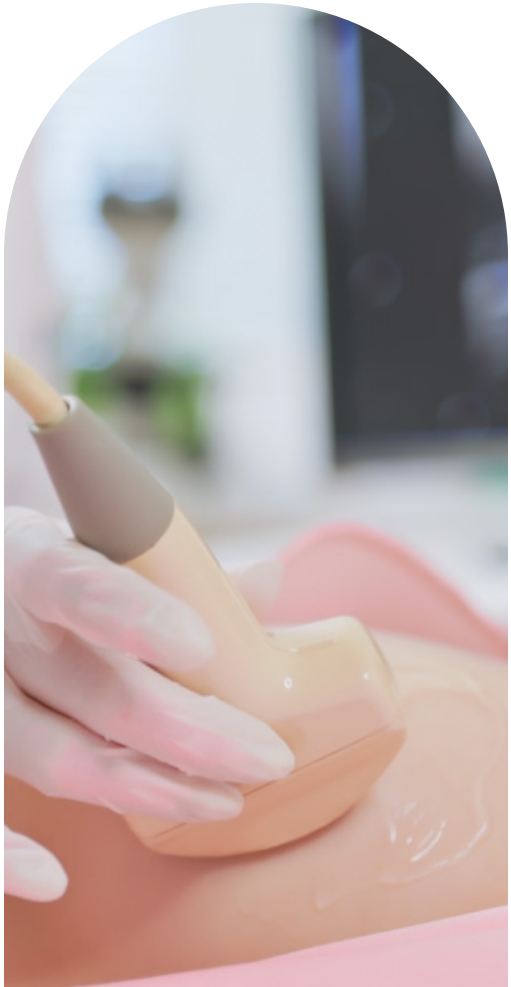
Breast tissue marking solutions to empower you with confidence and your patients with assurance

Options to Fit Your Needs in Different Modalities

BD



Unparalleled Choice of Breast Tissue Markers

The BD® Breast Tissue Markers portfolio is committed to you and your patients with options that fit your needs and aid in inventory control.

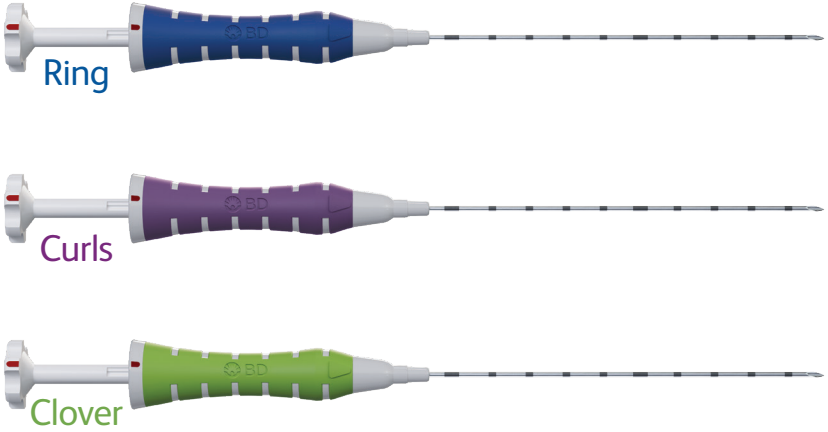
Its comprehensive offering includes 14 shapes across 10 breast tissue marker families designed for accurate placement, minimal migration and enhanced visibility in a variety of modalities.

Breast Tissue Markers for Placement Under

Ultrasound

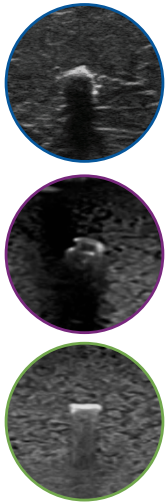
UltraCor™ Twirl™ Breast Tissue Markers

- **Three-dimensional nitinol** shapes designed to **maximize** ultrasound visualization
- Gel- and polymer- free for **long-term ultrasound visibility**
- **Self-incorporating shapes** designed for accurate placement and to **minimize migration**
- Indicated for soft breast tissue, including axillary lymph nodes



Marker Deployment

Ultrasound Visibility



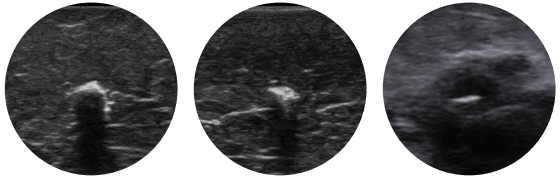
Marker Ordering Guide

Catalog Number	Use With	Gauge	Material	Shape
UCTW17	Independently or through an ultrasound coaxial	17G	Nitinol	Ring
UCLS17	Independently or through an ultrasound coaxial	17G	Nitinol	Curls
UCVR17	Independently or through an ultrasound coaxial	17G	Nitinol	Clover

SenoMark™ UltraCor™ Breast Tissue Markers

- Polyvinyl alcohol (PVA) polymer for **permanent ultrasound visibility**
- Polyglycolic acid (PGA) pad(s) for approximately **3 weeks of enhanced ultrasound visibility**
- PGA pads are designed to aid in accurate placement and to **minimize migration**

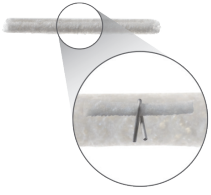
PVA Polymer Ultrasound Visibility



Upon Placement | 3 Weeks | Permanent

10 cm Markers

- 1 PGA pad
- 1 PVA polymer

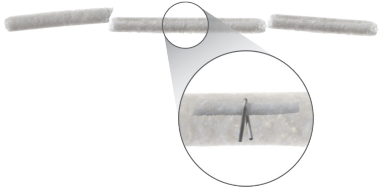


Marker Ordering Guide

Catalog Number	Use With	Gauge	Material	Shape
SMUC10R	Independently or through an ultrasound coaxial	14G	Titanium	Ribbon
SMUC10C		14G	BioDur™ 108	Coil
SMUC10H		14G	Titanium	Heart
SMUC10V		14G	BioDur™ 108	Venus

13 cm Markers

- 3 PGA pads
- 1 PVA polymer



Marker Ordering Guide

Catalog Number	Compatible With	Gauge	Material	Shape
SMUC13R	Independently or through an EnCor™ MRI Introducer or Standard Eviva™ coaxial with corresponding adapters	14G	Titanium	Ribbon
SMUC13C		14G	BioDur™ 108	Coil
SMUC13H		14G	Titanium	Heart
SMUC13V		14G	BioDur™ 108	Venus

UltraClip™ Dual Trigger Breast Tissue Markers

- **Choice of rear or front triggers**
- Five unique shapes, each interwoven with a polyvinyl alcohol (PVA) polymer for **permanent ultrasound visibility**
- Shapes designed for **accurate placement** and to **minimize migration**

Marker Ordering Guide

Catalog Number	Use With	Gauge	Material	Shape
862017D	Independently or through an ultrasound coaxial	17G	Inconel™ 625	Wing
862017DL		17G	Inconel™ 625	Wing
863017D		17G	Titanium	Ribbon
863017DL		17G	Titanium	Ribbon
864017D		17G	BioDur™ 108	Coil
864017DL		17G	BioDur™ 108	Coil
866017D		17G	Titanium	Heart
867017D		17G	BioDur™ 108	Venus

UltraClip™ II Breast Tissue Markers

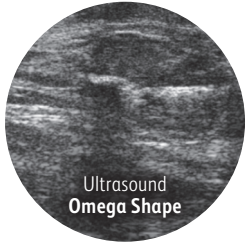
- Three shapes designed for **accurate placement** and to **minimize migration**
- **Ribbon shape** interwoven with a polyvinyl alcohol (PVA) polymer for **permanent ultrasound visibility**
- **Safety switch** designed to prevent premature marker deployment

Marker Ordering Guide

Catalog Number	Use With	Gauge	Material	Shape
861017	Independently or through an ultrasound coaxial	17G	Titanium	Ribbon
861217		17G	Titanium	Ribbon
862017		17G	Inconel™ 625	Wing
863017		17G	Titanium	Ribbon
864017		17G	BioDur™ 108	Coil
865017		17G	Titanium	Ribbon
865517		17G	Titanium	Ribbon

Gel Mark UltraCor™ Breast Tissue Markers

- Four polylactic acid (PLA)/ polyglycolic acid (PGA) pellets for approximately **4-6 weeks of enhanced ultrasound visibility**
- Available in two shapes positioned in the distal end of the needle tip

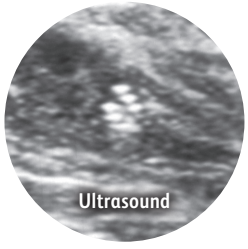


Marker Ordering Guide

Catalog Number	Use With	Gauge	Material	Shape
GMUTC005SS	Independently or through an ultrasound coaxial	14G	316L Stainless Steel	Omega
GMUTC005T		14G	Titanium	S

UltraCor™ Breast Tissue Markers

- One PEG push pellet in proximal position and one PEG plug in distal position
- Available in a 316L Stainless Steel Spring shape



Marker Ordering Guide

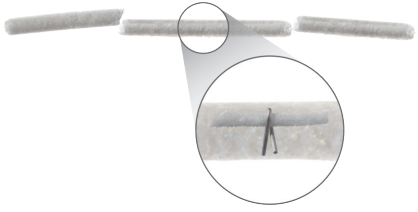
Catalog Number	Use With	Gauge	Material	Shape
UCTC17GSS	Independently or through an ultrasound coaxial	17G	316L Stainless Steel	Spring

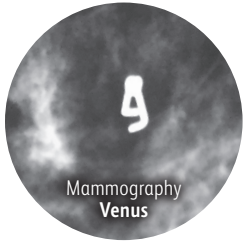
Breast Tissue Markers for Placement Under

Stereo

SenoMark™ UltraCor™ Breast Tissue Markers

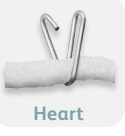
- Three polyglycolic acid (PGA) microfiber pads for **3 weeks of enhanced ultrasound visibility**
- Interwoven with a polyvinyl alcohol (PVA) polymer in center position for **permanent ultrasound visibility**
- PGA pads are designed to aid in **accurate placement** and to **minimize migration**






Ribbon


Coil


Heart

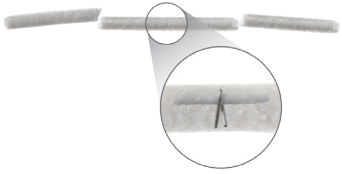

Venus

Marker Ordering Guide

Catalog Number	Compatible With	Gauge	Material	Shape
SMUC13R	Independently or through an EnCor™ MRI Introducer or Standard Eviva™ coaxial with corresponding adapters	14G	Titanium	Ribbon
SMUC13C		14G	BioDur™ 108	Coil
SMUC13H		14G	Titanium	Heart
SMUC13V		14G	BioDur™ 108	Venus

SenoMark™ Ultra Breast Tissue Markers

- Three polyglycolic acid (PGA) microfiber pads for **3 weeks of enhanced ultrasound visibility**
- Interwoven with a polyvinyl alcohol (PVA) polymer in center position for **permanent ultrasound visibility**



Compatible Breast Biopsy Devices

Classic Mammotome™ Probe

Probe Gauge	Compatible Marker Ordering Information			
	Shape		Material	Cat. Number
11G	Ribbon		Titanium	SMMA11R
11G	Coil		BioDur™ 108	SMMA11C

EnCor™ Probe

Probe Gauge	Compatible Marker Ordering Information			
	Shape		Material	Cat. Number
7G	Ribbon		Titanium	SMEC7R
7G	Coil		BioDur™ 108	SMEC7C
10G	Ribbon		Titanium	SMEC10R
10G	Coil		BioDur™ 108	SMEC10C
12G	Ribbon		Titanium	SMEC12R
12G	Coil		BioDur™ 108	SMEC12C

Hologic™ ATEC™ Probe

Probe Gauge	Compatible Marker Ordering Information			
	Shape		Material	Cat. Number
9G	Ribbon		Titanium	SMAT9R
9G	Coil		BioDur™ 108	SMAT9C
12G	Ribbon		Titanium	SMAT12R
12G	Coil		BioDur™ 108	SMAT12C

Hologic™ Standard EVIVA™ Probe

9G	Ribbon		Titanium	SMEV9R
9G	Coil		BioDur™ 108	SMEV9C

SenoMark™ Breast Tissue Markers

- Three polyglycolic acid (PGA) microfiber pads for **3 weeks of enhanced ultrasound visibility**
- Each marker shape is in center position

Compatible Breast Biopsy Devices

Classic Mammotome™ Probe

Probe Gauge	Compatible Marker Ordering Information			
	Shape		Material	Cat. Number
11G	O		Titanium	SMMA11R

EnCor™ Probe

Probe Gauge	Compatible Marker Ordering Information			
	Shape		Material	Cat. Number
7G	M		316L Stainless Steel	SMEC7GSS
10G	M		316L Stainless Steel	SMEC10GSS
10G	O		Titanium	SMTEC10G
12G	Omega		316L Stainless Steel	SMEC12GSS

Hologic™ ATEC™ Probe

Probe Gauge	Compatible Marker Ordering Information			
	Shape		Material	Cat. Number
9G	O		Titanium	SMTSU9G
9G	X		Titanium	SMSU9GT
12G	S		Titanium	SMRSU12GT

Hologic™ Standard EVIVA™ Probe

9G	X		Titanium	SMSE9GT

Breast Tissue Markers for Placement Under

MRI

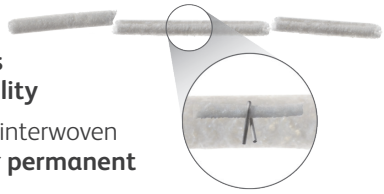
SenoMark™ UltraCor™ MRI Breast Tissue Markers

- Deploys three polyglycolic acid (PGA) pads for approximately **3 weeks of enhanced ultrasound visibility**
- Marker is in center of PGA pad

Marker Ordering Guide

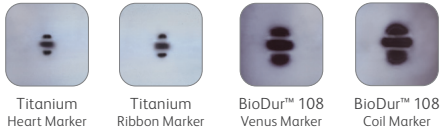
Catalog Number	Compatible With	Gauge	Material	Shape
SMUCMRI14GSS	Independently or through an EnCor™ MRI Introducer	14G	316L Stainless Steel	M
SMUCMRI14GT		14G	Titanium	X

SenoMark™ UltraCor™ Breast Tissue Markers



- Three polyglycolic acid (PGA) pads for approximately **3 weeks of enhanced ultrasound visibility**
- Polyvinyl alcohol (PVA) polymer interwoven with shape in center position for **permanent ultrasound visibility**
- 4 unique shapes in two metals for **more MRI visualization options**

MRI taken using Gradient Echo Pulse Sequence–Long Axis.



Titanium Heart Marker | Titanium Ribbon Marker | BioDur™ 108 Venus Marker | BioDur™ 108 Coil Marker

Marker Ordering Guide

Catalog Number	Compatible With	Gauge	Material	Shape
SMUC13R	Independently or through an EnCor™ MRI Introducer or Standard Eviva™ coaxial with corresponding adapters	14G	Titanium	Ribbon
SMUC13C		14G	BioDur™ 108	Coil
SMUC13H		14G	Titanium	Heart
SMUC13V		14G	BioDur™ 108	Venus

UltraCor™

Indications for use: The UltraCor™ Breast Tissue Marker is indicated for use to radiographically mark breast tissue during a percutaneous breast biopsy procedure. **Contraindications:** This device is not intended for use except as indicated. **Warnings:** 1)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. 2) 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. 3) Avoid the use of excessive force during removal of the Applicator to prevent breakage of the Applicator tip. 4) Patients with a known hypersensitivity to the materials listed in the device description may suffer an allergic reaction to this implant. 5) This device is not recommended for use in patients with breast implants. 6) Do not use in the presence of infection. 7) 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. **Precautions:** 1) Do not use if Temperature Indicator is black. 2) Do not use if the product sterile barrier system or its packaging is compromised. 3) Carefully inspect the device prior to use to verify that device has not been damaged. Do not use if product damage is evident and/or needle is bent. 4) This device should be used by physicians trained in percutaneous breast biopsy procedures. 5) Ensure the coil is completely dispensed. 6) Published studies with comparably sized 316L stainless steel biopsy markers have shown no marker movement and no significant marker heating when tested in an MRI system with a 1.5T field strength. **Complications:** Potential complications may include, but are not limited to hematoma, hemorrhage, infection, adjacent tissue injury, pain, allergic reaction, and migration.

UltraCor™ Twirl™

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:** 1) 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. 2) Use caution when inserting near a breast implant to avoid puncture of the implant capsule. 3) 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. 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. 4) 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. 5) 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. 6) Keep dry. Keep away from sunlight. 7) 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:** 1) Do not use if needle is bent and/or tip is damaged. 2) 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. NOTE: Breast Tissue Markers have the potential to migrate after placement. Based on a systematic literature search on commercially available breast tissue markers, the reported mean marker migration distances ranged from 3.4 mm - 28.1 mm and marker migration rates ranged from 0 - 54% in breast tissue and 0 - 10% in axillary lymph nodes.

UltraClip™ II

Indications for use: The UltraClip™ II tissue marker is intended for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure. **Contraindications:** This device is not intended for use except as indicated above. **Warnings:** The UltraClip™ II tissue marker is not recommended for use in patients with breast implants. 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. 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:** 1) The marker must only be deployed by depressing the plunger at the proximal end of the device. Do not attempt to deploy the marker by pressing or pulling on the safety switch. 2) This product should only be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of tissue marker placement. 3) 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. **Complications:** Potential complications of marker placement may consist of hematoma, hemorrhage, infection, adjacent tissue injury and pain.

UltraClip™ Dual Trigger

Indications for use: The UltraClip™ Dual Trigger breast tissue marker is intended for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure. **Contraindications:** None known. **Warnings:** 1) Use caution when inserting near a breast implant to avoid puncture of the implant capsule. 2) 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. 3) 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. 4) 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:** 1) Use caution when handling the device to prevent premature deployment of the marker. 2) This product should only be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of tissue marker placement. 3) 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. **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, hemorrhage, infection, marker migration, misdiagnosis, adjacent tissue injury and pain.

Gel Mark UltraCor™

Indications for use: The GelMark UltraCor™ Breast Tissue Marker is intended to radiographically mark breast tissue during a percutaneous biopsy procedure. **Contraindications:** This device is not intended for use except as indicated. **Warnings:** 1) 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. 2) 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. 3) Patients with a known hypersensitivity to the materials listed in the device description may suffer an allergic

reaction to this implant. 4) This device is not recommended for use in patients with breast implants. 5) 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. 6) Avoid the use of excessive force during removal of the Applicator to prevent breakage of the Applicator tip. 7) Do not use in the presence of infection. **Precautions:** 1) The device should only be used by physicians trained in percutaneous biopsy procedures. 2) Do not use if the product sterile barrier system or its packaging is compromised. 3) Do not use if Temperature Indicator is black. 4) Ensure all pellets are dispensed. 5) Carefully inspect the device prior to use to verify that device has not been damaged. Do not use if product damage is evident and/or needle is bent. 6) Published studies with comparably sized 316L stainless steel biopsy markers have shown no marker movement and insignificant marker heating when tested in MRI System with a 1.5T field strength. **Complications:** Potential complications may include, but are not limited to hematoma, hemorrhage, infection, adjacent tissue injury, pain, allergic reaction, and migration.

SenoMark™ UltraCor™

Indications for use: The SenoMark™ UltraCor™ Breast Tissue Marker is intended to radiographically and sonographically mark breast tissue during a percutaneous breast biopsy procedure. **Contraindications:** Patients with a known hypersensitivity to the materials listed in the device description may suffer an allergic reaction to this implant. **Warnings:** 1) Use caution when placing near a breast implant to avoid puncture of the implant capsule. 2) Do not use in the presence of infection. 3) 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. 4) 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:** 1) This product should only be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of breast tissue marker placement. 2) Store in a cool, dry place. 3) Use caution when handling the device to prevent premature deployment of the breast tissue marker. 4) Do not use if needle is bent and/or tip is damaged. 5) Ensure that all pads are dispensed. 6) 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. **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, hemorrhage, infection, adjacent tissue injury and pain.

SenoMark™ Ultra

Indications for use: The SenoMark™ Ultra Breast Tissue Marker is intended to radiographically and sonographically mark breast tissue during a percutaneous breast biopsy procedure. **Contraindications:** Patients with a known hypersensitivity to the materials listed in the device description may suffer an allergic reaction to this implant. **Warnings:** 1) Use caution when placing near a breast implant to avoid puncture of the implant capsule. 2) Avoid the use of excessive force during removal of the applicator to prevent breakage of the applicator tip. 3) Do not use in the presence of infection. 4) 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. 5) 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:** 1) This product should only be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of breast tissue marker placement. 2) Store in a cool, dry place. 3) Do not use if the temperature indicator is black. 4) Use caution when handling the device to prevent premature deployment of the breast tissue marker. 5) Do not kink the flexible tube. 6) Maintain correct alignment of the yellow indicator (D in Figure 1) with the red arrow of the biopsy probe when dispensing pads. 7) Ensure that all pads are dispensed. 8) 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. **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, hemorrhage, infection, adjacent tissue injury and pain.

SenoMark™

Indications for use: The SenoMark™ Breast Tissue Marker is intended to radiographically and sonographically mark breast tissue during a percutaneous breast biopsy procedure. **Contraindications:** This device is not intended for use except as indicated. **Warnings:** 1) Patients with a known hypersensitivity to the materials listed in the device description may suffer an allergic reaction to this implant. 2)This device is not recommended for use in patients with breast implants. 3) Do not use in the presence of infection. 4) 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. 5) Avoid the use of excessive force during removal of the Applicator to prevent breakage of the Applicator tip. 6) 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. 7) 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:** 1) This device should only be used by physicians trained in percutaneous biopsy procedures. 2) Do not use if the product sterile barrier system or its packaging is compromised. 3) Carefully inspect the device prior to use to verify that device has not been damaged. Do not use if product damage is evident and/or needle is bent. 4) Do not kink the flexible tube. 5) Do not use if Temperature Indicator is black. 6) Maintain correct alignment of the indicators (C, D) with the sample notch when dispensing pads. 7) Ensure all pads are dispensed. **Complications:** Potential complications may include, but are not limited to, hematoma, hemorrhage, infection, adjacent tissue injury, pain, allergic reaction, and migration.

SenoMark™ UltraCor™ MRI

Indications for use: The SenoMark™ UltraCor™ MRI Breast Tissue Marker is intended to radiographically and sonographically mark breast tissue prior to or during a breast biopsy procedure. **Contraindications:** This device is not intended for use except as indicated. **Warnings:** 1) 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. 2) 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. 3) Avoid the use of excessive force during removal of the applicator to prevent breakage of the applicator tip. 4) Patients with a known hypersensitivity to the materials listed in the device description may suffer an allergic reaction to this implant. 5) This device is not recommended for use in patients with breast implants. 6) Do not use in the presence of infection. 7) 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. **Precautions:** 1) This device should only be used by physicians trained in percutaneous biopsy procedures. 2) Do not use if Temperature Indicator is black. 3) Do not use if the product sterile barrier system or its packaging is compromised. 4) Carefully inspect the device prior to use to verify that device has not been damaged. Do not use if product damage is evident and/or needle is bent. 5) Ensure all pads are dispensed. 6) Published studies with comparably sized 316L stainless steel biopsy markers have shown no maker movement and insignificant marker heating when tested in an MRI system with a 1.5T field strength. **Complications:** Potential complications may include, but are not limited to hematoma, hemorrhage, infection, adjacent tissue injury, pain, allergic reaction, and migration.

Marker images are not to scale. Enlarged to show detail. Please consult product labels and inserts for complete indications, contraindications, hazards, warnings, precautions and directions for use.

A show of our support

As part of our 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 purchased*. This limited-time offer enables our customers to celebrate and support their patients with every marker placement.*

In Celebration of Her™

American Cancer Society®

MAKING STRIDES AGAINST BREAST CANCER®

* Applies to specially marked BD breast tissue marker products purchased from BD.

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

The American Cancer Society® does not endorse any service or product. Program started on October 1, 2014 and ends on September 30, 2025.

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