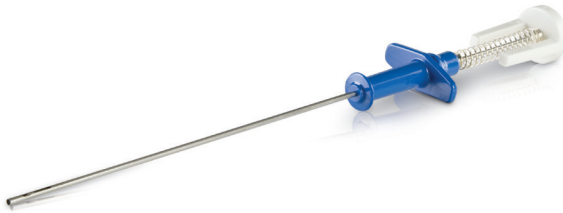
TriMark® for eviva®

Biopsy Site Identification System
Titanium Biopsy Site Marker



Instructions For Use

HOLOGIC®

This page is intentionally left blank

TriMark® for Eviva®
Biopsy Site Marker System

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 of the TriMark® biopsy site marker system for the Eviva® bopsy device system. It is not a reference to surgical techniques.

Indications

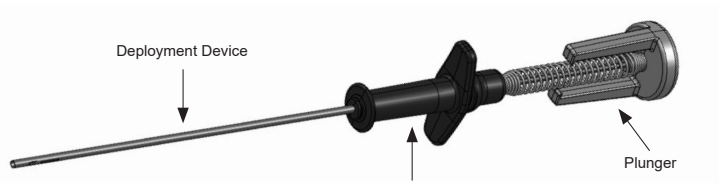
The TriMark for Eviva biopsy site marker system is indicated for use to mark an open or percutaneous biopsy site to radiographically mark the location of the biopsy site.

Contraindications

None known.

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.



Device Preparation and Use

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.

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 biopsy site marker system 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.
- Excess 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 voltage or movement but 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.

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.

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

For More Information

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
Belgium
Tel: +32 2 711 46 80

Symbols Used on Labeling

Authorized Representative in the European Community	EC REP
Batch code	LOT
Catalogue number	REF
CE marking of conformity with notified body identification number	CE 2797
Do not use if package is damaged	
Use by	
Manufacturer	
U.S. federal law restricts this device to sale by or on the order of a physician	Rx ONLY
Do not re-use	
Do not resterilize	
Sterilized using irradiation	STERILE R
Consult instructions for use	

Quantity	QTY

MAN-03485-002 Rev 006
07/2021

This page is intentionally left blank

HOLOGIC®

Hologic, Inc.
250 Campus Drive, Marlborough, MA 01752 USA
1-877-371-4372

EC REP

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

CE
2797

MAN-03485-002 Rev. 006
07/2021