

Системы биопсии молочной железы EleVation, EnCor Enspire, EnCor Ultra

Техническое описание

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And perfect together.

Individually, the EnCor® Breast Biopsy Systems are perfect for your practice; each contributes to efficiency with rapid set up and a 67% reduction in medical waste. But together, the practice efficiencies are even greater and include:

- Common probes to consolidate inventory requirements and simplify ordering
- Similar operation and set up for streamlined training



Inspired Solutions

At BD, we offer clinical and business solutions that ensure that you have access to the right device for your patients' needs. Your patients' dreams inspire you. Your clinical and business challenges drive us to provide inspired solutions.

EnCor® Product Codes

PRODUCT	PRODUCT CODE	DESCRIPTION
EnCor® Enspire™ Breast Biopsy System	E4115 DS4001 DS4002 SCCA401	EnCor® Enspire™ Vacuum Assisted Breast Biopsy System EnCor® Enspire™ Vacuum and Rinse Tubing Cassette EnCor® Enspire™ Vacuum Tubing Cassette EnCor® Enspire™ Vacuum Cassette
EnCor® Ultra™ Breast Biopsy System	ES115 SCTUB4003 SCCA402	EnCor® Ultra™ Breast Biopsy System EnCor® Ultra™ Vacuum Tubing EnCor® Ultra™ Vacuum Cassette
Ultrasound/Stereo Probes	ECOP112G ECOP110G ECOP117G	EnCor® Biopsy Probe – 12G EnCor® Biopsy Probe – 10G EnCor® Biopsy Probe – 7G
Vertical Stereo Probes	ECOP112GV ECOP110GV ECOP117GV	EnCor® Biopsy Probe – 12G vertical EnCor® Biopsy Probe – 10G vertical EnCor® Biopsy Probe – 7G vertical
Ultrasound Stylet and Coaxial Cannulas	ECSTUS0112G ECSTUS0110G	EnCor® Ultrasound Stylet and Coaxial Cannula – 12G EnCor® Ultrasound Stylet and Coaxial Cannula – 10G
MRI Probes	ECPMR0110G ECPMR0110GET ECPMR017G	EnCor® MRI Biopsy Probe – 10G EnCor® MRI Biopsy Probe – 10G with blunt tip EnCor® MRI Biopsy Probe – 7G
MRI Accessories	ECMRNTLOC ECMRNTLOC7G	EnCor® Introducer Set – 10G EnCor® Introducer Set – 7G

STUDY DESCRIPTION: Conducted by Bard Biopsy Systems, the study included the EnCor® Enspire™ Breast Biopsy System, Ensire® ATEC™ System, Ensire® EXO™ System, and Ensire® 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 mean diameter of the probe, needles were disassembled to access the cannula containing the sample vial. The mean diameter of the sample vial was measured using pin gauges.

STUDY DISCLOSURES: Please note that these values are approximate for comparison purposes. Performance in human breast tissue will vary. Different patient characteristics 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.

EnCor® Enspire™ and EnCor® Ultra™ Breast Biopsy Systems

Indications: The EnCor® Enspire™ and EnCor® Ultra™ Breast Biopsy Systems are indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities.

- Are intended to provide breast tissue for histologic examination with partial or complete removal of the investigated abnormality
- Are 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 discerned from palpation or imaging appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality or a 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 where a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g. Mammotome, Mammotome, Mammotome), the EnCor® Enspire™ and EnCor® Ultra™ Breast Biopsy Systems may also be used to partially remove such palpable lesions. However, breast 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 of removal using standard surgical procedures.

Contraindications: 1. These devices are not intended for use except as indicated. 2. The EnCor® Enspire™ and EnCor® Ultra™ Breast Biopsy Systems are 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: If after use, the product may be a potential biohazard. Handle and dispose of in accordance with applicable medical practice and applicable state, state, and federal laws and regulations.

Precautions: 1. All breast biopsies should be performed under imaging guidance to confirm the Probe position relative to the target region to be sampled and to help mitigate the occurrence of a false negative biopsy. 2. When performing a biopsy with EnCor® and EnCor® MRI Probe, the avoidance of the sample vial is critical to the image guidance utilized. Prior to initiating the procedure, confirm that the sample vial orientation is correct for the image guidance being used.

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

Perfect Partners
For you and your practice

EnCor Enspire™
Breast Biopsy System

EnCor Ultra™
Breast Biopsy System



EnCor Enspire™ and EnCor Ultra™ Breast Biopsy Systems

Perfect for you and your practice.

Built upon the powerful EnCor® Breast Biopsy System platform, today's vacuum-assisted breast (VAB) biopsy products from BD are designed to transform the biopsy experience, offering you:

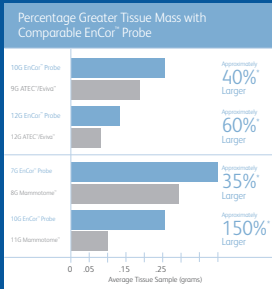
- The right choice for clinical performance, regardless of modality
- The flexibility and convenience your practice demands

A unique platform designed for control, confidence and comfort.

- Ergonomic, **lightweight handpiece** fits easily in your hand for improved maneuverability and comfort.
- Multiple samples from a **single insertion** improves procedural efficiency and accuracy.
- **Sharp tip** reduces drag and discomfort, increases control – especially through dense tissue.
- Choice of **12G, 10G and 7G** needles offers clinical flexibility.

Samples larger than other systems in simulated use testing.¹

The EnCor® Breast Biopsy Systems produced large, quality samples, helping to facilitate a more accurate diagnosis which can aid in diagnostic accuracy.



¹Reference percentages 17% calculated from data collected on "medium" gauge devices. Data on file. See Study Descriptions and Disclosures on test page.

EnCor Enspire™ Breast Biopsy System –
The smart breast biopsy system.

The EnCor Enspire™ Breast Biopsy System's intelligent design enables you to adapt in real time to challenging lesions while in the breast – potentially avoiding the need for reinsertion.

- In-breast adaptability
- Pre-programmed sampling
- Real-time, visual confirmation of needle orientation
- Half sample option – eliminates need for separate petite probes
- Designed for use with MRI, stereotactic, and ultrasound imaging



With a large, intuitive touch screen interface, the EnCor Enspire™ Breast Biopsy System provides visualization of needle activity and easy access to procedure options.

EnCor Enspire™ Breast Biopsy System

The compact EnCor Ultra™ Breast Biopsy System is easy to place within your workflow – with or without its space-saving procedure tray.

EnCor Ultra™ Breast Biopsy System –
Performance on a different scale.

EnCor Ultra™ Breast Biopsy System is designed for ultrasound – powerful enough to deliver the performance you need and small enough to give you the convenience and efficiency you want.

- Fully-powered vacuum unit
- Small footprint
- Easy set up
- Quieter noise when compared to Devicor Mammotome™ Breast Biopsy System and Hologic ATEC™ Breast Biopsy System



EnCor Ultra™ Breast Biopsy System

Elevate your expectations

- Choice of gauge sizes (10G, 12G and 14G)
- Half-notch support cannula reduces sample notch from 2cm to 1cm
- Removable support cannula, compatible with 10cm BD breast markers facilitates marker placement

- Sleep mode to preserve battery
- Inductive charger for easy-to-use, reliable recharge

[illegible]

BD EleVation™ Breast Biopsy System

- **Diagnostic quality sample:** Consistently capture samples you need for diagnosis
- **Smart mode:** Engages if additional sample sequences are required for tissue transport
- **Optional firing—20mm:** Provides additional placement control
- **Echogenicity:** Echogenic markings to visualize sample notch under ultrasound

- **SIMS:** Reliably capture multiple samples with a single insertion
- **Sample time:** Approximately 9 seconds per sample*
- **Reduced waste:** Requires no additional accessories such as tubing and canisters
- **Ease of set-up and breakdown:** Quick and intuitive set-up process and easy clean-up

- **Ergonomic:** Operates intuitively, with easy-to-identify buttons and ergonomic design
- **Needle-sharpness:** The probe features the sharp TriConcave™ tip, designed for ease of penetration
- **Gauge sizes:** Choice of 10G, 12G, and 14G sizes for the flexibility to handle different lesions and locations
- **Integrated coaxial:** Compatible with 10cm BD breast markers

* TE: Average sample time was observed in a preclinical model. Preclinical testing may not be predictive of actual clinical outcomes. Different test methods may yield different results. Data on File. Bard Peripheral Vascular, Inc., Tempe, AZ

- Aids in visualizing biopsy site

- Sharp needle for ease of penetration

- 10G
- 12G
- 14G

- Well-balanced and ergonomic to facilitate sampling in all clock positions and easy access to lesions in all locations of the breast
- Durable to withstand repeated torque, reasonable drops, and multiple cleanings without damage or discoloration

- Illuminated sample container
- Enables you to visualize sample tissue for faster clinical decision-making
- Easy to remove and fits into a standard formalin container for transfer to pathology lab

- Manages fluid during the biopsy to simplify the cleanup procedure



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