SecurMark® for Eviva®

Titanium Biopsy Site Marker

Instructions for Use

HOLOGIC®

SecurMark® Biopsy Site Marker For Eviva® Biopsy Device

Instructions For Use (IFU)

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

Important: This document 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.

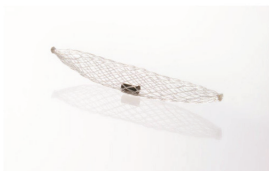
These instructions for Use can be located electronically at http://www.hologic.com/package-inserts.

Description

The SecurMark biopsy site marker is a sterile, single patient use device comprised of a single, biocompatible titanium 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, spacer and tip protector. The marker is located at the distal end of the deployment device.

There are two different versions of the SecurMark for Eviva deployment device. The SecurMark for Eviva deployment devices are available in 10cm and 13cm lengths. The SecurMark for Eviva deployment devices are compatible with either a 9Ga or 12Ga Eviva biopsy device or a 9Ga Brevera biopsy device.

The titanium 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 field or less, will not create an additional hazard or risk with respect to magnetic field-related interactions, movement/dislodgement or heating.



* Marker is available in multiple shapes

Intended Purpose/Use

Hologic SecurMark Biopsy Site Markers are indicated for the permanent radiographic marking of sites in soft tissue. The Hologic SecurMark Biopsy Site Markers are used following breast biopsy procedures performed with the Eviva® Breast Biopsy System or Brevera® Breast Biopsy System. The SecurMark markers provide the user with the ability to mark the location of the cavity where the breast biopsy was performed.

The markers are placed at the biopsy site under stereotactic guidance, depending on which type of biopsy device is used. Radiographic marking allows physicians to locate biopsy cavities should a follow-up lumpectomy or re-biopsy be necessary.

Indications

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

Intended User

The SecurMark Biopsy Site Markers should be used only by physicians trained in open or percutaneous biopsy procedures.

Intended Use Environment

The SecurMark Biopsy Site Markers are intended for use in clinical settings for surgical procedures.

Patient Target Group

Patients undergoing soft tissue biopsy with the need to subsequently locate the biopsy site with imaging.

Contraindications

There are no known contraindications.

Performance Characteristics

The measurable objectives / outcomes for evaluation of performance are accurate localization defined by minimal migration rates as well as visibility on ultrasound and x-ray. These outcomes should be similar to or better than similar devices.

Clinical Benefits

The SecurMark biopsy site marker enables medical professionals to identify a specific location in soft tissue under ultrasound or x-ray. This identification enables a medical professional to locate the area that has been biopsied in order to monitor or remove the tissue at a later time.

Adverse Effects

Adverse Effects can include:

- Pain
- Seroma formation
- Inflammation
- Bruising
- Hematoma
- Hemorrhage
- Infections
- Hypersensitivity or allergic reaction
- Soft tissue damage
- Misdiagnosis (due to marker migration)
- Perforation or scar tissue
- Needle Stick/Puncture
- Sepsis

Summary of Safety and Clinical Performance

The Summary of Safety and Clinical Performance (SSCP) report for the SecurMark biopsy site marker is available in the European database on medical devices. The database is named EUDAMED. The report is linked to the Basic UDI-DI.

Basic UDI-DI: 54200455SECURMARKBL

SSCP Document Number/Name: DHM-08590/SecurMark – Summary of Safety and Clinical Performance

Weblink: https://ec.europa.eu/tools/eudamed

⚠ WARNINGS

- The SecurMark deployment device is not recommended for use within the bore of an MRI magnet.
- There are possible adverse reactions when an object is implanted in the body.
- 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.
- $\text{R}_{\text{X}}\text{ONLY}$ 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.
- 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.
- Potential complications of marker placement consist of pain, seroma formation, inflammation, bruising, hematoma, hemorrhage, infections, hypersensitivity or allergic reaction, soft tissue damage, misdiagnosis (due to marker clip migration), perforation or scar tissue, Needle Stick/ Puncture, Sepsis.

- 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.
- Store the SecurMark biopsy site marker device in a clean and dry area.
- Do not use if package is damaged.

Material Information

Implantable Device

Marker	Material/Composition
Permanent Component	Titanium Grade II per ASTM F67-13: Nitrogen, max.....0.03 Carbon, max.....0.08 Hydrogen, max.....0.015 Iron, max .....0.30 Oxygen, max.....0.25 Titanium.....balance (99.32%)
Bioabsorbable Component	Glycoprene II (100%)

Deployment Device

The SecurMark deployment devices contain stainless steel and therefore may contain the following substance defined as CMR 1B in a concentration above 0.1% weight by weight:

Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

Current scientific evidence supports that medical devices manufactured from stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. A device specific evaluation has determined that the presence of Cobalt does not present a risk within the clinical use of this device.

Device Preparation and Use

NOTE: Please refer Eviva and Brevera breast biopsy system IFU for biopsy device instructions.

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.

Disposal Procedures

When it is necessary to dispose of the SecurMark deployment device and/or biopsy site marker, follow the local regulations.

Storage

Store the SecurMark biopsy site marker device in a clean and dry area. Handle with care. Packages should be stored in a manner that protects the integrity of the package and the sterile barrier.

MRI Artifacts

Artifacts for the SecurMark biopsy site marker have been evaluated using data from a 1.5 Tesla MRI system and T1-weighted, 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 and fast spin echo pulse sequences), the direction of the frequency encoding direction (larger if the frequency encoding direction is perpendicular to the device and smaller if it is parallel to the device), and the size of the field of view. Positional errors and artifacts on images 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.

MRI Safety Information

Marker only:

A patient with a SecurMark biopsy site marker can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T)
- Maximum spatial field gradient of 5,770 G/cm (57.70 T/m)
- Maximum MR system-reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg (First Level Operating mode).

Under the scan conditions defined above, the SecurMark biopsy site marker is expected to produce a maximum temperature rise that does not exceed 6.0°C after 15 minutes of continuous scanning.

Caution: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

The image artifact caused by the SecurMark biopsy site maker extends approximately 0.5 cm from the device when imaged with a gradient-echo pulse sequence in a 1.5 T MRI system and 0.8 cm from the device when imaged with a gradient-echo pulse sequence in a 3 T MRI system.

Deployment device only:

The SecurMark deployment device can be used in an MRI scanner suite under the following conditions:

- In scanner rooms with static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 330 G/cm (3.30 T/m).
- The deployment device is not intended to be used inside of the scanner bore or during imaging.

How Supplied

The SecurMark biopsy site marker device is sterilized by irradiation and supplied preloaded within the deployment device for single patient use. Discard into an appropriate container after use. A patient implant card and patient instruction leaflet will be supplied along with the device.

The patient implant card enables patients to:

- Identify the implanted devices,
- Access information related to the implanted device (e.g., via EUDAMED and other websites),
- And identify themselves as persons requiring special care in relevant situations (e.g., security checks, emergency clinical staff, or first responder to be informed about special care/needs for relevant patients in case of emergency situations).

As Identified on Labels:

QTY	Number of Devices Enclosed.
YYYY-MM-DD	Expiration date and Date of Manufacture are represented by the following: YYYY represents the year MM represents the month DD represents the day

Patient Implant Card Instructions (for Health Care Professionals)

SecurMark biopsy site markers are supplied with an implant card and patient instruction leaflet.

Healthcare providers are responsible for completing the following information on the provided patient implant card, in permanent ink.

1) Name of the patient
2) Date of implantation
3) Name and address of the healthcare institution and/or provider

The card should then be peeled off the backer, folded along the perforation and bonded together, front to back, to create a credit card sized patient implant card.

Healthcare providers must give both the completed patient implant card and patient instruction leaflet to the patient that has been implanted with the device.

A sample Implant Card is shown below:

Product Complaints and Technical Support

Report any complaints or problems in the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic Authorized Representative and Competent authority of the respective member state or country. The Competent Authorities, for medical devices, are usually the individual Member States' Ministry of Health, or an agency within the Ministry of Health.

For technical support or reorder information in the United States, please contact:

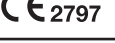
Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Phone: 877-371-4372
BreastHealth.Support@hologic.com

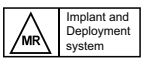
International customers, contact your distributor or local Hologic Sales Representative:

Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium
Tel: +32 2 711 46 80

Hologic Surgical Products
Costa Rica SRL
562 Parkway
Av. 0., Coyol Free Zone, El Coyol,
Alajuela, Costa Rica

Symbols Used On Labeling

Symbol	Description	Standard
	Prescription use only	FDA 21 CFR 801.109
	Authorized Representative in the European Community	ISO 15223-1, Reference 5.1.2
	CE mark with notified body reference number	MDR Regulation (EU) 2017/745
	Batch code	ISO 15223-1, Reference 5.1.5
	Catalog number	ISO 15223-1, Reference 5.1.6

Symbol	Description	Standard
	Do not use if package is damaged	ISO 15223-1, Reference 5.2.8
	Manufacturer	ISO 15223-1, Reference 5.1.1
	Use-by Date	ISO 15223-1, Reference 5.1.4
	Date of Manufacture	ISO 15223-1, Reference 5.1.3
	Do not re sterilize	ISO 15223-1, Reference 5.2.6
	Do not re-use	ISO 15223-1, Reference 5.4.2
 www.hologic.com/package-inserts	Consult instructions for use	ISO 15223-1, Reference 5.4.3
	Medical Device	ISO 15223-1, Reference 5.7.7
	Sterilized using irradiation	ISO 15223-1, Reference 5.2.4
	Quantity	Hologic
	Single sterile barrier system	ISO 7000-3707
	Single sterile barrier system with protective packaging outside	ISO 7000-3709
	Conditional use for magnetic resonance imaging	ASTM F2503 Reference no. Table 2;7.4.6.1; Fig 6,7
	Revision	Hologic

Symbol	Description	Standard
Patents	Patents	Hologic
CR	Country of Manufacture CC: Country code CR: Costa Rica US: United States of America	ISO 15223-1, Reference 5.1.11 ISO 3166-1 (Country Alpha-2 Code)
	Caution	ISO 15223-1, Reference 5.4.4
MATL	Material	Hologic
CC	Country code for translation	ISO 3166
	Warning	ISO 7010, Reference W001
	Contains hazardous substances	ISO 15223-1, Reference 5.4.10

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