Aurora Imaging Technology, Inc. 39 High Street North Andover, MA 01845 Attn: Regulatory Affairs & Quality Assurance P: 877-975-7530 F: 978-975-9930	Faulkner-Sagoff Breast Centre at Faulkner Hospital 1153 Centre Street Boston, MA 02130 P: 617-983-7089 F: 617-983-7090	**Clinical Utility / Effectiveness Form** **MR-Guided Breast Interventional Device** **Page 1 of 9** **Medical Record #:_____** **(Unique Patient ID Number)**

1.0 Administrative Information

Current Date _____ (Date Case Report Form is Completed - excluding supporting documents)
mm/dd/yy

Interventional Procedure Type: (check one)

❍ Initial Interventional Procedure — Date of Interventional Procedure: _____ mm/dd/yy

❑ Follow-up Interventional Procedure — Date of Previous Interventional Procedure: _____ mm/dd/yy

2.0 Patient and Demographic Information

Medical Record #: _____
(Unique Patient ID Number)

Date of Birth: _____
mm/dd/yy

Gender: ❍ M ❑ F

Ethnicity: ❍ Asian ❍ Black ❍ Hispanic ❍ White ❍ Other: _____

Inclusion Criteria: (all must be answered "yes" to enroll)

❑ Yes	❍ No	Patient was properly screened, has no contraindications for MRI, and is able to undergo an MRI exam.
❑ Yes	❍ No	Patient has no metal implants, extensive dental work, etc., which may affect diagnostic image quality
❑ Yes	❍ No	Patient has completed and signed Informed Consent Form

Exclusion Criteria: (all must be answered "no" to enroll)

❑ Yes	❍ No	Patient has breast implants currently in place or a history of breast implant removal within the past 12 months.
❑ Yes	❍ No	Patient is lactating, or is pregnant. (Patients suspected to be pregnant should have a pregnancy test before entering the study.)
❑ Yes	❍ No	Patient is NOT available for 6-month follow-up.

3.0 Indication(s) for Breast MRI

Check all applicable categories:

❑ Yes	❍ No	Known breast cancer, pre-operative evaluation.
❑ Yes	❍ No	Known breast cancer, post-operative evaluation of margins.
❑ Yes	❍ No	Ambiguous imaging finding on mammography, ultrasound, or both.
❑ Yes	❍ No	History of previous breast cancer.
❑ Yes	❍ No	High risk - family history of breast cancer, positive for BRCA1, BRCA2, or history of non-breast cancer.
❑ Yes	❍ No	Dense breasts, or augmented, difficult-to-image breasts (implants, previous surgical procedures, etc).
❑ Yes	❍ No	Evaluation of implant integrity.
❑ Yes	❍ No	Other (describe): _____

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4.0 Previous Diagnostic Procedures and Preliminary Diagnosis

Answer all categories, and describe as appropriate:

❍ CBE: ❍ No ❑ Yes: _____

❍ Mammography: ❍ No ❑ Yes: _____

❍ Ultrasound: ❍ No ❑ Yes: _____

❍ MRI: ❍ No ❑ Yes: _____

❍ Other: ❍ No ❑ Yes: _____

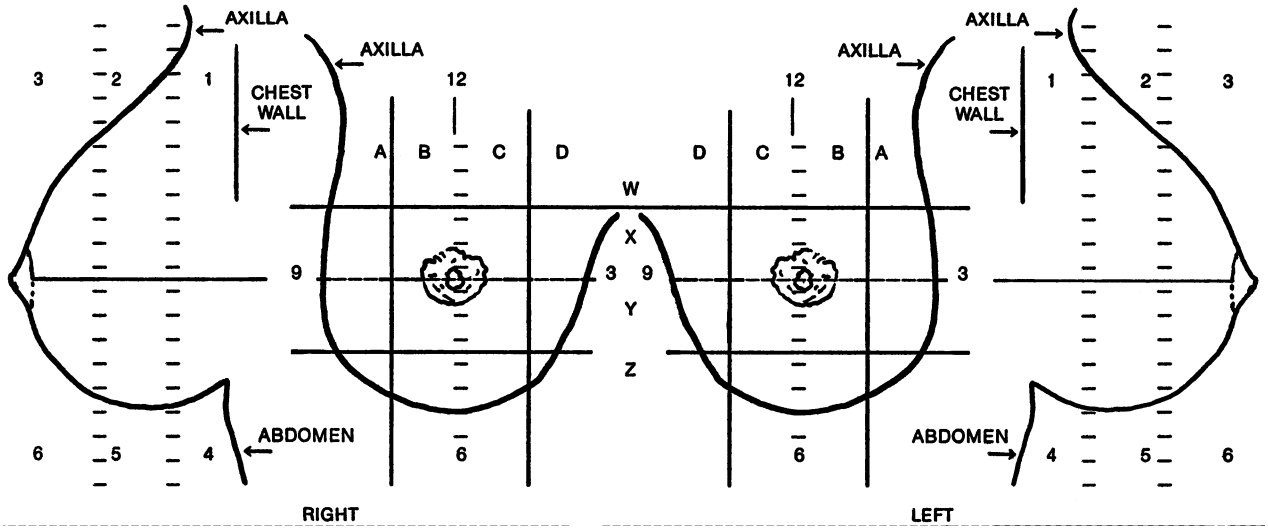
❍ Preliminary Diagnosis: _____

5.0 Lesion(s) Information

❍ Describe the lesion(s), size(s): _____

❍ Which breast? ❍ Left ❑ Right

❍ Describe the lesion location(s) on the illustration below:



6.0 Previous Therapies for Treatment

Check all that apply, describe treatment, and provide date(s):

❍ Surgery: _____

❍ Radiation Therapy (specify): _____

❍ Chemotherapy (specify agents): _____

❍ HRT (specify agents): _____

❍ Tamoxifen: _____

❍ Other (specify): _____

7.0 Surgical Preparation and Planning

Type of anesthesia planned
(check one)

❍ Local Anesthesia
❍ Pain Control
❍ Conscious Sedation
❍ General Anesthesia
❍ Other: _____

What conventional method was used for **surgical planning**?
(check all that apply)

❍ Mammo	❍ with contrast	❍ without contrast
❍ US	❍ with contrast	❍ without contrast
❍ MR	❍ with contrast	❍ without contrast

❍ Other: _____

Describe the procedural/surgical approach and anatomical location(s)
(i.e. medial, lateral, etc.):

❍ No ❑ Yes Was the Interventional Device disinfected?
What method: _____

❍ No ❑ Yes Was the Interventional Device sterilized?
What method: _____

❍ No ❑ Yes Was any portion of the AURORA draped?
Describe: _____

❍ No ❑ Yes Was the drape sterile?

Describe all patient preparation(s), e.g., Betadine, skin nick, anesthetic, etc.: BE SPECIFIC.

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8.0 Minimally Invasive Procedure Activities and Evaluation

Which of the following Components were used?

Check all that apply. For each component used, identify FUNCTIONAL / HELPFUL. Provide explanations if NOT FUNCTIONAL or NOT HELPFUL.

Component	Used		Functional		Helpful		Comments
	N	Y	N	Y	N	Y	
Needle Guidance Stage - Lateral	❍	❑	❍	❑	❍	❑	
Needle Guidance Stage - Medial	❍	❑	❍	❑	❍	❑	
Curved Breast Immobilization Paddles							
Left Medial	❍	❑	❍	❑	❍	❑	
Left Lateral	❍	❑	❍	❑	❍	❑	
Right Medial	❍	❑	❍	❑	❍	❑	
Right Lateral	❍	❑	❍	❑	❍	❑	
Planar Breast Immobilization Paddles							
Left Medial	❍	❑	❍	❑	❍	❑	
Left Lateral	❍	❑	❍	❑	❍	❑	
Right Medial	❍	❑	❍	❑	❍	❑	
Right Lateral	❍	❑	❍	❑	❍	❑	
Paddle Holder							
Left Medial Inferior	❍	❑	❍	❑	❍	❑	
Left Medial Superior	❍	❑	❍	❑	❍	❑	
Left Lateral Inferior	❍	❑	❍	❑	❍	❑	
Left Lateral Superior	❍	❑	❍	❑	❍	❑	
Right Medial Inferior	❍	❑	❍	❑	❍	❑	
Right Medial Superior	❍	❑	❍	❑	❍	❑	
Right Lateral Inferior	❍	❑	❍	❑	❍	❑	
Right Lateral Superior	❍	❑	❍	❑	❍	❑	
Paddle Tilt	❍	❑	❍	❑	❍	❑	
Paddle Medial-to-Lateral Offset	❍	❑	❍	❑	❍	❑	
Needle Guidance Arm - Fixed	❍	❑	❍	❑	❍	❑	
Needle Guidance Arm - Rotating	❍	❑	❍	❑	❍	❑	
Position Display Unit	❍	❑	❍	❑	❍	❑	
Targeting Application (software)	❍	❑	❍	❑	❍	❑	
			Explain		Explain		

Use additional pages if necessary

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9.0 Intra-Procedural Statistics

All times in military/24HR clock. Use additional pages as needed.

Time patient entered room: ☐☐:☐☐ Page _____of_______π

Pre-contrast Acquisition(s): ☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________

Time of contrast injection: ☐☐:☐☐

Post-contrast Acquisition(s): ☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________

Time of anesthetic injection: ☐☐:☐☐

Time of biopsy needle placement: ☐☐:☐☐

Verification Acquisition(s): ☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________

Time of biopsy needle placement: ☐☐:☐☐

Verification Acquisition(s): ☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________

Time of biopsy needle placement: ☐☐:☐☐

Verification Acquisition(s): ☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________

Time of biopsy needle placement: ☐☐:☐☐

Verification Acquisition(s): ☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________

Time of biopsy needle placement: ☐☐:☐☐

Verification Acquisition(s): ☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________

Time of biopsy needle placement: ☐☐:☐☐

Verification Acquisition(s): ☐☐:☐☐ Protocol:___________ # Images________________
☐☐:☐☐ Protocol:___________ # Images________________

Time patient exited room: ☐☐:☐☐

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10.0 Data Collection

Procedure type (check one)	Type of needle guide? _____ Guide manufacturer? _____ Guide size? _____	Type of needle used? _____ Needle manufacturer?_____ Needle size? _____
❍ Fine needle aspiration ❍ Core biopsy ❍ Wire localization		

Needle placement successful? ❑ Yes ❍ No (explain)

Number of biopsy passes needed? _____(explain)

What was the time per biopsy pass?

Where there any difficulties placing the biopsy needle? (explain)

Where there any difficulties with the accuracy of the placement of the biopsy needle? (explain)

11.0 Patient Management

Describe all post-procedure patient management activities, including, but not limited to:

- ❍ Apply pressure
- ❍ Gauze pad
- ❍ Suture
- ❍ Medication(s)
- ❍ Other: _____

❍ OBSERVATION

What was the length of post-procedure observation time?

12.0 Impressions

❑ Yes	❍ No	Did the use of the biopsy device **help** the performance of the surgical procedure? Explain.
❑ Yes	❍ No	Did the use of the biopsy device **hinder** the performance of the surgical procedure? Explain.
❑ Yes	❍ No	Did the use of the biopsy device **affect** the course of treatment in any way? Explain.
❑ Yes	❍ No	Did the use of the biopsy device **affect or alter** the length of stay? Explain.

13.0 Pathology Report and Follow-up

❍ Provide a complete Pathology report to Aurora Imaging Technology, Inc. Remove Patient Name from the report, and replace with Patient ID.

❍ Pathology report diagnosis:_____

❍ All Research Subjects with negative biopsies that do not yield a specific benign diagnosis (e.g., fibroadenoma, etc.) shall be referred to standard short-term (6 mo.) follow-up re-evaluation to ensure lesion stability.

❍ Provide the Aurora Imaging Technology, Inc. with a copy of all relevant reports at 6-month follow-up. Remove Patient Name from the report, and replace with Patient ID.

14.0 Clinical Images

❍ Provide all images from patient study to Aurora Imaging Technology, Inc. on DVD-RAM disk. Remove Patient Name from archived data, and replace with Patient ID.

15.0 Case Study Report

❍ Complete Case Study Report Form (this form) for each patient. Retain a copy with Clinical Investigational Protocol archives, and provide a copy to Aurora Imaging Technology, Inc, Attn: Regulatory Affairs.

16.0 Informed Consent Form, MR Procedure Screening Form

❍ Retain a copy of each completed form with Clinical Investigational Protocol archives.

17.0 Complications

❍ ADMISSION

❑ Yes ❍ No Was the patient admitted, post-procedure? Explain.

Reason for admission: _____

What was the length of hospital stay? _____

What was the length of ICU stay? _____

❍ **In the event of a serious adverse event or life-threatening problem, notify the study sponsor within 24 hours from the time of its occurrence. Complete the MedWatch Form 3500 and notify the sponsor (AURORA IMAGING TECHNOLOGY, INC.), the governing IRB, and the FDA.**

❍ Did any peri-operative procedural/surgical complications occur? If so, explain.

❍ Is the complication traceable to the use, misuse, or malfunction of any of the Interventional Device components? If so, explain, and identify which component(s).

❍ Did any post-operative procedural/surgical complications occur? If so, explain.

❍ Is the complication traceable to the use, misuse, or malfunction of any of the Interventional Device components? If so, explain, and identify which component(s).

18.0 Additional Notes

19.0 Product Enhancement Requests

20.0 Certification

Study Coordinator	Principal / Co-Investigator(s)
Name: _____	Name: _____
Signature: _____	Signature: _____
Date: _____	Date: _____