

Elevate your expectations

Ordering information

Product code	Item name	Size	Quantity	Product code	Item name	Size	Quantity
EV10	BD EleVation™ Probe	10G	5/Case	EVH14	BD EleVation™ Half-Notch Support Cannula	14G	5/Case
EV12	BD EleVation™ Probe	12G	5/Case	EV10S	BD EleVation™ Introducer Stylet	10G	5/Case
EV14	BD EleVation™ Probe	14G	5/Case	EV12S	BD EleVation™ Introducer Stylet	12G	5/Case
EVSC	BD EleVation™ Sample Container	One size	5/Case	EV14S	BD EleVation™ Introducer Stylet	14G	5/Case
EVH10	BD EleVation™ Half-Notch Support Cannula	10G	5/Case	EVCover	BD EleVation™ Instrument Cover	One size	25/Case
EVH12	BD EleVation™ Half-Notch Support Cannula	12G	5/Case	EVW1	1 Year Service Agreement	N/A	1 Ea
				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 indeterminate 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 sterilize BD EleVation™ Probe. After resterilization, the sterility of the BD EleVation™ Probe is not guaranteed because of an indeterminate 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.

The next level in ultrasound breast biopsy procedures

BD EleVation™ Breast Biopsy System

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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

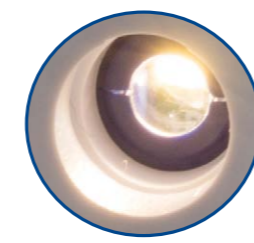
- **SIMS:** Reliably capture multiple samples with a single insertion
- **Sample time:** Approximately 9 seconds per sample*
- **Reduced waste:** Requires no additional accessories such as tubing and cannisters
- **Ease of set-up and breakdown:** Quick and intuitive set-up process and easy clean-up

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

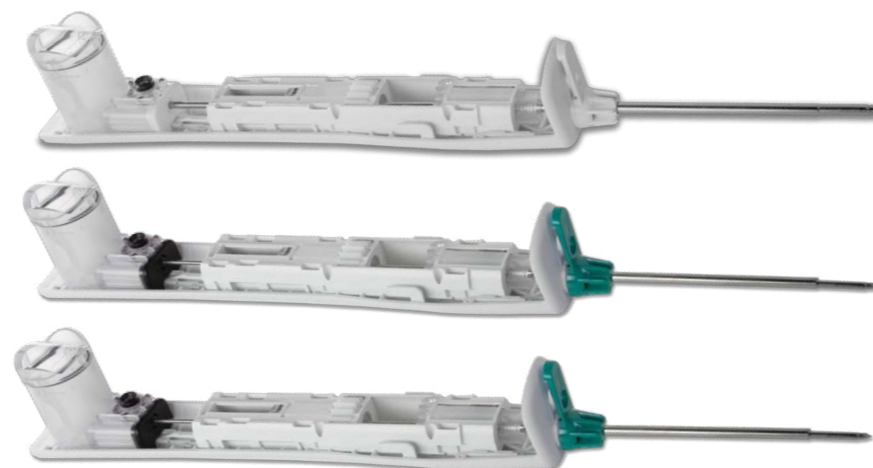
- Enables visualization under ultrasound

TriConcave™ tip

- Sharp needle for ease of penetration

Three probe sizes available

- 10G
- 12G
- 14G



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

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

Fluid management system

- Manages fluid during the biopsy to simplify the cleanup procedure

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

