



# The next level in ultrasound breast biopsy procedures

BD EleVation™ Breast Biopsy System



Elevate your expectations



# An ergonomic breast biopsy system with Single Insertion Multiple Sample (SIMS™) technology



## Reliable performance

- **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

## Efficient procedures

- **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 cannisters
- **Ease of set-up and breakdown:** Quick and intuitive set-up process and easy clean-up

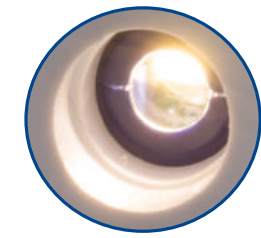
## Versatile usability

- **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

\*NOTE: 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.



# BD EleVation™ Breast Biopsy System



## LED light

- Aids in visualizing biopsy site

## Echogenic markings on cutting cannula

- Enables visualization under ultrasound

## TriConcave™ tip

- Sharp needle for ease of penetration

## Error indicator lights

- Alerts users of error

## Battery

- Indicates power level

## Smart mode

- Alerts physician to dense or difficult tissue

## Optional firing - 20mm

## Sample

- Activates sampling sequence with single press

## Wings

- Grip for easy removal

## Sample container

- 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

## Textured grip

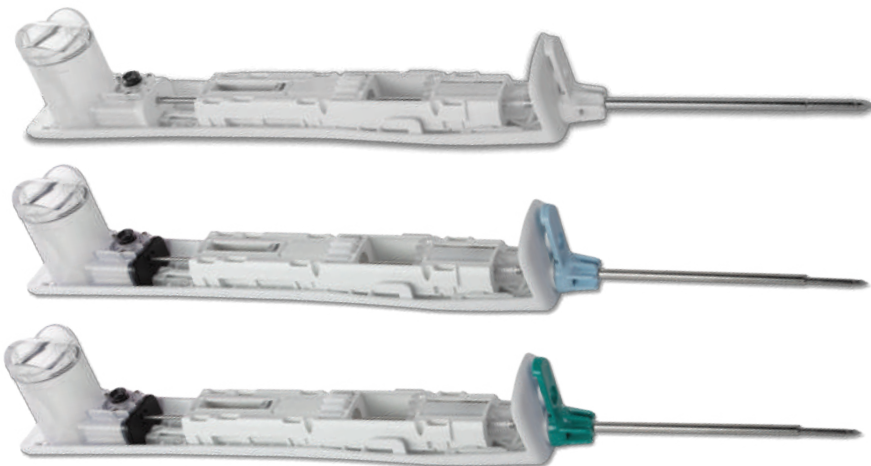
- Provides better control of device during a procedure

## Fluid management system

- Manages fluid during the biopsy to simplify the cleanup procedure

## Three probe sizes available

- 10G
- 12G
- 14G



## Lightweight, low-profile driver

- 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

## Choice of cannula for procedural flexibility

- 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

## Efficient battery

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



# Order Chart

| Product code | Item name                                | Size     | Quantity |
|--------------|--|----------|----------|
| EV10         | BD EleVation™ Probe                      | 10G      | 5/Case   |
| EV12         | BD EleVation™ Probe                      | 12G      | 5/Case   |
| EV14         | BD EleVation™ Probe                      | 14G      | 5/Case   |
| EVSC         | BD EleVation™ Sample Container           | One size | 5/Case   |
| EVH10        | BD EleVation™ Half-Notch Support Cannula | 10G      | 5/Case   |
| EVH12        | BD EleVation™ Half-Notch Support Cannula | 12G      | 5/Case   |

| Product code | Item name                                | Size     | Quantity |
|--------------|--|----------|----------|
| EVH14        | BD EleVation™ Half-Notch Support Cannula | 14G      | 5/Case   |
| EV10S        | BD EleVation™ Introducer Stylet          | 10G      | 5/Case   |
| EV12S        | BD EleVation™ Introducer Stylet          | 12G      | 5/Case   |
| EV14S        | BD EleVation™ Introducer Stylet          | 14G      | 5/Case   |
| EVcover      | BD EleVation™ Instrument Cover           | One size | 25/Case  |
| EVDriver     | BD EleVation™ Driver                     | One size | 1 Ea     |

## 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, 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.

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

## Contact information

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