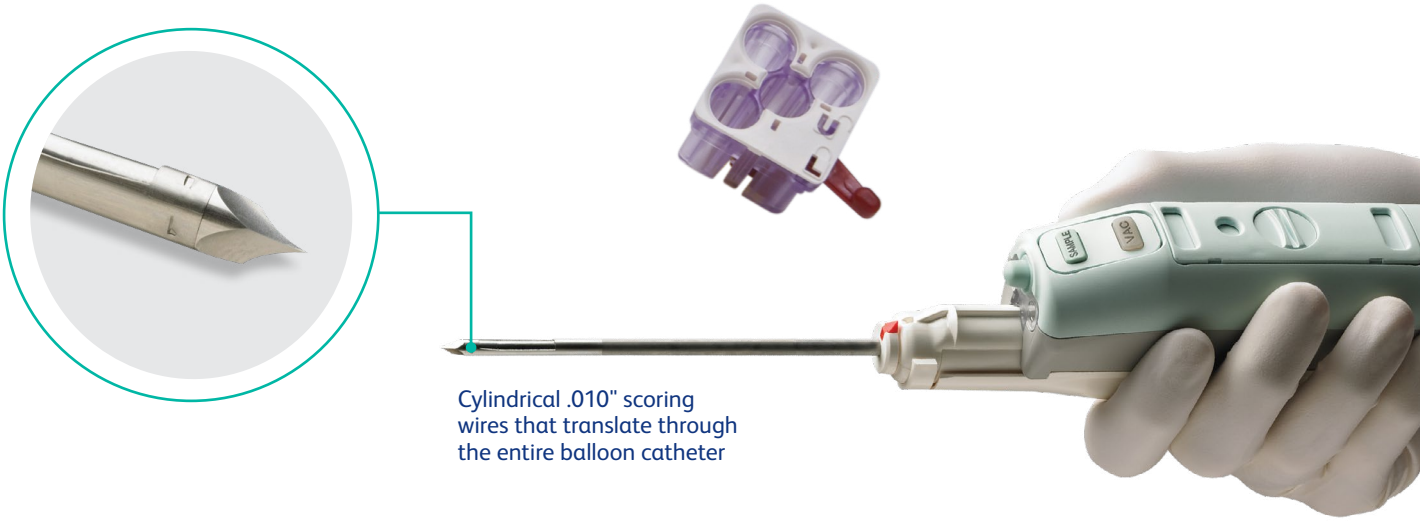
- Sharp TriConcave tip provides control and facilitates targeting
- Dense mode designed to sample the most challenging tissue
- Ergonomically designed to improve physician comfort and reduce muscle effort[2]

MRI

Superior visibility, targeting ease



- VisiLoc MRI Obturator for improved visibility
- Double-locking block for procedure stability
- Blunt tip probe to accommodate sensitive structures



The EnCor Enspire™ breast biopsy system makes inventory management easier

Up to 67% less biohazard waste[3]

- Smaller probe reduces biohazard waste costs and volume
- Detachable tubing simplifies sharps disposal

Simplified inventory management

- Single probe style can be used for all upright and prone stereotactic and tomography-guided biopsies
- Half-sample option with every gauge size eliminates the need to stock additional probes (example: petite)

No saline required

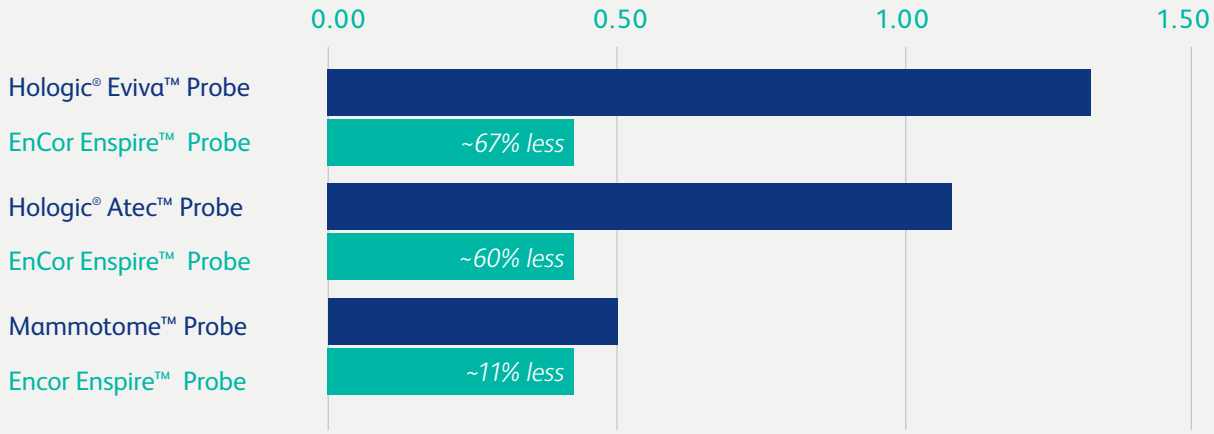
- Reduced consumable costs and no delays due to lack of saline supply on hand

Fast set-up

- Unique snap-in tubing cassette instead of manual threading
- Simplified set-up and clean-up for efficient room turnover

3. Data represents the average weight of five samples. The probes used for comparison were the largest gauge size available for each console system. **Study description:** Conducted by Peripheral Vascular, Inc. (Tempe, AZ), the study included the EnCor Enspire™ breast biopsy system, Hologic Atec™ system, Hologic Eviva™ system, and Devicor Mammotome™ system. Engineering tests were performed utilizing the latest available packaged products. The weight of the disposable probe and tubing was measured with a mass balance. Due to differences in breast biopsy system operation, canister and fluid weights were omitted from the study.

Biohazard waste *(lbs)*



EnCor Enspire™ breast biopsy system

Indications For Use: The EnCor Enspire™ Brest Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities

- It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality
- It is intended to provide breast tissue for histologic examination with partial or complete removal of a palpable abnormality

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence or an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/r radiological criteria(e.g., fibroadenoma, fibrocystic lesion), the EnCor Enspire™ Breast Biopsy System may also be used to partially remove such palpable lesions. Whenever beast tissue is removed., histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness or removal using standards surgical procedures.

Contraindications: 1. This device is not intended for use except as indicated. **2.** The EnCor Enspire™ Breast Biopsy System is contraindicated for those patients where, in the physician´s judgment, there is an increased risk of complications associated with percutaneous removal of tissue samples.

Warnings: 1. The EnCor Enspire™ Breast Biopsy System must be properly grounded to ensure patient safety. The system is supplied with a medical grade power cord with AC plug. Do not connect the included power cord to extension cords or three-prong to two-prong adapters. To avoid the risk of electric shock , this equipment must only be connected to supply mains with protective earth. **2.** To minimize interference with other equipment, cables should be positioned in such a manner to precent contact with other cables. **3.** Use of accessories not compatible with the EnCor Enspire™ Breast Biopsy System may create potentially hazardous conditions. **4.** Only use EnCor® and EnCor® MRI drivers with script version 1.19 or greater with the EnCor Enspire™ Breast Biopsy System. The system is not compatible with earlier driver scripts. The script version is identified on the touch screen display during system initialization. **5.** The EnCor Enspire™ Breast Biopsy System console may not be placed in an MRI suite. Place the console outside of the MRI suite and use the appropriate EnCor® MRI accessories when performing a biopsy under MRI guidance. **6.** No modification of this equipment is allowed. Do not remove the EnCor Enspire ™ Breast Biopsy System housing. Removal of the housing may cause electrical shock. **7.** The EnCor Enspire™ Breast Biopsy System is not classified as an AP or APG classified device. The system is not suitable for use in the presence of flammable anesthetic. **8.** Do not use in the presence of infection. **9.** After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state, and federal laws and regulations.

Please consult product labels and inserts for complete indications, contraindications, hazards, warnings, precautions and directions for use.

Not all products, services, claims or features of products and services may be available or valid in your local area. Please check with your local BD representative

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