




































Breast Tissue Markers

Ordering information

Catalog Number	Use With	Gauge	Material	Shape	Ultrasound Visibility	Specifications*
UltraCor™ Breast Tissue Marker						
UCTC17GSS	Independently or through a coaxial	17G	316L Stainless Steel	Spring		n/a 10 cm rigid needle contains one radiopaque marker in center position and 2 PEG plugs in the distal and proximal positions.
UltraCor™ Twirl™ Breast Tissue Marker						
UCTW17	Independently or through a coaxial	17G	Nitinol	Ring		n/a 10 cm rigid needle contains one radiopaque marker.
UltraClip™ Breast Tissue Markers						
861017	Independently or through a coaxial	17G	Titanium	Ribbon		n/a 10 cm rigid needle contains one radiopaque marker.
861217		17G	Titanium	Ribbon		n/a 12 cm rigid needle contains one radiopaque marker.
862017		17G	Inconel™ 625	Wing		n/a 10 cm rigid needle contains one radiopaque marker.
863017		17G	Titanium	Ribbon		Permanent 10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
864017		17G	BioDur™ 108	Coil		n/a 10 cm rigid needle contains one radiopaque marker.
865017		17G	Titanium	Ribbon		n/a MRI compatible 10 cm rigid needle contains one radiopaque marker.
865517		17G	Titanium	Ribbon		n/a MRI compatible 15 cm rigid needle contains one radiopaque marker.
UltraClip™ Dual Trigger Breast Tissue Markers						
862017D	Independently or through a coaxial	17G	Inconel™ 625	Wing		Permanent 10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
862017DL		17G	Inconel™ 625	Wing		Permanent 12 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
863017D		17G	Titanium	Ribbon		Permanent 10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
863017DL		17G	Titanium	Ribbon		Permanent 12 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
864017D		17G	BioDur™ 108	Coil		Permanent 10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
864017DL		17G	BioDur™ 108	Coil		Permanent 12 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
866017D		17G	Titanium	Heart		Permanent 10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
867017D		17G	BioDur™ 108	Venus		Permanent 10 cm rigid needle contains one radiopaque marker with interwoven PVA polymer.
Gel Mark UltraCor™ Breast Tissue Markers						
GMUTC005SS	Independently or through a coaxial	14G	316L Stainless Steel	Omega		4-6 weeks 10 cm rigid needle contains 4 PLA/PGA pellets and one radiopaque marker in distal position.
GMUTC005T		14G	Titanium	S		4-6 weeks 10 cm rigid needle contains 4 PLA/PGA pellets and one radiopaque marker in distal position.
Gel Mark Ultra™ Breast Tissue Markers						
GMUEC10GSS	EnCor™ Probe	10G	316L Stainless Steel	Omega		4-6 weeks Applicator with side deployment contains 10 PLA/PGA pellets and one radiopaque marker located in the center position.
GMUEC7GSS	EnCor™ Probe	7G	316L Stainless Steel	Omega		4-6 weeks Applicator with side deployment contains 10 PLA/PGA pellets and one radiopaque marker located in the center position.
SenoMark™ UltraCor™ Breast Tissue Markers						
SMUC10R	Independently or through a coaxial	14G	Titanium	Ribbon		Permanent 10 cm rigid needle contains one PGA microfiber pad with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMUC10C		14G	BioDur™ 108	Coil		Permanent 10 cm rigid needle contains one PGA microfiber pad with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMUC10H		14G	Titanium	Heart		Permanent 10 cm rigid needle contains one PGA microfiber pad with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMUC10V		14G	BioDur™ 108	Venus		Permanent 10 cm rigid needle contains one PGA microfiber pad with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMUC13R	Independently or through EnCor™ MRI cannula and Eviva™ coaxial with Adapters	14G	Titanium	Ribbon		Permanent 13 cm rigid needle contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMUC13C		14G	BioDur™ 108	Coil		Permanent 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		Permanent 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		Permanent 13 cm rigid needle contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SenoMark™ Ultra Breast Tissue Markers						
SMEC7R	EnCor™ Probe	7G	Titanium	Ribbon		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMEC7C	EnCor™ Probe	7G	BioDur™ 108	Coil		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMEC10R	EnCor™ Probe	10G	Titanium	Ribbon		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMEC10C	EnCor™ Probe	10G	BioDur™ 108	Coil		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMEC12R	EnCor™ Probe	12G	Titanium	Ribbon		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMEC12C	EnCor™ Probe	12G	BioDur™ 108	Coil		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMMA11R	Mammotome™ Probe	11G	Titanium	Ribbon		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMMA11C	Mammotome™ Probe	11G	BioDur™ 108	Coil		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMAT9R	ATEC™ Probe	9G	Titanium	Ribbon		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMAT9C	ATEC™ Probe	9G	BioDur™ 108	Coil		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMAT12R	ATEC™ Probe	12G	Titanium	Ribbon		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMAT12C	ATEC™ Probe	12G	BioDur™ 108	Coil		Permanent Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMEV9R	Eviva™ Probe	9G	Titanium	Ribbon		Permanent Applicator with end deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SMEV9C	Eviva™ Probe	9G	BioDur™ 108	Coil		Permanent Applicator with end deployment contains 3 PGA microfiber pads with one radiopaque marker, interwoven with PVA polymer, located in the center position.
SenoMark™ Breast Tissue Markers						
SMEC12GSS	EnCor™ Probe	12G	316L Stainless Steel	Omega		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	O		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	M		3 weeks Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position.
SMEC7GSS	EnCor™ Probe	7G	316L Stainless Steel	M		3 weeks Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position.
SMTMT11G	Mammotome™ Probe	11G	Titanium	O		3 weeks Applicator with side deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position.
SMTSU9G	ATEC™ Probe	9G	Titanium	O		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	X		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.
SMRSU12GT	ATEC™ Probe	12G	Titanium	S		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.
SMSE9GT	Eviva™ Probe	9G	Titanium	X		3 weeks Applicator with end deployment contains 3 PGA microfiber pads with one radiopaque marker located in the center position.
SenoMark™ UltraCor™ MRI Breast Tissue Markers						
SMUCMRI14GSS	Independently or through a coaxial	14G	316L Stainless Steel	M		3 weeks 13 cm rigid needle contains 3 PGA microfiber pads with one radiopaque marker located in the center position.
SMUCMRI14GT		14G	Titanium	X		3 weeks 13 cm rigid needle contains 3 PGA microfiber pads with one radiopaque marker located in the center position.

Legend: EnCor™, Mammotome™, Hologic™, Universal

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

INDICATIONS FOR USE: Breast Tissue Markers are intended to radiographically mark the location of the breast biopsy during an open surgical breast biopsy or a percutaneous breast biopsy procedure. **CONTRAINDICATIONS:** Do not use this device in patients with a known hypersensitivity to the materials listed in the device description as they may suffer an allergic reaction to this implant. **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) **BARO™** Breast Tissue Markers have been designed for single use only. Reusing these medical devices 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. 4) 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. **PRECAUTIONS:** 1) The **BARO™** Breast Tissue Markers 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. 2) Do not use the product if the sterile barrier has been previously opened or if the package is damaged. 3) Although polysaccharide (starch) has known hemostatic properties, the user should continue to employ standard methods for obtaining hemostasis following the biopsy procedure. 4) After use, the product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local laws and regulations. **COMPLICATIONS:** Potential complications of marker placement may consist of hematoma, hemorrhage, infection, adjacent tissue injury and pain. Please consult product labels and inserts for complete indications, contraindications, hazards, warnings, precautions and directions for use.

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