Mammotome revolve

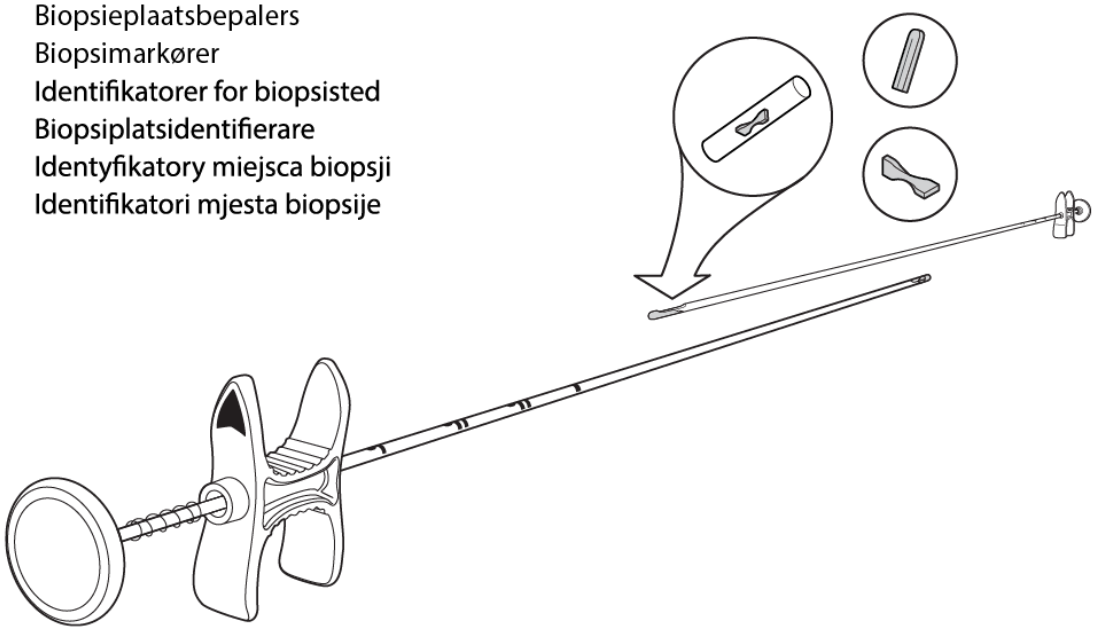
mammomark

8G | 10G

Biopsy Site Identifiers

Identificateurs de site de biopsie
Marker für Probeentnahmestellen
Identificatori per sito di biopsia
Marcadores do Local da Biópsia
Identificadores de sitio de biopsia
Biopsieplaatsbepalers
Biopsimarkører
Identifikatorer for biopsisted
Biopsiplatsidentifierare
Identyfikatory miejsca biopsji
Identifikatori mjesta biopsije

Identifikátory místa biopsie
Bioptické markery
생검 부위 식별기
生検部位アイデンティファイア
活检部位标识



Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences.

Important: This package insert is designed to provide instructions for use of the MammoMark, Biopsy Site Identifiers instrument. It is not a reference to surgical techniques.

DEVICOR
MEDICAL PRODUCTS, INC.

Instructions

Indications
The MammoMARK Biopsy Site Identifier is intended for use after an open surgical or percutaneous breast biopsy procedure to mark the biopsy site.

Contraindications
Do not implant in infected areas.

Though rare, hypersensitivity or an immune response to the MammoMARK device may occur. The safety and efficacy of the MammoMARK device have not been established for patients who have known allergies to bovine products, collagen and/or collagen products. The physician should closely monitor the patient for such a reaction and treat accordingly.

Undesirable Side Affects
Although low, a potential for foreign body reaction is possible with use of MammoMARK markers. As with any implanted device, the implant site should be monitored for any signs of irritation or reaction following the surgical procedure.

Potential for puncturing of breast implants exists with use of the MammoMARK markers. Use caution when inserting near a breast implant to avoid puncture of the implant capsule.

When using a collagen biopsy site marker, there should be no reason for collagen to contaminate the tissue for biopsy as it is placed after the tissue is removed. However, the patient record should include the use of a collagen marker information for follow up biopsies due to the potential use of Congo red stain in pathology which can exhibit similar characteristics on collagen as amyloidosis.

Infection is a possible adverse reaction as a result of any surgical procedure. Doctors should monitor patient to ensure no sign of infection following procedure.

The radiopaque tip of the MammoMARK applicator shaft may shear when the marker applicator is removed independently from the probe. The probability of a tip shear can increase as a result of the following:

- Improper deployment of the collagen plug from a failure to align the MammoMARK applicator as specified
- Inserting beyond the appropriate color depth indicator band.
- Diagnostic tissue remaining in biopsy probe needle aperture during marker insertion and deployment.

Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize.

Post procedure stereotactic (x-Ray) images may indicate marker migration has occurred. This is predominantly the result of varying techniques of breast compression and breast tissue density. Care should be taken to use same technique and targeting measurements for post procedure images.

Potential for removal of the clip during excisional surgery exists with biopsy site markers. Doctors should take care to properly locate prior marker to minimize opportunity of unintended removal during surgical excision procedure.

Device Description

Product Code	Product Description	Gauge Size	Marker Shape	Applicator	Deployment	Insertion	Table
MMK0801	MammoMARK for 8G revolve probes	8G	Bowtie	Flexible	Side Deploy	Probe	Table 1
MMK0802	MammoMARK for 8G revolve probes	8G	U-shape	Flexible	Side Deploy	Probe	Table 1
MMK1001	MammoMARK for 10G revolve probes	10G	Bowtie	Flexible	Side Deploy	Probe	Table 1
MMK1002	MammoMARK for 10G revolve probes	10G	U-shape	Flexible	Side Deploy	Probe	Table 1

The MammoMARK Biopsy Site Identifiers are composed of a bioresorbable collagen plug embedded with a non-resorbable permanent radiopaque titanium wire marker. Each MammoMARK Site Identifier is packaged sterile in a flexible, disposable applicator for single patient use (See Illustration 2).

The packaging also includes a sterile marker sheath at the distal end of the applicator shaft designed to retain the marker within the applicator shaft prior to use with Mammotome revolve Biopsy Probes.

The MammoMARK applicator shafts are marked with 6 depth indicator bands: 3 for use with the specimen management system ON the probe (solid band lines marked with numbered longitudinal stripe in corresponding gauge color) and 3 for use with the specimen management system OFF (solid band marked in corresponding gauge colors) (See Illustration 1). Each depth indicator band is used to indicate depth confirmation of the applicator device when using with Mammotome revolve Biopsy Probes.

Illustration 1. MammoMark Applicator Shaft Depth Indicator Bands

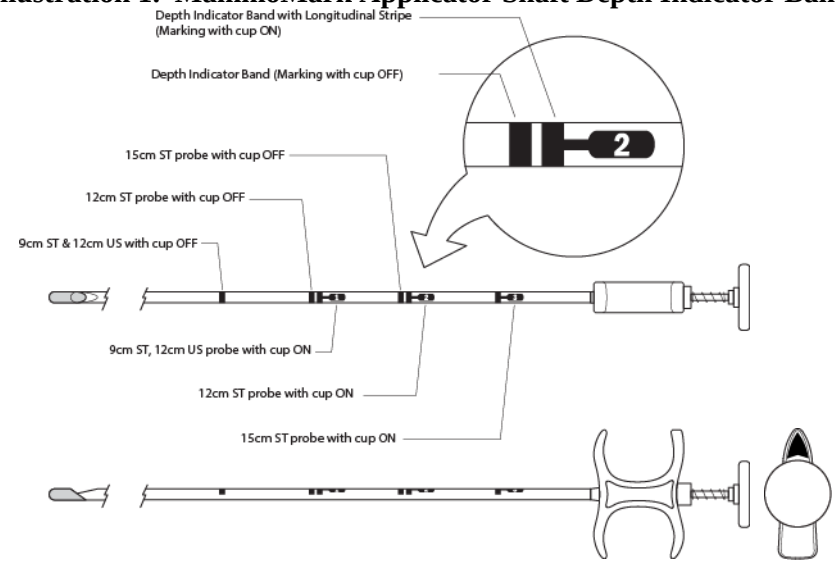
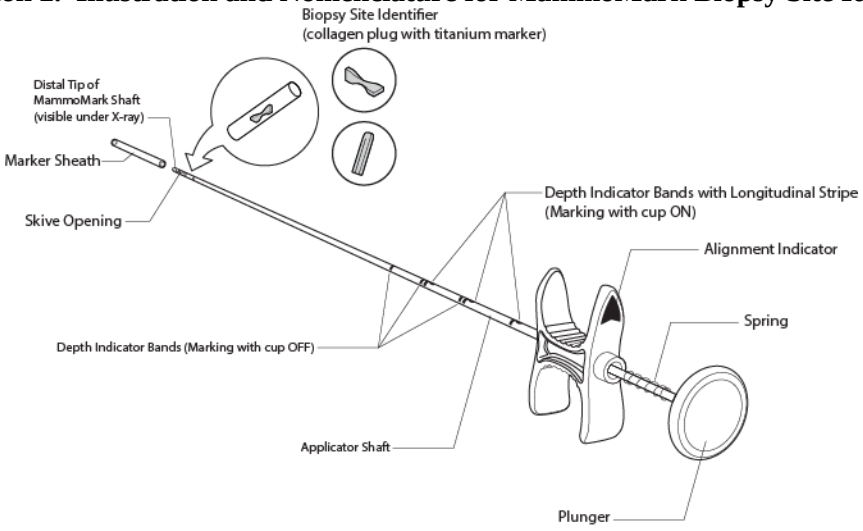


Illustration 2. Illustration and Nomenclature for MammoMark Biopsy Site Identifiers



- Distal Tip of MammoMARK Shaft (visible under X-ray)
- Biopsy Site Identifier (collagen plug with titanium marker)
- Marker Sheath
- Solid Color Depth Indicator Bands (Marking with cup OFF)
    + Orange (8G) / Blue (10G) indicates marker length 9 cm ST, 12 cm US
    + Purple indicates marker length 12 cm ST
    + Black indicates marker length 15 cm ST
- Depth Indicator Bands with numbered Longitudinal Stripe in Corresponding Colors for Gauge Size Indication (Marking with cup ON)
    + Orange (8G) / Blue (10G) indicates marker length 9 cm ST, 12 cm US
    + Purple indicates marker length 12 cm ST
    + Black indicates marker length 15 cm ST
- Applicator Shaft
- Alignment Indicator

- Spring
- Plunger

The MammoMARK Tissue Markers are designed for use with Mammotome revolve Biopsy Probes. At the completion of a percutaneous breast biopsy procedure, the MammoMARK collagen plug is deployed into the biopsy site through the biopsy probe. After deployment, a spring retracts the plunger, leaving the collagen plug and marker in place.

Because of its absorbent characteristics, the MammoMARK collagen plug swells within the cavity when infused with tissue fluids. The collagen is slowly absorbed, and the radiopaque marker is left behind as the permanent indicator of the biopsy site. Once placed, the different shaped markers will allow the physician to distinguish between biopsy sites for patients who require multiple biopsies in the same breast. The collagen plug of the biopsy site identifier is temporarily visible on ultrasound, while the titanium marker is permanently visible under x-ray and MRI imaging. To facilitate proper evaluation of subsequent biopsies, the pathologist should be made aware of the presence of the biopsy site identifier in the biopsy site.

Warnings and Precautions

- This device should be used only by physicians trained in percutaneous breast biopsy procedures. Please read all information carefully. Refer also to the Users Instructions for the proper use of the Mammotome revolve Biopsy Probe.
- Do not use the MammoMARK device if the package is found opened, punctured, torn or tampered with, as sterility may be compromised.
- Store the MammoMARK device in a clean, dry and protected area.
- Do not use the MammoMARK device if the applicator shaft or distal tip is twisted or kinked. Avoid operator or instrument contact with the distal end of the device. The marker sheath can be used to avoid contact with the distal end of the device.
- If significant resistance is met during the advancement of the MammoMARK prior to reaching the appropriate colored depth indicator band, remove the probe and the marker to inspect the integrity of the distal tip of the marker device and repeat insertion with a new marker.
- Failure to align the MammoMARK applicator as specified may result in improper deployment of the collagen plug.
- Do not use product beyond the expiration date.
- Biopsy Probe devices vary by manufacturer. If using MammoMARK Tissue Markers through devices other than Mammotome revolve, verify compatibility prior to initiating a procedure including, but not limited to, comparing the respective device diameters for proper fit and the marker aperture – probe aperture alignment and referring to such other device manufacturers' package inserts for instructions for use.
- Dispose of all opened packages whether used or unused.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- If the probe's sample aperture is outside the breast, a tissue marker cannot be used.

MR Safety Information for Device

MammoMARK: Static Field

MammoMARK Devices were determined to be MR Conditional according to information provided in the following ASTM standard. Magnetic Resonance Imaging (MRI) procedures should also be performed according to the following guidelines provided by the American Society for Testing and Materials (ASTM) International, Designation: F 2503-05.Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 19428, 2005.
Non-clinical testing has demonstrated the permanent marker of the biopsy site identifier of the MammoMARK devices is MR Conditional. It can be scanned safely under the following conditions and will not create an additional hazard or risk with respect to magnetic field-related interactions or heating:

- Static magnetic field of 3.0 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less

MammoMARK: Radiofrequency (RF) Fields

While the **MammoMARK devices** will be used in the MRI Environment, they will not be used during actual MR Imaging. The patient will be moved out of the magnet bore, and then the deployment device will be used to place the marker. As such, they will not be exposed to an MR imaging procedure or RF heating.

MR Safety Information for Biopsy Site Identifier

Static Field

The **MammoMARK Biopsy Site Identifiers** were determined to be MR Conditional according to information provided in the following ASTM standard. Magnetic Resonance Imaging (MRI) Procedures should also be performed according to the following guidelines provided by American Society for Testing and Materials (ASTM) International, Designation: F 2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 19428, 2005.

Non-clinical testing has demonstrated the permanent marker in the biopsy site identifier of the MammoMARK is MR Conditional. It can be scanned safely under the following conditions and will not create an additional hazard or risk with respect to magnetic field-related interactions or heating:

- Static magnetic field of 3.0 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 3.05 W/ kg for 20 minutes of scanning

Radiofrequency (RF) Field

In non-clinical testing, the permanent marker of the biopsy site identifier produced a temperature rise of less than 0.23°C at a maximum whole body averaged specific absorption rate (SAR) of 3.05W/kg for 20 minutes of MR scanning in a (3 Tesla) (Magnetom Trio) (Siemens Medical Solutions) MR scanner.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the MammoMARK device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

The biopsy site identifier does not exhibit magnetic field interactions with respect to translational force or torque during exposure to a shielded 3.0 Tesla MRI system (maximum spatial gradient, 720 Gauss/cm).

MRI Artifacts

Artifacts for the biopsy site identifier have been characterized using a 3.0 Tesla MR system and T1 weighted, spin echo and gradient echo pulse sequences. Based on this information, MR imaging quality may be slightly compromised if the area of interest is in the exact same area as the biopsy site identifier.
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 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 MR images will be smaller for MR systems with lower static magnetic field strengths using the same imaging parameters as those operating at higher static magnetic field strengths.

Instructions for Use of MammoMARK Tissue Markers with Mammotome revolve Biopsy Probes

Device Description	Product Codes	Table
MammoMARK MMK devices used with MAMMOTOME revolve Biopsy Probes	MMK0801 MMK0802 MMK1001 MMK1002	Table 1

Table 1: Instructions for Use of MammoMARK Tissue Markers with Mammotome revolve Biopsy Probes

Procedure Step	Instruction For Use	Troubleshooting	Product/Procedure/Patient	Potential Undesirable Side Effect
Pre-insertion	1. Ensure the tissue marker being used is the correct type for use with the selected gauge needle and the Mammotome revolve Biopsy Probe.			
	2. Inspect the package to ensure the package integrity has not been compromised. If packaging is compromised, dispose and begin procedure with new device.	Open packaging	This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. Do not use the MammoMARK device if the package is found opened, punctured, torn or tampered with, as sterility may be compromised. Do not use product beyond the expiration date. Store the MammoMARK device in a clean, dry and protected area.	Contamination of the device may lead to injury, illness, or death of the patient. This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize.

Procedure Step	Instruction For Use	Troubleshooting	Product/Procedure/Patient	Potential Undesirable Side Effect
			Dispose of all opened packages whether used or unused.	
	3. Remove the MammoMARK Tissue Marker and folder from the package using standard aseptic technique. To remove, lift tab at tissue marker handle and slide marker out of folder. Remove marker sheath prior to insertion into probe.		Avoid operator or instrument contact with the distal end of the device. The marker sheath can be used to avoid contact with the distal end of the device.	Contamination of the device may lead to injury, illness, or death of the patient. Use aseptic technique.
	4. Check to ensure that the distal end of the MammoMARK has not been damaged, kinked, or bent. Dispose of MammoMARK Tissue Marker if damaged. In order to preserve sterility, do not contact the distal end of the tissue marker.	Damaged tip	Special care should be taken to avoid twisting or kinking the applicator shaft.	Do not use if tip is bent or damaged to ensure ease of marker deployment and applicator retraction.
	5. It is recommended to clear the probe of any remaining diagnostic tissue or fluids prior to marker insertion and deployment.			
	6. Retract the cutter from the Mammotome revolve Biopsy Probe. **Note:** Ensure probe sample aperture is fully open for marker placement. If the variable aperture setting is being used on the Mammotome revolve Biopsy System, it must be changed to the full aperture setting for marker placement. **Note:** Prior to marker deployment, the biopsy probe can be pulled back up to 1 cm.		Markers and devices vary from manufacturer to manufacturer. If using MammoMARK in devices other than MAMMOTOME, verify compatibility prior to initiating a procedure including, but not limited to, comparing the respective device diameters for proper fit and the aperture-aperture alignment and referring to such other device manufacturers' package inserts for instructions for use.	Incompatibility.

Procedure Step	Instruction For Use	Troubleshooting	Product/Procedure/Patient	Potential Undesirable Side Effect
	7. If the specimen management system is ON, remove the marker port plug from the marker chamber port (See Illustration 3).			
Insertion	8. Place the MammoMARK Tissue Marker applicator into the Mammotome revolve Biopsy Probe Marker Chamber Port. Advance the MammoMARK Tissue Marker until the appropriate colored depth indicator band on the MammoMARK Tissue Marker shaft is aligned with the proximal edge of the specimen management system (See Illustration 4, 5). **Note:** Ensure "M" indicator on the probe is aligned with the marker chamber port for proper tissue marker insertion (See illustration 3). If the specimen management system is OFF, be sure to insert the marker into the larger opening at the proximal end of the probe (See Illustration 4). Advance the MammoMARK Tissue Marker until the appropriate colored depth indicator band on the MammoMARK Tissue Marker shaft is aligned with the proximal end of the probe body (See Illustration 4).	High Insertion Force / Tip shear	If significant resistance is met during the advancement of the MammoMARK Tissue Marker prior to reaching the colored depth indicator band, remove the marker to inspect the integrity of the distal tip of the marker device and consider conducting a "clear probe" before inserting a new marker device. Do not insert beyond appropriate band or tip damage may occur. See Illustrations 4 & 5 for proper seating of the tissue marker with the specimen management system ON and OFF. If tissue remains in the probe upon insertion of the MammoMARK applicator it may result in the distal end of the MammoMARK ramping out of the probe needle aperture. Use caution when inserting near a breast implant to avoid puncture of the implant capsule. If the probe's sample aperture is outside the breast, a tissue marker cannot be used.	The radiopaque tip of the MammoMARK applicator shaft may shear when the marker applicator is removed independently from the probe. The probability of a tip shear can increase as a result of the following: - Improper deployment of the collagen plug from a failure to align the MammoMARK applicator as specified - Inserting beyond the appropriate color depth indicator band. - Diagnostic tissue remaining in biopsy probe needle aperture during marker insertion and deployment.

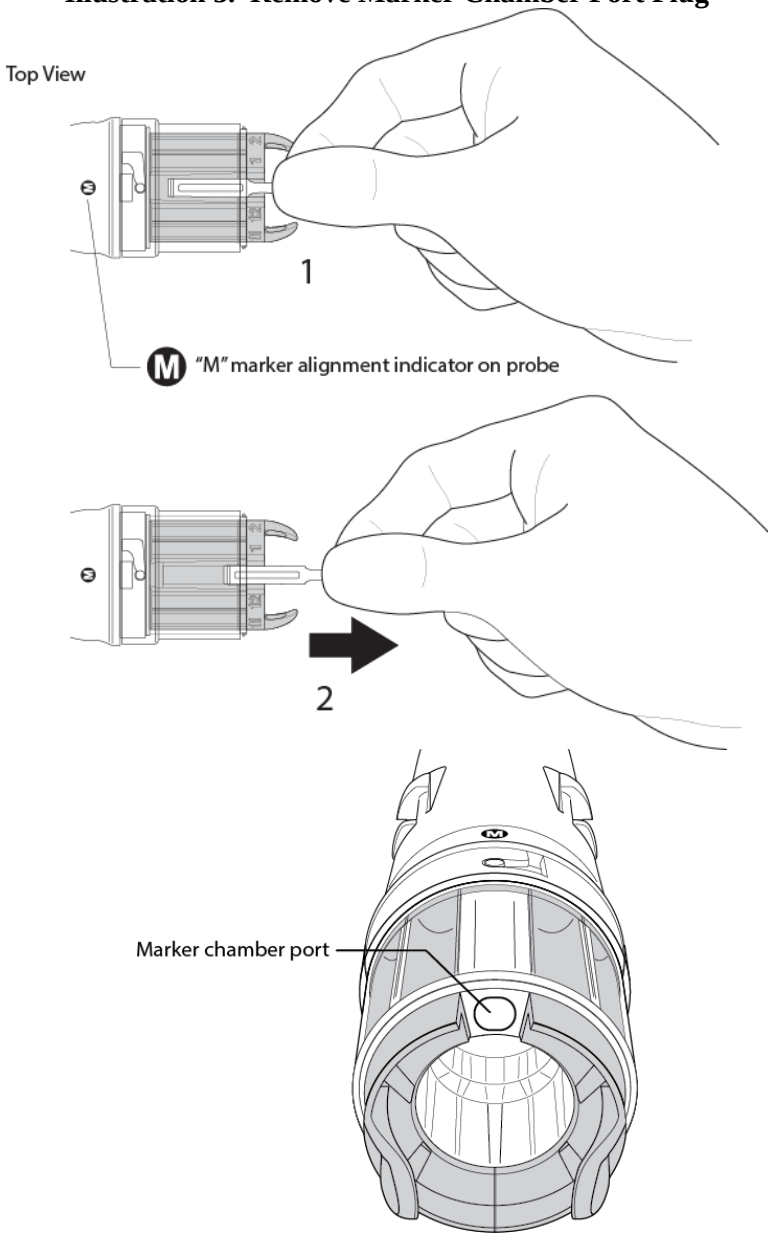
Procedure Step	Instruction For Use	Troubleshooting	Product/Procedure/Patient	Potential Undesirable Side Effect
	9. Position alignment indicator on the MammoMARK Tissue Marker handle and the longitudinal stripe on the MammoMARK shaft with the position relative to the Mammotome revolve probe's sample aperture orientation.	Deployment / Tip shear	DO NOT activate the probe cutter or other clinical functions while a marker is inserted in the probe. Take care to completely remove the marker out of the probe before activating any of the holster's clinical functions. Failure to align the MammoMARK applicator as specified may result in improper deployment of the biopsy site identifier. Do not activate vacuum. Vacuum is not required for marker deployment.	The radiopaque tip of the MammoMARK applicator shaft may shear when the marker applicator is removed independently from the probe. The probability of a tip shear can increase as a result of the following: - Improper deployment of the collagen plug from a failure to align the MammoMARK applicator as specified - Inserting beyond the appropriate color depth indicator band. - Diagnostic tissue remaining in biopsy probe needle aperture during marker insertion and deployment.
Deployment	10. Grasp the tissue marker handle and, using firm, but gentle force, advance the plunger forward completely until it contacts the finger tabs on the handle to deploy the biopsy site identifier into the biopsy cavity. **Note:** Ensure the alignment indicator on the tissue marker handle ALWAYS remains in the position corresponding with the probe's sample aperture orientation.	High Marker Deployment Force Marker Stuck in Probe	Failure to align the MammoMARK applicator as specified may result in improper deployment of the collagen plug. If excessive resistance is met during deployment, check the alignment of the MammoMARK applicator as specified in step 9.	Difficult or inaccurate deployment. The radiopaque tip of the MammoMARK applicator shaft may shear when the marker applicator is removed independently from the probe. The probability of a tip shear can increase as a result of the following: - Improper deployment of the collagen plug from a failure to align the MammoMARK applicator as specified - Inserting beyond the appropriate color depth indicator band. - Diagnostic tissue remaining in biopsy probe needle aperture during marker insertion and deployment.
Applicator removal	11. After deployment, release pressure from plunger to allow spring to retract plunger away from the finger tabs on the handle.	Difficult Removal / Tip Shear	If significant resistance is met during the rotation of the Mammotome probe, remove the MammoMARK applicator and Mammotome probe together as a single unit from the site and obtain images to	The radiopaque tip of the MammoMARK applicator shaft may shear when the marker applicator is removed independently from the probe. The probability of a tip shear

Procedure Step	Instruction For Use	Troubleshooting	Product/Procedure/Patient	Potential Undesirable Side Effect
	12. Rotate the Mammotome revolve probe body or thumbwheel 90 to 180 degrees to position the sample aperture away from the deployed biopsy site identifier. 13. Remove the MammoMARK applicator and the Mammotome revolve Biopsy Probe together as a single unit from the site and obtain images to confirm marker placement.		confirm marker placement. Significant resistance during the removal of the MammoMARK applicator with the Mammotome probe may require additional intervention.	can increase as a result of the following: - Improper deployment of the collagen plug from a failure to align the MammoMARK applicator as specified - Inserting beyond the appropriate color depth indicator band. - Diagnostic tissue remaining in biopsy probe needle aperture during marker insertion and deployment.
Post procedure	14. Record the lot number from the MammoMARK Tissue Marker package and place it in the patient's record.			
Post procedure		Infection		Infection is a possible occurrence as a result of any surgical procedure if aseptic technique is not employed.
Post procedure		Potential Foreign Body Reaction		
Post procedure		Hypersensitivity	Hypersensitivity to any implant may occur. The safety and efficacy of the MammoMARK device have not been established for patients who have known allergies to bovine products, collagen and/or collagen products. Precautions including pre-operative consult information and availability of treatment should a hypersensitivity reaction occur.	As with any implanted device, the implant site should be monitored for any signs of irritation or reaction following the surgical procedure.

Procedure Step	Instruction For Use	Troubleshooting	Product/Procedure/Patient	Potential Undesirable Side Effect
Post procedure		Displacement of microcalcification		The insertion of the marker may cause existing microcalcifications to move, as a result of the insertion. Confirm the location of all microcalcification with images pre- and post-marking.
Post procedure		Marker Migration	Post procedure stereotactic (x-Ray) images may indicate marker migration has occurred. This is predominantly the result of varying techniques of breast compression and breast tissue density. Care should be taken to use same technique and targeting measurements for post procedure images.	Marker may migrate from intended placement location. Confirm placement through images obtained after deployment.
Post procedure		More than one Titanium Element within the Marker	Each marker device should have a single titanium element. If more than one titanium element is observed, note on the patient record and notify the manufacturer.	Confirm single titanium element through images obtained after deployment.
Post procedure		Missing Titanium Element within the Marker	Each marker device should have a single titanium element. If no titanium element is observed, note on the patient record and notify the manufacturer.	Confirm single titanium element through images obtained after deployment. Consider the deployment of a second marker.
Post procedure		Punctured implant	Use caution when inserting near a breast implant to avoid puncture of the implant capsule.	Use caution when inserting near a breast implant to avoid puncture of the implant capsule.
Post procedure		Amyloidosis	When using a collagen biopsy site marker, there should be no reason for collagen to contaminate the tissue for biopsy as it is placed after the tissue is removed. However, the patient record should include the use of a collagen marker information for follow up biopsies due to the potential use of Congo red stain in pathology which can exhibit similar characteristics on collagen as amyloidosis.	It has been reported that collagen and amyloidosis can exhibit the same characteristics when tested with Congo Red stain. It is recommended that physicians specify in all patient records, including notes to the pathologist, that a collagen plug with a titanium marker has been used.

Procedure Step	Instruction For Use	Troubleshooting	Product/Procedure/Patient	Potential Undesirable Side Effect
Post procedure		Removal during surgical excision	If the marker is removed during surgery, it should be noted on the patient record.	Potential for removal of the marker during excisional surgery exists.
Post procedure		User protection	Devices which come into contact with bodily fluids require special disposal handling to prevent contamination.	Infection if not handled and disposed of correctly.

Illustration 3. Remove Marker Chamber Port Plug



Note: Ensure probe sample aperture is fully open for marker placement. If the variable aperture setting is being used on the Mammotome revolve Biopsy System, it must be changed to the full aperture setting for marker placement.

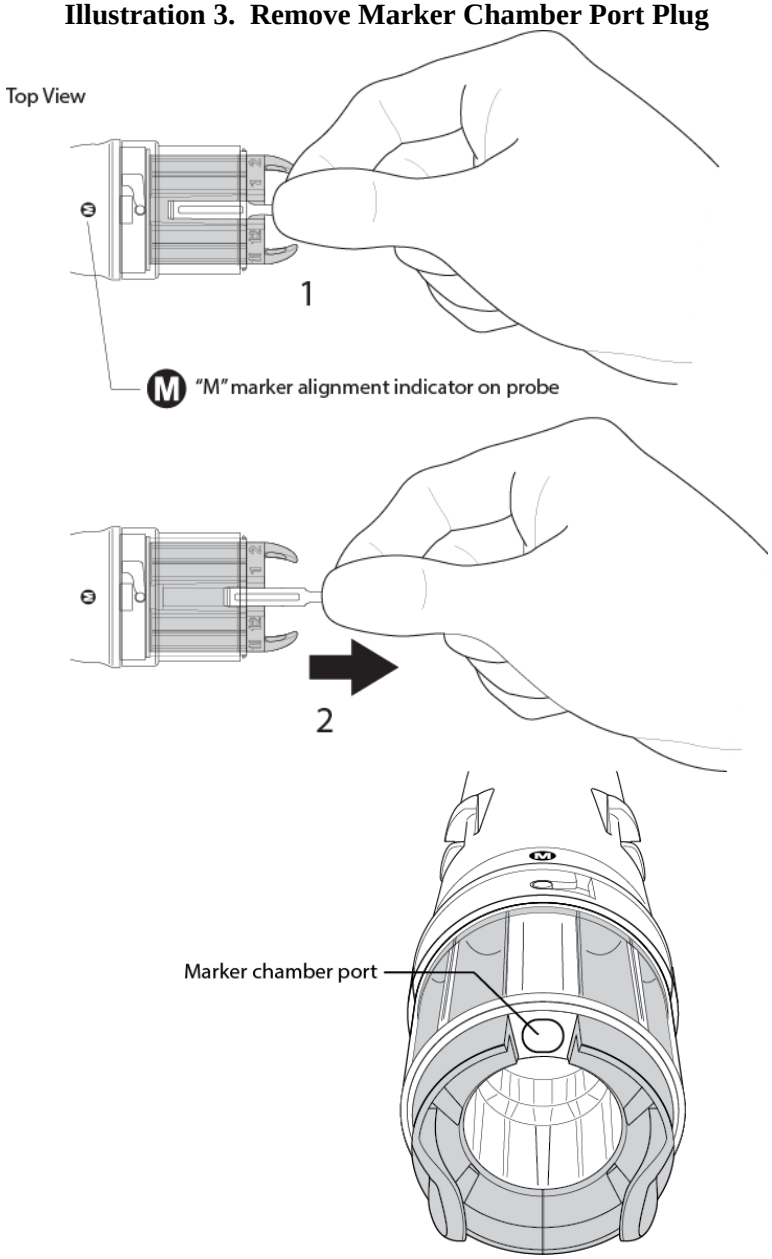
Note: ***Prior to marker deployment, the biopsy probe can be pulled back up to 1 cm.***

1. **If the specimen management system is ON,** remove the marker port plug from the marker chamber port (See Illustration 3).

2. Place the MammoMARK Tissue Marker applicator into the Mammotome revolve Biopsy Probe Marker Chamber Port. Advance the MammoMARK Tissue Marker until the appropriate colored depth indicator band on the MammoMARK Tissue Marker shaft is aligned with the proximal edge of the specimen management system (See Illustration 4, 5).

   Note: Ensure "M" indicator on the probe is aligned with the marker chamber port for proper tissue marker insertion (See illustration 3).

Illustration 3. Remove Marker Chamber Port Plug



If the specimen management system is OFF, be sure to insert the marker into the larger opening at the proximal end of the probe (See Illustration 4). Advance the MammoMARK Tissue Marker until the appropriate colored depth indicator band on the MammoMARK Tissue Marker shaft is aligned with the proximal end of the probe body (See Illustration 4).

CAUTION: If significant resistance is met during the advancement of the MammoMARK Tissue Marker prior to reaching the appropriate colored depth indicator band, remove the probe and the marker together to inspect the integrity of the distal tip of the marker device and consider conducting a "clear probe" before inserting a new marker device.

CAUTION: Do not insert beyond appropriate colored depth indicator band or tip damage may occur. See Illustrations 4 & 5 for proper seating of the tissue marker with the specimen management system ON and OFF.

Illustration 4. Tissue Marker Insertion Alignment with Specimen Management System OFF

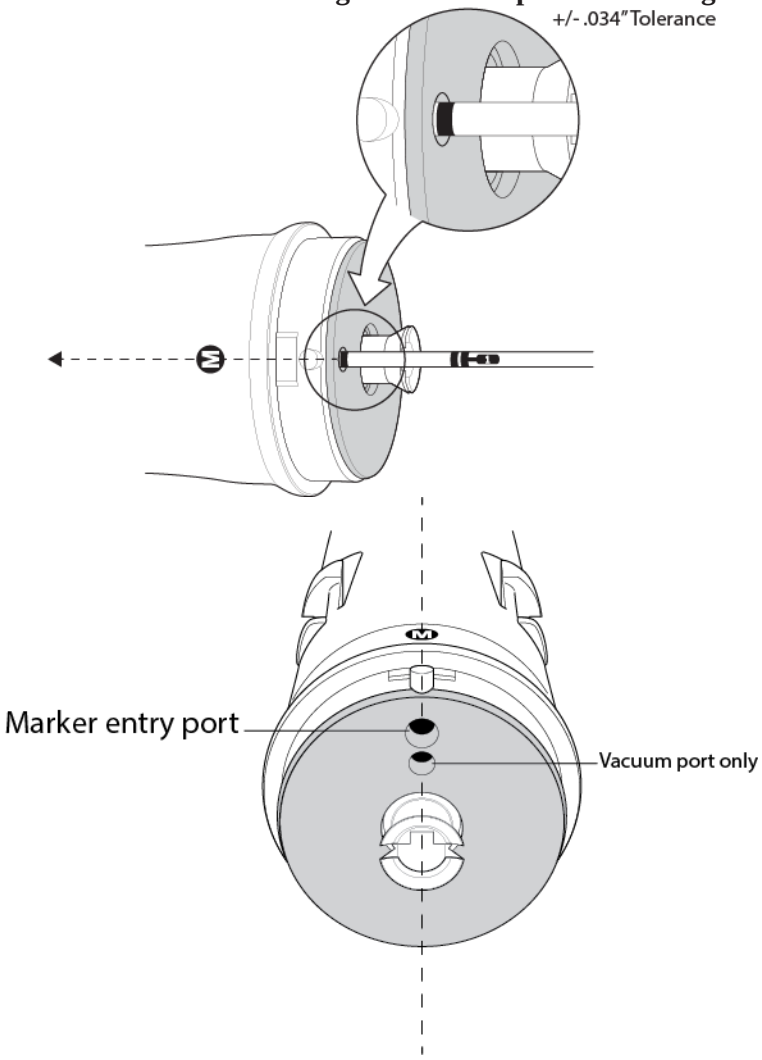
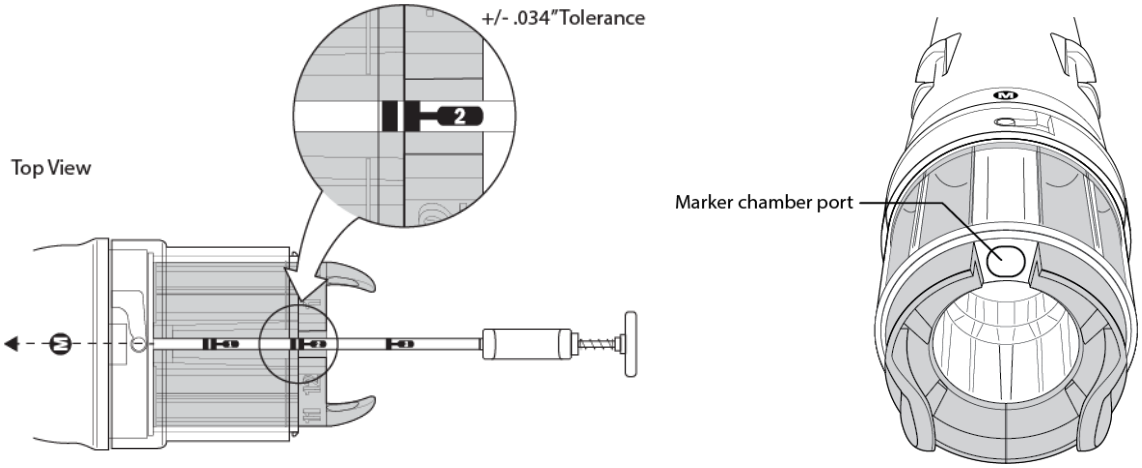


Illustration 5. Tissue Marker Depth Seating with Specimen Management System ON



3. Position alignment indicator on the MammoMARK Tissue Marker handle and the longitudinal stripe on the MammoMARK shaft with the position relative to the Mammotome revolve probe's sample aperture orientation.

   CAUTION: DO NOT activate the probe cutter or other clinical functions while a marker is inserted in the probe. Take care to completely remove the marker out of the probe before activating any of the holster's clinical functions.

   CAUTION: Failure to align the MammoMARK applicator as specified may result in improper deployment of the biopsy site identifier.

   CAUTION: Do not activate vacuum. Vacuum is not required for marker deployment.

4. Grasp the tissue marker handle and, using firm, but gentle force, advance the plunger forward completely until it contacts the finger tabs on the handle to deploy the biopsy site identifier into the biopsy cavity.

   Note: Ensure the alignment indicator on the tissue marker handle ALWAYS remains in the position corresponding with the probe's sample aperture orientation.

   CAUTION: If excessive resistance is met during deployment, check the alignment of the MammoMARK applicator shaft as specified in step 9.

5. After deployment, release pressure from plunger to allow spring to retract plunger away from the finger tabs on the handle.

6. Rotate the Mammotome revolve probe body or thumbwheel 90 to 180 degrees to position the sample aperture away from the deployed biopsy site identifier.

7. Remove the MammoMARK applicator and the Mammotome revolve Biopsy Probe together as a single unit from the site and obtain images to confirm marker placement.

8. Record the lot number from the MammoMARK Tissue Marker package and place it in the patient's record.

Specifications

Shelf Life	18 months from date of manufacturer

How Supplied
The MammoMARK Biopsy Site Identifiers are supplied sterile and preloaded for single patient use. Discard into an appropriate container after use. Do not resterilize.

Calling for Service

Call 1-877-9-A-MAMMO (U.S. calls), or +1-513-864-9000 (International calls - English speaking only) or contact your local representative.

Customer support is also available by sending an email to clinicalsupport@mammotome.com.

Additional Product Information

For a complete listing and description of available products for use with the Mammotome™ Biopsy System, visit the following website: www.mammotome.com.

REF
Catalog Number

MMK0801, MMK0802, MMK1001, MMK1002

EC REP

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AW001185 | REV B