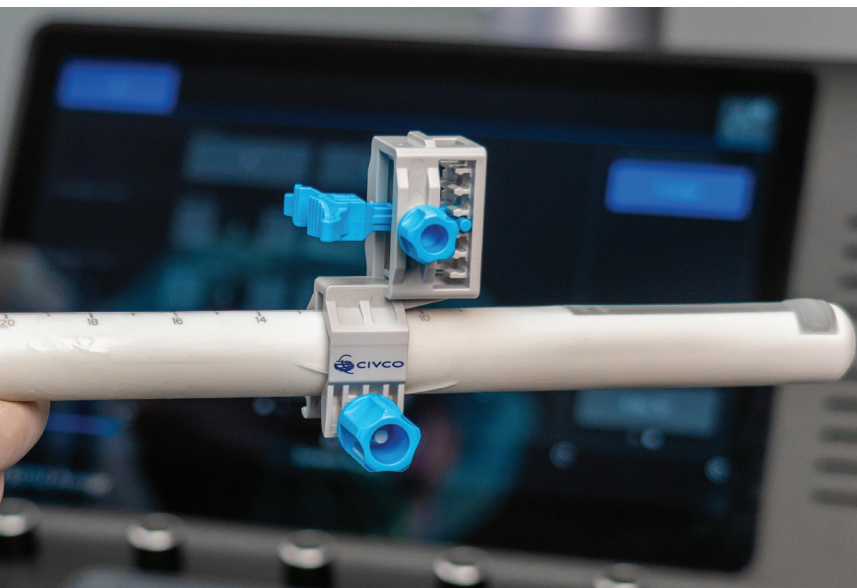


TP **PIVOT** PRO™

THE
**SMARTER
APPROACH**
TO PROSTATE BIOPSIES

Uncovering the clinical reasons why to adopt the freehand, minimally invasive approach to transperineal biopsy.



EMPOWERING

PROSTATE CANCER DETECTION WITH TRANSPERINEAL BIOPSY OF TP PIVOT PRO

TP Pivot Pro was designed with clinicians, for clinicians, to enable a smarter approach to transperineal prostate biopsies.

Prostate cancer affects millions each year, ranking second in cancer diagnoses and fifth in cancer-related deaths for men globally. ¹

As of 2022, transrectal ultrasound-guided biopsies are the most commonly used biopsy method by clinicians worldwide, with millions of procedures performed each year. ²

Even though TRUS has been the most common system for performing prostate biopsies for the past 30 years, Thomas J. Polascik, MD, urologic oncologist, says it poses serious risks, even for relatively healthy men.

“The hospitalization rate for sepsis after prostate biopsy around the world is about 3%, but with 3 out of 100 patients, that’s like rolling the dice – healthy men who come in for a biopsy can possibly end up in the ICU due to sepsis.” ³

Fortunately, an alternative method is rapidly gaining momentum internationally – the freehand, minimally invasive transperineal (TP) prostate biopsy. Statistics confirm growing adoption of the transperineal technique due to its safety, increased guidance from professional organizations and new reimbursement policies in some countries.

When utilized, the transperineal biopsy can offer urologists:

- Improved clinical advantages compared to the transrectal approach
- Greater workflow efficiencies
- Better provider economics



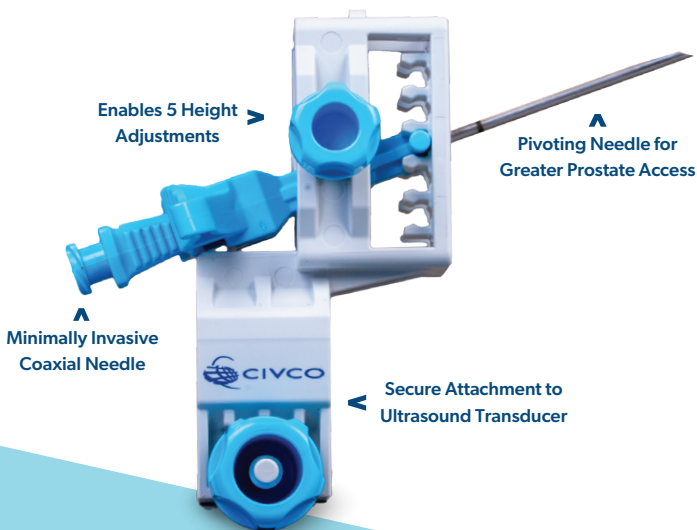
INTRODUCING

TP PIVOT PRO

CIVCO's TP Pivot Pro disposable needle guides for ultrasound-guided transperineal prostate biopsies enable a freehand, minimally invasive approach to prostate biopsy.

NOTABLE FEATURES:

- Pivoting coaxial needle
- Allows height adjustments without removing coaxial needle from guide or patient
- Use under local or general anesthesia
- Single-use device, no reprocessing required
- Designed to fit a range of ultrasound probes
- Secure transducer attachment, no taping required



IMPROVED

CLINICAL ADVANTAGES OF TRANSPERINEAL BIOPSIES

A freehand, minimally invasive transperineal approach to prostate biopsy can offer improved clinical advantages compared to the transrectal approach.

Reduces risk of negative patient outcomes:

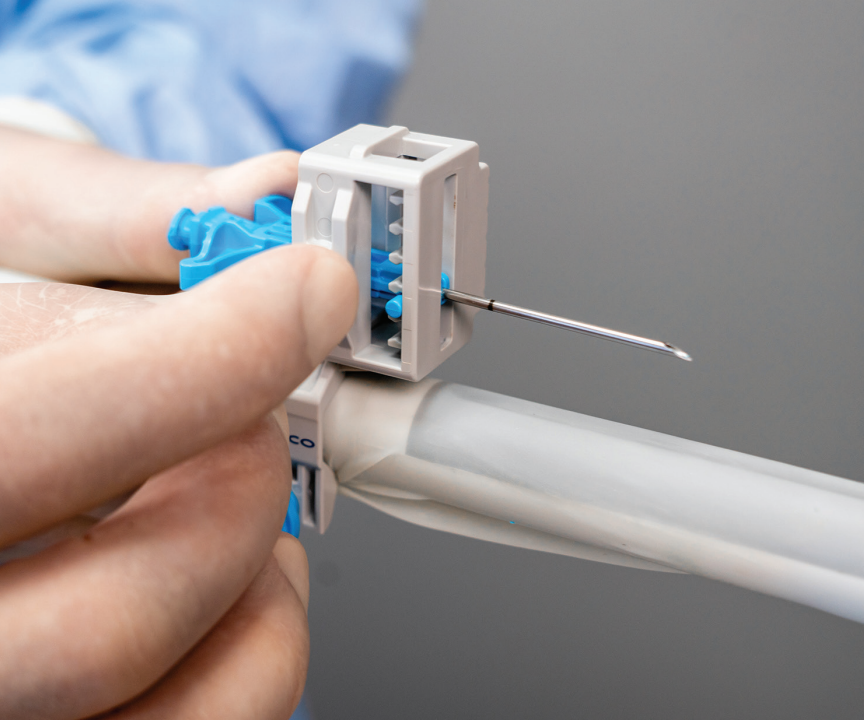
Reducing complications such as infection, fever, rectal bleeding, urinating pain, gross hematuria, and hematospermia.

A recent literature review shows that the rate of sepsis after TRUS biopsy appears to be increasing, with the rates of multi-resistant bacteria found in rectal flora post-TRUS procedures reaching as high as 5%. In stark contrast, various clinical studies have recently demonstrated the potential of transperineal biopsies to significantly decrease infection rates. A study by Pepe involving 3000 patients who underwent transperineal prostate biopsies revealed an infection complication rate post-procedure of under 1%; meanwhile, a meta-analysis conducted by Grummet reported a sepsis rate of less than 0.1% after the procedure. ⁴

Effective Targeting of the Entire Prostate:

Improving tissue sampling access to all zones of the prostate, including the anterior and peripheral zones.

Studies have shown that the transperineal approach is superior at detecting and accessing anteriorly located prostate tumors when compared with the transrectal approach, with the transperineal approach's improved sampling being directly associated with an increased likelihood of upgrading to clinically significant prostate cancer. Meanwhile, the TR biopsy is less effective at detecting such tumors - in fact, in a recent study of 108 men who underwent TR or MR-guided biopsy, 23% of anterior apex lesions were missed with TR procedures. This is critical, given that anterior tumors constitute roughly 20% of all prostate tumors. Due to the enhanced cancer detection rates linked to TP biopsy when compared to TR biopsy, numerous medical facilities are transitioning away from TR biopsy entirely in favor of TP prostate biopsy. ⁵



Minimizing Post-Biopsy Complications:

TP Pivot Pro's minimally invasive coaxial or introducer needle reduces the total number of puncture sites required through the perineum while improving tissue sampling access to all zones of the prostate. The freehand transperineal approach's direct anatomic access through the perineal skin has been shown to result in higher cancer detection rates for anterior lesions, including patients with prior negative TRPBx.⁵

Additionally, by removing the need to pass the biopsy needle through the rectal mucosa, healthcare workers are also able to avoid potential infection risks by reducing the transfer of bacteria, which in turn allows for increased patient safety. This approach also minimizes pain when compared to standard grid-phased TP biopsies, allowing for a more comfortable experience for patients.⁵

BETTER

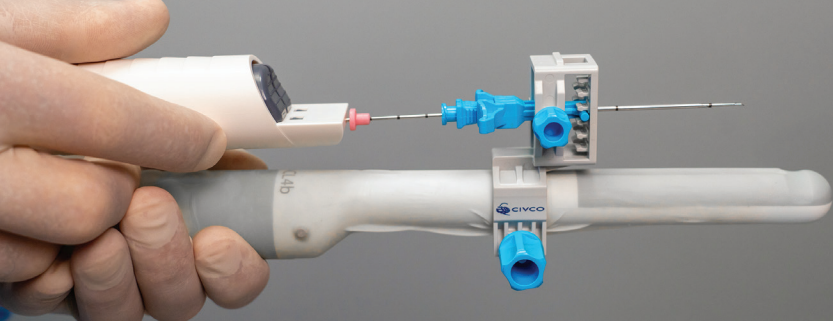
PROVIDER ECONOMICS

While transperineal biopsy has traditionally been performed using a brachytherapy grid and stepper, the freehand approach to transperineal biopsy may be performed in an office under local anesthesia, reducing overhead costs associated with general anesthesia, operating room and equipment requirements.

One obstacle that has often been cited as preventing the widespread adoption of transperineal biopsy is the elevated expenses often linked to using specialized tools. To address this issue, a method for transperineal biopsy has been introduced, involving freehand transperineal biopsies conducted under local anesthesia through two parallel access points. This technique doesn't necessitate any specialized equipment – a significant advantage that, in turn, helps to lower the overall procedure costs.^{6,7}



Freehand transperineal biopsies can also save time for the clinic and patient, with one study showing a freehand biopsy procedure time of 13 minutes compared to 22 minutes using a grid.⁵



GREATER

WORKFLOW EFFICIENCIES

A freehand, minimally invasive transperineal prostate biopsy reduces the biopsy procedure length compared to historical TP methods and also decreases the total number of patient visits required.

Studies show that the freehand transperineal approach can also save clinicians significant time, with the procedure typically able to be completed in one in-office visit using only local anesthetic (as opposed to TRUs procedures, which require separate appointments for both a pre-biopsy rectal swab and subsequent biopsy once culture results are known).³ Freehand transperineal biopsies also have a shallow learning curve and feature a procedure time that is shorter than that of grid-based procedures, with the average procedure time having been shown to drop to 9 minutes once proficiency has been achieved.⁵

TP Pivot Pro's intuitive design allows for quick and easy setup and use, enabling easier learning curves and faster procedure times.

- Easy height adjustments without removing the needle from the guide or the patient.
- Unique pivot feature allows parallel and angling options of the introducer needle while maintaining visualization within the imaging plane.
- Secure attachment to the transducer on a range of biplane probe diameters, without the need to tape the transducer.
- Eliminates need for patient rectal swab and antibiotic use.

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