EnCor Enspire™ Breast Biopsy System

Quick Reference Guide

MRI

BD

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This Quick Reference Guide for the EnCor Enspire® Breast Biopsy System is intended as a summary overview only. Please consult product labels and inserts for indications, contraindications, hazards, warnings, precautions, and directions for use.

1

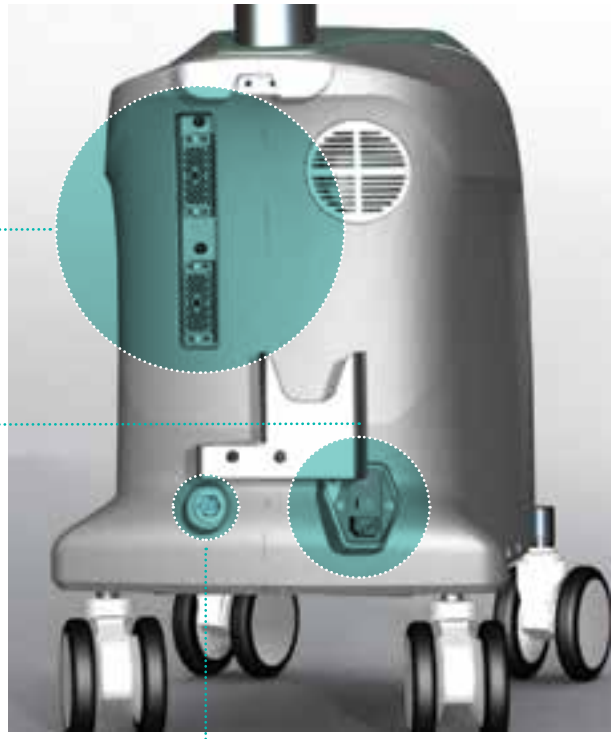
Easy setup

System power up
Vacuum setup
Probe setup

System power up

1 Main power switch

2 Driver connectors



3 Standby power switch

4 Foot pedal

Easy setup 4 steps

1. Turn Main Power Switch ON (rear of console).
2. Connect appropriate EnCor® Driver/s to rectangular connector on rear of console. The Active Driver is indicated by a green LED light above connector.
3. Turn Standby Power Switch ON (front of console).
4. Connect the Foot Pedal at rear of console (if desired).

1

Easy setup

System power up

Vacuum setup

Probe setup

Vacuum setup

1

Secure lid onto canister.

2

Secure large cap and
tandem cap to lid of canister.

3

Place canister into console.

4

Load tubing cassette
(ensure it “clicks” into place).

5

Connect elbow to
center of canister lid.

6

Connect tubing cassette
to patient port on canister.

7

If using rinse cassette,
spike and attach saline bag.

Easy setup

System power up
Vacuum setup
Probe setup

Probe setup

1

Slide the front of the MRI probe beneath the leading edge guides on the MRI Driver.

2

Snap the rear of the probe into place. An audible click should be heard.

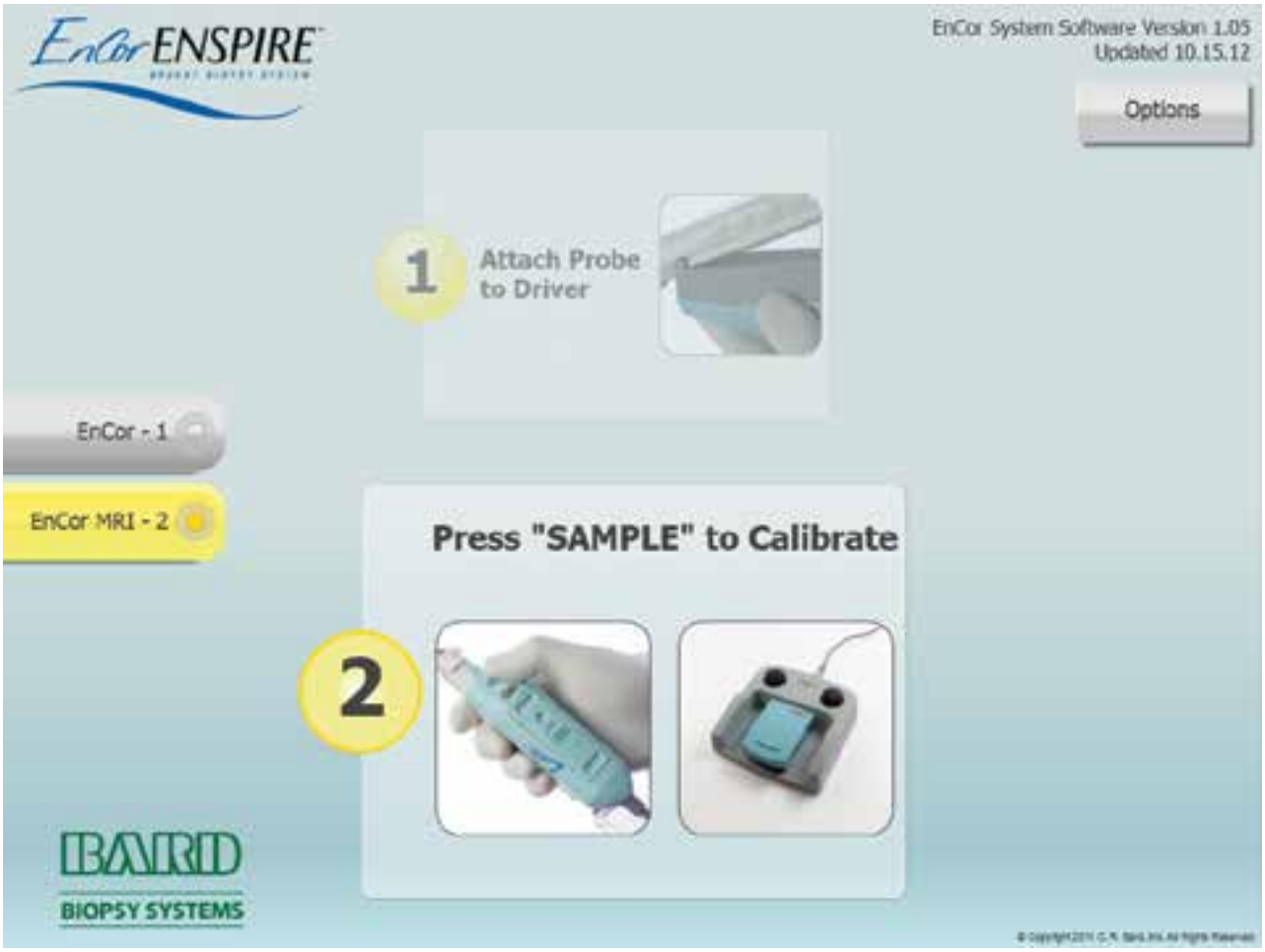
3

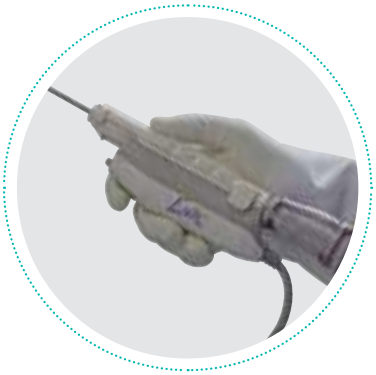
Connect the extension tubing to the cassette (large purple port). Then, attach other end of extension tubing to the probe's tubing. Connect rinse lines (small blue port) if using rinse.


EnCor ENSPIRE
Stereotactic 10G
Cutter is closed. To open press SAMPLE handswitch/footswitch. To vacuum press VAC handswitch/footswitch.
Sample
Anesthetic
Marker
Options
Full
Half
VAC
12
2
4
6
8
10
BARD
BIOPSY SYSTEMS

Touch screen setup

Ensure that the correct driver is selected prior to calibration.





Press the sample switch on either the foot pedal or the handpiece to calibrate the probe.

2

Targeting

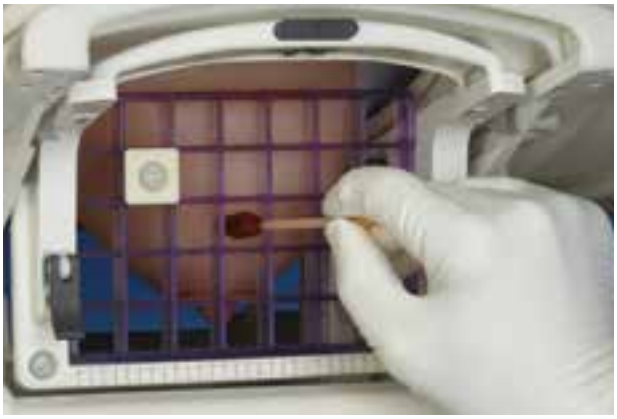
Prepping the breast surface
Trocar preparation
Locking the block
Securing the cannula
Verifying VisiLoc™ position

Prepping the breast surface

1. Target the region of interest using the MRI gridworksheet and/or CAD system.

   Identify the appropriate grid fenestration based on the targeted location.

2. Sterilize the area of the breast in and around the targeted fenestration of the grid.



3. Anesthetize along the entire targeted path and ~2cm beyond the targeted region.

4. Use an MRI approved scalpel to make a skin nick at the targeted area.

Targeting

Prepping the breast surface

Trocar preparation

Locking the block

Securing the cannula

Verifying VisiLoc™ position

Trocar preparation

1 Insert trocar through the cannula.

2 Set the leading edge of the depth stop to calculated depth. Be sure to add 2 cm to the calculated depth to account for the thickness of the block.

3 Slide trocar and cannula through the appropriate aperture of the locking block.

2

Targeting

Prepping the breast surface

Trocar preparation

Locking the block

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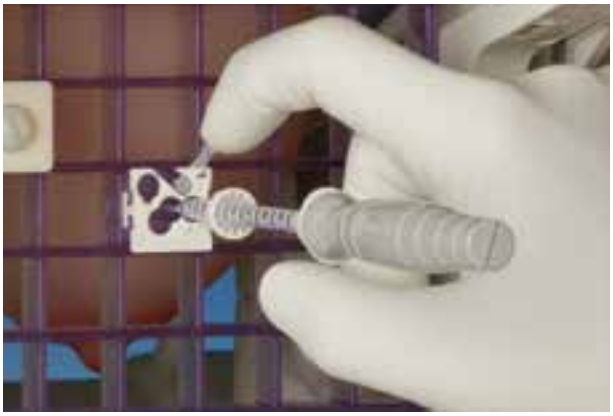
Verifying VisiLoc™ position

Locking the block

1. Place block in correct orientation and fenestration of grid based onthe calculated target depth and location.

2. Seat the block firmly into place in the grid without advancing the trocar.



3. Insert the tip of the trocar into the skin nick and lock the block into the grid fenestration by rotating the lever into the locked position, denoted by the “L” on the block.

2

Targeting

Prepping the breast surface
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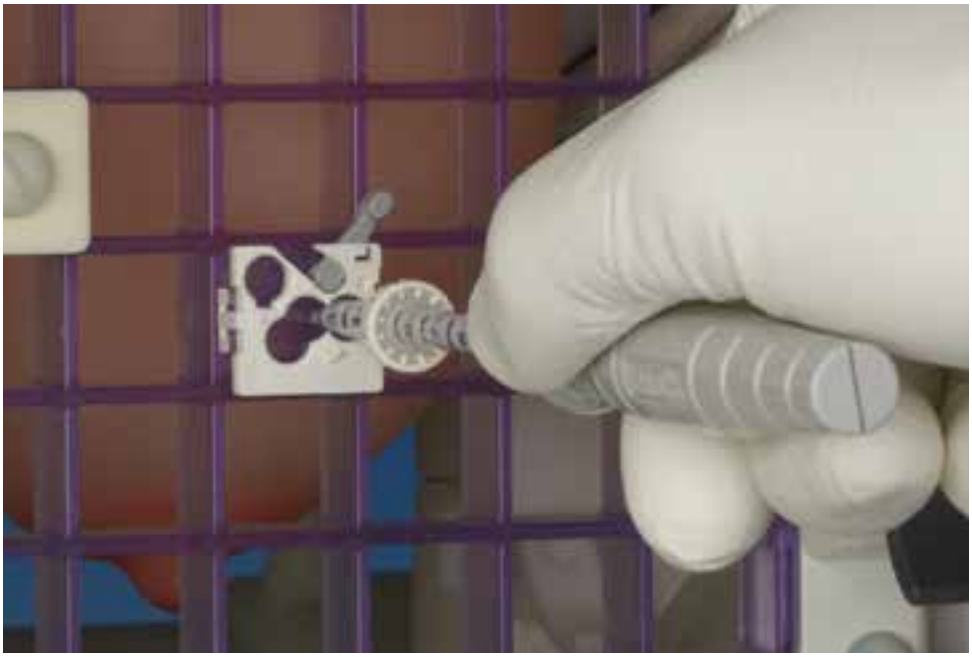
Securing the cannula



1. While holding the cannula hub, gently twist the trocar and cannula while inserting to the set depth.

2. Lock the cannula into place by rotating the depth stop clockwise.

2

Targeting

Prepping the breast surface
Trocar preparation
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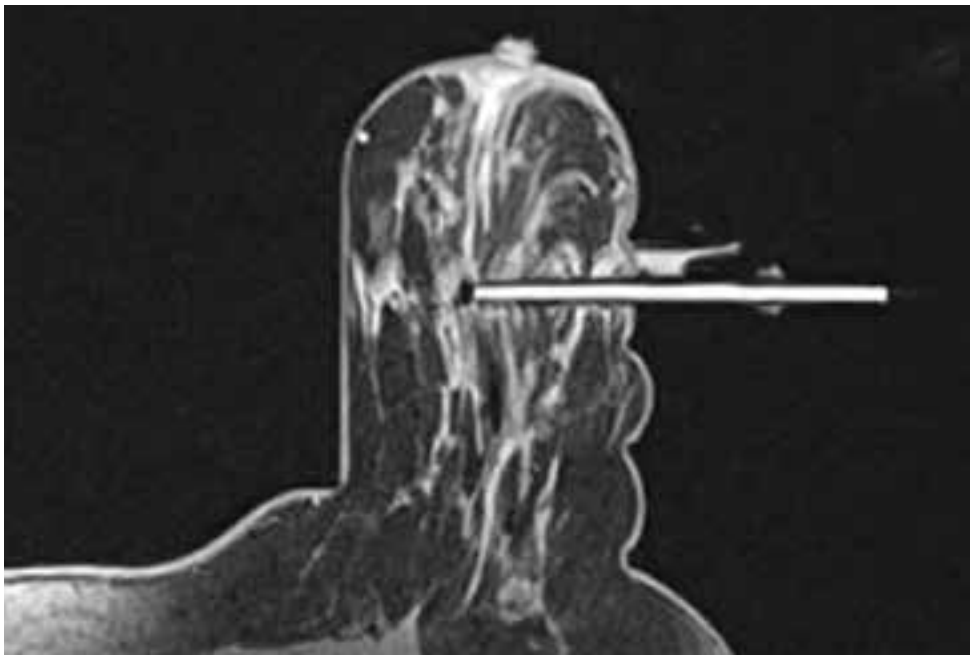
Verifying VisiLoc™ position

Verifying VisiLoc™ position

1. Remove trocar and replace with VisiLoc™ MRI-visible obturator.



2. Confirm placement by repeating scan sequence. The tip of obturator represents middle of sample notch.

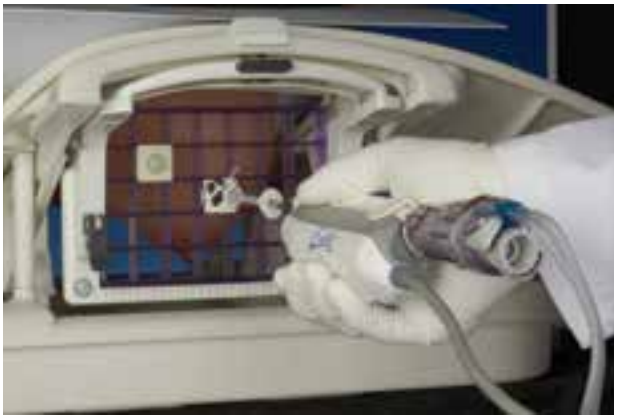
3

Routine procedures

Sampling
Marker placement
Cleanup
Probe specifications

Sampling

1 Choose sampling pattern. If necessary, change tissue density setting (dense) or sample size (half).



2 Remove the obturator and insert the MRI probe into the cannula until it is flush against the hub.

3 Press and hold down sample switch on the foot pedal or handpiece to begin sampling. To stop sampling, simply release the switch.

4 After sampling is complete, vacuum 3-4 seconds by depressing the VAC switch on the foot pedal or handpiece.

5 While the collection chamber remains sealed at all times during tissue acquisition, the tray can be removed for close inspection of samples.

3

Routine procedures

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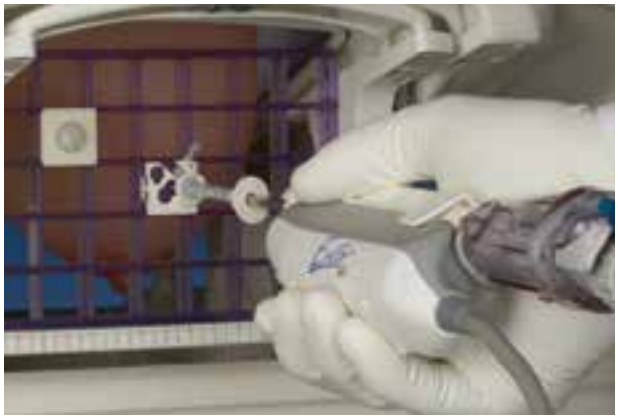
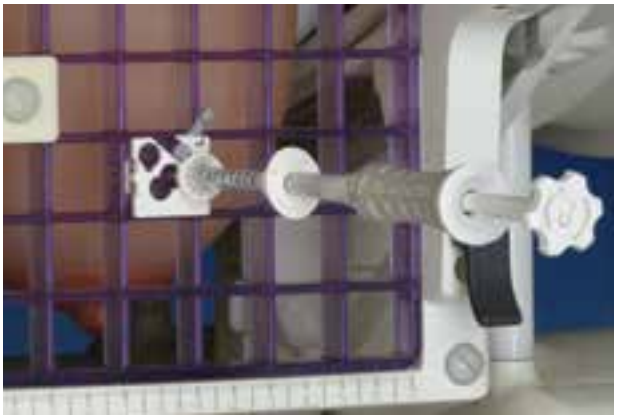
Marker placement



1 Upon completion of sampling, carefully remove the probe from the cannula.



2 Insert the SenoMark UltraCor™ MRI marker applicator into the cannula until it is firmly seated.

3 Unlock the plunger by rotating clockwise 90°.

4 Fully advance the plunger to deploy the marker.

5 Re-image per facility protocol. To re-image in MRI, remove the marker applicator and re-insert the obturator into the cannula. Leave about 1 cm extending from the hub to prevent disturbance of the marker in the cavity.

3

Routine procedures

Sampling
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Probe specifications

Cleanup

1. Disconnect tubing from system, cap end of the tube and roll up.

2. Disconnect tubing and sample collection chamber from probe and dispose in red bag.

3. Remove probe from driver and dispose in sharps biohazard container.

4. Remove and dispose of canister, tubing cassette and optional saline bag.

3

Routine procedures

Sampling
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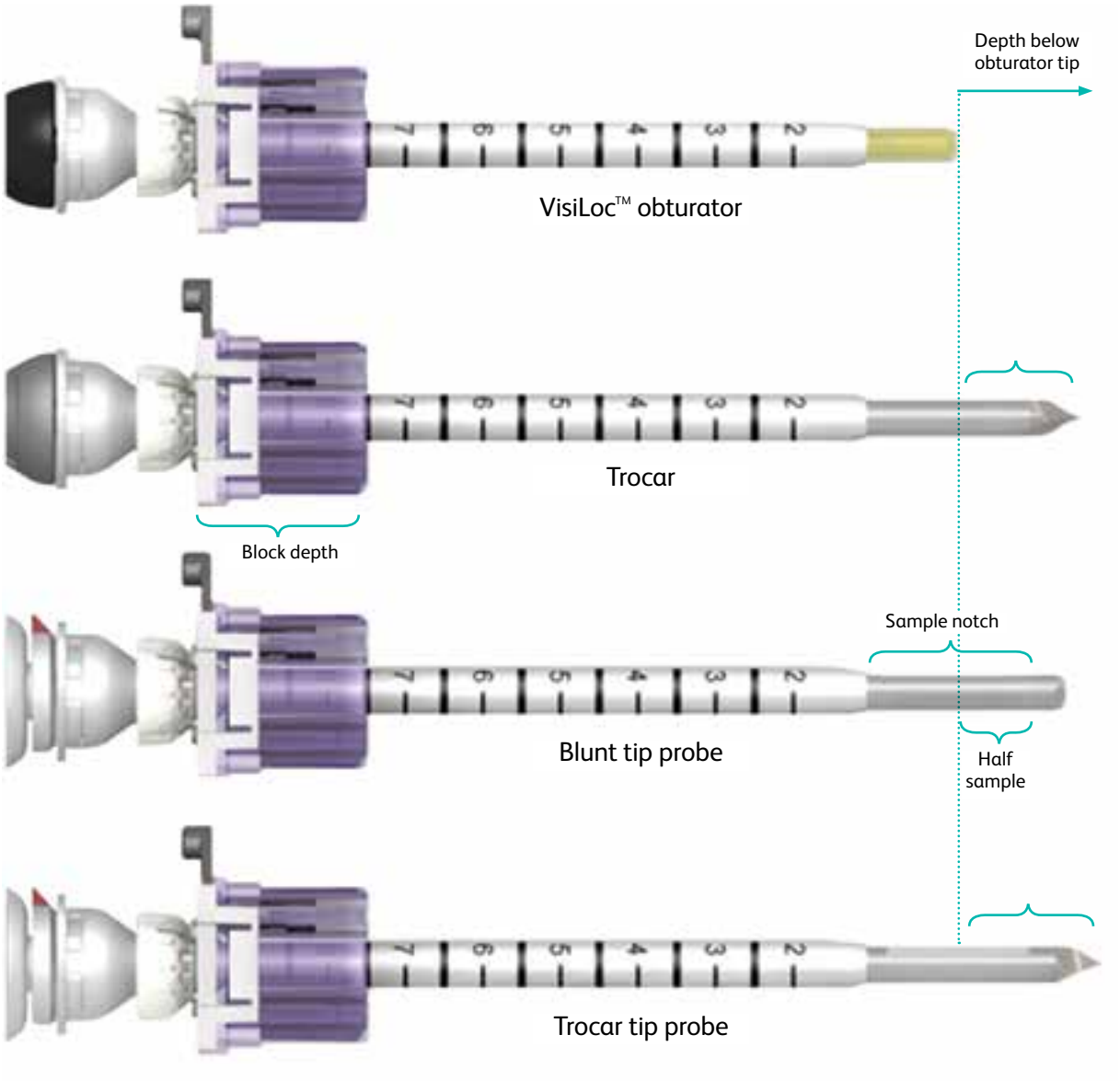
Probe specifications



Probe size	7G	10G
Depth beyond Obturator tip:		
Trocar	18 mm	17 mm
Blunt tip probe	n/a	15 mm
Trocar tip probe	21 mm	20 mm
Sample notch length:		
Full sample	19.0 mm	19.0 mm
Half sample	9.5 mm	9.5 mm
Block depth	**2 cm**	**2 cm**

Notes

INDICATIONS FOR USE:

The Encor Enspire™ Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities
- It is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.
- It is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g. fibroadenoma, fibrocystic lesion), the Encor Enspire™ Breast Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

CONTRAINDICATIONS:

1. This device is not intended for use except as indicated. **2.** The Encor Enspire™ Breast Biopsy System is contraindicated for those patients where, in the physician's judgment, there is an increased risk of complications associated with percutaneous removal of tissue samples.

WARNINGS:

1. The Encor Enspire™ Breast Biopsy System must be properly grounded to ensure patient safety. The system is supplied with a medical grade power cord with AC plug. Do not connect the included power cord to extension cords or three-prong to two-prong adapters. **2.** To minimize interference with other equipment, cables should be positioned in such a manner to prevent contact with other cables. **3.** Use of accessories not compatible with the Encor Enspire™ Breast Biopsy System may create potentially hazardous conditions. **4.** Only use Encor® and Encor® MRI drivers with script version 1.19 or greater, or Encor® 360 drivers with script version 1.05 or greater with the Encor Enspire™ Breast Biopsy System. The system is not compatible with earlier driver scripts. The script version is identified on the touch screen display during system initialization. **5.** The Encor Enspire™ Breast Biopsy System console may not be placed in an MRI suite. Place the console outside of the MRI suite and use the appropriate Encor® MRI accessories when performing a biopsy under MRI guidance. **6.** Do not remove the Encor Enspire™ Breast Biopsy System housing. Removal of the housing may cause electrical shock. Contact Bard for service. **7.** The Encor Enspire™ Breast Biopsy System is not classified as an AP or APG classified device. The system is not suitable for use in the presence of flammable anesthetic.

Please consult package insert for more detailed safety information and instructions for use.

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