BREAST BIOPSY SOLUTIONS

Instructions For Use

SECURMARK® for ATEC®

Biopsy Site Markers

HOLOGIC®

SecurMark® Biopsy Site Marker For ATEC® Biopsy Device

Instructions for Use

Please read all information carefully. Failure to properly follow the instructions may lead to unanticipated surgical consequences.

Important: This package insert is designed to provide Instructions for Use for the SecurMark® biopsy site marker for the ATEC® biopsy device. It is not a reference to surgical techniques.

Upon completion of the breast biopsy procedure, the user will have the option of using the SecurMark biopsy site marker for the ATEC biopsy device.

Indications

The SecurMark biopsy site marker is indicated for the permanent radiographic marking of sites in soft tissue.

** Available in multiple shapes*

Contraindications

None known.

Device Description

The SecurMark biopsy site marker is a sterile, single patient use device comprised of a single, biocompatible titanium or stainless steel marker surrounded by a bioabsorbable suture-like material and a deployment device. Refer to product label for marker material.

The deployment device is a hand-held device that delivers the marker from the distal tip. The deployment device consists of a flexible cannula, handle, flexible push rod, and plunger. The marker is located at the distal end of the deployment device.

The titanium or stainless steel marker is classified as magnetic resonance (MRI) conditional at 3.0 Tesla field strength or less. The marker, when present in a patient undergoing an MRI procedure at 3.0 Tesla or less, will not create an additional hazard or risk with respect to magnetic field-related interactions, movement/dislodgement or heating.

MRI Artifact Considerations

Artifacts for the SecurMark biopsy site marker have been characterized using a 3.0 Tesla MRI system with spin echo and gradient echo pulse sequences. Based on this information, imaging quality may be slightly compromised if the area of interest is in the exact same area as the SecurMark biopsy site marker.

Artifact size is dependent on the type of pulse sequence used for imaging (larger for gradient echo pulse sequences and smaller for spin echo pulse sequences), and the size of the field of view. Image artifact will be smaller for MRI systems with lower static magnetic field strengths using the same imaging parameters as those operating at higher static magnetic field strengths.

Device Preparation and Use

1. Prior to use of the SecurMark biopsy site marker, inspect the protective packaging and device to verify that neither has been damaged during shipment. If it appears the packaging has been compromised, do not use the device.

2. Remove the SecurMark deployment device from its protective packaging using standard interventional technique.

NOTE: For the 36-09 and 36-12, remove the deployment guide from the protective packaging and attach it to the proximal end of the biopsy device.

3. Pull back the biopsy device so that the open aperture is accurately positioned for marker placement (pull back 10mm for a 20mm aperture biopsy device (standard) or 6mm for a 12mm aperture device (petite).

4. When placement of the SecurMark biopsy site marker is desired, advance the deployment device to the targeted site.

5. Align the directional arrow on the hub of the deployment device with the aperture of the biopsy device.

NOTE: Always deploy the marker towards the center of the biopsy cavity.

6. Deploy the marker by fully advancing the deployment plunger.

7. Rotate the biopsy device 180 degrees.

NOTE: Following the insertion of the marker deployment device, the console should NOT be put back into “Biopsy” mode.

8. Verify the deployment and proper position of the marker prior to removal of the device with the appropriate imaging modality.

9. Slowly remove the deployment device, or biopsy device and deployment device, from the breast as one unit and properly dispose.

Warnings and Precautions

• A small percentage of patients experience an allergic reaction to stainless steel due to the presence of nickel. It is not recommended to use the stainless steel SecurMark markers in patients with known metal allergies.

• The SecurMark deployment device is not recommended for use within the bore of an MRI magnet.

• The SecurMark biopsy site marker is not recommended for use in patients with breast implants.

• The biopsy site marking procedure should be performed only by persons having adequate training and familiarity with this procedure. Consult medical literature relative to techniques, complications, and hazards prior to performing any minimally invasive procedure.

• The SecurMark biopsy site marker should be used only by physicians trained in open or percutaneous biopsy procedures.

• **Rx Only** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

• The SecurMark biopsy site marker should be deployed into the cavity created during the biopsy procedure. Deployment into tissue outside of the biopsy cavity is not recommended.

• If the deployment device is difficult to insert or remove from the biopsy device, do not apply excessive force. Excessive force may cause damage or breakage of the deployment device which may result in a portion of the deployment device being left behind in the patient. If the deployment device cannot be easily removed from the biopsy device, remove the deployment device and biopsy device as one unit.

• Marker position relative to established landmarks may change under mammography upon subsequent breast compressions.

• The SecurMark biopsy site marker is not intended to be repositioned or recaptured after deployment.

• Users should take care not to unintentionally deploy the marker.

• Excess hematoma within the biopsy cavity and/or introducer can lead to marker adhesion to the deployment device, increasing the risk of marker drag out.

• Care should be taken to avoid damaging the cannula. Avoid operator or instrument contact with the SecurMark biopsy site marker or the distal end of the deployment device.

• The implanted SecurMark biopsy site marker is magnetic resonance imaging (MRI) conditional. The implanted marker presents no additional risk to the patient or operator from magnetic forces, torque, heating, induced voltages, or movement, but it may affect MRI image quality.

• Minimally invasive instruments and accessories manufactured or distributed by companies not authorized by Hologic, Inc. may not be compatible with the SecurMark biopsy site marker device. Use of such products may lead to unanticipated results and possible injury to the user or patient.

• Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.

Warnings and Precautions (Continued)

• Following the insertion of the marker deployment device into the handpiece, the console should NOT be put back into "Biopsy" mode. If the console is put into "Biopsy" mode after the deployment device has been inserted, there is a possibility that the marker deployment device could be damaged by the cutting blade of the handpiece when it advances. This could result in a portion of the deployment device being left behind in the patient.

• Dispose of all opened instruments whether used or unused.

• Do not resterilize and/or reuse the SecurMark biopsy site marker device. Resterilization and/or reuse may compromise the integrity of the instrument. This may lead to potential risks of failure of the device to perform as intended and/or cross-contamination associated with using inadequately cleaned and sterilized devices.

•Store the SecurMark biopsy site marker device in a clean and dry area. Avoid storage or handling temperatures above 50°C (122°F).

How Supplied

The SecurMark biopsy site marker device is sterilized by gamma radiation and supplied preloaded for single patient use. Discard into an appropriate container after use.

As Identified on Labels:

QUANTITY	Number of Devices Enclosed.
YYYY-MM-DD	Expiration date is represented by the following:
	YYYY represents the year
	MM represents the month
	DD represents the day

For More Information

For more information, U.S. and Canadian customers can contact the Hologic Customer Support Department at: 1-877-887-8767 or CSupport@hologic.com.

International customers, please contact your local distributor.

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Patent: http://hologic.com/patentinformation

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