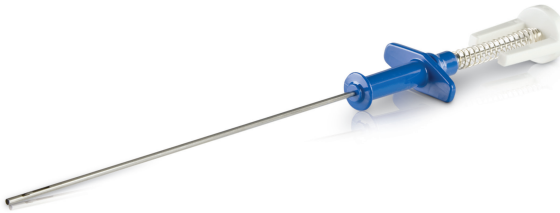
TriMark® for eviva®

Titanium Biopsy Site Marker



Instructions for Use

HOLOGIC®

TriMark® for Eviva®
Biopsy Site Marker System

Instructions for Use (IFU)

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 of the TriMark biopsy site marker system. It is not a reference to surgical techniques.

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

Device Description

The TriMark for Eviva biopsy site marker system is supplied as a sterile, single patient use system, comprised of a singular implant-grade titanium marker. The deployment device is a hand held device that delivers the marker from the distal tip. The deployment device consists of a cannula, handle, rigid push rod and plunger.

The deployment devices are available in 10cm and 13cm lengths. The deployment devices are compatible with either a 9Ga or 12Ga Eviva biopsy device.

The marking component consists of a single permanent, radiopaque, titanium component that is available in cork and hourglass shapes.

Figure 1: Representative Image of TriMark for Eviva markers (cork shape, left and hourglass shape, right)

Figure 2: Representative Image of TriMark for Eviva deployment device

Imaging modality compatibility				
Device model	Deployment device length	Marker shape	Stereotactic (X-Ray)	Compatible biopsy device and gauge
TRIMARK-EVIVA-10	10 cm	Shape 1 (Cork)	X	For use with 9 Ga or 12 Ga EVIVA biopsy devices
TRIMARK-EVIVA-2S-10	10 cm	Shape 2 (Hourglass)	X	
TRIMARK-EVIVA-13	13 cm	Shape 1 (Cork)	X	For use with 9 Ga or 12 Ga EVIVA and Brevera biopsy devices
TRIMARK-EVIVA-2S-13	13 cm	Shape 2 (Hourglass)	X	

Intended Purpose

The TriMark for Eviva biopsy site marker system is intended to be used to permanently mark an open or percutaneous biopsy site to radiographically mark the location of the biopsy site.

The Biopsy Site Markers are used following breast biopsy procedures performed with Eviva breast biopsy system. The 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, 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 TriMark for Eviva biopsy site marker system is indicated for use to mark an open or percutaneous biopsy site to radiographically mark the location of the biopsy site.

Intended User

TriMark for Eviva biopsy site marker is intended to be used only by physicians trained in open or percutaneous biopsy procedures.

Intended Use Environment

The TriMark for Eviva biopsy site markers are indicated for use in clinical settings for surgical procedures.

Patient Target Group

Patients undergoing open or percutaneous tissue biopsy procedure with the need to subsequently locate the biopsy site with imaging.

Contraindications

None known.

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 TriMark for Eviva biopsy site marker enables a medical professional to identify a specific location in soft tissue under mammography. 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.

Possible Adverse Effects

The patient can experience during and after the implant the following adverse effects:

- Pain
- Seroma
- Inflammation
- Blunt trauma
- Hematoma
- Hemorrhage/Bleeding/Blood loss/Minor vascular injury
- Infection
- Hypersensitivity/Allergic reaction
- Foreign body reaction
- Tissue damage
- Marker migration
- Perforation
- Needle Stick/Puncture
- Scar Tissue
- Sepsis

Summary of Safety and Clinical Performance

The Summary of Safety and Clinical Performance (SSCP) report for the TriMark for Eviva 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: 54200455TRIMARKNW

SSCP Document Number/Name: DHM-08855/TriMark and CeleroMark Summary of Safety and Clinical Performance

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

Warnings and Precautions

- There are possible adverse reactions when an object is implanted in the body. It is the responsibility of the physician to evaluate any risk or benefit prior to the use of this device.
- Potential complications of marker clip 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.
- The TriMark for Eviva deployment device is not recommended for use within the bore of an MRI magnet.
- The TriMark for Eviva biopsy site marker system is not intended for use in patients with breast implants.
- The TriMark for Eviva biopsy site marker system should be used only by persons having adequate training and familiarity with this procedure. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- This TriMark for Eviva biopsy site marker system should be used only by physicians trained in open or percutaneous biopsy procedures.
- **℞ONLY** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- The TriMark for Eviva 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 TriMark for Eviva biopsy site marker is not intended to be repositioned or recaptured after it has been deployed.
- Hematoma within the biopsy device can lead to marker adhesion, increasing the risk of marker drag out.
- Care should be taken to avoid damaging the cannula. Avoid operator or instrument contact with the TriMark for Eviva biopsy site marker system or the distal end of the device. Contact with the distal end may result in loss of sterility.
- The implanted TriMark for Eviva biopsy site marker is magnetic resonance imaging (MRI) conditional. The implanted TriMark for Eviva biopsy site marker presents no additional risk to 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 may not be compatible with the TriMark for Eviva biopsy site marker system. 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 TriMark for Eviva biopsy site marker system. 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 inadequately cleaned and sterilized devices.

Material Information

Implantable

Model	Material/Composition
TRIMARK-EVIVA-2S-13 TRIMARK-EVIVA-2S-10	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 (99.3%)
TRIMARK-EVIVA-13 TRIMARK-EVIVA-10	Titanium Sponge Powder per ASTM F1580-18: Nitrogen, max ..... 0.02 Carbon, max ..... 0.03 Hydrogen, max ... 0.03 Iron, max..... 0.15 Oxygen, max ..... 0.40 Aluminum, max... 0.05 Silicon, max ..... 0.04 Chlorine, max ..... 0.20 Titanium ..... balance (99.08%)

Deployment device

The TriMark 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:

Component	CAS N°	EC N°
Cobalt	7440-48-4	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 to the Eviva breast biopsy system IFU for biopsy device instructions.

1. Prior to use of the TriMark for Eviva biopsy site marker system, inspect the protective packaging and device to verify that neither has been damaged during shipment. If it appears that the packaging has been compromised, do not use the device.
2. Remove the TriMark for Eviva biopsy site marker system from its protective packaging using sterile technique.
3. Remove the biopsy device from the introducer sheath.
4. Place the TriMark for Eviva biopsy site marker system through the hub of the introducer sheath.
5. Advance the TriMark for Eviva biopsy site maker system until the handle snaps to the hub.
6. Deploy the TriMark for Eviva biopsy site marker by advancing the deployment plunger all the way forward until it latches onto the handle.
7. Slowly remove the deployment device and introducer sheath as one unit from the breast and properly dispose.

Disposal Procedures

When it is necessary to dispose of any product, follow the local regulations.

Storage

Store at room temperature. 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 TriMark for Eviva biopsy site marker have been characterized using 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 TriMark for Eviva 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

Non-clinical testing has demonstrated that Hologic Inc.'s TriMark for Eviva biopsy site markers can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T)
- Maximum spatial field gradient of 5,700 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, Hologic, Inc.'s TriMark for Eviva biopsy site markers are 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.

In non-clinical testing, the image artifact caused by Hologic, Inc.'s TriMark for Eviva biopsy site markers extend 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.

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.

How Supplied

The TriMark for Eviva biopsy site marker system is sterilized by radiation and supplied preloaded 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 is represented by the following: YYYY represents the year MM represents the month DD represents the day

Patient Implant Card Instructions (For Healthcare Professionals)

TriMark for Eviva biopsy site markers are provided with an Implant Card and a 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:

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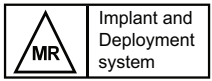
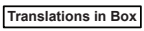
Tel: +32 2 711 46 80

CR
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
EC REP	Authorized Representative in the European Community	ISO 15223-1, Reference 5.1.2
LOT	Batch code	ISO 15223-1, Reference 5.1.5
REF	Catalogue number	ISO 15223-1, Reference 5.1.6
CE 2797	CE marking of conformity with notified body identification number	MDR Regulation (EU) 2017/745
	Do not use if package is damaged	ISO 15223-1, Reference 5.2.8
	Use-by Date	ISO 15223-1, Reference 5.1.4
	Manufacturer	ISO 15223-1, Reference 5.1.1
℞ ONLY	Prescription use only	FDA 21 CFR 801.109
	Do not re-use	ISO 15223-1, Reference 5.4.2
	Do not re sterilize	ISO 15223-1, Reference 5.2.6
STERILE R	Sterilized using irradiation	ISO 15223-1, Reference 5.2.4
 www.hologic.com/package-inserts	Consult instructions for use	ISO 15223-1:2016, Reference 5.4.3
QTY	Quantity	Hologic

Symbol	Description	Standard
	Conditional use for magnetic resonance imaging	ASTM F2503 Reference no. Table 2; 7.4.6.1; Fig 6,7
	Contains hazardous substances	ISO 15223-1, Reference 5.4.10
	Caution	ISO 15223-1, Reference 5.4.4
	Medical Device	ISO 15223-1, Reference 5.7.7
	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)
	Single sterile barrier system	ISO 7000-3707
	Single sterile barrier system with protective packaging outside	ISO 7000-3709
	Translations in Box	Hologic
	Patents	Hologic
	Unique Device Identifier	ISO 15223-1, Reference 5.7.10
	Country code for translation	ISO 3166

Symbol	Description	Standard
YYYY-MM-DD	Date format: YYYY represents the year MM represents the month DD represents the day	Hologic
MATL	Material	Hologic
	Warning	ISO 7010, Reference W001

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