

I n s t r u c t i o n s F o r U s e

SECURMARK[®] for Eviva[®]

Biopsy Site Marker System

SecurMark[®] Biopsy Site Marker for Eviva[®] 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 Eviva[®] 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 Eviva biopsy device.

Indications

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

Contraindications

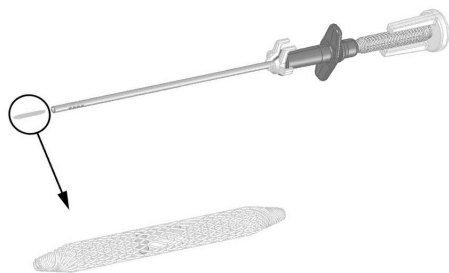
None known.

Device Description

The SecurMark biopsy site marker is a sterile, single patient use device comprised of a single, permanent biocompatible marker surrounded by a bioabsorbable suture-like material and a deployment device. The permanent marker is manufactured from either Titanium or Stainless Steel. Refer to the product label for the marker material.

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, spacer and tip protector. The marker is located at the distal end of the deployment device.

The 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.



** Available in multiple shapes*

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

NOTE: For use with the Petite aperture biopsy device, remove the spacer from the deployment device by pushing it off with thumb.

3. Remove the biopsy device from the introducer sheath.
4. Place the SecurMark deployment device through the hub of the introducer sheath.
5. Advance the SecurMark deployment device until the handle snaps to the introducer hub.
6. Deploy the marker by advancing the deployment plunger all the way forward until it latches onto the handle.
7. Verify the deployment and proper position of the marker prior to removal of the device with the appropriate imaging modality.
8. Slowly remove the deployment device, or introducer sheath and deployment device, as one unit from the breast 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 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.
- 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.

Warnings 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

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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HOLOGIC®



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