

MAMMOTOME® BIOPSY SYSTEM INDICATIONS FOR USE

The Mammotome Biopsy System is indicated to provide tissue samples for diagnostic sampling of breast abnormalities.

- The Mammotome Biopsy System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.
- The Mammotome Biopsy System 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 Mammotome 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.