# **BD** Breast Tissue Markers

# Ordering Information

<b>IltraCor</b> ™ Breast	Tissue Marker						
UCTC17GSS	Independently or through a coaxial	17G	316L Stainless Steel	Spring	M	N/A	10 cm rigid needle contains one radiopaque marker in center position and 2 PEG plugs in the distal a proximal positions.
JltrαCor™ Twirl™	Breast Tissue Marker				siblic.		
UCTW17	Independently or through a coaxial	17G	Nitinol	Ring	0	N/A	10 cm rigid needle contains one radiopaque marker.
<b>ItraClip</b> ™ Breast	Tissue Markers				0		
861017	Independently or through a coaxial	17G	Titanium	Ribbon	X	N/A	10 cm rigid needle contains one radiopaque marker.
861217		17G	Titanium	Ribbon	X	N/A	12 cm rigid needle contains one radiopaque marker.
862017		17G	Inconel <sup>™</sup> 625	Wing	Ą	N/A	10 cm rigid needle contains one radiopaque marker.
863017		17G	Titanium	Ribbon	1	Yes	10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
864017		17G	BioDur <sup>™</sup> 108	Coil	<b>M.</b>	N/A	10 cm rigid needle contains one radiopaque marker.
865017		17G	Titanium	Ribbon	X	N/A	MRI compatible 10 cm rigid needle contains one radiopaque marker.
865517		17G	Titanium	Ribbon	X	N/A	MRI compatible 15 cm rigid needle contains one radiopaque marker.
·	<mark>rigger</mark> Breast Tissue Mo	:		146		<u>.</u>	
862017D	Independently or through a coaxial	17G	Inconel <sup>™</sup> 625	Wing		Yes	10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
862017DL		17G	Inconel <sup>™</sup> 625	Wing		Yes	12 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
863017D		17G	Titanium	Ribbon	\[\bar{\}\]	Yes	10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
863017DL		17G	Titanium	Ribbon	1	Yes	12 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
864017D		17G	BioDur <sup>™</sup> 108	Coil		Yes	10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
864017DL		17G	BioDur™ 108	Coil		Yes	12 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
866017D		17G	Titanium	Heart	1	Yes	10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
867017D		17G	BioDur <sup>™</sup> 108	Venus	- 5	Yes	10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
el Mark UltraCo	<b>or</b> ™ Breast Tissue Marke	rs					
GMUTC005SS	Independently or	14G	316L Stainless Steel	Omega	8	Yes, 4-6 weeks	10 cm rigid needle contains 4 PLA/PGA pellets and one radiopaque marker in distal position.
GMUTC005T	through a coaxial	14G	Titanium	S	5	Yes, 4-6 weeks	10 cm rigid needle contains 4 PLA/PGA pellets and one radiopaque marker in distal position.
el Mark Ultra™ [	Breast Tissue Markers						
GMUEC10GSS	EnCor™ Probe	10G	316L Stainless Steel	Omega	8	Yes, 4-6 weeks	Applicator with side deployment contains 10 PLA/PGA pellets and one radiopaque marker located in center position.
GMUEC7GSS	EnCor <sup>™</sup> Probe	7G	316L Stainless Steel	Omega	8	Yes, 4-6 weeks	Applicator with side deployment contains 10 PLA/PGA pellets and one radiopaque marker located in center position.
enoMark™ Ultra	<b>Cor</b> ™ Breast Tissue Mar	kers					
SMUC10R	Independently or through a coaxial	14G	Titanium	Ribbon	A	Yes	10 cm rigid needle contains one PGA microfiber pad with one radiopaque marker, interwoven with PN polymer, located in the center position.
SMUC10C		14G	BioDur™ 108	Coil		Yes	10 cm rigid needle contains one PGA microfiber pad with one radiopaque marker, interwoven with Pipolymer, located in the center position.
SMUC10H		14G	Titanium	Heart		Yes	10 cm rigid needle contains one PGA microfiber pad with one radiopaque marker, interwoven with Pipolymer, located in the center position.
SMUC10V		14G	BioDur <sup>™</sup> 108	Venus	L	Yes	10 cm rigid needle contains one PGA microfiber pad with one radiopaque marker, interwoven with P polymer, located in the center position.
SMUC13R	Independently or with EnCor™ coaxial, EnCor™ MRI coaxial and Eviva™ coaxial with Adapters	14G	Titanium	Ribbon	$\lambda$	Yes	13 cm rigid needle contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PV/polymer, located in the center position.
SMUC13C		14G	BioDur <sup>™</sup> 108	Coil		Yes	13 cm rigid needle contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMUC13H		14G	Titanium	Heart		Yes	13 cm rigid needle contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMUC13V		14G	BioDur™ 108	Venus		Yes	13 cm rigid needle contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PV/polymer, located in the center position.
noMark™ Ultra	Breast Tissue Markers						polymer, rocated in the center position.
SMEC7R	EnCor™ Probe	7G	Titanium	Ribbon	<del>\</del>	Yes	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwith PVA polymer, located in the center position.
SMEC7C	 EnCor™ Probe	7G	BioDur <sup>™</sup> 108	Coil	1,	Yes	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interw with PVA polymer, located in the center position.
SMEC10R	 EnCor™ Probe	10G	Titanium	Ribbon	_	Yes	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interw with PVA polymer, located in the center position.
SMEC10C	 EnCor™ Probe	10G	BioDur <sup>™</sup> 108	Coil	17	Yes	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interw
SMEC12R	EnCor <sup>™</sup> Probe	12G	Titanium	Ribbon		Yes	with PVA polymer, located in the center position.  Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interw
SMEC12C	EnCor™ Probe	12G	BioDur™ 108	Coil	<u> </u>	Yes	with PVA polymer, located in the center position.  Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interw
							with PVA polymer, located in the center position.  Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interw
SMMA11R	Mammotome <sup>™</sup> Probe	11G	Titanium	Ribbon	<u> </u>	Yes	with PVA polymer, located in the center position.  Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interw
SMMA11C	Mammotome <sup>™</sup> Probe	11G	BioDur <sup>™</sup> 108	Coil		Yes	with PVA polymer, located in the center position.  Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interw
SMAT9R	ATEC™ Probe	9G	Titanium	Ribbon	V	Yes	with PVA polymer, located in the center position.  Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interw
SMAT9C	ATEC™ Probe	9G	BioDur <sup>™</sup> 108	Coil		Yes	with PVA polymer, located in the center position.
SMAT12R	ATEC™ Probe	12G	Titanium	Ribbon	Λ	Yes	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwith PVA polymer, located in the center position.
SMAT12C	ATEC <sup>™</sup> Probe	12G	BioDur <sup>™</sup> 108	Coil		Yes	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwith PVA polymer, located in the center position.
SMEV9R	Eviva™ Probe	9G	Titanium	Ribbon	\(\)	Yes	Applicator with end deployment contains 3 PGA microfiber pads with one radiopaque marker, interwith PVA polymer, located in the center position.
SMEV9C	Eviva™ Probe	9G	BioDur <sup>™</sup> 108	Coil		Yes	Applicator with end deployment contains 3 PGA microfiber pads with one radiopaque marker, interw with PVA polymer, located in the center position.
noMark <sup>™</sup> Breas	t Tissue Markers				h		
SMEC12GSS	EnCor <sup>™</sup> Probe	12G	316L Stainless Steel	Omega	R	Yes, 3 weeks	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position.
SMTEC10G	EnCor™ Probe	10G	Titanium	0	0	Yes, 3 weeks	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position.
SMEC10GSS	EnCor™ Probe	10G	316L Stainless Steel	М	M	Yes, 3 weeks	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position.
SMEC7GSS	EnCor <sup>™</sup> Probe	7G	316L Stainless Steel	М	M	Yes, 3 weeks	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position.
SMTMT11G	Mammotome <sup>™</sup> Probe	11G	Titanium	0	Ò	Yes, 3 weeks	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position.
SMTSU9G	ATEC <sup>™</sup> Probe	9G	Titanium	0	Ó	Yes, 3 weeks	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position. Designed to be inserted through the ATEC™ 9g cannula.
SMRSU9GT	ATEC™ Probe	9G	Titanium	Χ	Х	Yes, 3 weeks	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position. Designed to be inserted through rear of the ATEC 9g biopsy probe.
	ATEC™ Probe	12G	Titanium	S	S	Yes, 3 weeks	Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position. Designed to be inserted through rear of the ATEC ** 12g biopsy probe.
SMRSU12GT			_	X	Х	Yes, 3 weeks	Applicator with end deployment contains 3 PGA microfiber pads with one radiopaque marker
SMRSU12GT SMSE9GT	Eviva™ Probe	9G	Titanium	^			Located in the center recition
SMSE9GT	Eviva <sup>™</sup> Probe <b>Cor™ MRI</b> Breast Tissue			^	/\		located in the center position.
SMSE9GT	Eviva <sup>™</sup> Probe  Cor <sup>™</sup> MRI Breast Tissue  Independently or			M	M	Yes, 3 weeks	13 cm rigid needle contains 3 PGA microfiber pads with one radiopaque marker located in the center position.

\* PVA — polyvinyl alcohol; PGA — polyglycolic acid; PLA — polylactic acid; PEG — polyethylene glycol



Legend

EnCor™

 $Mammotome^{\text{\tiny{M}}}$ 

Hologic™

Universal

## 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.

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) The The UltraCor™ Twirl™ Breast Tissue Marker is not recommended for use in patients with breast implants. 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 metabalical changes.

**Precautions:** 1) 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. 2) Do not use if needle is bent and/or tip is damaged. 3) Use caution when handling the device to prevent premature deployment of the breast tissue marker. 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.

**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.

# UltraClip

**Indications for use:** The UltraClip<sup>m</sup> 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  $UltraClip^{\mathbb{M}}$  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 Trig

**Indications for use:** The UltraClip<sup>TM</sup> 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.

## GelMark UltraCor

Indications for use: The GelMark UltraCor<sup>TM</sup> 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 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.

#### GelMark Ultra

Indications for use: The GelMark Ultra™ Breast Tissue Marker is intended to radiographically mark breast tissue during a percutaneous breast biopsy procedure.

#### Contraindications: None known.

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) Do not use in the presence of infection. 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. 7) Avoid the use of excessive force during removal of the Applicator to prevent breakage of the Applicator tip.

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) Do not kink the flexible tube. 4) Maintain correct alignment of the Yellow Indicator Key (D) with the red arrow of the biopsy probe when dispensing pellets. 5) Ensure all pellets are dispensed. 6) Published studies with comparably sized 316L stainless steel biopsy markers have shown no marker movement and insignificant marker heating when tested in an MRI System with a 1.5T field strength. 7) Do not use if Temperature Indicator is black. 8) 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.

**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.

 $\label{lem:contraindications:} Patients with a known hypersensitivity to the materials listed in the device description may suffer an allergic reaction to this implant.$ 

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, hemorrhaae, 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 crosspatient 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 resterlize. 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

**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.

on components that are influenced by thermal and/or mechanical changes.

**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.

1) Patients with a known hypersensitivity to the materials listed in the device description may

**Contraindications:** This device is not intended for use except as indicated.

# Warnings:

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.

 $\textbf{Contraindications:} \ \text{This device is not intended for use except as indicated}.$ 

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.

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

