BREAST BIOPSY SOLUTIONS

Instructions For Use

SECURMARK® MRI

Biopsy Site Markers

HOLOGIC®

SecurMark® MRI Biopsy Site Marker for use with ATEC® MRI 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® MRI biopsy site markers. It is not a reference to surgical techniques.

Upon completion of the ATEC® MRI breast biopsy procedure, the user will have the option of using the SecurMark MRI biopsy site marker by Hologic, Inc.

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, permanent biocompatible stainless steel marker surrounded by a bioabsorbable suture-like material and a deployment device.

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

The deployment device and marker are 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 MRI 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 MRI 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. Carefully remove the SecurMark deployment device from its protective packaging using standard interventional technique.

NOTE: Remove the tip protector prior to use of the device.

3. Turn or activate the console to “Set Up” or “Lavage” mode.

4. Lavage the biopsy cavity thoroughly before insertion of the marker deployment device.

5. Disconnect the saline line at the proximal end of the Y-Valve.

6. Turn or activate the console to “Biopsy” mode.

7. Remove the biopsy device from the introducer sheath and properly dispose.

8. Place the distal end of the SecurMark deployment device through the hub of the introducer sheath.

9. Carefully advance the SecurMark deployment device until the handle contacts the introducer sheath hub. Ensure that the position of the introducer sheath is maintained throughout the deployment of the marker by holding it in place with your off hand.

10. Deploy the marker by advancing the deployment plunger all the way forward until it latches onto the handle.

11. Slowly remove the deployment device from the introducer and properly dispose.

12. Insert obturator into the introducer sheath.

13. Verify the deployment and proper position of the marker prior to removal of the introducer.

14. Remove the introducer sheath and needle guide 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 biopsy site marker 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.

- 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.

- 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.

- 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.

Warning and Precautions (Continued)

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

- 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 devices are 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

MR ASTM F 2503-08 defines MR Conditional as: an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

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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