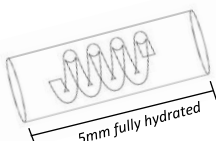


OneMark® Breast Localization Marker

Instructions for Use

DEVICE DESCRIPTION

The OneMark® Breast Localization Marker (marker) is a small, implantable tissue marker pre-loaded in an Applicator delivery system. The marker is made of a hydrogel matrix containing microspheres for distinct visualization with ultrasound and when using the OneMark Detection Imaging System. The marker contains a metal coil that is permanently visible under standard radiologic imaging per hospital protocol.



For information on detection technique, refer to the Instructions for Use for the OneMark Detection Imaging System (08-9009).

The applicator is designed for direct tissue insertion or can be used with 14G or 16G coaxial introducer needles.

The OneMark Markers are offered in two handle types: a longer plastic molded handle with dual actuation on the side and back of the handle (dual slide), and a shorter handle with a single actuation mechanism at the back of the handle (single slide).

INDICATIONS FOR USE

The OneMark Breast Localization Marker is intended to be placed percutaneously in soft tissue (>30 days) to mark a biopsy site or soft tissue intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or detection imaging (OneMark Detection Imaging System), the OneMark Breast Localization Marker is located and may be surgically removed with the target tissue. The OneMark Detection Imaging System is intended only for the detection of the OneMark Breast Localization Marker.

WARNINGS AND CAUTIONS

Warnings

- This device is SINGLE PATIENT, SINGLE USE only. Reuse of the implantable device and delivery system could cause infection and/ or device malfunction.
- Exercise caution with using the device on patients with prostheses and when placing the device near the chest wall so as not to puncture the prosthesis or chest wall during deployment.
- Should the marker fail to be visible with detection imaging or ultrasound, standard surgical practices should be applied to accommodate the appropriate resection method, which may include CT, mammography or X-ray imaging and remarking of the lesion.
- OneMark Breast Localization Markers are intended for adult patients who are medically eligible for tumor resection.

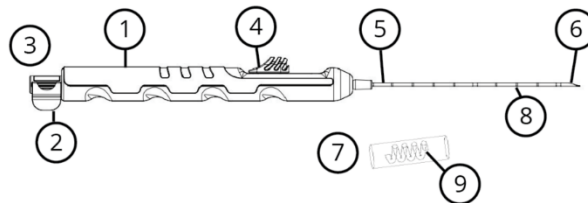
Cautions

- Federal law restricts this device to sale by or on the order of a physician.
- This product should only be used by a physician who is familiar with the indications, contraindications, limitations, typical findings and possible side effects of marker placement.
- Implantation of 4 markers in a single procedure is the maximum exposure dose from a safety perspective.
- Do NOT resterilize.
- Do NOT use if the package is open or damaged.
- Do NOT use if the package is thermally compromised as indicated by the thermal indicators on the outer packaging.
- The marker contains USP grade porcine derived collagen gelatin and polyethylene glycol (PEG) with a low allergenic potential. Do not use the marker in patients that are allergic to gelatin, porcine materials, or PEG.
- The implanted marker is MR Conditional.
- The applicator is MR Unsafe and should not be used in the MR environment.
- If the OneMark Detection Imaging System is not used, ultrasound imaging by trained technicians using color Doppler is recommended.

DUAL SLIDE APPLICATOR

Illustration and Nomenclature

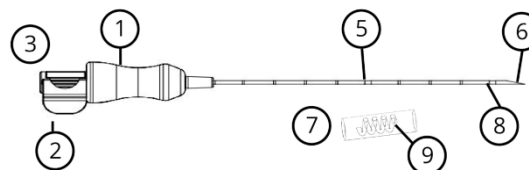
1. Handle
2. Deployment lock
3. Plunger
4. Slider button
5. Cannula
6. Sharp end of cannula with tip plug
7. OneMark breast localization marker
8. 1cm markings
9. Coil inside OneMark breast localization marker



SINGLE SLIDE APPLICATOR

Illustration and Nomenclature

1. Handle
2. Deployment lock
3. Plunger
5. Cannula
6. Sharp end of cannula with tip plug
7. OneMark breast localization marker
8. 1cm markings
9. Coil inside OneMark breast localization marker



RECOMMENDED PROCEDURE

Delivery

- Remove the applicator pre-loaded with the Marker from the package using standard aseptic technique. Remove the tip protector.
- Check to ensure that the marker tip plug is visible in the sharp end (6) of the cannula (5), and that the cannula (5) is not damaged or bent.
- Locate the desired marker placement location using the preferred imaging technique.
- Remove the deployment lock (2) on the plunger (3).
- Insert the applicator into the breast either directly or through a coaxial introducer needle. Advance the applicator to the desired depth using the 1cm markings (8) on the cannula of the applicator. If necessary, reposition the needle and reconfirm placement.
- To deploy the marker (7), depress the plunger (2) or advance the slider button (4) until it locks. The marker (7) containing a titanium coil (9) will deploy into the tissue at the biopsy or surgical site.
- Remove the applicator and coaxial needle (if used) from the site and discard according to standard hospital protocol for sharps and biohazard disposal. Confirm placement with imaging.

Surgical Removal

- Determine the location of the marker by using the OneMark Detection Imaging System, and/or by using imaging guidance (ultrasound or x-ray).
- Perform an excision of the intended tissue. The OneMark Detection Imaging System or other guidance can be used to identify the marker during excision.
- The OneMark Detection Imaging System or imaging guidance (ultrasound or x-ray) can be used to confirm the marker is present in the excised specimen.

SYMBOLS

SYMBOL	DESIGNATION		
	Federal (USA) law restricts this device to sale by or on the order of a physician		Lot Number
	Attention: See Instructions for Use		Sterilized using irradiation
	Caution: Consult accompanying documents		Manufacturer
	Do not use if package is damaged		Non-Pyrogenic
	For Single Use Only		Storage Temperature
	Use By: YYYY-MM-DD		MR Conditional
	Catalog/ Model Number		

Storage and Handling

Limit temperature exposure to no less than 0° C, and humidity to 10% to 95% non-condensing.

MRI Safety Information



MRI Safety Information

A person implanted with the OneMark Breast Localization Marker may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name:	OneMark Breast Localization Marker
Static Magnetic Field Strength (B ₀):	1.5 T or 3.0 T
Maximum Spatial Field Gradient:	30 T/m (2,000 gauss/cm)
RF Excitation:	Circularly Polarized (CP)
RF Transmit Coil Type:	There are no Transmit Coil restrictions
Operating Mode:	Normal Operating Mode
Maximum Whole-Body SAR:	2 W/kg (Normal Operating Mode)
Maximum Head SAR:	3.2 W/kg (Normal Operating Mode)
Scan Duration:	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact:	The presence of this implant may produce an image artifact
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

The OneMark Detection Imaging System and OneMark Marker Applicator is MR Unsafe and should not be brought into an MR Scanner.

Note

These instructions for the Marker and the OneMark Detection Imaging System are NOT meant to define or suggest any medical or surgical technique. The individual physician is responsible for the proper procedure and techniques to be used with this product.