BD EleVation™

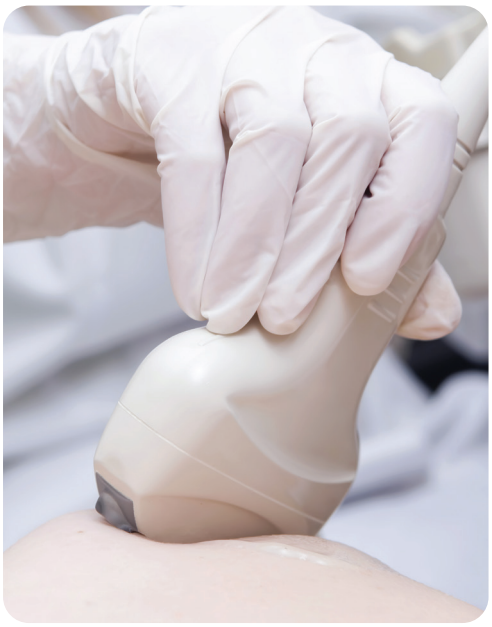
Breast Biopsy System

Value Analysis Brief

BD

The need for breast biopsy as a diagnostic tool for breast cancer after mammography is high

- Mammograms may yield **high false positive rates** resulting in **patient anxiety** and **high expenditures.**[1; 2]
- **High false positive rates** have created the **need to confirm** the presence of abnormalities following mammography.[1]
- In the U.S. it is estimated that **more than 1.6 million breast biopsies are performed annually**[3] and the Agency for Healthcare Research and Quality reported in 2016 that ~20% of all biopsies yielded a diagnosis of breast cancer.[4]



- Biopsy methods have evolved from open surgery to minimally invasive techniques (ie, core needle (CNB) and vacuum-assisted breast biopsy (VABB)), with clinical practice shifting to needle biopsy techniques as the standard diagnostic modality for breast lesions.[5-8]
- Non-invasive techniques have shown positive predictive value in their ability to diagnose abnormalities following mammography with lower complication rates compared to open surgery.[9; 10]
- Currently, three minimally invasive image-guided biopsy techniques are available.[7; 10; 11]

Ultrasound-guided: is considered the preferred first-line imaging modality for breast biopsy.

Stereotactic-guided: commonly recommended for biopsy of breast lesions with calcifications invisible on ultrasound.[7; 12; 13]

Magnetic resonance imaging (MRI)-guided: Appropriate for lesions only detectable by MRI.

Core needle biopsy (CNB) was one of the first minimally invasive techniques introduced but has been associated with certain limitations

- CNB involves insertion of a hollow needle (multiple times) to withdraw small cylinders or cores of tissue from abnormal breast tissue.[14]
- A 2014 systematic review and meta-analysis of 160 studies published between 1990 and 2013 quantified the diagnostic characteristics of CNB:[15]
  - For ultrasound-guided imaging, high-risk lesion* underestimation rates were reported to be 25% (21 studies, 601 biopsies), and ductal carcinoma in situ (DCIS) underestimation rates were reported at 38% (14 studies, 307 biopsies).[15]
- Diagnosis with CNB is dependent on the number of adequate sample cores taken resulting in multiple needle insertions which may contribute to patient anxiety.[11; 16; 17]
- CNB is spring loaded, rendering the forward throw a potential limitation for use near sensitive structures (eg, nipple, thoracic wall, skin surfaces).[18; 19]

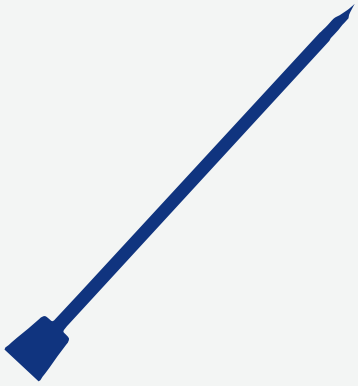
Reported limitations of CNB: [5; 7; 10; 11; 14; 18; 19]

- Underestimation of lesions
- Multiple needle insertions
- May be limited in sensitive areas (eg, nipple
- Cannot excise lesions
- Yields smaller specimens

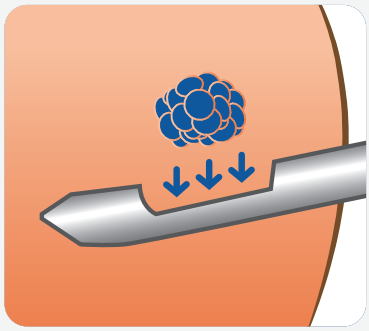
* High risk lesions include: atypical ductal hyperplasia (ADH), lobular neoplasia, phyllodes tumors, papillary lesions, mucocele-like lesions, complex sclerosing lesions and radial scars[20; 21]

Vacuum-assisted breast biopsy (VABB) is an important minimally invasive biopsy option that is designed to help mitigate certain limitations of CNB

A key advantage with the majority of VABB devices is the need for only **a single needle insertion**, whereas multiple insertions are required with CNB.[5; 10; 18; 21]

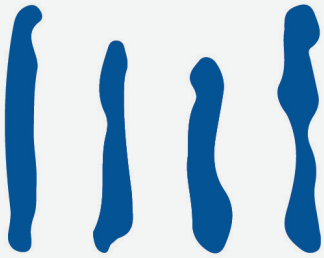


The sampling method in VABB consists of a **combination of vacuum suction and a cutting needle**, which produces a **more contiguous** sample than CNB.[5; 7; 18]

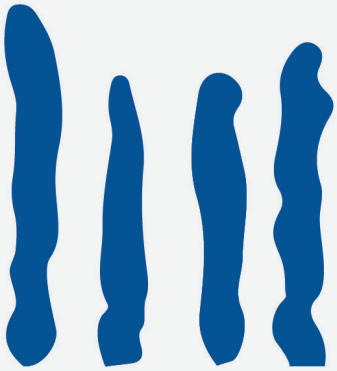


The average sample retrieved by VABB has been **consistently reported to be larger in volume** than that retrieved by CNB.*[5; 7; 11; 12; 21]

Core Needle Biopsy



Vacuum-Assisted Breast Biopsy

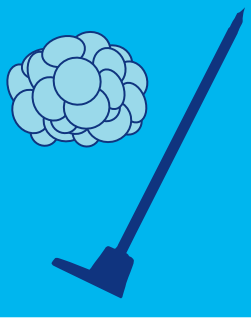


* Images are not to scale and are for illustration purposes only. Individual experiences with sampling may vary.

- As more tissue can be obtained in a VABB cycle compared with CNB, better lesion characterization can be achieved, potentially reducing repeat biopsy frequency.[5; 7]
- Accurate diagnosis after CNB has been reported to be proportional to the number of cores taken, whereas the accuracy of VABB can be independent of the number of cores[17]

Potential benefits of a larger biopsy sample may include:[5; 11; 18; 22; 23]

- Intact histological patterns
- Accurate representation of the lesion
- Reduced likelihood of non-diagnostic samples
- Reduced re-biopsy rate



- Optional firing modes with VABB allow the forward throw of the needle to be controlled, potentially affording better access to lesions near sensitive structures compared with CNB.[18; 19]
- VABB may offer more satisfactory outcomes for cosmetics and patient comfort compared with CNB:[21; 24]
  - Patients reported satisfaction with the cosmetic result in 85% (n=41/45) of cases following excision of fibroadenomas with VABB.[25]
  - In a single-center utilizing two tetherless ultrasound-guided VABB devices, 97% (n=73/75) of patients reported satisfaction with the procedure.[16]
  - Despite using a larger needle, patients experienced less pain with ultrasound-guided VABB than with automated CNB (median Visual Analogue Scale (VAS) score: 3 vs 6; N=723).[24]

VABB has demonstrated improved diagnostic accuracy as compared to CNB for ultrasound imaging guidance

- Larger samples typically associated with VABB may **help to reduce non-diagnostic sample rates** and indeterminate findings and provide better characterization of the lesions.[5; 26]
- Significantly **fewer patients biopsied with VABB had an indeterminate finding (2.5%; 18/724)** compared with patients initially biopsied with CNB (11.3%; 81/719).[26]
- A 2014 meta-analysis by Dahabreh, I., et al. reported on the **accuracy of VABB** and CNB based on 160 studies including a total of 69,804 breast lesions, and assessed underestimation rates of high-risk lesions and DCIS, sensitivity, and specificity.[15]

Accuracy parameters for ultrasound-CNB and ultrasound-VABB

Accuracy Parameters	CNB		VABB	
	N Studies [N biopsies]	Value(s)	N Studies [N biopsies]	Value(s)
High-risk lesion histological underestimation*[15]	21 [601]	25%	9 [20]	11%
DCIS underestimation[15]	14 [307]	38%	5 [48]	9%
Sensitivity[15]	27 [16,287]	99%	12 [1,543]	97%
Specificity[15]	27 [16,287]	97%	12 [1,543]	98%

- Mismatches can often occur between ultrasound-image findings and biopsy results; however, increased tissue volumes obtained with VABB vs. CNB may enable a greater proportion of representative biopsies to be obtained.[12]
- In a retrospective analysis of 2,477 patients (2002 to 2011), ultrasound-guided VABB had a 98.7% agreement rate with excisional analyses for underestimation of high-risk lesions and DCIS†.[21]
- A number of clinical studies published since 2014 showed high accuracy parameters‡ for ultrasound-VABB, which were improved compared to the accuracy values reported in a 2014 meta-analysis by Dahabreh, I., et al.[15; 21; 27; 28]
- For example, 2 studies (n=2,477 and n=2,596 US-VABB procedures), demonstrated historical underestimation rates from 0.20% to 3.1% for high risk lesions.[21; 27]

When performing ultrasound-guided VABB, use of tetherless devices§ has demonstrated a number of advantages compared with tethered systems

Tetherless VABB can be **easier to handle** because of the lack of a connecting tube set and can be lighter than their tethered counterparts, which may reduce the level of involvement for setup and cleanup.[29-31]

Reduced equipment preparations can translate to **faster biopsy procedure times,** allowing for breast biopsy to be promptly performed with faster room turnover.[29]

Tetherless VABB devices provide the advantages of both spring-loaded CNB (eg, minimal setup time and limited space requirements) and tethered VABB (consistently high sample quality, single insertion step) into a single device.[10; 29]

* High risk lesions include: atypical ductal hyperplasia (ADH), lobular neoplasia, phyllodes tumors, papillary lesions, mucocele-like lesions, complex sclerosing lesions and radial scars.20; 21

† Agreement rate between histological diagnosis of samples obtained using US-VABB versus whole tumor analysis following excision. ‡ Parameters include: high-risk lesion and DCIS underestimation, sensitivity, and non-diagnostic rate. Terminology used for defining accuracy: Sensitivity: The proportion of positives (patients with lesions) correctly identified; Specificity: The proportion of negatives (healthy patients) correctly identified; Indeterminate Findings: The sample quality/amount is insufficient to enable a definitive interpretation of the results (ie, cancerous/benign).

§ Tetherless VABB devices evaluated include: Mammotome Elite® 10; 29; 31, Vacora® Breast Biopsy System30, and Finesse® Ultra10.

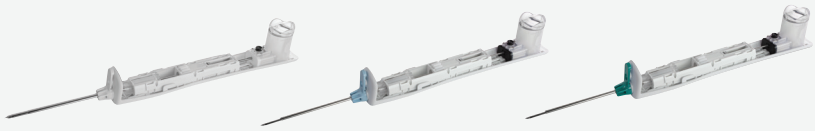
The EleVation™ Breast Biopsy System is BD's latest tetherless ultrasound-guided VABB device

The BD EleVation™ Breast Biopsy System is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. The BD EleVation™ Breast Biopsy System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality[32]

An ergonomic breast biopsy system with Single Insertion Multiple Sample (SIMS™) technology[33]

- Innovative BD EleVation™ SIMS™ technology gives you the ability to complete a biopsy by reliably capturing multiple samples with a single insertion.[32; 33]
- On average, a single sample cycle requires 9 seconds from start to finish.[32; 33]

Three color-coded probe sizes in 10 cm length available to give physicians the versatility they require to target a wide range of lesions based on size and location[32; 33]



White 10G | Blue 12G | Green 14G

TriConcave™ tip and echogenic markings on cutting cannula[32; 33]

- Features a sharp tip designed for ease of penetration.[33]
- Enables confident visualization and placement under ultrasound.[32]
- Echogenic markings on probe allows user to visualize sample notch under ultrasound imaging.[33]

Smart Mode Indicator[33]

- A green light alerts the user to dense or difficult tissue that will require additional sampling time.[32; 33]
- SMART Mode will engage automatically if the device senses additional time is required to ensure sample transport.[32]

Optional firing – 20 mm[33]

- Provides additional placement control,[33] that may aid in affording access to sensitive structures or advancing through dense tissue.[32]
- Allows user to fire needle into breast tissue 20 mm for needle positioning.[32]

The BD EleVation™ Breast Biopsy System, with its tetherless ultrasound-guided design, can offer a number of economic advantages compared with tethered breast biopsy methods

- When operating VABB systems, there are a number of different cost components that can be considered:[30]
  - Fixed costs, including the system depreciation, maintenance, and auxiliary image-guidance equipment.
  - Variable costs, including medical or paramedical staff, disposable kit costs (ie, tubing set, fluid container, and probe), and other consumables (eg, anesthesia, dressings, marker clips).
- A cost analysis in a single-center study reported that the average cost per ultrasound-guided procedure was €86.66 less with the Vacora™ system (tetherless VABB) compared with the Mammotome™ system (tethered VABB) given its lower capital equipment costs (€65.06), calculated over a 5-year typical depreciation, and disposable costs (€21.60), which included a tubing set, probe, and fluid container.[30]
- Lower capital equipment acquisition costs for the BD EleVation™ Breast Biopsy System may reduce the cost per biopsy procedure over a 5-year device lifespan compared with tethered VABB systems.[34]

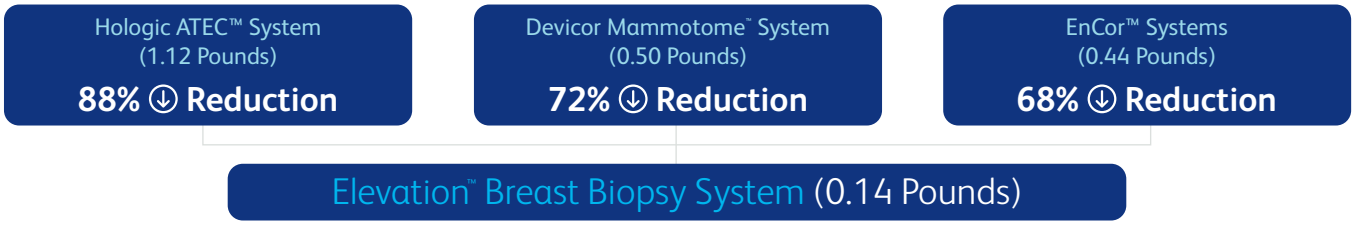
Capital Equipment Cost Estimation Comparing the EleVation™ Breast Biopsy System to a Competitive Console System**[; 34]

	EleVation™ Breast Biopsy System	Competitive Console System†
Scenario 1: Low Volume, 2 Weekly Cases		
Capital Equipment Cost per Biopsy Procedure	**$32.69**	**$76.92**
Annual Difference in Capital Costs	**$4,600 Savings with the EleVation™ System**	
5-Year Difference in Capital Costs	**$23,000 Savings with the EleVation™ System**	
Scenario 2: Average Volume, 5 Weekly Cases		
Capital Equipment Cost per Biopsy Procedure	**$13.08**	**$30.77**
Annual Difference in Capital Costs	**$4,600 Savings with the EleVation™ System**	
5-Year Difference in Capital Costs	**$23,000 Savings with the EleVation™ System**	

** Capital equipment cost per biopsy procedure was calculated using straight-line depreciation over 5 years for biopsy system capital equipment list prices ($17,000 for the EleVation™ Breast Biopsy System and $40,000 for the EnCor Enspire™ System). The cost of disposables were assumed to be equivalent between the two systems and therefore were not included. † Competitive console system list price estimate is assumed to be similar to BD EnCor Enspire™ System pricing, which was used as a proxy for the competitive console system list price in this analysis. Actual competitive console system list pricing may vary and impact this economic analysis accordingly.

- The cost of medical waste disposal is substantial, with the annual cost in the U.S. predicted to rise over time.[35]
- Although only 10% to 25% of medical waste is considered infectious/regulated, it is estimated to account for >40% of total waste management budgets to handle.[35; 36]
- In breast biopsy procedures, use of products generating less regulated medical waste, such as the EleVation™ Breast Biopsy system with its lack of tubing set and low probe weight, presents an opportunity for hospitals to reduce potentially unnecessary costs.

Potential Reduction in Biohazardous Waste with the EleVation™ Breast Biopsy System‡[; 37]



‡ The probes used for comparison were the largest gauge size available for each console system.

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DISCLAIMER: The information contained herein is for general information purposes only to inform the reader regarding the current standards of care for breast biopsies and associated economics. The information is not intended to make any representations or guarantees regarding clinical or economic outcomes, nor does it constitute legal, reimbursement, business or other advice. Economic information presented herein represents only one of many potential scenarios, based on the assumptions, variables, and data presented. The ultimate responsibility for determining cost-effectiveness and obtaining payment/reimbursement remains with the customer.

BD Elevation™ Breast Biopsy System

Indications For Use:
The BD EleVation™ Breast Biopsy System is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. The BD EleVation™ Breast Biopsy System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, eg, 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.

Contraindications:
1. The BD EleVation™ Breast Biopsy System is for diagnostic use only, NOT for therapeutic use.
2. The BD EleVation™ 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. Patients who may have a bleeding disorder, or who are receiving anticoagulant therapy, may be at increased risk of complications.
2. As with any biopsy instrument, there is a potential risk of infection.
3. The BD EleVation™ Breast Biopsy System should not be used in a Magnetic Resonance Imaging (MRI) Suite.
4. The BD EleVation™ Breast Biopsy System has not been tested using stereotactic guidance or for use with an MRI.
5. The BD EleVation™ Breast Biopsy System should not be used in an operating room.
6. The BD EleVation™ Breast Biopsy System is not classified as an AP or APG device.
7. The BD EleVation™ Breast Biopsy System is not suitable for use in the presence of flammable anesthetic.
8. The BD EleVation™ Breast Biopsy System is not suitable for use in an oxygen rich environment.
9. The BD EleVation™ Probe must only be used with BD EleVation™ Probes and BD EleVation™ Accessories.
10. All breast biopsies should be performed under ultrasound guidance to confirm the BD EleVation™ Probe's position relative to the target region to be sampled and to help mitigate the occurrence of a false negative biopsy. The BD EleVation™ Breast Biopsy System is intended for use with ultrasound imaging only.
11. The battery may only be replaced or disposed of by an authorized Service and Repair facility.
12. Use only with supplied AC power BD EleVation™ Accessories. Removing the AC adapter plug from wall power shall serve as isolation means. Do not position the AC adapter plug and wireless charging stand such that it is difficult to remove the AC adapter plug from the wall outlet if needed to remove mains power.
13. Do not reuse BD EleVation™ Probe. Reusing the BD EleVation™ Probe bears the risk of cross-patient contamination as biopsy probes, particularly those with long and small lumina, joints, and/ or crevices between components, are difficult or impossible to clean once bodily fluids or tissues with potential pyrogenic or microbial contamination have had contact with the BD EleVation™ Probe for an indeterminable period of time. The residue of biological material can promote the contamination of the BD EleVation™ Probe with pyrogens or microorganisms which may lead to infectious complications.
14. Do not resterilize BD EleVation™ Probe. After resterilization, the sterility of the BD EleVation™ Probe is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilizing the BD EleVation™ Probe increases the probability that it will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

Precautions:
1. The BD EleVation™ Breast Biopsy System should only be used by a physician trained in its indicated use, limitations, and possible complications of percutaneous needle techniques.
2. Do not attempt to remove the cover or modify the device in any way.

Potential Complications:
1. 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, lymphedema, hemorrhage, infection, non-healing wound, pain, nerve injury, and tissue adherence to the BD EleVation™ Probe while removing it from the breast.
2. As per routine biopsy procedures, it may be necessary to cut tissue adhering to the BD EleVation™ Probe while removing it from the breast.

Please consult package insert for more detailed safety information and instructions 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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