ULTRACOR® TWIRL®
Breast Tissue Marker

Product Code	Needle Size	Material	Shape	Quantity
UCTW17	17 G x 10 cm	Nitinol	Ring	5 Units / Carton

To mark our commitment to breast cancer awareness and to finding a cure, Bard created the In Celebration of Her™ program. With feminine marker shapes to celebrate women, Bard has the opportunity to support those affected by breast cancer. As part of our In Celebration of Her™ program, Bard will contribute $1 to the American Cancer Society™ in honor of breast biopsy patients with every BARD® Heart, BARD® Venus, and BARD® Ring breast tissue marker purchased.* The ULTRACOR® TWIRL® Breast Tissue Marker is one of three BARD® breast tissue markers included in this program.

In Celebration of Her™

ULTRACOR® TWIRL® Breast Tissue Marker

INSTRUCTIONS FOR USE Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

DESCRIPTION The ULTRACOR® TWIRL® Breast Tissue Marker consists of a disposable beveled needle applicator containing a Nitinol radiographic ring wireform. The wireform is intended for long-term radiographic marking of the tissue site. The applicator has a beveled 17G x 10cm needle with 1cm depth marks and a locking plunger. The ring is deployed from the beveled needle tip into the tissue site. **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 and pain.

*Applies to specially marked Bard® breast tissue marker products purchased from Bard. The American Cancer Society™ does not endorse any service or product. Visit incelebrationofher.com for details.

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

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Also Available from Bard

ULTRACLIP® Dual Trigger Breast Tissue Marker

SENOMARK® ULTRACOR® Breast Tissue Marker

GAMMA FINDER® Cordless Probe

Not shown to scale

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BD

BARD
has joined BD

ULTRACOR® TWIRL®
Breast Tissue Marker

A **Unique** Marker for Your **Unique** Needs

- **Indicated for axillary lymph nodes and 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**

BD

BARD
has joined BD

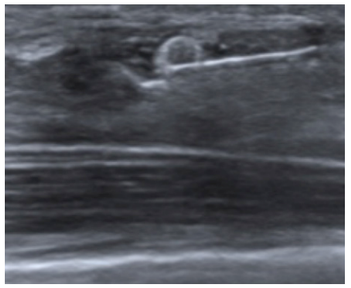
UltraCor® Twirl®
Breast Tissue Marker

A **Unique** Marker for Your **Unique** Needs

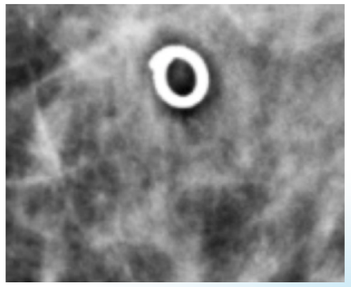
On Your Mark

The UltraCor® Twirl® Breast Tissue Marker consists of a nitinol, ring-shaped marker, designed and sized for visibility. As the latest addition to the Bard® 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.

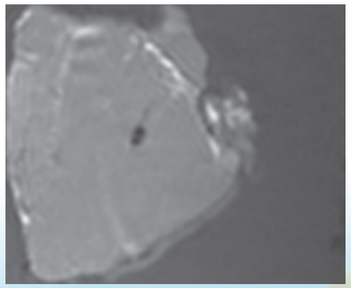
Ultrasound



Mammography



Magnetic Resonance Imaging (MRI)



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.

Actual Size

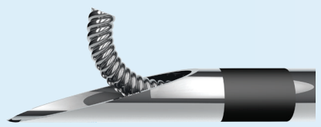
17 gauge needle with beveled tip, to allow visualization of markers during deployment in ultrasound

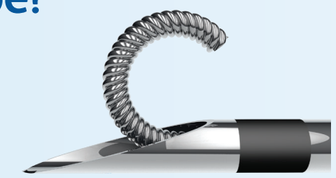
Depth markings in 1 cm increments to assist in locating target tissue site

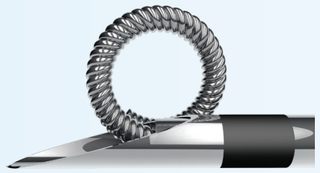
Easy-to-use, rigid applicator, with locking plunger

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

What's in a Shape?







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.

Where is nitinol used?

Bard, 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 Bard products made with nitinol.

Not shown to scale

Self-incorporating marker designed to assist in placement accuracy