ATEC® TriMark®

Titanium Biopsy Site Marker

Instructions for Use

HOLOGIC®

ATEC® TriMark®
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 ATEC® TriMark® biopsy site marker. It is not a reference to surgical techniques.

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

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Upon completion of the ATEC breast biopsy procedure, the user will have the option of using the ATEC TriMark biopsy site marker system by Hologic, Inc. Depending on the type of application (imaging modality) used to guide the breast biopsy, the user will follow one of the outlined processes for use of the ATEC TriMark biopsy site marker system. The three imaging modalities used to guide deployment of the ATEC TriMark biopsy site marker system include ultrasound (U/S), stereotactic x-ray (STX), and magnetic resonance imaging (MRI). There are two deployment methods for the ATEC TriMark biopsy site marker system associated with U/S and STX; both are described separately.

Device Description

The ATEC TriMark biopsy site marker system is a sterile, single use system comprised of a titanium marker and a deployment device. The deployment device consists of a rigid cannula, plunger, rigid push rod and handle. The ATEC TriMark biopsy site marker is located at the distal end of the deployment device. The ATEC TriMark biopsy site marker system may be used with imaging guidance (e.g., stereotactic x-ray, ultrasound and MRI). 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 or less, will not create an additional hazard or risk with respect to magnetic field-related interactions, movement/dislodgment, or heating.

The deployment device is offered in five versions. It is available for use with ATEC in 13cm and 36cm lengths, with options for compatibility with either a 9Ga or 12Ga biopsy device. Additionally, the deployment device is available in a 13cm length for use with the ATEC MR 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 ATEC TriMark markers (cork shape, left and hourglass shape, right)

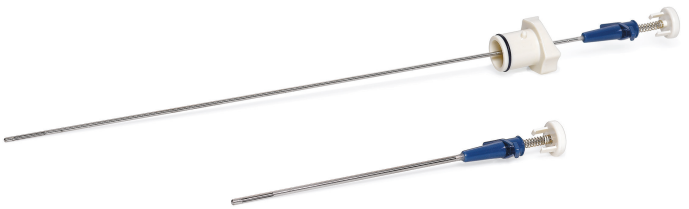


Figure 2: Representative Image of ATEC TriMark deployment devices

Biopsy Device Configurations			Imaging modality compatibility			Compatible biopsy device and gauge
Device model	**Deployment device length**	**Marker shape**	**Stereotactic (X-Ray)**	**Ultrasound**	**MRI**	
TRIMARK TD 1309	13 cm	Shape 1 (Cork)	X	X		For use with 9 Ga ATEC biopsy device
TRIMARKTD-2S-13-09	13 cm	Shape 2 (Hourglass)	X	X		
TRIMARK TD 3609	36 cm	Shape 1 (Cork)	X			
TRIMARKTD-2S-36-09	36 cm	Shape 2 (Hourglass)	X			
TRIMARK TD 1312	13 cm	Shape 1 (Cork)	X	X		For use with 12 Ga ATEC biopsy device
TRIMARKTD-2S-13-12	13 cm	Shape 2 (Hourglass)	X	X		
TRIMARK TD 3612	36 cm	Shape 1 (Cork)	X			
TRIMARKTD-2S-36-12	36 cm	Shape 2 (Hourglass)	X			
TRIMARK TD 13MR	13 cm	Shape 1 (Cork)			X	For use with 9 Ga ATEC MR biopsy device
TRIMARKTD-2S-13-MR	13 cm	Shape 2 (Hourglass)			X	

Indications

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

Intended Purpose

The ATEC TriMark biopsy site marker system is intended to be used to 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 ATEC breast biopsy system. The markers provide the user with the ability to mark permanently the location of the cavity where the breast biopsy was performed.

The markers are placed at the biopsy site under stereotactic, ultrasound, or magnetic resonance imaging (MRI) 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.

Intended User

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

Intended Use Environment

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

Patient Target Group

Patients undergoing open or percutaneous tissue biopsy procedures 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 ATEC TriMark biopsy site marker enables a medical professional to identify a specific location in soft tissue under mammography. The marker showed limited migration and enhanced visibility on mammographic imaging, which 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 ATEC TriMark 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: 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 ATEC TriMark deployment device is not recommended for use within the bore of an MRI magnet.
- The ATEC TriMark biopsy site marker system is not recommended for use in patients with breast implants.

- The ATEC TriMark procedure should be performed only by physicians 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 device 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 ATEC TriMark 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.
- If the deployment device is difficult to insert or remove from the biopsy device do not apply excessive force. Excessive force may cause damage or breakage of the deployment device which may result in a portion of the deployment device being left behind in the patient. If the deployment device cannot be easily removed from the biopsy device, remove the deployment device and the biopsy device as one unit.
- Marker position relative to established landmarks may change under mammography upon subsequent breast compressions.
- The ATEC TriMark biopsy site marker is not intended to be repositioned or recaptured after deployment.
- Excess hematoma within the biopsy cavity 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 ATEC TriMark biopsy site marker or the distal end of the depployment device.
- The implanted ATEC TriMark biopsy site marker is magnetic resonance imaging (MRI) conditional. The implanted ATEC TriMark 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 not authorized by Hologic, Inc., may not be compatible with the ATEC TriMark 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.
- Following the insertion of the marker deployment device, the console should NOT be put into the “Biopsy” mode.
- Dispose of all opened instruments whether used or unused.
- Do not resterilize and/or reuse the ATEC TriMark 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 using inadequately cleaned and sterilized devices.
- If deployment guide is not used for 36-09 or 36-12 devices, damage may occur to the deployment device, resulting in device malfunction.

Material Information

Implantable

Model	Permanent Material/Composition (%mass/mass)
TRIMARKTD-2S-13-09 TRIMARKTD-2S-13-12 TRIMARKTD-2S-36-09 TRIMARKTD-2S-36-12 TRIMARKTD-2S-13-MR	**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%)
TRIMARK TD 1309 TRIMARK TD 1312 TRIMARK TD 3609 TRIMARK TD 3612 TRIMARK TD 13MR	**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.

Compatibility

U/S			
Approach	Hand Piece Gauge	Biopsy Site Access	ATEC TriMark Device
Non Introducer Method	9G	NA	TRIMARK TD 1309 TRIMARKTD-2S-13-09
		NA	
	12G	NA	TRIMARK TD 1312 TRIMARKTD-2S-13-12
		NA	
ATEC Outer Cannula Introducer Method	9G	ATEC 0909-20 Outer Cannula	TRIMARK TD 1309 TRIMARKTD-2S-13-09
		ATEC 0909-12 Outer Cannula	
		ATEC 0912-20 Outer Cannula	
		ATEC 0912-12 Outer Cannula	
	12G	ATEC 1209-20 Outer Cannula	TRIMARK TD 1312 TRIMARKTD-2S-13-12
		ATEC 1212-20 Outer Cannula	
STX			
Approach	Hand Piece Gauge	Biopsy Site Access	ATEC TriMark Device
ATEC Outer Cannula Introducer Method	9G	ATEC 0909-20 Outer Cannula	TRIMARK TD 1309 TRIMARKTD-2S-13-09
		ATEC 0909-12 Outer Cannula	
		ATEC 0912-20 Outer Cannula	
		ATEC 0912-12 Outer Cannula	
	12G	ATEC 1209-20 Outer Cannula	TRIMARK TD 1312 TRIMARKTD-2S-13-12
		ATEC 1212-20 Outer Cannula	
ATEC Handpiece Introducer Method	9G	ATEC 0909-20 Handpiece	TRIMARK TD 3609 TRIMARKTD-2S-36-09
		ATEC 0909-12 Handpiece	
		ATEC 0912-20 Handpiece	
		ATEC 0912-12 Handpiece	
		ATEC 0914-20 Handpiece	
	12G	ATEC 1209-20 Handpiece	TRIMARK TD 3612 TRIMARKTD-2S-36-12
		ATEC 1212-20 Handpiece	
MRI			
Approach	Hand Piece Gauge	Biopsy Site Access	ATEC TriMark Device
ATEC Introducer Sheath Method	9G	ILS 0914-20	TRIMARK TD 13MR TRIMARKTD-2S-13-MR
		ILS 0914-12	

Ultrasound Application

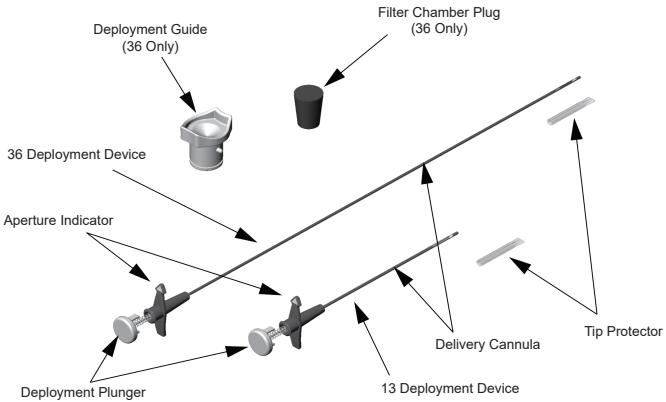
Non Introducer Method (13-12 and 13-09 only)

NOTE: Please refer to the ATEC breast biopsy system IFU for biopsy device instructions.

1. Prior to use of the ATEC TriMark 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. Carefully remove the ATEC TriMark biopsy site marker system from its protective packaging using sterile technique.

Figure A: ATEC TriMark Biopsy Site Marker System



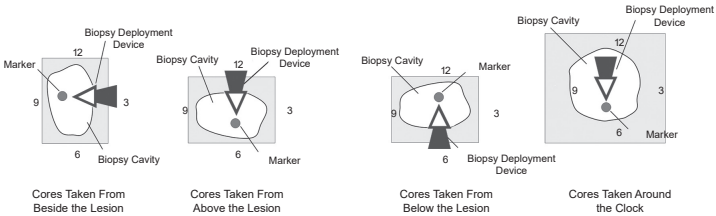
Note: Remove tip protector prior to use of the device.

3. Turn or activate the console to “Set Up” or “Lavage” mode.
4. Lavage the biopsy cavity thoroughly before insertion of the 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 handpiece from the breast and properly dispose.
8. Place the distal end of the deployment device into the needle tract that was created by the outer cannula.
9. Carefully advance the deployment device to the desired marker deployment location.
10. Locate the white directional arrow on the aperture indicator. This shows the orientation of the marker aperture and the direction the marker will deploy.
11. Rotate the aperture indicator so the white arrow is pointing towards the radial center of the biopsy cavity. (Figure B)
12. Deploy the marker towards the center of the biopsy cavity by advancing the deployment plunger with your thumb until it latches onto the aperture indicator.

13. After the audible and tactile click, release your thumb from the white plunger.
14. Rotate the aperture indicator 180 degrees.
15. Verify the deployment and proper position of the marker prior to removal of the device.

Slowly remove the deployment device from the breast and properly dispose.

Figure B: Radial Center of Biopsy Cavity



ATEC Outer Cannula Introducer Method (13-12 and 13-09 only)

NOTE: Please refer to the ATEC breast biopsy system IFU for biopsy device instructions.

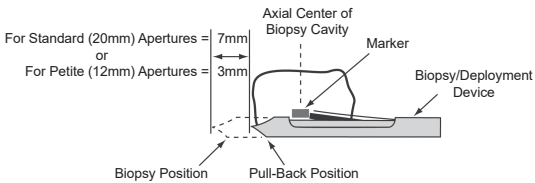
1. Prior to use of the ATEC TriMark biopsy site marker system, inspect the protective packaging and device to verify that neither has been damaged during shipment. If it appears that the packaging has been compromised, do not use the device.
2. Carefully remove the ATEC TriMark biopsy site marker system from its protective packaging using sterile technique.

Note: Remove 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 deployment device.
5. Disconnect the saline line at the proximal end of the Y-Valve and strip the line up to the hub.
6. While holding the hub firmly in one hand, rotate the handpiece 1/8 of a turn counter-clockwise and pull-back to separate it from the outer cannula.
7. Pull back the hub 7mm for 20mm aperture devices or 3mm for 12mm aperture devices. This will position the system to deploy the marker in the axial center of the biopsy cavity. (Figure C)
8. Rotate the hub so the white dot indicating needle aperture position is pointing towards the radial center of the biopsy cavity. (Figure B)

9. Place the distal end of the deployment device into the outer cannula through the hub.
10. Carefully advance the deployment device until it reaches a definitive stop at the distal tip of the outer cannula. Make sure this position is maintained throughout the deployment of the marker by holding it in place with your off hand.
11. Locate the white directional arrow on the aperture indicator and line it up with the white dot of the hub. This shows the orientation of the marker aperture and the direction the marker will deploy.
12. Deploy the marker towards the center of the biopsy cavity by advancing the deployment plunger with your thumb until it latches onto the aperture indicator.
13. After the audible and tactile click, release your thumb from the white plunger.
14. Rotate the aperture indicator 180 degrees.
15. Rotate the hub 180 degrees.
16. Verify the deployment and proper position of the marker prior to removal of the device.
17. Slowly remove the deployment device and outer cannula/hub as one unit from the breast and properly dispose.

Figure C: Axial Center of Biopsy Cavity



Stereotactic Application

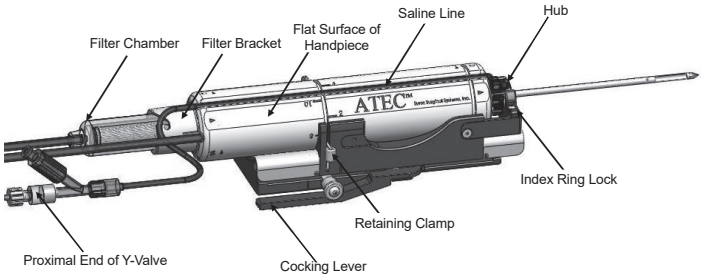
ATEC Outer Cannula Introducer Method (13-12 and 13-09 only)

NOTE: Please refer to the ATEC breast biopsy system IFU for biopsy device instructions.

1. Prior to use of the ATEC TriMark 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. Carefully remove the ATEC TriMark biopsy site marker system from its protective packaging using sterile technique.

3. Note: Remove tip protector prior to use of the device.
4. Turn or activate the console to “Set Up” or “Lavage” mode.
5. Lavage the biopsy cavity thoroughly before insertion of the deployment device.
6. Pull back the adapter 7mm for 20mm aperture devices or 3mm for 12mm aperture devices. This will position the system to deploy the marker in the axial center of the biopsy cavity. (Figure C)
7. Rotate the handpiece so the flat surface is pointing towards 12 o’clock.
8. Disconnect the saline line at the proximal end of the Y-Valve and strip the line up to the hub.
9. Rotate the handpiece so the flat surface is pointing towards the radial center of the biopsy cavity. The flat surface shows where the needle aperture is pointing. (Figure B)
10. Engage one index ring lock to hold the hub in place. (Figure D)
11. Rotate the handpiece 1/8 of a turn counter-clockwise.
12. Unlock the retaining clamp, and pull the handpiece back to separate it from the hub. (Figure D)
13. Place the distal end of the deployment device into the outer cannula through the hub.
14. Carefully advance the deployment device until it reaches a definitive stop at the distal tip of the outer cannula. Make sure this position is maintained throughout the deployment of the marker by holding it in place with your off hand.
15. Locate the white directional arrow on the aperture indicator and line it up with the white dot of the hub. This shows the orientation of the marker aperture and the direction the marker will deploy.
16. Deploy the marker towards the center of the biopsy cavity by advancing the deployment plunger with your thumb until it latches onto the aperture indicator.
17. After the audible and tactile click, release your thumb from the white plunger.
18. Disengage the index ring lock.
19. Rotate the aperture indicator 180 degrees.
20. Rotate the hub 180 degrees.
21. Engage one index ring lock to hold the hub in place.
22. Initial pull-back of deployment device and outer cannula/hub should be controlled by slowly moving the adapter back 20mm.
23. Verify the deployment and proper position of the marker prior to removal of the device.
24. Disengage the index ring lock.
25. Slowly remove the deployment device and outer cannula/hub as one unit from the breast and properly dispose.
26. Slowly decompress the breast.

Figure D: ATEC Handpiece & Stereotactic Adapter Descriptions



ATEC Handpiece Introducer Method (36-12 and 36-09 only)

NOTE: Please refer to the ATEC breast biopsy system IFU for biopsy device instructions.

1. Prior to use of the ATEC TriMark 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. Carefully remove the ATEC TriMark biopsy site marker system from its protective packaging using sterile technique.

Note: Remove 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 deployment device.
5. Pull back the adapter 7mm for 20mm aperture devices or 3mm for 12mm aperture devices. This will position the system to deploy the marker in the axial center of the biopsy cavity. (Figure C)
6. Disconnect the saline line at the proximal end of the Y-Valve.
7. Remove the filter chamber from the proximal end of the handpiece.
8. Remove the tissue filter from the filter chamber and replace it with the filter chamber plug.
9. Remove deployment guide from the protective packaging.
10. Attach the deployment guide to the filter bracket of the handpiece.
11. Rotate the handpiece so the flat surface is pointing towards the radial center of the biopsy cavity. The flat surface shows where the needle aperture is pointing. (Figure A)
12. Engage one index ring lock to hold the handpiece in place. (Figure D)

13. Carefully advance the deployment device through the deployment guide until it reaches a definitive stop at the distal tip of the outer cannula. Make sure this engagement is maintained throughout the deployment of the marker by holding it in place with your off hand.
14. Locate the white directional arrow on the aperture indicator and line it up with the flat surface of the handpiece. This shows the orientation of the marker aperture and the direction the marker will deploy.
15. Deploy the marker towards the center of the biopsy cavity by advancing the deployment plunger with your thumb until it latches onto the aperture indicator.

Note: Following the insertion of the marker deployment device, the console should NOT be put back into “biopsy” mode.

16. After the audible and tactile click, release your thumb from the white plunger.
17. Disengage the index ring lock. (Figure D)
18. Rotate the aperture indicator 180 degrees.
19. Rotate the handpiece 180 degrees.
20. Initial pull-back of deployment device and handpiece should be controlled by slowly moving the adapter back 20mm.
21. Verify the deployment and proper position of the marker prior to removal of the device.
22. Unlock the retaining clamp. (Figure D)
23. Slowly remove the deployment device and handpiece as one unit from the breast and properly dispose.
24. Slowly decompress the breast.

MRI Application

ATEC Introducer Sheath Method (13-MR only)

NOTE: Please refer to the ATEC breast biopsy system IFU for biopsy device instructions.

1. Prior to use of the ATEC TriMark 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. Carefully remove the ATEC TriMark biopsy site marker system from its protective packaging using sterile technique.

Note: Remove 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 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 handpiece from the Introducer Sheath and properly dispose.
8. Place the distal end of the deployment device through the Introducer Sheath.
9. Carefully advance the deployment device until the aperture indicator contacts the Introducer Sheath hub. Make sure this position is maintained throughout the deployment of the marker by holding it in place with your off hand.
10. Locate the white directional arrow on the aperture indicator. This shows the orientation of the marker aperture and the direction the marker will deploy.
11. Rotate the aperture indicator so the white arrow is pointing towards the radial center of the biopsy cavity. (Figure A)
12. Deploy the marker towards the center of the biopsy cavity by advancing the deployment plunger with your thumb until it latches onto the aperture indicator.
13. After the audible and tactile click, release your thumb from the white plunger.
14. Rotate the aperture indicator 180 degrees.
15. Slowly remove the deployment device from the breast and properly dispose.
16. Verify the deployment and proper position of the marker prior to removal of the Introducer Sheath.

MRI Artifacts

Artifacts for the ATEC TriMark 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 ATEC TriMark 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

ATEC TriMark Biopsy Site Markers

Non-clinical testing has demonstrated that Hologic Inc.'s ATEC TriMark 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 ATEC TriMark 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 ATEC TriMark 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.

ATEC TriMark Deployment Device

Non-clinical testing has demonstrated that the deployment device used for Hologic, Inc.'s ATEC TriMark TD-13-MR and TriMark TD-2S-13-MR Biopsy Site Markers 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.

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.

How Supplied

The ATEC TriMark biopsy site marker system is sterilized 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)

ATEC TriMark biopsy site markers are provided with an Implant Card and a patient 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

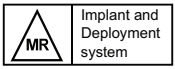
Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium
Tel: +32 2 711 46 80

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 Mark with Notified Body reference 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
Rx 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, Reference 5.4.3 Hologic
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
	Caution	ISO 15223-1, Reference 5.4.4
	Contains hazardous substances	ISO 15223-1, Reference 5.4.10
	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
YYYY-MM-DD	Date format: YYYY represents the year MM represents the month DD represents the day	Hologic
	Unique Device Identifier	ISO 15223-1, Reference 5.7.10

Symbol	Description	Standard
	Country code for translation	ISO 3166
	Material	Hologic
	Warning	ISO 7010, Reference W001

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