



TARGETED BIOPSY MADE EASY



This device does not currently have regulatory approval for commercial distribution.

FUSION BIOPSY

FOR IMPROVED PROSTATE CANCER DIAGNOSIS

HOW IT WORKS

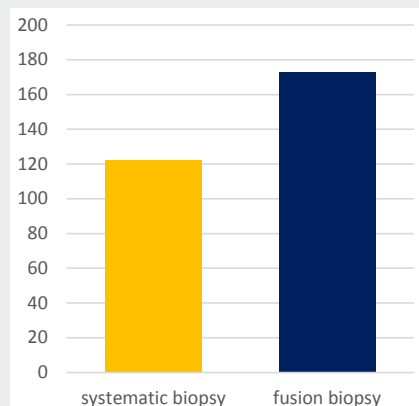
In a fusion biopsy, previously-acquired MR images are fused with live ultrasound images to enable targeted biopsies directly from suspected cancer regions.

MRI offers an increased ability to visualize potentially-cancerous tissue. However, biopsy inside the MRI bore is not feasible. Fusion biopsy bypasses these challenges and allows clinicians to perform targeted prostate biopsies in an outpatient clinic.

RESEARCH SUPPORTS FUSION BIOPSY

- 1 in 7 American men will get prostate cancer in their lifetime^[1].
- Fusion biopsies can detect 30% more high-risk cancer than traditional systematic biopsies^[2].
- An estimated <10% of men have access to fusion biopsy.

DETECTION OF HIGH RISK CANCER



A recent prospective study of a group of 1003 men found that fusion biopsy detected 173 cases of high-risk cancer in 173 men vs. 122 in systematic ($p < 0.001$)^[2].

THE FOCAL HEALTHCARE SOLUTION

Focal Healthcare recognizes that urology practices of all sizes need access to a practical, easy fusion procedure. Fusion Bx has been developed with three principles in mind:



ACCURACY

- Fusion with the most advanced software algorithms.
- Hardware is designed for reliable probe tracking and maximum range-of-motion.



EFFICIENCY

- A simple workflow guarantees seamless integration into existing practice.
- Minimal training and procedure time.
- Doesn't require an extra assistant.



ACCESSIBILITY

- Compatible with leading ultrasound systems.
- Affordable for clinics of all sizes.
- Mobile and compact.

FUSION Bx™

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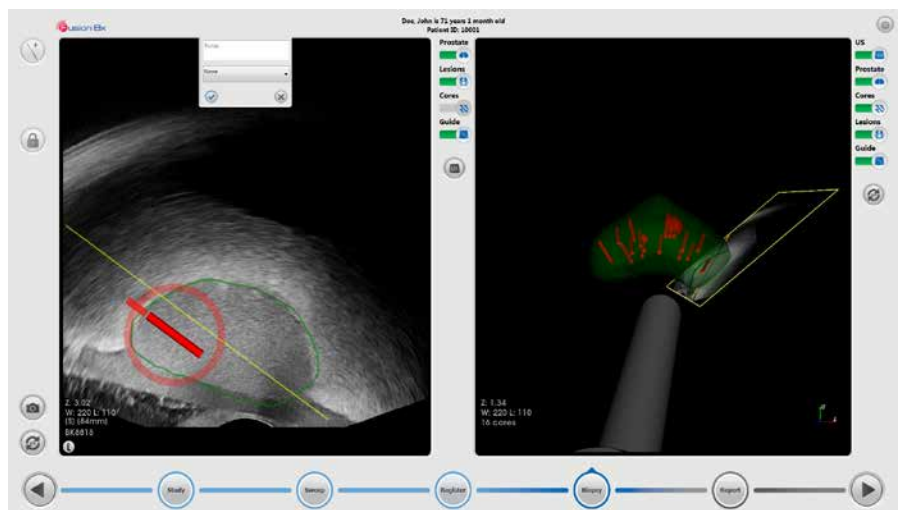
HARDWARE

- **Probe has 6 degrees of freedom** to provide full-gland access
- **Quick and easy set-up**
- **Only requires 2 hours of training** for fast integration into your clinic
- **Hardware acts as 3rd arm** so the procedure only requires one assistant
- **Supports end-fire and side-fire mode** for increased access to entire prostate gland



SOFTWARE

- **Semi-automated segmentation** takes less than a minute
- **Non-rigid registration** to maximize accuracy
- **2D and 3D Imaging** allows easy navigation to targets
- **Save report** to discuss with patients and physician
- **Automatic data transfer** for smooth workflow



Fusion Bx software guides users through the fusion biopsy procedure in 5 simple steps, while advanced 3D visualization allows fast tracking and targeting



Intelligently Simple Solutions

Focal Healthcare is committed to advancing prostate cancer management through technical innovation. Through the development of imaging tools that are accurate, efficient, and accessible to all healthcare practices, Focal Healthcare provides technology to enable confident prostate cancer diagnosis and increased patient satisfaction.

“We are committed to improving the lives of prostate cancer patients and their families by producing world-class medical equipment”

Chicuong La, PhD, JD
CEO, Focal Healthcare

CONTACT US to learn how our flexible pricing options can get fusion biopsy into your practice today

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References:

1. Siegel, Rebecca, et al. “Cancer statistics, 2014.” *CA: a cancer journal for clinicians* 64.1 (2014): 9-29
2. Siddiqui M. Minhaj, et al. Comparison of MR/ultrasound fusion-guided biopsy with ultrasound-guided biopsy for the diagnosis of prostate cancer. *JAMA* 2015. 313(4):390-397.