BD EleVation™ Breast Biopsy System and UltraCor™ Twirl™ Breast Tissue Marker

Combined solution for efficient breast biopsy with diagnostic quality samples, accurate tissue marking and permanent ultrasound visibility

BD

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—20 mm:** Provides additional placement control
- **Echogenicity:** Echogenic markings to visualize sample notch under ultrasound

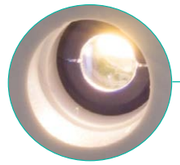
Efficient procedures

- **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 10 cm BD breast markers

*NOTE: Average sample time was observed in a preclinical model. Preclincial 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.



TriConcave™ tip
Sharp needle for ease of penetration

LED light
Aids in visualizing biopsy site

Echogenic markings on cutting cannula
Enables visualization under ultrasound

Battery
Indicates power level

Error indicator lights
Alerts users of error

Smart mode
Alerts physician to dense or difficult tissue

Optional firing - 20 mm

Sample
Activates sampling sequence with single press

Textured grip
Provides better control of device during a procedure

BD EleVation™
Breast Biopsy System

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

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

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 2 cm to 1 cm
- Removable support cannula, compatible with 10 cm BD breast markers facilitates marker placement

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

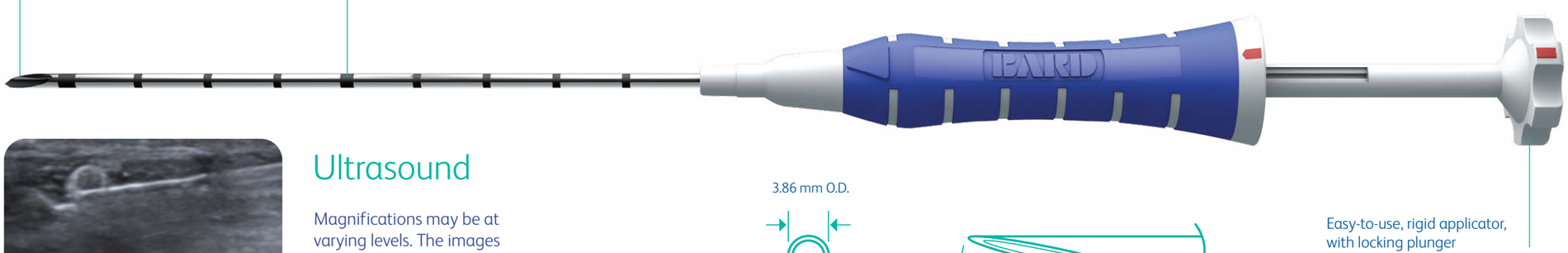
On your mark

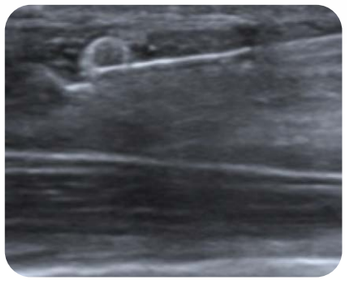
UltraCor™ Twirl™
Breast Tissue Marker

The UltraCor™ Twirl™ Breast Tissue Marker consists of a nitinol, ring-shaped marker, designed and sized for visibility. As the latest addition to the BD breast tissue marker portfolio, the UltraCor™ Twirl™ Breast Tissue Marker is available in a 17 gauge, 10 cm needle.

Intended for use to attach to soft breast tissue, including axillary lymph nodes, to radiographically mark the location of the biopsy procedure, the UltraCor™ Twirl™ Breast Tissue Marker offers visibility in ultrasound, mammography, and MR imaging modalities.

Not shown to scale





Ultrasound

Magnifications may be at varying levels. The images shown are to provide an example of product visibility and are not intended to compare visibility in a clinical setting.

Indicated for axillary lymph nodes and soft breast tissue

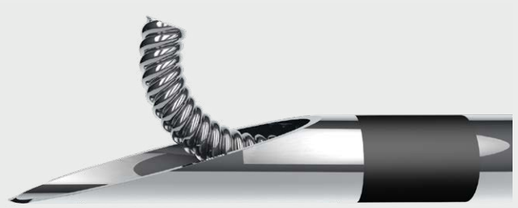
Nitinol marker designed and sized for visibility

Polymer- and gel-free to limit materials introduced into patient's breast

Self-incorporating design to assist in accurate placement

4 mm, twirled nitinol marker, designed and sized for visibility

What is nitinol?



Nitinol is a nickel-titanium alloy, in which the two elements are present in approximately equal percentages.

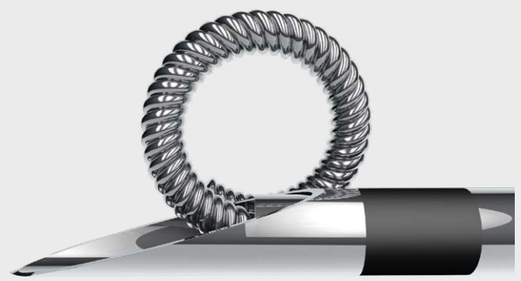
NOTE: Patients with a known hypersensitivity to the materials listed in the device description may suffer an allergic reaction to the implant. The UltraCor™ Twirl™ Breast Tissue Marker is made from a nickel-titanium alloy; if there is a known allergy to nickel, use of the UltraCor™ Twirl™ Breast Tissue Marker is not advised.

Why is nitinol unique?

Nitinol is known for its unique properties of shape memory and superelasticity. Shape memory is the ability of nitinol to undergo deformation at one temperature, and recover its original shape upon heating. Thus, the "twirled ring" of the UltraCor™ Twirl™ Breast Tissue Marker is the marker's original shape, and upon deployment, the marker resumes this shape.

Self-incorporating marker designed to assist in placement accuracy

Where is nitinol used?



BD, in addition to other manufacturers, offers medical devices made with nitinol, due to its unique characteristics. For example, the Denali™ Vena Cava Filter, the Simon Nitinol™ Vena Cava Filter, and the LifeStent™, LifeStent™ XL, and LifeStent™ Solo™ Vascular Stents are all BD products that have been made with nitinol.

BD EleVation™

Breast Biopsy System

Ordering information

BD Elevation™ Breast Biopsy System

Cat. no.	Item Description	Size	Quantity
EV10	BD EleVation™ Probe	10G	5 units per case
EV12	BD EleVation™ Probe	12G	5 units per case
EV14	BD EleVation™ Probe	14G	5 units per case
EVSC	BD EleVation™ Sample Container	One size	5 units per case
EVH10	BD EleVation™ Half-Notch Support Cannula	10G	5 units per case
EVH12	BD EleVation™ Half-Notch Support Cannula	12G	5 units per case
EVH14	BD EleVation™ Half-Notch Support Cannula	14G	5 units per case
EV10S	BD EleVation™ Introducer Stylet	10G	5 units per case
EV12S	BD EleVation™ Introducer Stylet	12G	5 unies per case
EV14S	BD EleVation™ Introducer Stylet	14G	5 units per case
EVCover	BD EleVation™ Instrument Cover	One size	25 units per case
EVW1	1 Year Service Agreement		Single
EVDriver	BD EleVation™ Driver	One size	Single

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 facilility. 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.

UltraCor™ Twirl™

Biopsy Tissue Marker

Ordering information

UltraCor™ Twirl™ Breast Tissue Marker

Cat. no.	Needle size	Shape	Material	Quantity
UCTW17	17G x 10 cm	Ring	Nitinol	5 units per case

UltraCor™ Twirl™ Breast Tissue Marker

INDICATIONS FOR USE: The UltraCor™ Twirl™ Breast Tissue Marker is intended for use to attach to soft breast tissue, including axillary lymph nodes, to radiographically mark the location of the biopsy procedure.

CONTRAINDICATIONS: Patients with a known hypersensitivity to the materials listed in the device description may suffer an allergic reaction to this implant. The implant is made from a nickel-titanium alloy; if there is a known allergy to nickel, use of the UltraCor™ Twirl™ Breast Tissue Marker is not advised.

WARNINGS: As with any foreign object implanted into the body, potential adverse reactions are possible. It is the responsibility of the physician to evaluate the risk/benefit prior to the use of this device. · The UltraCor™ Twirl™ Breast Tissue Marker is not recommended for use in patients with breast implants. · This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.

Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

PRECAUTIONS: This product should only be used by a physician who is completely familiar with the indications, contraindications, limitations and typical findings and possible side effects of breast tissue marker placement. · Do not use if needle is bent and/or tip is damaged. · Use caution when handling the device to prevent premature deployment of the breast tissue marker. · After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state, and federal laws and regulations.

POTENTIAL COMPLICATIONS: Potential complications of breast tissue marker placement may include, but are not limited to: hematoma, hemorrhage, infection, allergic reaction, marker migration, misdiagnosis, lymphedema, adjacent tissue injury, pain, and nerve injury.

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

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