BD Receives FDA 510(k) Clearance for EnCor EnCompass™ Breast Biopsy and Tissue Removal System

State-of-the-art, multi-modality breast biopsy system slated to be in the market in early 2026

FRANKLIN LAKES, N.J., Jan. 15, 2026 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for the EnCor EnCompass™ Breast Biopsy and Tissue Removal System, a state-of-the-art multi-modality breast biopsy system designed to provide clinicians with flexibility across breast imaging modalities in the diagnosis of breast disease.

"This milestone for our new breast biopsy system marks a meaningful advancement in breast health, playing a critical role in aiding the early detection and diagnosis of breast disease," said Rima Alameddine, worldwide president, Peripheral Intervention at BD. "This innovation underscores our commitment to partnering with clinical leaders to deliver patient-centered solutions. Guided by our vision to transform breast health, we remain focused on developing technologies that empower providers and inspire confidence in care."

The EnCor EnCompass™ Biopsy System is designed to streamline the breast biopsy experience by enabling clinicians to perform procedures across a range of breast imaging platforms using one integrated system. The system, which is expected to enter the market in early 2026, offers a combination of advanced features and user-focused design to support procedural efficiency.

"The FDA clearance of the EnCor EnCompass™ Biopsy System demonstrates our ongoing focus on addressing the evolving needs of clinicians and patients in breast health," said Stacie Watson, vice president and general manager of the Oncology Platform at BD Interventional–Peripheral Intervention. "This multi-modality platform is engineered to provide flexibility, control, and ease of use, with features designed to support both clinician confidence and the patient experience."

Key features of the EnCor EnCompass™ Biopsy System include:

- Multi-modality use to support procedures performed across breast imaging platforms
- High and low vacuum strengths and a variable sample notch that can be adjusted during the procedure
- 360° sampling capability to access lesions located throughout the breast
- Features to enhance visualization, including an echogenic cutting cannula and illuminated sample container
- Choice of 12G, 10G, and 7G probes to accommodate different lesion types and locations

"Our goal is always to provide the best possible care for patients while maintaining efficiency, accuracy, and safety," said Dr. Shadi Aminololama-Shakeri, M.D., Chief of Breast Radiology at UC Davis. "The EnCor EnCompass™ Biopsy System combines multi-modality capability and enhanced control into one platform that supports intraprocedural customization and helps streamline the biopsy process."

The clearance of the EnCor EnCompass™ Biopsy System expands BD's breast health portfolio and reflects the Company's ongoing commitment to advancing technologies that support early detection and diagnosis.

About BD

BD is one of the largest global medical technology companies in the world and is *advancing the world of health*™ by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its more than 70,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiency, improve safety and expand access to health care. For more information on BD, please visit bd.com or connect with us on LinkedIn at www.linkedin.com/company/bd1/, X (formerly Twitter) at @BDandCo or Instagram at @becton_dickinson.

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Indications for Use: The EnCor EnCompass™ Breast Biopsy and Tissue Removal System is indicated to acquire breast tissue for histologic examination with partial or complete removal of the abnormality.
Contraindications: 1.) This device is not intended for use except as indicated. 2.) The EnCor EnCompass™ Breast Biopsy and Tissue Removal 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: Attention: Histologic findings require correlation with imaging and clinical findings to determine concordance. If there is discordance between imaging, clinical findings, and/or pathology, further histological evaluation and potential, additional diagnostic or excisional procedures are still needed. Whenever breast tissue is removed, histological evaluation of the tissue should be performed per standard of care. Clinical and imaging surveillance should be conducted in accordance with established clinical practice guidelines and institutional protocols.
Potential Complications: Potential complications include, but are not limited to, hematoma, hemorrhage, hemothorax, pneumothorax, surgical intervention, infection, adjacent tissue injury, pain, allergic reaction, and tissue adherence to the biopsy probe during removal from the breast.

For more information, please consult the product labels and inserts for any indication, contraindications, hazards, precautions
and directions for use.

SOURCE BD (Becton, Dickinson and Company)

Additional assets available online: Photos (1)

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