

Position Statement on Stereotactic Breast Procedures

The American Society of Breast Surgeons (the Society) was formed to encourage the study of breast surgery, promote research and development of advanced surgical techniques, improve standards of practice for breast surgery, and serve as a forum for the exchange of ideas.

Article I - Introduction

This publication, *The American Society of Breast Surgeons Performance and Practice Guidelines for Stereotactic Breast Procedures*, is intended to provide the surgeon with guidelines for performing stereotactic breast procedures in an optimal fashion to ensure the best possible patient outcomes. The following guidelines reflect what the Society considers to be the basic criteria for stereotactic breast procedures. However, use of these guidelines may require modification to adapt to a specific clinical situation.

These guidelines attempt to define principles of practice that should generally produce high quality breast care. Adherence to the guidelines will not ensure a successful outcome in every situation. The surgeon should follow a reasonable course of action based on current knowledge, available resources and the needs of the patient to deliver effective and safe medical care. The purpose of these guidelines is to assist surgeons in achieving this objective.

The guidelines should not be deemed inclusive of all proper methods of care nor exclusive of other methods of care reasonably directed to obtaining the same results. They are not intended to establish a legal standard of care and deviation from a guideline does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care.

These guidelines are based on the opinions of a panel of Society members who are experts in stereotactic breast procedures, many of whom have lectured on and taught stereotactic biopsy techniques. The stereotactic platform can be used for several image guided interventions including but not limited to breast biopsy, needle localization for surgery and percutaneous therapy. This document will focus on guidelines for the stereotactic breast biopsy procedures.

Article II – Qualifications of the Surgeon Performing Stereotactic Breast Procedures

To be qualified as a surgeon performing stereotactic breast biopsy, a surgeon should:

- a. Have successfully completed an American Board of Medical Specialties (ABMS) or American Osteopathic Board of Surgery (AOBS) or comparable international equivalent approved residency program and have attained board certification by the appropriate certifying Board upon completion of training or be admissible for

certification. The surgeon must meet the qualifications for active membership in the American Society of Breast Surgeons, but does not necessarily need to be a member.

- b.** Have at least four (4) hours of AMA-PRA Category 1 CME in medical radiation physics or can attest to the review of Radiation Physics and Safety by Howard Snider, MD, provided with the Certification Application for Stereotactic Breast Procedures and available on the Society website www.breastsurgeons.org.
- c.** Have evaluated a minimum of 480 mammograms in the previous two (2) years that have been interpreted by a radiologist qualified to interpret mammography under MQSA.
- d.** If the surgeon has not previously performed stereotactic procedures, then the following criteria should be met:
 - i.** Performance of at least three (3) hands-on stereotactic breast procedures in conjunction with a physician who is certified in stereotactic biopsy procedures by the American Society of Breast Surgeons or a radiologist who meets the stereotactic breast biopsy accreditation of the American College of Radiology.
 - ii.** Have a minimum of 15 hours of AMA-PRA Category 1 CME in mammography and/or stereotactic breast procedures earned in the preceding five (5) years, with five (5) of these within the previous year.
- e.** If the surgeon has performed stereotactic procedures in the past, then the following criteria should be met:
 - i.** Have performed twelve (12) or more stereotactic procedures within the last year.
 - ii.** Have a minimum of five (5) hours of AMA-PRA Category 1 CME in breast imaging and/or image-guided breast procedures earned in the preceding five (5) years.

Article III – Stereotactic Breast Biopsy

Section 1. Introduction

The stereotactic platform can be used for several image guided breast interventions including but not limited to breast biopsy, needle localization for excision and percutaneous therapy. This section will provide guidelines for performing stereotactic breast biopsy.

Section 2. Indications for Stereotactic Breast Biopsy

Indications for stereotactic breast biopsy include, but are not limited to, the following:

- a. Primary diagnosis (see Appendix)
 - i. Highly suspicious microcalcifications or densities (BIRADS 5) to confirm the diagnosis and facilitate treatment planning.
 - ii. Suspicious microcalcifications or densities (BIRADS 4).
 - iii. Probably benign microcalcifications or densities (BIRADS 3) when there are valid clinical indications.
 - iv. Multifocal or multicentric lesions to facilitate treatment planning.
- b. Rebiopsy
 - i. Stereotactic biopsy is an option for repeat biopsy when the initial biopsy results are discordant with the imaging assessment.

Although there are no absolute contraindications to stereotactic breast biopsy, the patient should be asked about allergies, use of aspirin or anticoagulants, and bleeding diatheses. The patient's weight and ability to remain in the position required for the procedure should also be assessed in determining the appropriateness of the procedure for that patient.

Section 3. Stereotactic Breast Biopsy Procedure

- a. A complete mammographic examination of the area of the breast in which the stereotactic procedure is planned should be performed and reviewed prior to the procedure. Additionally, there should be documentation of a clinical breast examination and, if appropriate, breast ultrasound.
- b. The indication for the stereotactic breast procedure should be presented to the patient. The benefits, limitations and risks of the procedure as well as alternative procedures should be reviewed, including of the possibility of a non-diagnostic result. Informed consent should be documented. Adherence to a protocol for preventing wrong person, wrong procedure, and wrong site surgery is required.
- c. The breast is compressed between the image receptor and the compression plate. Imaging is performed to confirm that the targeted lesion lies within the area of accessibility. The computer generated coordinates are then transferred to the stereotactic targeting device.

- d. The breast should be cleaned and prepared for the procedure following the principals of sterile technique to minimize the risk of infection.
- e. Appropriate local anesthesia should be utilized prior to performing the breast biopsy.
- f. Accurate needle positioning should be determined by stereotactic images.
- g. Placement of a radiopaque tissue marker at the biopsy site should be performed, particularly if there is no radiographic evidence of the lesion after the biopsy is complete. Sonographically visible markers are preferable.
- h. Specimen radiographs must be obtained to document appropriate sampling in all cases in which microcalcifications were targeted.
- i. Efforts should be made to select an approach to avoid puncturing blood vessel adjacent to the target and to minimize hematoma by compressing the breast and skin entry site at the conclusion of the procedure. Appropriate skin closure should be performed.
- j. Post-procedure 2 view mammography or stereotactic views should be performed to document tissue marker position.
- k. The surgeon who performs the procedure, or his/her designee, should be available to manage any complications including, but not limited to, pneumothorax, hemorrhage, infection, or other wound complications.
- l. The surgeon should be responsible for obtaining the pathology report, assuring concordance of the imaging and pathologic findings, informing the patient in a timely manner and discussing the appropriate management of the patient's diagnosis. A follow-up plan should be formulated based on the pathology report, and the patient's questions invited and answered.

Section 4. Documentation

- a. Each stereotactic breast biopsy procedure should have a permanent record along with the accompanying set of images in retrievable image storage format. The images and report should become a part of the patient's permanent medical record.
- b. Each individual patient study should include the facility name; date of examination; patient's first and last name; identification number, if applicable; and a notation of left or right breast, either written or diagrammed. The technologist's identification, if applicable, should also be included.
- c. Standard form reports may be used as long as they are comprehensive in nature.
- d. The report of the stereotactic breast biopsy procedure should include:

1. Procedure performed
2. Designation of right or left breast
3. Description of the type of lesion (indication)
4. Location of lesion (e.g. upper outer quadrant)
5. Type of local anesthetic
6. Approach used to target and biopsy the lesion
7. Gauge of needle and type of biopsy device used
8. Number of specimen cores or samples
9. Specimen radiographs (if indicated), were performed, and their results
10. Clip placement
11. Postprocedure imaging describing the position of the tissue marker in relation to the biopsy site
12. Complications during procedure, if any

Article IV – Quality Control Responsibilities

Surgeons are responsible for patient selection and quality assurance, including medical audit and image interpretation. Surgeons are responsible for ensuring that there is proper oversight of all quality control and quality assurance activities and supervision of the radiology technologist(s) and the medical physicist(s).

Article V – Quality Assessment/Improvement

- a. Policies and procedures related to quality, personnel and patient safety, and infection control should be developed in accordance with the appropriate American College of Surgeons policies.
- b. Quality assessment procedures should exist and should be systematically monitored for appropriateness and technical accuracy. The Society encourages participation in quality monitoring programs that may exist on a national level.
- c. Complications and adverse events incurred during stereotactic breast procedures should be recorded and regularly reviewed to identify opportunities to improve patient care.

- d. Results of stereotactic procedures should be recorded, monitoring the false-negative rates, inadequate tissue samples, and follow-up recommendations. Concordance/discordance of imaging findings and pathology reports should be addressed by policies developed for resolution of discordant findings.

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APPENDIX
American College of Radiology
Breast Imaging Reporting and Data System—
Mammographic Assessment Categories*

A. Mammographic Assessment Is Incomplete

Category 0: Need additional imaging evaluation and/or Prior Mammograms for Comparison.

Finding for which additional imaging evaluation is needed. This is almost always used in a screening situation. Under certain circumstances this category may be used after a full mammographic workup. A recommendation for additional imaging evaluation may include, but is not limited to, the use of spot compression, magnification, special mammographic views, and ultrasound.

Whenever possible, if the study is not negative and does not contain a typically benign finding, the current examination should be compared to previous studies. The radiologist should use judgment in how vigorously to attempt obtaining previous studies. Category 0 should only be used for old film comparison when such comparison is required to make a final assessment.

B. Assessment Is Complete—Final Categories

Category 1: Negative

There is nothing to comment on. The breasts are symmetric and no masses, architectural distortion or suspicious calcifications are present.

Category 2: Benign Finding(s)

Like Category 1, this is a “normal” assessment, but here the interpreter chooses to describe a benign finding in the mammography report. Examples include involuting calcified fibroadenomas, multiple secretory calcifications, fat-containing lesions such as oil cysts, lipomas, galatocoeles, and mixed-density hamartomas all have characteristically benign appearances, and may be labeled with confidence. The interpreter may also choose to describe intramammary lymph nodes, vascular calcifications, implants or architectural distortion clearly related to prior surgery while still concluding that there is no mammographic evidence of malignancy.

Note that both Category 1 and Category 2 assessments indicate that there is no mammographic evidence of malignancy. The difference is that Category 2 should be used when describing one or more specific benign mammographic findings in the report, whereas Category 1 should be used when no such findings are described.

Category 3: Probably Benign Finding—Short Interval Follow-Up Suggested

A finding placed in this category should have less than a 2% risk of malignancy. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability.

There are several prospective clinical studies demonstrating the safety and efficacy of initial short-term follow-up for specific mammographic findings.

Three specific findings are described as being probably benign (the noncalcified circumscribed solid mass, the focal asymmetry and the cluster of round punctate calcifications). All the published studies emphasize the need to conduct a complete diagnostic imaging evaluation before making a probably benign assessment; hence it is inadvisable to render such an assessment when interpreting a screening examination. Also, all the published studies exclude palpable lesions, so the use of a probably benign assessment for a palpable lesion is not supported by scientific data. Finally, evidence from all the published studies indicates the need for biopsy rather than continued follow-up when most probably benign findings increase in size or extent.

While the vast majority of findings in this category will be managed with an initial short-term follow-up (6 months) examination followed by additional examinations until longer-term (2 years or longer) stability is demonstrated, there may be occasions where biopsy is done (patient wishes or clinical concerns).

Category 4: Suspicious Abnormality—Biopsy Should Be Considered

This category is reserved for findings that do not have the classic appearance of malignancy but have a wide range of probability of malignancy that is greater than those in Category 3. Thus, most recommendations of breast interventional procedures will be placed within this category. By subdividing Category 4 into 4A, 4B and 4C, it is encouraged that relevant probabilities for malignancy be indicated within this category so the patient and her physician can make an informed decision on the ultimate course of action.

Category 5: Highly Suggestive of Malignancy—Appropriate Action Should Be Taken (Almost Certainly Malignant)

These lesions have a high probability (>95%) of being cancer. This category contains lesions for which one-stage surgical treatment could be considered without preliminary biopsy. However, current oncologic management may require percutaneous tissue sampling as, for example, when sentinel node imaging is included in surgical treatment or when neoadjuvant chemotherapy is administered at the outset.

Category 6: Known Biopsy-Proven Malignancy—Appropriate Action Should Be Taken

This category is reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.

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