

## Precision Without Compromise

How the Navigo™ 4D MRI Fusion Biopsy System  
Redefines the Standard for Prostate Fusion

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MRI-US fusion biopsy is now the **standard of care** for prostate cancer diagnosis - endorsed by the American Urological Association for all men at risk, including biopsy-naive patients.<sup>1</sup> As urologists move fusion into their preferred setting (office, ASC or hospital), the platform they choose determines whether that transition actually delivers on its clinical and financial promise.

Not all fusion systems are equal. Automation, workflow stability, and long-term planning capability vary significantly between platforms. The Navigo 4D Fusion Navigation System was built to address every step of the process - from positioning to procedure to focal therapy planning and active surveillance.

### THE CHALLENGE: Why Fusion Technology Can Still Fall Short

#### The Problem With “Good Enough” Fusion

Bringing fusion into your facility is only half the battle. The real measure of a fusion platform is what happens during the procedure - when a patient shifts, ultrasound settings are adjusted, or a core must be captured precisely on target. Systems that rely on manual intervention at these moments introduce risk: missed registrations, workflow interruptions, incomplete biopsy maps, and degraded accuracy.

#### *The Clinical Stakes Are High*

*In the PROMIS study, MRI-guided fusion delivered 93% sensitivity in detecting clinically significant high-grade cancer (Gleason >4+3), while standard biopsies only detected 48%.<sup>3</sup> A platform that interrupts workflow, requires manual adjustments or scans, or misses biopsy markings compromises the precision that makes fusion superior.*

## THE SOLUTION: Navigo 4D Fusion Engineered for Real-World Practice

### Real-Time Motion Compensation: Fusion That Stays True

Patients move. They breathe, shift position, and respond to discomfort throughout a TRUS biopsy. Any change in patient position or probe placement can cause the fused MRI-US model to drift - and in conventional systems, the only fix is to **stop and manually re-register**. Every interruption adds non-clinical time, breaks workflow, and risks the re-registration being skipped entirely.

Navigo 4D **automatically adapts to patient motion in real time** - continuously, without any intervention. The same is true for ultrasound settings changes: adjusting view, depth or image status (i.e. if image is frozen) does not require re-registration. Physicians can optimize their image freely, and the fusion stays stable throughout.

*Navigo automatically adapts to patient motion and ultrasound settings changes in real time - no stopping, no re-registration, no missed targets.*

### Automatic Biopsy Marking: Every Core Accounted For

In systems that require a foot pedal or button press to register each biopsy, the burden falls on the clinician mid-procedure. Missed markings are a predictable consequence of divided attention - not user error. And if manual re-registration does not occur for each systematic biopsy, the markings may not be accurate anyway.

Navigo **automatically marks every biopsy core** on the prostate model as it is taken. No pedal. No button. No additional action. The result is a complete, accurate biopsy map - every time.

This also has a direct **financial impact**. Payers now reimburse for each additional MRI-targeted lesion biopsied, as well as additional reimbursement for systematic biopsies during a fusion procedure. A complete, automatically generated biopsy map provides the documentation needed to **support claim submission for every targeted site** - meaning missed markings in a conventional system are not just a clinical gap, they are a lost billing opportunity.

## BUILT FOR WHAT COMES NEXT Active Surveillance, Focal Therapy, Transperineal Approach

### Active Surveillance: Biopsy-Over-Biopsy Precision

Effective active surveillance depends on returning to the **same biopsy locations** on follow-up - and detecting progression at the exact sites where disease was previously found. Navigo supports upload and comparison of prior studies, enabling physicians to overlay previous biopsy maps with current imaging. Follow-up biopsies are guided by the patient's own history, not estimation.

#### *Active Surveillance Done Right*

*Prior biopsy locations and positive pathology results upload directly into Navigo for precise comparison across studies. Each procedure builds on the last - creating a longitudinal picture of each patient's disease.*

## The Path to Focal Therapy Starts with the Biopsy

Focal therapy (HIFU, cryoablation, and other energy-based treatments) requires precise knowledge of where cancer lives within the prostate. That precision starts with the biopsy map.

Because Navigo auto-marks every core, the completed 3D prostate model is immediately usable for treatment planning. Navigo includes integrated **3D focal therapy planning software**, allowing urologists to translate biopsy data directly into targeted treatment zones - keeping the entire workflow within one system.

### A Complete Navigo-Based Focal Therapy Program Delivers:

- ✓ Comprehensive prostate maps from every procedure - automatically
- ✓ Longitudinal cancer localization via prior study upload and comparison
- ✓ Integrated focal therapy planning software - no separate platform required
- ✓ SmartBx core-level precision for accurate focal treatment zone identification
- ✓ Incremental treatment revenues that follow naturally from fusion infrastructure already in place

## Option to Transition to Transperineal Biopsies at Any Time

And if your practice wants to transition to transperineal biopsies now or in the future, the Navigo **SmartGuide free-hand transperineal guide** enables integrated 3-D MRI-fusion needle targeting of even small lesions in difficult locations, without having to switch to 2D ultrasound cognitive fusion as with other transperineal needle guides.

### SMARTBX™ Biopsy Management + NAVIGO™ Fusion A Complete Solution at a Predictable Cost

## Specimen Integrity: Closing the Accuracy Loop

Even a perfectly-targeted biopsy can yield incorrect cancer staging if the specimen is damaged in processing. Up to **40% of tissue can be lost** during biopsy gun transfer/transport due to tangling, fragmentation, and multiple forceps transfers before the slide is read.<sup>4</sup> And the higher the Gleason score, the more fragile and fragmented the specimen becomes. SmartBx preserves core location and orientation from needle to slide - preventing the fragmentation that leads to mis-grading, and providing the core-level precision that focal therapy planning requires.

**Three published clinical studies show SmartBx delivers more tissue for evaluation and an extra layer of confidence in your pathology results.**

**30%**

*increase in biopsy  
core length<sup>5</sup>*

**95%**

*reduction in biopsy  
fragmentation<sup>5</sup>*

**31%**

*increase in detection of clinically  
significant high-grade disease<sup>5</sup>*

The SmartBx Management System is included in Navigo's **pay-per-procedure program** - along with all disposables, service, and support. No large capital commitment required. Practices access the full Navigo + SmartBx suite (+ SmartGuide for TP if desired) at a predictable per-procedure cost, making fusion financially viable in any facility from the very first case.

## EASIER BY DESIGN: The Navigo Learning Curve Advantage

### Physician-Operated. Staff-Friendly. Clinic-Ready.

Conventional fusion platforms typically require two people working in parallel - one managing the ultrasound and biopsy gun, and one operating the fusion software and manually registering each core. That model adds staffing complexity and limits scheduling flexibility.

Navigo's automation and ultrasound integration makes **single-operator use a realistic option – and is made even easier by allowing you to use your preferred ultrasound.**

**MotionLock™** motion compensation, **SmartSync™** ultrasound integration, biopsy marking, and image registration all happen automatically - reducing procedural steps, shortening training time, and allowing the care team to stay focused on the patient.

#### *Workflow Comparison at a Glance*

*Conventional systems: physician positions probe → technician registers image → physician takes core → technician presses foot pedal or button to mark biopsy → repeat. Patient moves or settings change = stop and re-register.*

*Navigo: physician positions probe → motion compensation runs automatically → physician takes core → biopsy marked automatically. Settings changes are seamless. One operator. Continuous precision.*

## FORWARD-THINKING TECHNOLOGY: Annual Updates & Continuous Improvement

### A Platform That Evolves with Your Practice

Many fusion platforms are static after installation — fixed to the software version at the time of purchase. Navigo delivers **annual software updates** that bring new automation features, workflow improvements, and enhancements informed by real-world clinical use. As AI and imaging technology advance, Navigo is built to integrate those gains - keeping the platform current without requiring hardware replacement.

*Annual software updates are included in Navigo's pay-per-procedure program with no additional fees. The system the practice invests in today will be more capable next year.*

## NAVIGO vs. CONVENTIONAL FUSION PLATFORMS

| Capability                            | Navigo 4D                                               | Conventional Systems                                 |
|---------------------------------------|---------------------------------------------------------|------------------------------------------------------|
| Real-Time Motion Compensation         | ✓ <b>MotionLock.</b><br>Automatic, continuous           | ✗ Manual re-registration or scan required            |
| Fully Automated Biopsy Marking        | ✓ <b>Every core.</b><br>No action needed                | ✗ Foot pedal or button press required                |
| US Settings Change = Re-registration? | ✓ <b>No. With SmartSync,</b><br>fusion remains stable   | ✗ Yes - workflow interrupted                         |
| Multi-Target Billing Documentation    | ✓ <b>Complete biopsy map</b><br>auto-generated          | ✗ Manual marking may leave gaps                      |
| Prior Study Upload & Comparison       | ✓ <b>Biopsy-over-biopsy</b><br>tracking                 | ✗ Limited or unavailable in some cases               |
| Focal Therapy Planning Software       | ✓ <b>3-D Integrated with all</b><br>biopsy core results | ✗ Not included in most; not all biopsy cores tracked |
| Biopsy Specimen Preservation System   | ✓ <b>SmartBx included in</b><br>pay-per-procedure       | ✗ Separate purchase required                         |
| Single-Operator Capable               | ✓ <b>Physician-only</b><br>use supported                | ✗ Often requires dedicated technician                |
| Annual Software Updates               | ✓ <b>Included — ongoing</b><br>improvements             | ✗ Infrequent or fee-based                            |
| Fusion-Integrated TP Guide            | ✓ <b>Yes. SmartGuide.</b>                               | ✗ Most require switch to US cognitive fusion         |

## FINAL WORDS

The decision to bring MRI-US fusion into your facility is the right one - clinically, financially, and for the long-term growth of your practice. But the platform makes the difference.

Navigo 4D delivers real-time motion compensation that never interrupts a procedure, transperineal fusion integration, automatic biopsy marking that never misses a core, complete documentation to support multi-target claim submission, prior study comparison for rigorous active surveillance, integrated focal therapy planning software, and SmartBx specimen integrity - all at a predictable per-procedure cost, and in a system simple enough for a physician to operate alone, with software that improves every year.

**This is not just a fusion system. It is the clinical infrastructure for a complete, modern prostate cancer practice.**

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## References

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