



SenoMark™ Ultra

Breast Tissue Markers

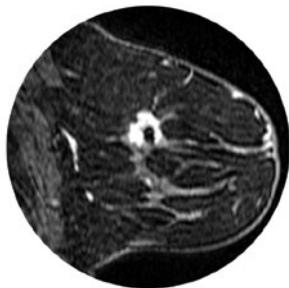
Right on the Mark

Ideal for every patient—no matter how you look at it



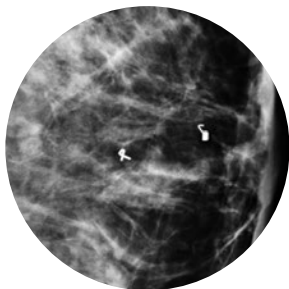
Ultrasound

Designed to provide both remarkable visibility for 3 weeks and permanent ultrasound enhancement



MRI

BioDur™ 108, one of two options for MR visualization

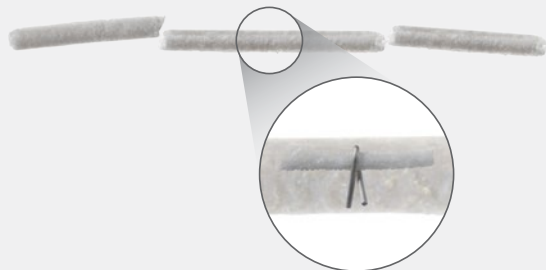


Mammography

Two unique wireform shapes—ribbon and coil—clearly mark multiple sites

Accuracy and minimal migration

- Three PGA microfiber absorbent pads are designed to assist in accurate placement and to minimize migration until they are resorbed in approximately 12 weeks.
- The proximal and distal pads are designed to keep the center pad, containing the wireform with interwoven PVA, in place.



Ease of use

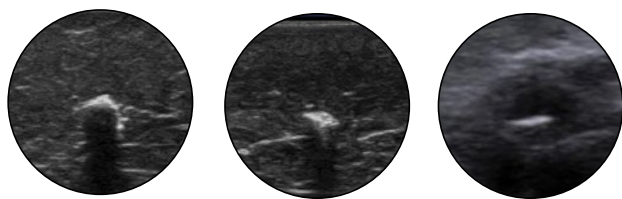
- Compatible with a range of vacuum-assisted biopsy probes.

It's everything you're looking for in a marker: Accurate placement, minimal migration, remarkable visibility in all modalities, and ease of use.

Visibility in Three Modalities

Ultrasound

- Polyglycolic acid (PGA) microfiber absorbent pads provide 3 weeks of ultrasound visibility.
- Non-absorbable polyvinyl alcohol (PVA) polymer, interwoven in a wireform, provides permanent ultrasound enhancement.



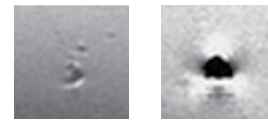
Upon placement

3 Weeks

Permanent

MRI

- Each of the two unique shapes is made of different material, allowing a choice of MR visualization.



Titanium Ribbon marker

Biodur™ 108 Coil marker

MRI taken using spin echo pulse sequence-long axis.

Mammography

- Two unique wireform shapes—ribbon and coil—clearly mark multiple sites within the same breast.



Ribbon

Coil

Ordering information

Vacuum-assisted biopsy probes

Senomark™ Ultra Breast Tissue Marker

Encor™	7g	SMEC7R*	Ribbon		SMEC7C*	Coil	
	10g	SMEC10R	Ribbon		SMEC10C	Coil	
	12g	SMEC12R	Ribbon		SMEC12C	Coil	
ATEC™	9g	SMAT9R	Ribbon		SMAT9C	Coil	
	12g	SMAT12R	Ribbon		SMAT12C	Coil	
Eviva™	9g	SMEV9R	Ribbon		SMEV9C	Coil	
Mammotome™	11g	SMMA11R	Ribbon		SMMA11C	Coil	

*Product codes ending in "R" have the Titanium ribbon shape wireform. Product codes ending in "C" have the BioDur™ 108 coil shape wireform.

INDICATIONS FOR USE:

The SENO MARK™ 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 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. 5. 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. 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.

Please consult product labels and instructions for use, indications, contraindications, hazards, warnings, and precautions. Not all products, services, claims, or features of products and services may be available or valid in your local area. Please check with your local BD representative.

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