
The Benefits of the Hologic Eviva™ Vacuum-Assisted Stereotactic Breast Biopsy Device

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The Hologic Eviva™ stereotactic breast biopsy device

Introduction

More than 1.6 million breast biopsies are performed each year in the United States, 70-80% of which result in benign diagnoses¹. Given the frequency of benign biopsy results, and the important clinical information that can be obtained prior to definitive surgery in malignant cases, minimally invasive, compassionate biopsy techniques have become the standard of care for the initial diagnosis of breast cancer.

Until the mid-1990s, approximately 60% of breast biopsies were invasive surgical procedures. Today, open surgical biopsies are considerably less common, accounting for an estimated 30% of all biopsies performed in 2008. Most breast biopsies are now performed using minimally invasive image-guided techniques².

In this paper, the features of the new Eviva™ stereotactic breast biopsy device from Hologic, Inc. are described. The Eviva stereotactic biopsy device offers several significant advantages over other available needle biopsy systems.

Reduced Patient Anxiety

Stereotactic biopsy devices have traditionally advanced forward within the breast on a spring-loaded adapter. Eviva incorporates a pneumatic remote firing mechanism into the device instead of the typical spring release adapter. The pneumatic firing mechanism results in a significant reduction in noise thereby eliminating the patient movements that often accompany the adapter release with other devices.

In some biopsies performed with other biopsy systems, patients can actually lift off the table in response to the sound of the adapter firing. Even if the patient is warned in

advance of the noise, the sound of the adapter firing is startling and increases patients’ likelihood of movement. In my experience with more than 100 biopsies using the Eviva device, there has been no significant patient reaction when the Eviva needle is fired.

The pneumatic firing capability of the Eviva device represents a major advance over conventional biopsy systems. The decrease in the sound of the firing mechanism has a major impact on patients’ perception of the procedure, reducing their overall anxiety and perception of pain.

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Continuous Pain Management System

With other biopsy systems, patients frequently reported feeling pain during the tissue acquisition phase of the procedure. In these cases, it is necessary to interrupt the procedure and attach a syringe to the biopsy device to inject anesthetic into the biopsy cavity before proceeding. This extra step adds significant time to the procedure, thus lengthening the amount of time the patient spends on the biopsy table with her breast in compression.

The Eviva device’s patent-pending y-valve, first introduced with the Hologic ATEC® biopsy device, delivers pain medication directly into the cavity in a radial pattern, covering the necessary area to anesthetize the tissue with each biopsy cycle. In my experience using the Eviva device, there have been no patients that have complained of pain during the procedure,

¹ MedTech Insight, *U.S. Markets for Breast Cancer Detection and Diagnostic Technologies*, October 2009, p. 5-1.

² Ibid. p 5-1.

representing a dramatic difference from my experience using other devices. This significant improvement benefits the patient by eliminating pain during the biopsy, and benefits the patient, the physician, and the imaging center by decreasing the amount of time necessary to complete the procedure.

Increased Physician Confidence in the Procedure

The Eviva device utilizes clear tubing between the device and the remote tissue filter, enabling visual confirmation of tissue acquisition as the specimen passes through the tubing into the collection chamber. There is no need to continuously stop and re-start the procedure to remove or review samples, improving procedure efficiency. This efficiency leads to a significant savings in time and results in faster room turnover. Using Eviva, the total procedure time from skin anesthesia to clip placement usually takes under five minutes, compared to fifteen or more minutes using other biopsy devices.

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The integrated end-deploy biopsy site marking solution of the Eviva device also streamlines workflow. Biopsy site marking is an essential component of a percutaneous biopsy procedure, as it allows future localization of the biopsied area in cases requiring complete surgical excision or other treatment. Following tissue acquisition using the Eviva device, the biopsy system slides off, leaving an introducer sheath in place. The SecurMark® for Eviva deployment device is then inserted through the introducer and the clip is deployed at the biopsy site. There is no need to pull back or rotate the deployment device.

The Eviva device also allows biopsy options for a wide spectrum of patients. The petite needle design can be used for superficial lesions and in patients with breasts that compress to as small as 16 mm. Due to limitations with other needle systems, many of these patients would otherwise need to have surgical excision rather than core biopsy.

Conclusion

The Hologic Eviva device incorporates a number of features designed to provide a more compassionate biopsy experience for women while providing a more efficient, effective clinical solution.

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In clinical use, the Eviva device provides a better patient experience as a result of quiet firing, continuous application of pain medication with each biopsy cycle, and simplified, accurate site marking. Pain during the procedure is virtually eliminated, and the time to perform the procedure is reduced by at least fifty percent, thus reducing patient time on the biopsy table, streamlining the workflow, and allowing for more effective use of staff and physician time.

Dr. Stuart Kaplan is section chief of breast imaging and vice chairman of radiology, Mount Sinai Medical Center, Miami Beach, Florida. He is also the chairman of the stereotactic breast biopsy accreditation program from the American College of Radiology Commissions on Standards and Accreditation. Dr. Kaplan was one of the first adopters of the Eviva breast biopsy device in clinical practice.