



MammoMARK™ User Guide

This is the Point.

The Mammotome® Quick Reference Guide is intended as an adjunct to the Operator's Manual. Before using this guide, read full instructions in Operator's Manual.

Mammotome®

The purpose of the Quick Reference Guide is to support the use of the Mammotome® Marker Product Line.

Mammotome® Marker Quick Reference Guide is intended as an adjunct to the manufacturer's Operator Manuals and Instructions for Use.

Before using the product or reading the Guide, read full instructions in your Operator's Manuals and Instructions for Use.

Table of Contents

Redesigned Features

Redesigned Features	6
Redesigned Outer Packaging	8
Available Product Codes	9
Marker Clip Dimensions	9

Compatibility

Competitive Compatibility	12
Removing from Packaging	14

Instructions for Use

ST (Stereotactic)	18
EX (Ultrasound)	24
MR (MRI) - Through Targeting Set	32
MR (MRI) - Through Probe and Holster	39



Redesigned Features

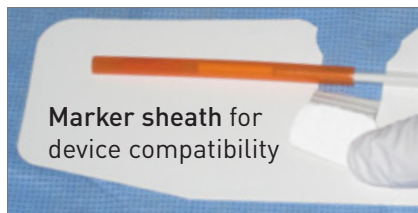
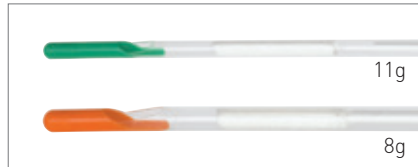


Redesigned Features

MammoMARK™ offers compatibility with most breast biopsy systems while providing visibility under all imaging modalities – **Mammography, Ultrasound, and MRI.**

- Redesigned system for consistent and reliable deployment
- Collagen pad shape changed to a dowel shape, still providing over 300% expansion in less than 60 seconds
- Revised tip geometry to eliminate probe pullback
- Bread tie marker shape changed to bowtie shape 

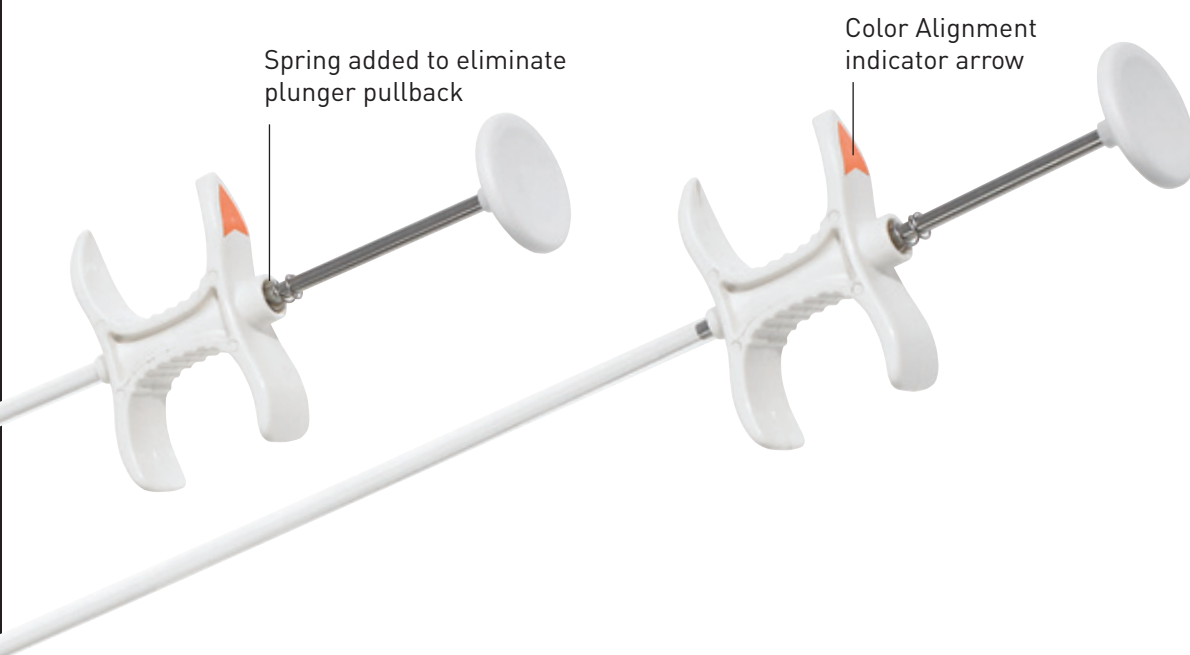
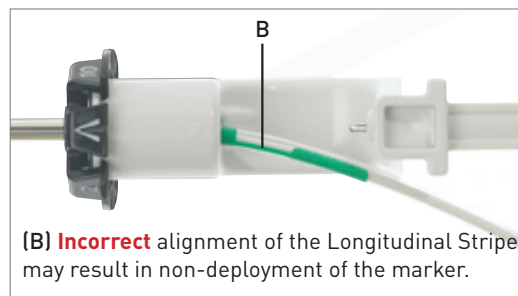
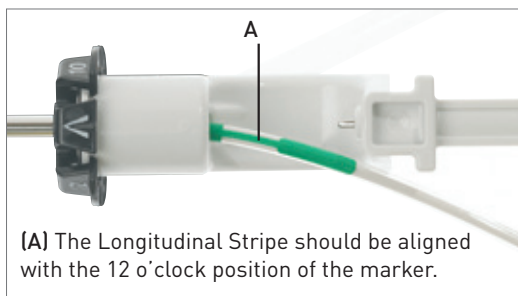
Robust and Enhanced tip Redesigned colored tips now distinguish 8g and 11g



Color Depth Indicators with Longitudinal stripe to help proper advancement and alignment



Note: Align the indicator arrow with the longitudinal stripe on shaft, at 12 o'clock

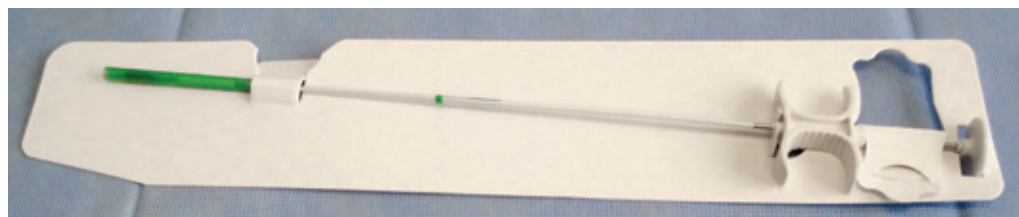
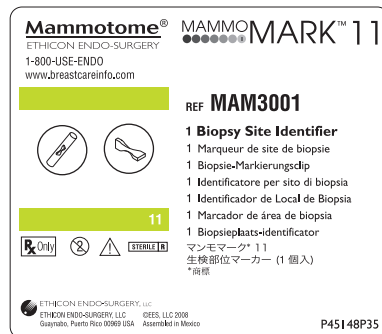
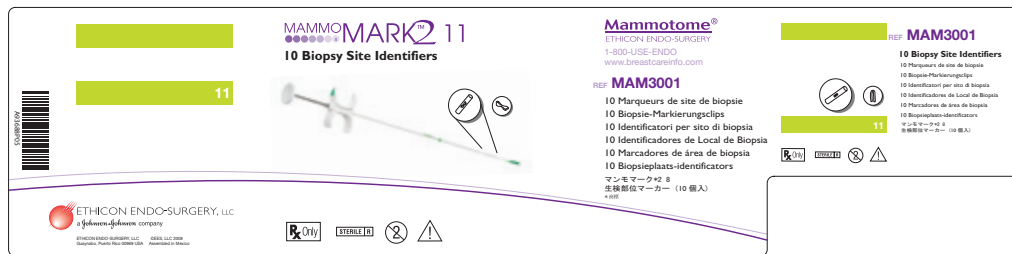


Note: Advance plunger completely to deploy (plastic to plastic), and then release plunger



Redesigned Outer Packaging

- Colored bars indicate gauge
- Image of new bowtie marker shape
- New folder design with tip protector sheath



Available Product Codes

MAM3001	11G Short	Green	
MAM3002	11G Short	Green	
MRM4002	11G Long	Green	
MAM3008	8G Short	Orange	
MRM4008	8G Long	Orange	
MAM3014	14G Short	Gray	

Marker Clip Dimensions



V Shape

L: 3.0mm
W: 0.7mm



BowTie

L: 3.0mm
W: 0.8mm



Compatibility



Competitive Compatibility

Suros: EVIVA - Marker Sheath must remain ON.

	Special instructions	Marker Choice
Eviva 0913-20	Coax Only	MAM3008 MAM3001/3002 MRM4008 MRM4002
Eviva 0913-12	Coax Only	MAM3008 MRM4008 MRM4002
Eviva 1213-20	Coax Only	MAM3001/3002 MRM4002

Suros: ATEC - Marker Sheath must be removed.

	Special Instructions	Marker Choice
ATEC 0909-20	Probe	MRM4002
ATEC 0912-20	Probe	MRM4002
ATEC 0909-20	Needle	MAM3001/3002 MRM4002
ATEC 0912-20	Needle	MAM3001/3002 MRM4002
ATEC 0914-20	Needle	MAM3001/3002 MRM4002

Suros: ATEC ILS - Marker Sheath must remain ON.

	Special Instructions	Marker Choice
ILS 0914-20	Coax	MAM3008 MAM3001/3002 MRM4008 MRM4002

Bolded codes indicate first product choice.

BARD: Vacora & Finesse - Marker Sheath must be removed.

	Special Instructions	Marker Choice
VC10118	Coax	MAM3008
		MRM4008
		MAM3001/3002
		MRM4002
		MAM3014
VC10140	Coax	MAM3008
		MRM4008
		MAM3001/3002
		MRM4002
F14105US	Coax	MAM3014

SenoRx: EnCor - Marker Sheath must be removed.

	Special Instructions	Marker Choice
ECP01-7G	Probe	MRM4008
		MRM4002
ECP01-10G	Probe	MRM4002
ECPMR01-10G	Probe without tissue collection	MRM4002

SenoRx: EnCor - Marker Sheath must remain ON.

	Special Instructions	Marker Choice
ECMRINTLOC (10G)	Coax	MAM3001/3002
		MAM3008
		MRM4002
		MRM4008

Bolded codes indicate first product choice.

Removing from Packaging

Removing MammoMARK™ from the Packaging Folder: Use with biopsy devices other than Mammotome® products.

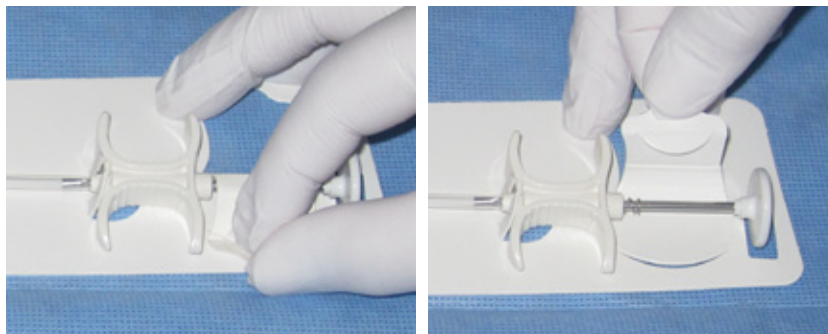
1: Remove from foil pouch.



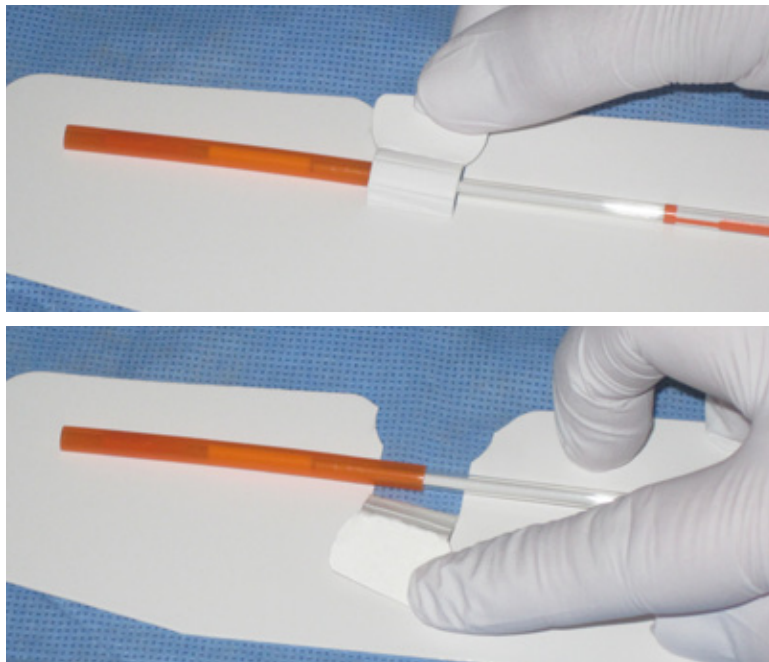
Note: New folder packaging includes a sterile marker sheath at the distal end of the shaft to retain the marker within the applicator.



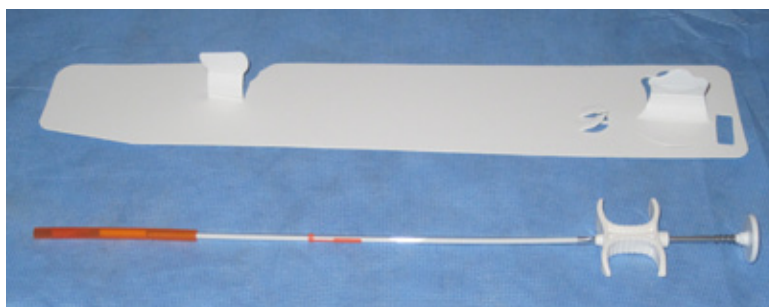
2: Lift the tab at the proximal end that secures the handle.



- 3: Lift the tab at the distal end that secures the sheath.**



- 4: Remove device, including marker sheath, from folder. When using MammoMARK™ products with non-Mammotome® biopsy devices, the sheath can remain on the proximal end of the device during use.**



Please see Compatibility Section for specific codes in which the marker sheath is needed.



Instructions for Use



ST

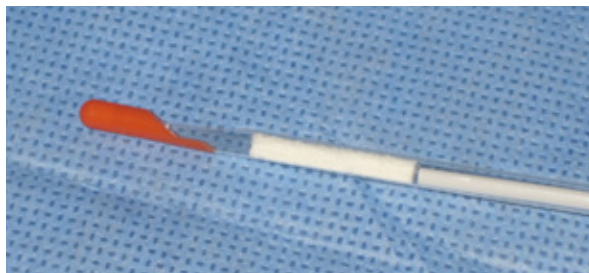
- 1: **Inspect the package to ensure the package integrity has not been compromised.**



- 2: **Remove the MammoMARK™ product from the package using standard aseptic technique. Remove marker sheath prior to use.**



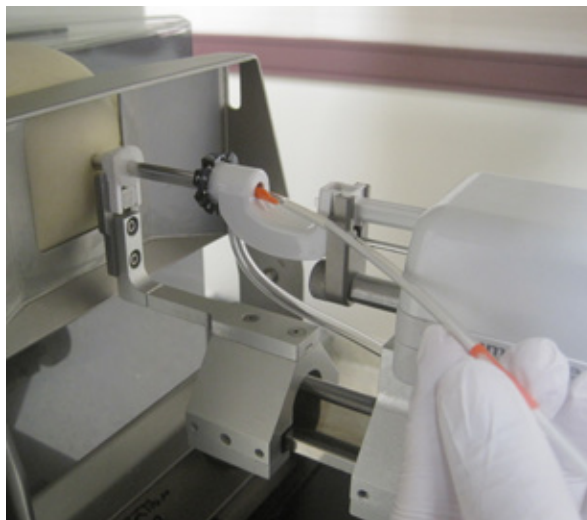
- 3: Check to ensure that the distal end of the MammoMARK™ product has not been damaged, kinked, or bent.**



- 4: Retract the specimen cutting/collection tube from the Mammotome® Biopsy Probe per the instructions for use of the probe. Prior to retracting the cutting/collection tube the needle can be pulled back up to 1cm.**



- 5: Place the MammoMARK™ applicator into the Mammotome® Biopsy Probe. Advance the MammoMARK™ until the colored depth indicator band on the MammoMARK™ shaft is aligned with the distal edge of the Mammotome® tissue collection chamber.**



Caution: If significant resistance is met during the advancement of the MammoMARK™ prior to reaching the colored depth indicator band, remove the marker to inspect the integrity of the distal tip of the marker device, and repeat insertion with a new marker.

Caution: Do not insert beyond appropriate band or tip damage may occur.

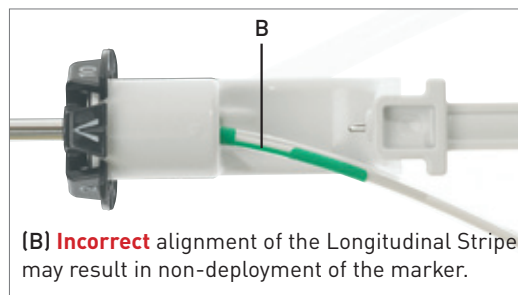
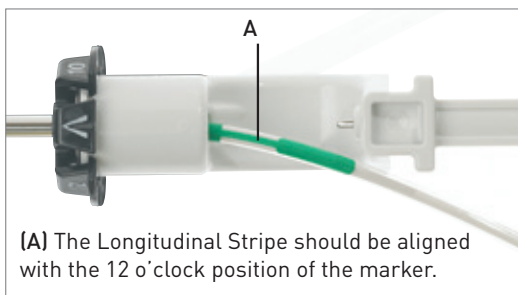
- 6: Align the triangular indicator on the MammoMARK™ handle and the longitudinal stripe on the MammoMARK™ shaft with the 12 o'clock position relative to the Mammotome® probe's tissue collection chamber.**



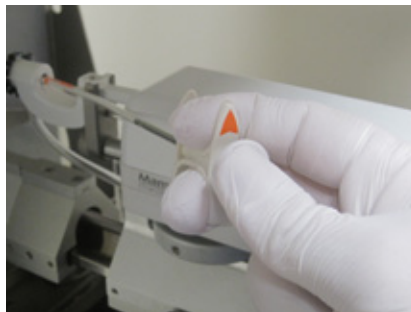
WARNING: Failure to align the MammoMARK™ applicator as specified may result in improper deployment of the collagen plug and possible tip shear.

Caution: Do not activate vacuum. Vacuum is not required.

Note: Align the indicator arrow with the longitudinal stripe on shaft, at 12 o'clock

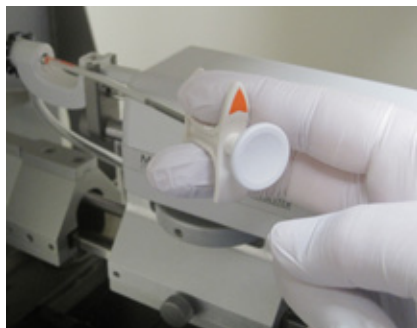


- 7: Using firm but gentle force, advance the plunger completely until it contacts the finger tabs on the handle to deploy the biopsy site identifier into the biopsy cavity.**



Caution: If excessive resistance is met during deployment, check the alignment of the MammoMARK™ applicator as specified in step 6.

- 8: After deployment, release pressure from plunger to allow spring to retract plunger away from the finger tabs on the handle.**



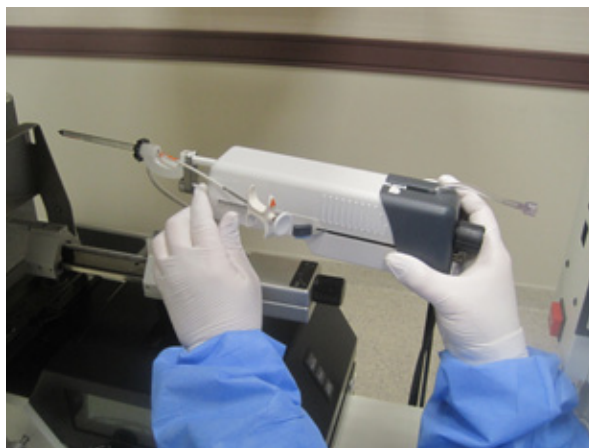
Note: Advance plunger completely to deploy (plastic to plastic), and then release plunger



- 9: Rotate the Mammotome® probe body or thumbwheel 90 to 180 degrees to position the sample aperture away from the deployed collagen plug.



- 10: Remove the MammoMARK™ applicator and the Mammotome® Biopsy Probe together as a single unit from the site and obtain images to confirm marker placement.



- 11: Record the lot number from the MammoMARK™ package and place it in the patient's record.

EX

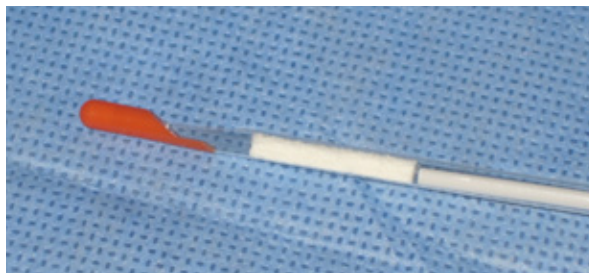
- 1: Inspect the package to ensure the package integrity has not been compromised.



- 2: Remove the MammoMARK™ product from the package using standard aseptic technique. Remove marker sheath prior to use.



- 3: Check to ensure that the distal end of the MammoMARK™ product has not been damaged, kinked, or bent.**



- 4: Retract the specimen cutting/collection tube from the Mammotome® Biopsy Probe per the instructions for use of the probe. Prior to retracting the cutting/collection tube the needle can be pulled back up to 1cm.**



- 5: Place the MammoMARK™ applicator into the Mammotome® Biopsy Probe. Advance the MammoMARK™ until the colored depth indicator band on the MammoMARK™ shaft is aligned with the distal edge of the Mammotome® tissue collection chamber.**



Caution: If significant resistance is met during the advancement of the MammoMARK™ prior to reaching the colored depth indicator band, remove the marker to inspect the integrity of the distal tip of the marker device, and repeat insertion with a new marker.



Caution: Do not insert beyond appropriate band or tip damage may occur.



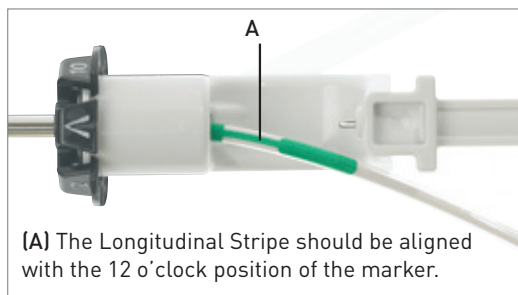
- 6: Align the triangular indicator on the MammoMARK™ handle and the longitudinal stripe on the MammoMARK™ shaft with the 12 o'clock position relative to the Mammotome® probe's tissue collection chamber.



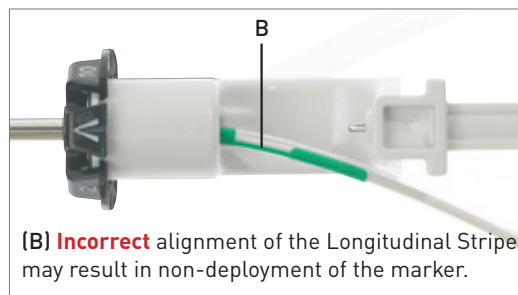
WARNING: Failure to align the MammoMARK™ applicator as specified may result in improper deployment of the collagen plug and possible tip shear.

Caution: Do not activate vacuum. Vacuum is not required.

Note: Align the indicator arrow with the longitudinal stripe on shaft, at 12 o'clock



(A) The Longitudinal Stripe should be aligned with the 12 o'clock position of the marker.



(B) **Incorrect** alignment of the Longitudinal Stripe may result in non-deployment of the marker.

- 7: Using firm but gentle force, advance the plunger completely until it contacts the finger tabs on the handle to deploy the biopsy site identifier into the biopsy cavity.**



Caution: If excessive resistance is met during deployment, check the alignment of the MammoMARK™ applicator as specified in step 6.



Note: Advance plunger completely to deploy (plastic to plastic), and then release plunger



- 8: After deployment, release pressure from plunger to allow spring to retract plunger away from the finger tabs on the handle.**



- 9: Rotate the Mammotome® probe body or thumbwheel 90 to 180 degrees to position the sample aperture away from the deployed collagen plug.**



- 10: Remove the MammoMARK™ applicator and the Mammotome® Biopsy Probe together as a single unit from the site and obtain images to confirm marker placement.**



- 11: Record the lot number from the MammoMARK™ package and place it in the patient's record.**

MR - Through Targeting Set

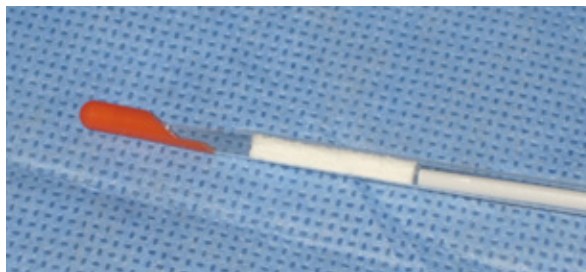
- 1: Inspect the package to ensure the package integrity has not been compromised.



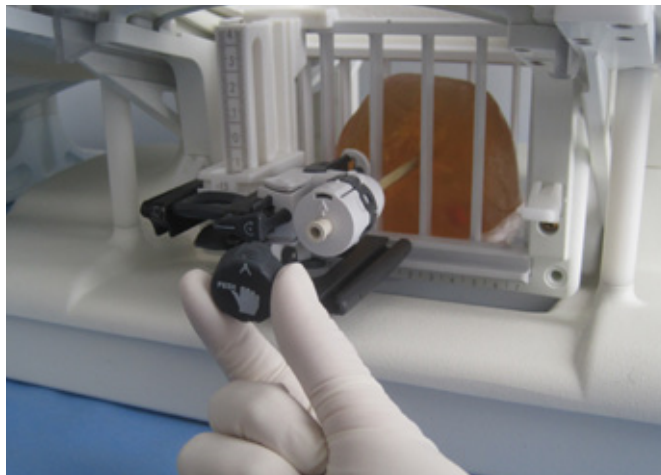
- 2: Remove the MammoMARK[™] product from the package using standard aseptic technique. Remove the marker sheath prior to use.



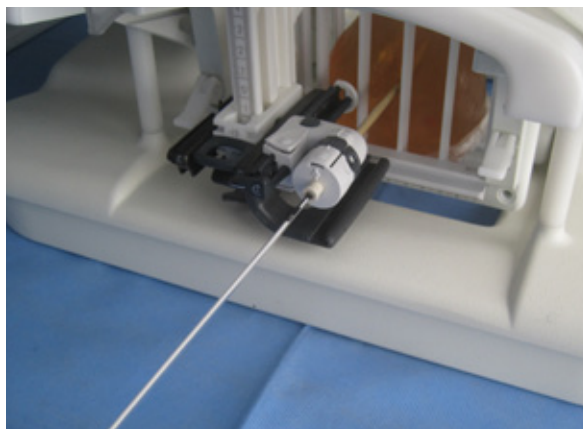
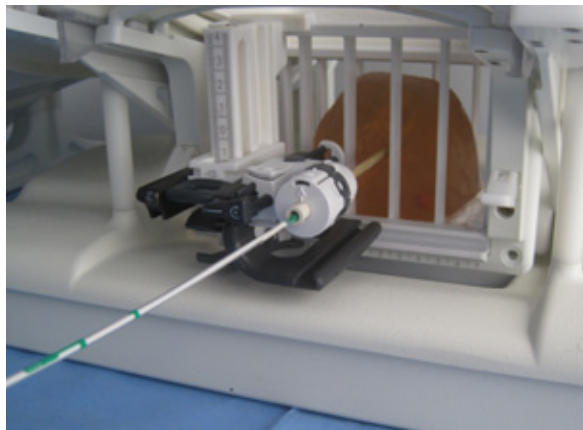
- 3: Check to ensure that the distal end of the MammoMARK[™] product has not been damaged, kinked, or bent.



4: Remove cap from Mammotome® Targeting Set obturator/stylet.



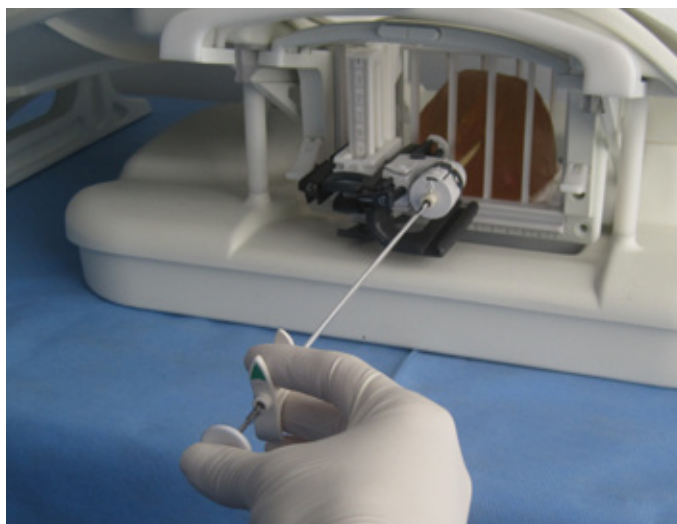
- 5: Place the MammoMARK[™] applicator shaft into the obturator/ stylet. Advance the MammoMARK[™] until the appropriate colored band on the MammoMARK[™] applicator is aligned with the proximal edge of the obturator/stylet.**



Caution: If significant resistance is met during the advancement of the MammoMARK[™] prior to reaching the appropriate band, remove the marker to inspect the integrity of the distal tip of the marker device, and repeat insertion with a new marker.

Caution: Do not insert beyond appropriate band or tip damage may occur.

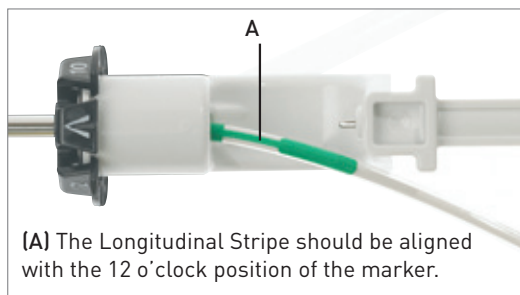
- 6: Align the colored triangular indicator on the MammoMARK™ handle and the appropriate longitudinal stripe on the MammoMARK™ applicator shaft with the 12 o'clock arrow position on the Mammotome® obturator/stylet.



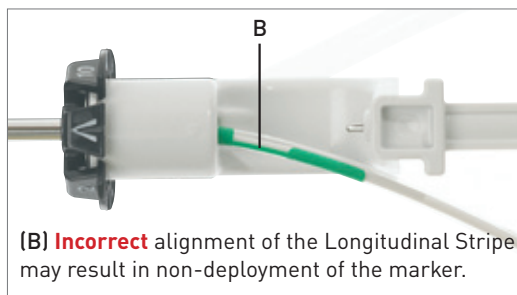
WARNING: Failure to align the MammoMARK™ applicator as specified may result in improper deployment of the collagen plug and possible tip shear

Caution: Do not activate vacuum. Vacuum is not required.

Note: Align the indicator arrow with the longitudinal stripe on shaft, at 12 o'clock

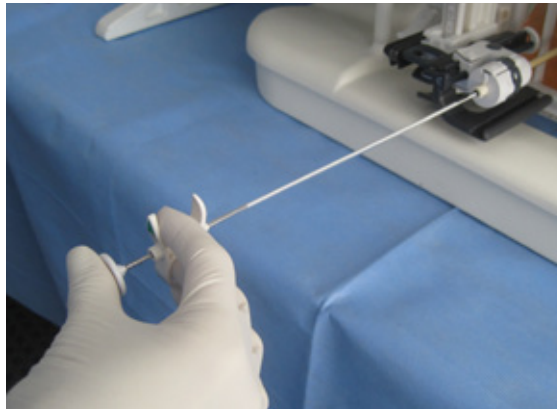


(A) The Longitudinal Stripe should be aligned with the 12 o'clock position of the marker.

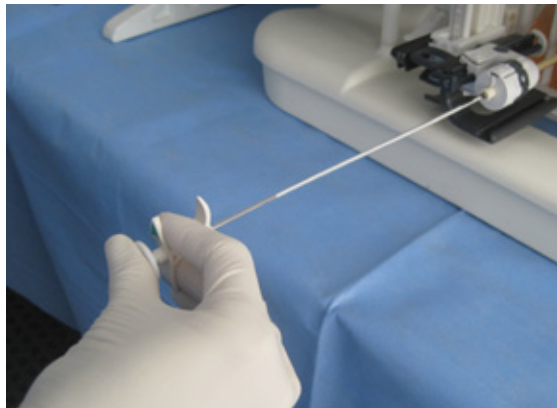


(B) **Incorrect** alignment of the Longitudinal Stripe may result in non-deployment of the marker.

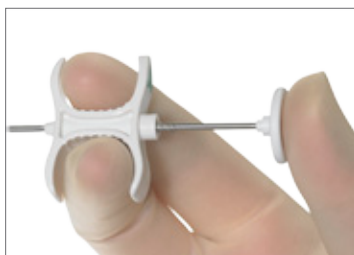
- 7: Using firm but gentle force, advance the plunger completely to deploy the collagen plug into the biopsy cavity.**



Caution: If excessive resistance is met during deployment, check the alignment of the MammoMARK™ applicator as specified in step 6.



Note: Advance plunger completely to deploy (plastic to plastic), and then release plunger



- 8: After deployment, release pressure from plunger to allow spring to retract plunger away from the finger tabs on the handle.**



- 9: Rotate the thumbwheel of the Mammotome® Targeting Set 90 to 180 degrees to position the sample aperture away from the deployed collagen plug.**



10: Remove the MammoMARK™ applicator shaft from the biopsy site using either of the following methods:

a. Remove the applicator with the Mammotome® Targeting Set together as a single unit from the site.

- OR -

b. Remove the applicator from the Targeting Set obturator/stylet and replace cap on obturator/stylet.

Obtain images to confirm marker placement.



WARNING: If significant resistance is met using the method described in step 10b, stop and proceed with method 10a.

11: Record the lot number from the MammoMARK™ package and place it in the patient's record.

MR - Through Probe and Holster

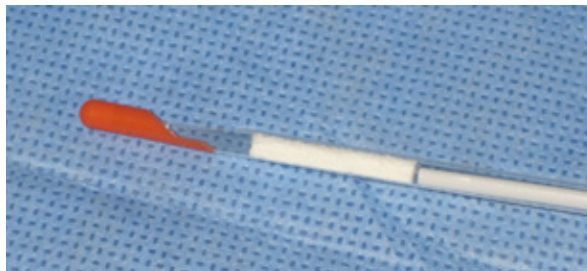
- 1: **Inspect the package to ensure the package integrity has not been compromised.**



- 2: **Remove the MammoMARK™ product from the package using standard aseptic technique. Remove the marker sheath prior to use.**



- 3: **Check to ensure that the distal end of the MammoMARK™ product has not been damaged, kinked, or bent.**



- 4: **Retract the specimen cutting/collection tube from the Mammotome® Biopsy Probe per the instructions for use of the probe. Prior to retracting the cutting/collection tube the needle can be pulled back up to 1cm.**



Caution: If pullback is needed when using with the Mammotome® MR probe, the probe must be pulled back with the targeting set as a single unit.

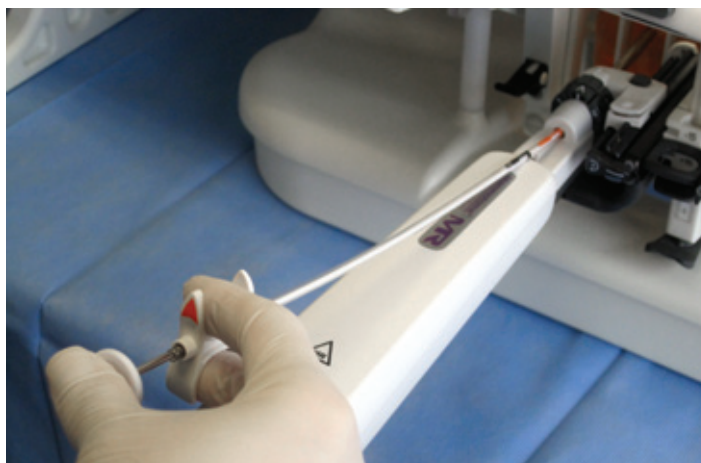
- 5: Place the MammoMARK™ applicator shaft into the Mammotome® Biopsy Probe. Advance the MammoMARK™ until the appropriate colored band on the MammoMARK™ shaft is aligned with the distal edge of the Mammotome® tissue collection chamber.**



Caution: If significant resistance is met during the advancement of the MammoMARK™ prior to reaching the appropriate band, remove the marker to inspect the integrity of the distal tip of the marker device, and repeat insertion with a new marker.

Caution: Do not insert beyond appropriate band or tip damage may occur.

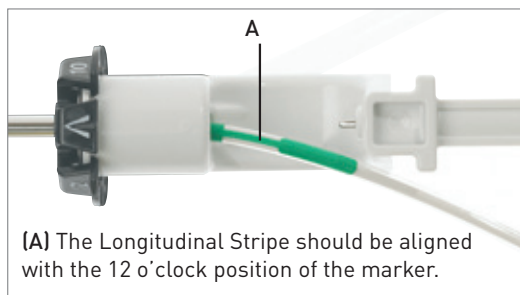
- 6: Align the colored triangular indicator on the MammoMARK™ handle and the longitudinal stripe on the MammoMARK™ applicator shaft with the 12 o'clock position on the Mammotome® probe.



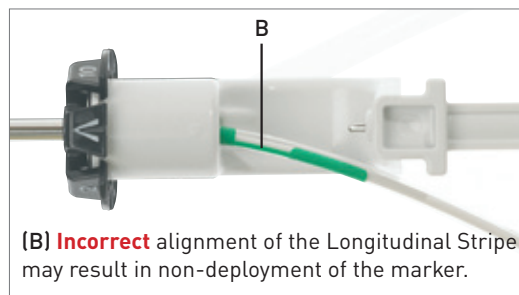
WARNING: Failure to align the MammoMARK™ applicator shaft as specified may result in improper deployment of the collagen plug and possible tip shear.

Caution: Do not activate vacuum. Vacuum is not required.

Note: Align the indicator arrow with the longitudinal stripe on shaft, at 12 o'clock



(A) The Longitudinal Stripe should be aligned with the 12 o'clock position of the marker.



(B) Incorrect alignment of the Longitudinal Stripe may result in non-deployment of the marker.

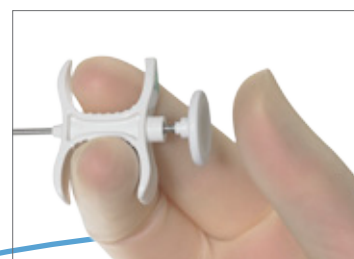
- 7: Using firm but gentle force, advance the plunger completely to deploy the collagen plug into the biopsy cavity.**



Caution: If excessive resistance is met during deployment, check the alignment of the MammoMARK™ applicator shaft as specified in step 6.



Note: Advance plunger completely to deploy (plastic to plastic), and then release plunger



- 8: After deployment, release pressure from plunger to allow spring to retract plunger away from the finger tabs on the handle.**



- 9: Rotate the Mammotome® Probe body or thumbwheel 90 to 180 degrees to position the sample aperture away from the deployed collagen plug.**



- 10: Remove the MammoMARK™ applicator shaft and the Mammotome® Biopsy Probe together as a single unit from the site and obtain images to confirm marker placement.**



WARNING: If significant resistance is met using the method described in step 10b, stop and proceed with method 10a.

- 11: Record the lot number from the MammoMARK™ package and place it in the patient's record.**

Mammotome®

We are dedicated to helping you help your patients, so you can trust us to be there with you – providing an array of products, superb clinical training and outstanding customer service.

For more information about Mammotome®, Neoprobe® and other products, or to place an order, contact your MAMMOTOME sales representative or call 1-877-9-A-MAMMO (1-877-926-2666), Option 3, 2.



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For complete product details, see Instructions for Use.

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