ATEC® TriMark®

Biopsy Site Identification System
Titanium Biopsy Site Marker

Instructions for Use

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

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.

Indications

The ATEC TriMark 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 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/dislodgement, or heating.

Safety information for MRI procedures should be performed according to the following guidelines:

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.

Compatibility

U/S			
Approach	Hand Piece Gauge	Biopsy Site Access	ATEC TriMark Device
Non Introducer Method	9G	NA	TriMark TD 13-09 TriMark TD-2S-13-09
		NA	
	12G	NA	TriMark TD 13-12 TriMark TD-2S-13-12
		NA	
ATEC Outer Cannula Introducer Method	9G	ATEC 0909-20 Outer Cannula	TriMark TD 13-09 TriMark TD-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 13-12 TriMark TD-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 13-09 TriMark TD-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 13-12 TriMark TD-2S-13-12
		ATEC 1212-20 Outer Cannula	
ATEC Handpiece Introducer Method	9G	ATEC 0909-20 Handpiece	TriMark TD 36-09 TriMark TD-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 36-12 TriMark TS-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 ILS 0914-20-OB	TriMark TD 13-MR TriMark TD-2S-13-MR
		ILS 0914-12 ILS 0914-12-OB	

Ultrasound Application

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

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 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 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.

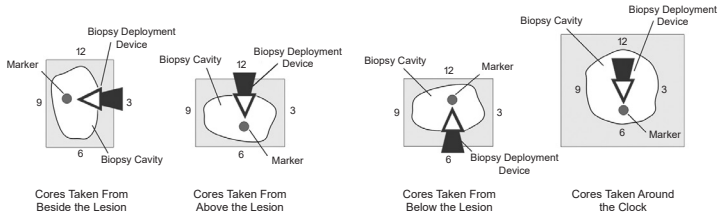
13. After the audible and tactile click, release your thumb from the white plunger.

14. Rotate the aperture indicator 180 degrees.

15. Verify the deployment and proper position of the marker prior to removal of the device.

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

Figure A: Radial Center of Biopsy Cavity



Ultrasound Application

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

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 A)

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 B: ATEC TriMark Description

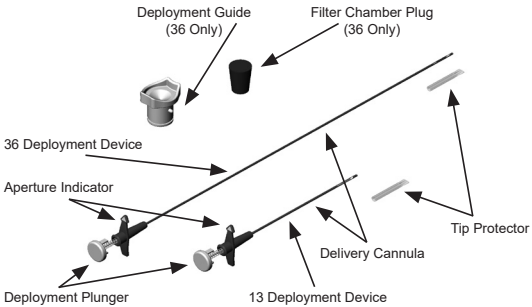
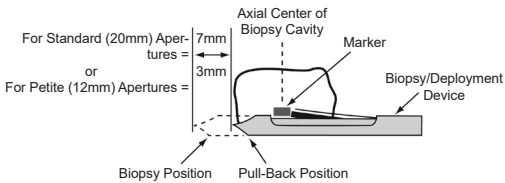


Figure C: Axial Center of Biopsy Cavity



Stereotactic Application

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

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. Rotate the handpiece so the flat surface is pointing towards 12 o’clock.

7. Disconnect the saline line at the proximal end of the Y-Valve and strip the line up to the hub.

8. 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)

9. Engage one index ring lock to hold the hub in place. (Figure D)

10. Rotate the handpiece 1/8 of a turn counter-clockwise.

11. Unlock the retaining clamp, and pull the handpiece back to separate it from the hub. (Figure D)

12. Place the distal end of the deployment device into the outer cannula through the hub.

13. 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.

14. 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.

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.

16. After the audible and tactile click, release your thumb from the white plunger.

17. Disengage the index ring lock.

18. Rotate the aperture indicator 180 degrees.

19. Rotate the hub 180 degrees.

20. Engage one index ring lock to hold the hub in place.

21. Initial pull-back of deployment device and outer cannula/hub should be controlled by slowly moving the adapter back 20mm.

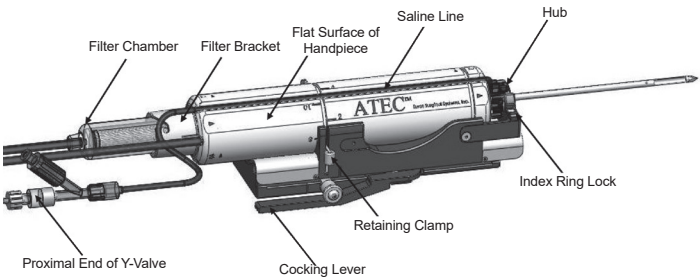
22. Verify the deployment and proper position of the marker prior to removal of the device.

23. Disengage the index ring lock.

24. Slowly remove the deployment device and outer cannula/hub as one unit from the breast and properly dispose.

25. Slowly decompress the breast.

Figure D: ATEC Handpiece & Stereotactic Adapter Descriptions



Stereotactic Application

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

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)

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.

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.
- R_{X} **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.

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.

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

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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

MR Conditional	

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