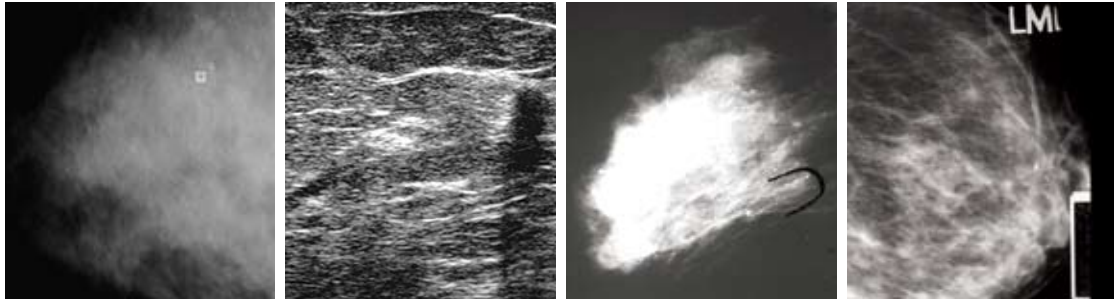


Sparing Patients Surgery When Facing Four Common Challenges:

**Case 1:**

Tightly clustered calcifications

Case 2:

Small (<2cm) masses

Case 3:

Dense breast

Case 4:

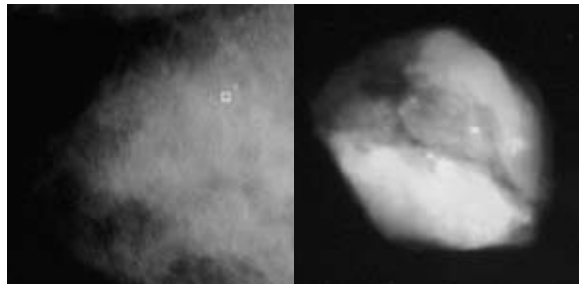
Fibrous tissue

Vacuum-Assisted Core Needle Biopsy (VACNB) produces fragmented samples that can leave diagnostic questions open—for example, the involvement of non-invasive cancer in high-risk lesions such as sclerosing adenosis or sclerosing papilloma. In sclerosing lesions, for instance, the strips of tissue produced by VACNB shred the lobes, making it impossible to differentiate lobulocentric growth patterns. Margins are lost. Diagnoses can not be made with confidence, which leads patients to surgery often merely to confirm a benign diagnosis.

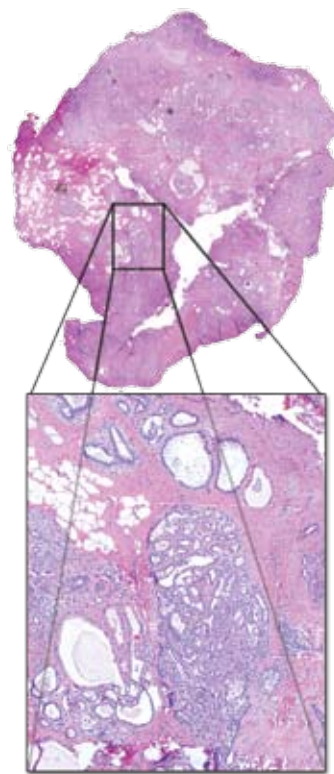
There's a better way. In each of the cases presented here, the confidence provided by the *Intact* specimen eliminated the need for surgical biopsy, where open excision otherwise would have been recommended.

How many surgeries could you spare your patients?

Case 1



The microcalcifications seen in the targeting image is clearly visible in the specimen radiograph. High correlation with the specimen radiograph supported a diagnosis of ductal papilloma.



Challenge: Tightly Clustered Calcifications

The strips of tissue captured in CNB rarely contain the entire cluster of calcifications, making histopathological correlation impossible. In contrast, the *Intact* BLES captures clusters of calcifications as large as 2cm for fast and easy pathology review and correlation.

Case: A 41 year-old woman presented for screening mammography.

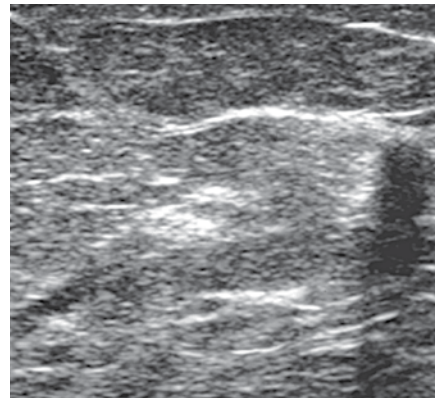
Indication: The mammogram revealed a small cluster of microcalcifications in the left breast. The lesion was classified as BIRADS IV, and an incisional biopsy was recommended.

Method: An *Intact* BLES procedure was performed because the calcifications were tightly clustered. Post-procedure images on the stereotactic table, and the specimen radiograph, indicated that most of the lesion had been removed.

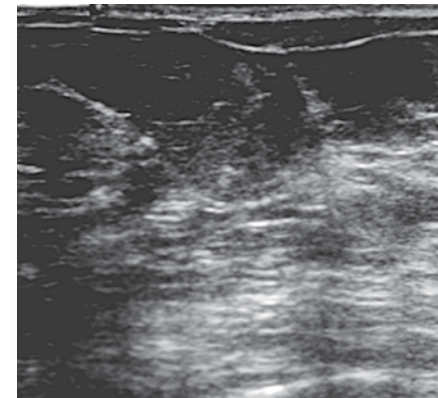
Diagnosis: Sclerotic and adenotic variant of a ductal papilloma with fibrocystic changes, including apocrine metaplasia; associated with microcalcifications. Sections reveal somewhat fibrotic and elastotic breast tissue with rather crowded populations of heterogeneous ductal groups in a rather organoid lobulated distribution. Foci of adenosis were also present. At times ductal proliferation revealed sclerotic papillary type features involved by adenosis as well as apocrine metaplasia. These foci were also associated with microcalcifications. Malignant process was absent.

Surgery avoided: This *Intact* BLES specimen permitted a more confident diagnosis, and eliminated the need for surgery to confirm the benign diagnosis.

Case 2



Pre-and post-biopsy ultrasound...



...confirming the small mass was excised

Challenge: Small (< 2cm) Masses

Small masses can be completely excised in a single pass with the *Intact* BLES, preserving the architectural integrity of the mass for a confident diagnosis.

Case: This 90 year-old patient had already had a wide excision of breast cancer in her left breast, without adjuvant treatment, at age 82. Her age and fragile health made her a poor candidate for surgery, so when a suspicious density was confirmed in her right breast, a non-surgical diagnostic was required.

Using the *Intact* Breast Lesion Excision System (BLES), the mass was completely excised in a short in-office procedure using only local anesthesia.

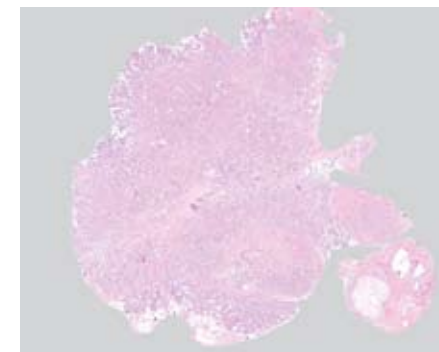
Method: Complete excision performed using *Intact* Breast Lesion Excision System (BLES).

The procedure removed a specimen approximately 25mm × 13mm × 9mm. A post-procedure ultrasound of the specimen demonstrated the solid density entirely captured.

Diagnosis: Pathology results showed Invasive Ductal Adenocarcinoma, well differentiated, SBR Grade 1, with negative margins of at least 0.2cm. Surgical margins were negative, with the nearest cauterized margin free of invasive tumor by 0.2cm. Single focus DCIS was present, adjacent to the invasive tumor. These were also free of the margins by 0.2cm.

HER2 staining ruled out HER2/neu gene amplification, suggesting the tumor had a loss of the centromeric region of chromosome 17 without overt HER2/neu gene amplification.

Surgery avoided: With clear margins around the lesion indicating complete capture, this diagnostic procedure functioned as the therapeutic procedure, sparing this fragile patient a second surgery.



Histopathology of the *Intact* sample shows that the SPR Grade I invasive ductal carcinoma is entirely contained

Challenge: Dense Breast Tissue

The *Intact*™ BLES adjusts the level of RF energy in real-time to facilitate smooth advancement to the lesion of interest, even in the most dense of breast tissue.

Case: 54 year-old woman presented for screening mammography.

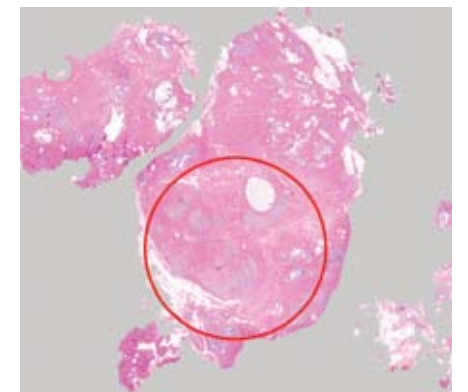
Indication: Mammogram revealed extremely dense breasts with multiple punctate calcifications bilaterally, characteristic of sclerosing adenosis (image, page 1). Interval development of a 1.0cm focus of pleomorphic calcifications inferiorly in the left breast required further evaluation with focal spot magnification view, which confirmed the observation.

An *Intact* BLES procedure was performed to differentiate sclerosing adenosis from Ductal Carcinoma *in situ*.

Case 3



Radiograph confirms calcifications are completely contained within the specimen

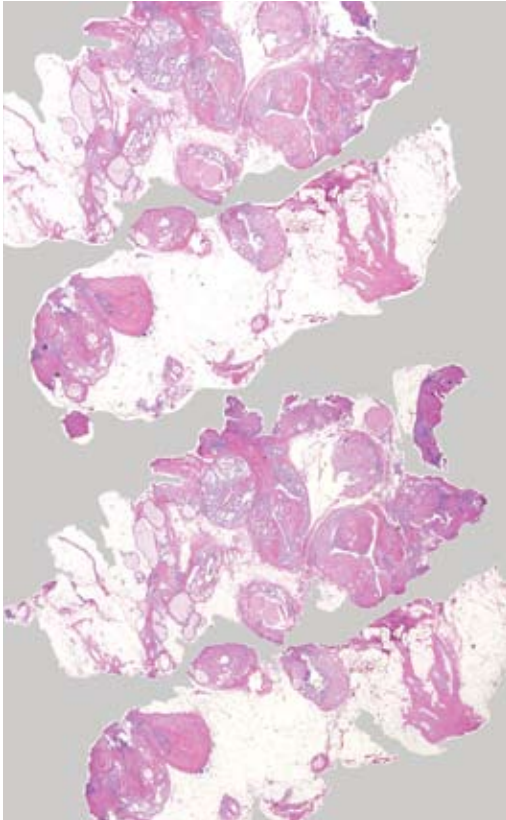


Intact architecture of the specimen permitted confident diagnosis

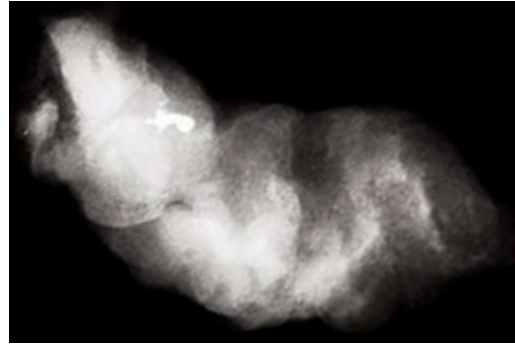
Diagnosis: Histopathological examination revealed Lobular Carcinoma *in situ* (LCIS) involving multiple terminal ductal lobular units. There were also fibrocystic changes with microcalcifications, adjacent to the LCIS.

Surgery avoided: The large, intact specimen acquired by the *Intact* BLES procedure permitted a definitive diagnosis of LCIS in this patient. There was no need for open surgical biopsy to confirm the diagnosis.

Case 4



Sclerosing lesion with florid fibrocystic changes, and no evidence of malignancy



Specimen radiograph confirms the entire fibrous mass has been excised

Case: 56 year-old woman presented for further evaluation of a suspicious area found on a previous mammogram.

Indication: Focal spot magnification views confirmed branching calcifications within the deep subareolar region of the left breast (image, page 1). An **Intact** BLES procedure was performed on the branching calcifications.

Diagnosis: Sclerosing papillary lesion with florid fibrocystic changes, and no evidence of mammary carcinoma. Around the periphery of the lesion, there were dense stromal sclerosis which entrapped ductular structures in a pseudo-infiltrative pattern.

Surgery avoided: Post-biopsy images and the specimen radiograph revealed the lesion had been completely removed with the large, intact specimen from the **Intact** BLES procedure, sparing the patient an open surgical excision.

Challenge: Fibrous Tissue

The **Intact** BLES removes a fibroadenoma in a single pass, in seconds. While fibrous tissue is typically crushed by VACNB, the **Intact** BLES glides through the most fibrous of tissue to completely excise small lesions, such as a fibroadenoma or benign mass.