

To mark our commitment to breast cancer awareness and to finding a cure, BD created the In Celebration of Her™ program. With feminine marker shapes to celebrate women, BD has the opportunity to support those affected by breast cancer. As part of the In Celebration of Her™ program, **BD will contribute \$1 to the American Cancer Society™** in honor of breast biopsy patients with every Heart, Venus, and Ring breast tissue marker shape purchased.*

* Applies to specially marked BD breast tissue marker products purchased from BD. The American Cancer Society™ does not endorse any service or product. Valid through September 30. Visit bd.com/ICOH for details.



*In Celebration
of Her™*

The art of ultrasound visibility
3D shapes designed to maximize your visualization
without the need for polymers or gels

UltraCor™ Twirl™ Breast Tissue Markers

Product Code	Shape	Use	Needle Size	Mat.	Qty.
UCLS17	Curls	Independently or through a coaxial	17G x 10 cm	Nitinol	5 Units/ Carton
UCTW17	Ring				
UCVR17	Clover				

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. This device is not intended for use except as indicated above.

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. Use caution when inserting near a breast implant to avoid puncture of the implant capsule. 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 indeterminate 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. Additionally, re-use and/or repackaging may compromise the structural integrity and/or material and design characteristics of the device, which may lead to device failure, and/or lead to patient injury. Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminate 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. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and local, state and federal laws and regulations. Dispose of sharps in designated sharps disposal containers. This product should be disposed of appropriately, not recapped or resterilized. Keep dry. Keep away from sunlight. Examine the product to ensure it has not been damaged during shipment and that its size, shape, and condition are suitable for the procedure for which it is to be used. Do not use if product damage or contamination is evident.

Precautions: 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.

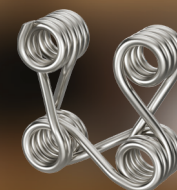
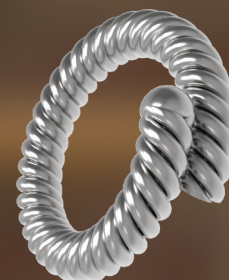
Potential Complications: Complications may occur at any time during or after the procedure. Potential complications of breast tissue marker placement may include, but are not limited to: hematoma/bleeding, hemorrhage, infection, lymphedema, unspecified tissue injury, pain, marker migration, allergic reaction and inaccurate marker placement, which may affect the accuracy of future tissue diagnoses. Note: Users should report any serious incident that has occurred in relation to the device to the manufacturer and the regulatory authority of the country in which the user and/or patient is established.

Please consult packaging inserts for more detailed safety information and instructions for use.



BD EleVation™ Breast Biopsy System with Coaxial (left);
UltraCor™ Twirl™ Breast Tissue Marker with Coaxial (right)

UltraCor™ Twirl™ Breast Tissue Marker



bd.com/twirl

BD, Tempe, AZ, 85281 USA

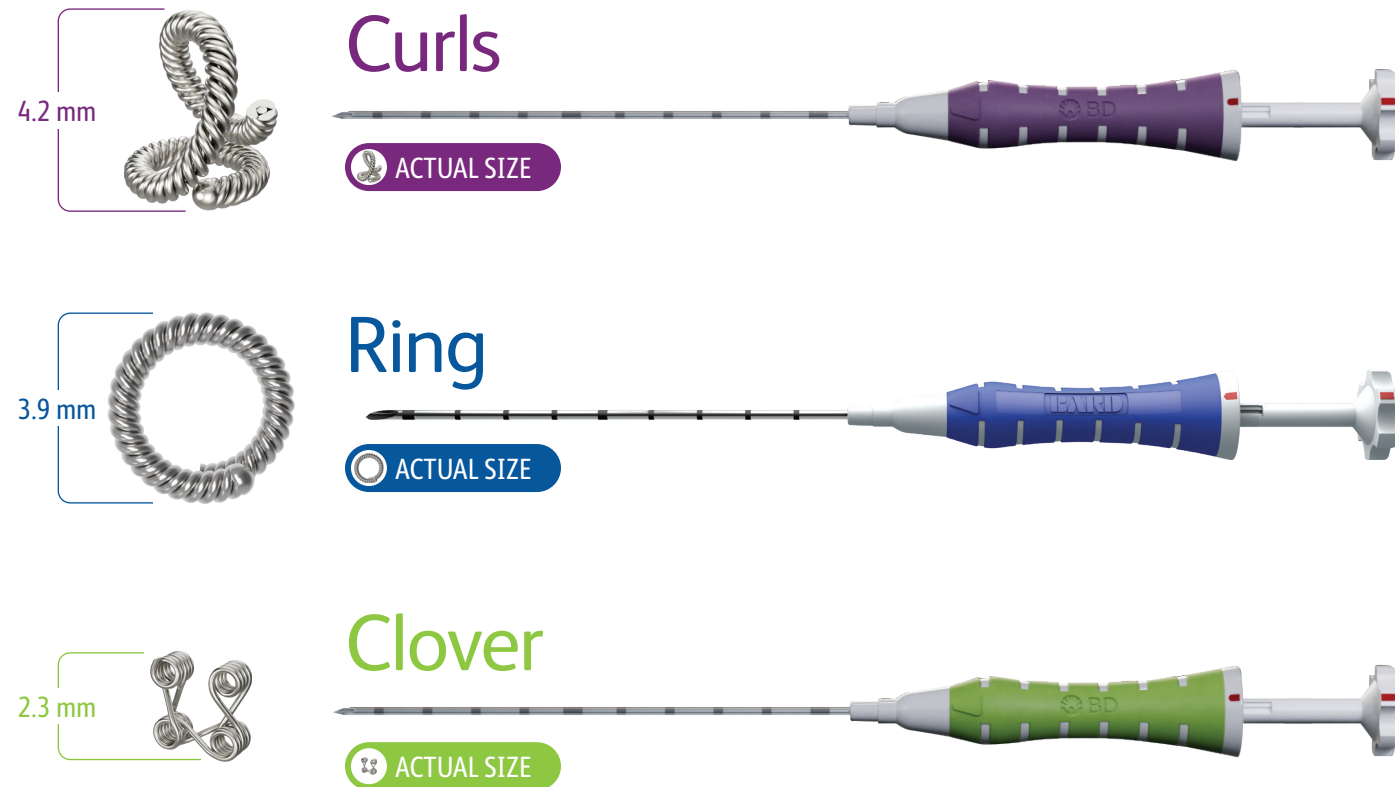
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Three unique shapes, three unique sizes in 3D

Designed and sized for an elevated ultrasound deployment & visualization

The UltraCor™ Twirl™ Breast Tissue Marker offers three, 3D shapes and sizes designed to maximize visualization. The three shapes offer visibility under ultrasound, mammography and MR imaging* modalities, and are differentiable under mammography to mark and distinguish lesions within the same breast.



Shapes designed to self-incorporate upon deployment for accurate placement and to minimize migration

The Curls, Ring and Clover are made from nitinol, a nickel-titanium alloy known for its unique properties of shape memory and superelasticity. The “twirled” shapes are designed to resume its shape once deployed from the applicator.

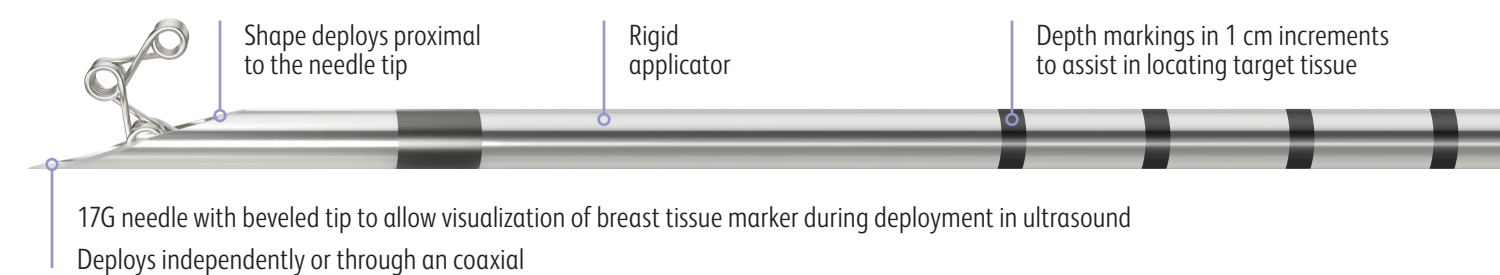


Long-term ultrasound visualization without gels and polymers

The Curls, Ring and Clover are completely gel- and polymer- free for long-term ultrasound visibility and to limit resorbable materials introduced into the patient’s breast and axilla.



Rigid, easy-to-use applicator design



* Not for placement in the MR suite. The wireform is MR conditional. Please see the IFU for MRI Safety Information.
** The average volumes of the UltraCor™ Twirl™ Breast Tissue Marker Clover shape (n=5) and the gel capsule of the HydroMARK™ Breast Biopsy Site Marker (n=5) after 24 hours of hydration were compared using a benchtop model. Preclinical testing may not be predictive of actual clinical outcomes. Different test methods may yield different results. Data on file. BD, Tempe, AZ.