

## Two Million Women and More to Come – The Mammotome® Breast Biopsy System

a report by

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### Introduction

The Mammotome Breast Biopsy System has been used in more than two million breast biopsy procedures since 1996, making it one of the fastest growing minimally invasive breast biopsy devices. The Mammotome system can be used to perform biopsies on the widest range of breast lesions of any biopsy device available today. The types of lesions that a biopsy can be conducted on using the Mammotome device include, but are not limited to, microcalcifications, masses, spiculated masses, asymmetric densities, multifocal disease and diffused tissue.

Biopsies with the Mammotome system require no stitches, may be performed in a doctor's office in less than an hour and women may return to normal activity immediately following the procedure. Women avoid a trip to the operating room and have a high level of satisfaction with the procedure. The device can be used in both stereotactic and ultrasound imaging modalities. This article summarises the product, clinical and healthcare economic information related to the procedure and how Mammotome compares to core needle and open surgical biopsy options.

### Background

There are basically three options for a breast biopsy procedure: open surgical biopsy, standard (mechanical) core needle biopsy and vacuum-assisted biopsy. Physician and patient preference for the biopsy method varies depending on the individual clinical situation.

### Mammotome Benefits

The Mammotome system has been the minimally invasive biopsy choice of over two million women so far, mainly due to the benefits the procedure offers when compared with open surgical and core needle biopsies. *Table 1* summarises the key benefits of Mammotome.

### How does the Mammotome Work?

The Mammotome probe has a specially designed

needle that is inserted into the breast only once through a one-quarter inch incision. Vacuum is applied to pull the breast tissue into the sample aperture of the needle and a cutter is rotated and translated through the needle to sever the tissue. The tissue specimen is then retrieved to a collection chamber. A tissue marker can be deployed through the aperture on the probe needle. *Figure 1* explains the working steps of the Mammotome.

### What is Unique about the Mammotome Vacuum-assisted Breast Biopsy?

Mammotome is the benchmark device in the vacuum-assisted breast biopsy procedure category. The intent behind the design of the Mammotome is to provide tissue samples for accurate clinical diagnosis. To achieve this goal, the physician should be able to locate the lesion, cut and transport tissue, evacuate blood and other fluids and mark the biopsy site. The product has been designed with features to accomplish the above-mentioned tasks (see *Table 2*).

### Clinical Benefits of the Mammotome

#### Stereotactic Breast Biopsy

With nearly 300,000 biopsies performed under stereotactic guidance in 2003, many breast care specialists regard Mammotome as the standard of care for stereotactic breast biopsy. This growth is primarily due to migration from open surgical and core needle to use of Mammotome for biopsies of micro-calcifications. Clinically, the Mammotome is a cost-effective alternative that provides similar diagnostic value to open surgery. Compared with the core needle, Mammotome provides significantly improved accuracy and sensitivity and reduces underestimation. The larger core tissue specimens obtained with the 11-gauge Mammotome (eight times the size of a 14G core needle) and the increased ability to acquire tissue from the target lesion with the help of vacuum have contributed to adoption. From a physician's perspective, the ease of use of the Mammotome when compared with a core needle under stereotactic guidance could also have contributed to this migration.



Table 1

Procedure	Mammotome	Core Needle	Open Surgical
Description	Tissue sample obtained using a needle with gentle vacuum, which draws, cuts and removes tissue.	Tissue sample obtained using a needle using a spring loaded device which cuts and removes tissue.	Incision made in the breast and a large sample is cut and removed. In some cases, a wire is inserted into the breast to localise the lesion.
Accuracy	Highly Accurate	Accurate	Highly Accurate
Sample Size	Sufficient tissue samples ensure accurate diagnosis	Limited sample size may underestimate more serious diagnosis	Tissue sample is one large piece which ensures accurate diagnosis
Scarring	Minimal	Minimal	External scar, internal scarring may interfere with future mammography
No. of Needle Insertions	1	4 to 6	N/A
Incision Size	1/4 inch	< 1/4 inch	1 to 2 inches
Incision Closure	1 adhesive bandage	1 adhesive bandage	Stitches and surgical bandage
Normal Recovery Time	Immediate	Immediate	A few hours
Anaesthesia	Local (awake)	Local (awake)	General (asleep) or local anaesthesia with sedation
Normal Length of Procedure	30 min to 1 hr	30 minutes to 1 hr	2 to 4 hrs
Location where procedure is performed	Doctor's office or out-patient setting	Doctor's office or out-patient setting	Operating room or out-patient setting

Figure 1

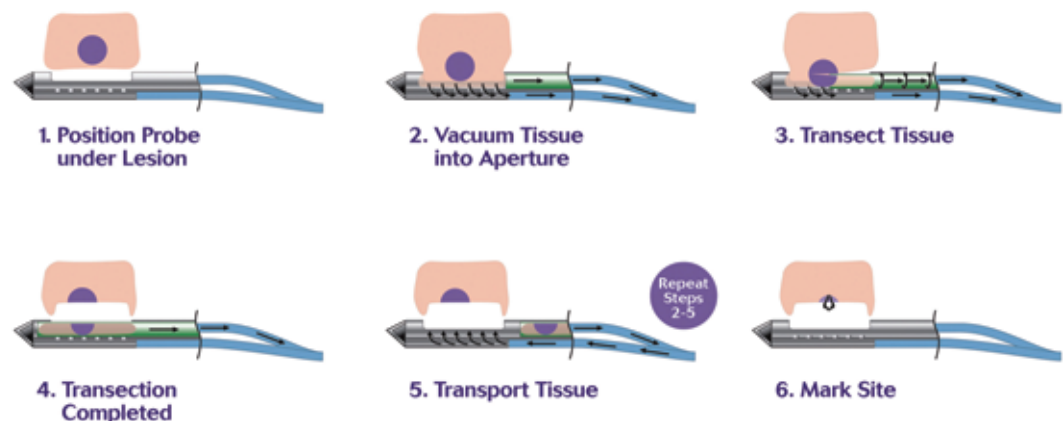


Table 2

Task	Product design features and benefits
Locate the lesion	The sharpness of the needle and the bladed tip option provide smooth and controlled insertion into the breast. The asymmetric needle geometry provides strength, control and visibility.
Cut and transport tissue	The angled edges of the sample aperture help to cleanly transect tissue and the tissue stop at the needle tip enables clean tissue severance. The constant cutting speed provides consistent sampling across different tissue densities. The polished internal cutter surface helps to minimise crush artifact.
Evacuate blood and other fluids	Vacuum on demand provides the ability to manage blood and fluids.
Mark biopsy site	The probe design provides the ability to introduce a tissue marker through the sample aperture.

An example of the body of clinical evidence, which supports the diagnostic accuracy achieved by stereotactic sampling with Mammotome versus core needle, is found in Burbank's study of patients with atypical ductal hyperplasia (ADH) and differentiated ductal carcinoma *in situ* (DCIS) lesions.<sup>1</sup> Following

1. F Burbank, "Stereotactic breast biopsy of atypical ductal hyperplasia and ductal carcinoma in situ lesions: improved accuracy with directional vacuum-assisted biopsy", *Radiology* (1997); 202: pp. 843–847.

open surgical excision of 113 ADH and DCIS lesions in 101 patients, he found 23% underestimated diagnosis in lesions initially diagnosed with 14-gauge automated needle (n=73) versus no lesions underestimated when sampled using Mammotome stereotactically (n=40). Further support for use of the Mammotome system is seen in the landmark article by Jackman et al., reporting reduced incidence of underestimation of DCIS.<sup>2</sup> It was found that DCIS underestimation was 1.8 times more frequent with core needle than with vacuum-assisted biopsy and 1.5 times more frequent with 10 or fewer specimens per lesion than with 10 or more specimens per lesion.

### Ultrasound Breast Biopsy

The benefits of the Mammotome system also apply to biopsy procedures using ultrasound imaging. Studies of 11-gauge Mammotome under ultrasound guidance show diminished false-negatives and underestimation, common shortcomings of automated cored needles.<sup>3,4</sup> A recent conference publication indicates that the use of a 14G core needle in ultrasound-guided breast biopsy greatly increases the chance that re-biopsy will be needed when compared with outcomes of vacuum-assisted biopsies.<sup>5</sup>

### Mammotome – New Indication for Use

The use of the Mammotome Breast Biopsy System keeps on expanding. In October 2003, the Mammotome added an indication for use on palpable lesions such as fibroadenomas, becoming the only minimally invasive breast biopsy device to have this indication. Once patients become aware that they can deal with fibroadenomas with the Mammotome system, more will likely request management of them through minimally invasive methods. It has been shown that the Mammotome system can help physicians manage fibroadenomas with minimal scarring and high patient satisfaction.<sup>6</sup>

Fibroadenomas occur in about 10% of all women and account for about half of the 1.6 million breast biopsies performed each year in the US. Although fibroadenomas are non-cancerous, they are a

significant source of anxiety for some women. They are particularly common among girls in their teens and women in their 20s and 30s. According to the National Institutes of Health (NIH), they occur twice as often in African-American women as in the general population.

Open surgical removal of fibroadenomas may involve the removal of nearby normal breast tissue, which can cause scarring and breast disfigurement requiring stitches to close an incision of one to two inches long. In a single visit, the Mammotome system can be used to obtain tissue for diagnosis from a suspected benign lesion and to remove tissue until the lesion is no longer visible under ultrasound imaging.

In a study published in the October 2003 edition of the *American Journal of Surgery*,<sup>6</sup> it was shown that use of the Mammotome system could reduce the palpability of the benign lesion. According to the study, 98% of the patients at their six-month post-biopsy follow-up visit had no palpable evidence of the initial lesion and 73% had no imaged evidence under ultrasound.

In addition, the study showed a high degree of patient satisfaction with the Mammotome Breast Biopsy System for the management of benign lesions:

- at 10 days post-biopsy, 82% were satisfied with appearance and healing of the incision and 92% would recommend the procedure to other women; and
- by six months follow-up, 100% were satisfied with incision appearance and would recommend the procedure.

### Healthcare Economics

In any clinically proven medical procedure, the cost of the procedure and the reimbursement play important roles in the practice of that procedure. A breast biopsy using the Mammotome system is a cost-effective alternative to open surgical biopsy. According to an *American Journal of Managed Care* study, the cost differences between vacuum-assisted breast biopsies and open surgical biopsies allow healthcare

2. R J Jackman et al., "Stereotactic breast biopsy of non-palpable lesions: Determinants of ductal carcinoma in situ underestimation rates", *Radiology* (2001); 218: pp. 497–502.

3. S H Parker et al., "Sonographically guided directional vacuum-assisted breast biopsy using a handheld device", *AJR* (2001); 177: pp. 405–408.

4. Simon J R, et al., "Accuracy and complication rates of ultrasound guided vacuum-assisted core biopsy: initial results", *Radiology* (2000); 215: pp. 694–697.

5. N Duchesne et al., "Ultrasound-guided breast biopsies: A multicenter retrospective analysis of factors influencing the re-biopsy rate", *Vienna Conference*, March 2004.

6. R E Fine et al., "Low-risk palpable breast masses removed using a vacuum-assisted hand-held device", *AJS* (2003), 186: pp. 362–367.

administrators to find hundreds of thousands of US dollars in annual cost savings, depending on their volume of cases.<sup>7</sup> The study concluded that facilities must consider the total costs of the new technology, especially when the new technology is as effective as the present technology. When the total facility costs were analysed, vacuum-assisted biopsy was less costly.

Vacuum-assisted breast biopsies are reimbursed under the code CPT 19103, the core needle procedures under CPT 19102 and the open surgical biopsies under CPT 19120 and CPT 19125.<sup>8</sup> Currently, there is no separate procedure code for minimally invasive management of fibroadenoma.

### Conclusions

Vacuum-assisted, minimally invasive breast biopsy using the Mammotome biopsy system is an

innovative yet proven alternative to open surgical and core needle biopsies. Over two million women have trusted the Mammotome procedure for a breast biopsy and experienced the many benefits of this option. Moreover, with the use of the system expanding from purely diagnostic purposes to help manage benign disease, many millions more can be expected to experience the procedure in the future. ■

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7. B Bodai et al., "Total cost comparison of 2 biopsy methods for nonpalpable breast lesions", *American Journal of Managed Care*, (2001), 7: pp. 527–538.
8. Current Procedural Terminology (CPT) 2004, *American Medical Association*, ©2003.
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