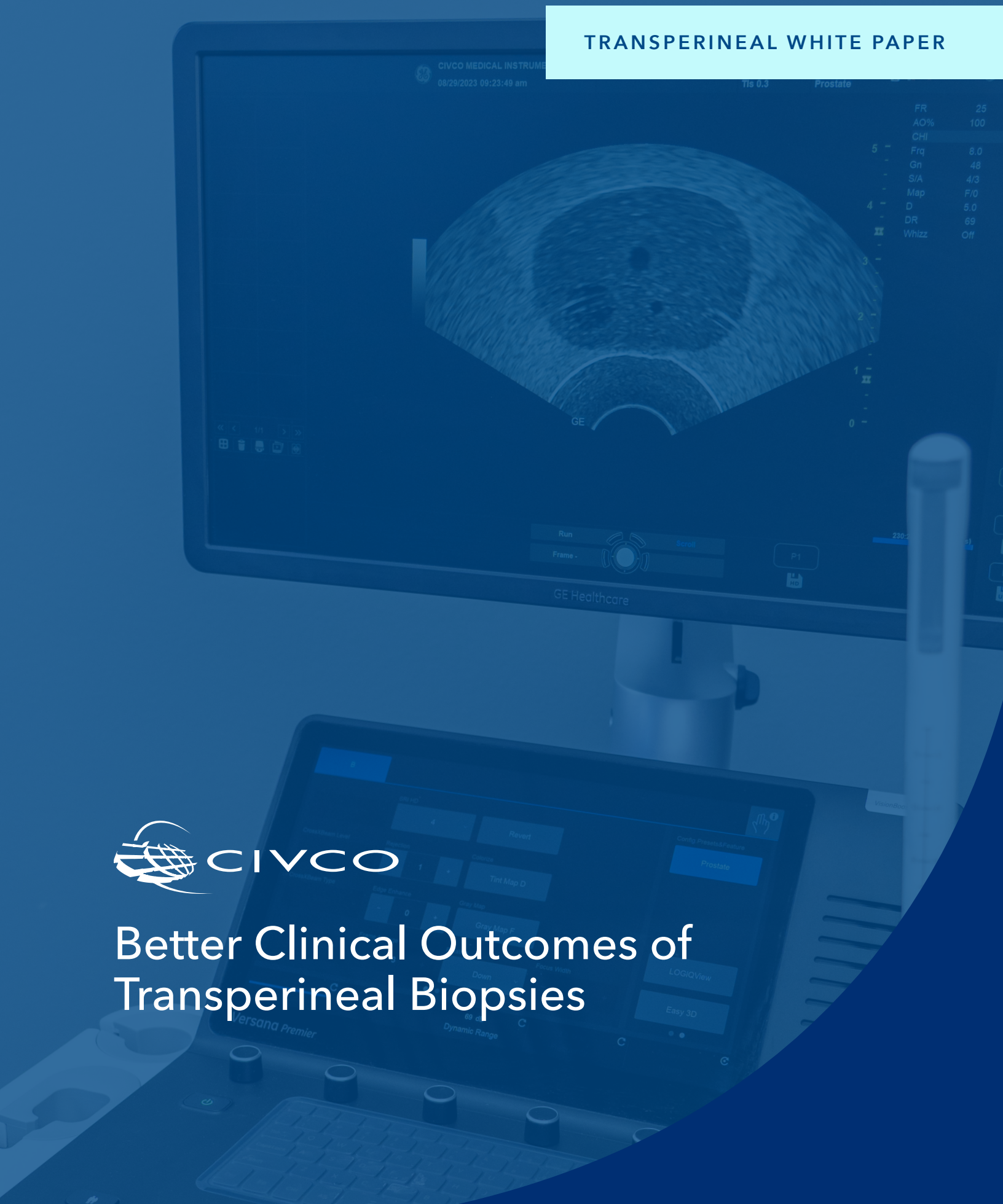
TRANSPERINEAL WHITE PAPER



CIVCO

Better Clinical Outcomes of Transperineal Biopsies

Each year, prostate cancer affects hundreds of thousands of men across the United States. According to the American Cancer Society (ACS), it is the second most commonly diagnosed cancer in American men, with 2024 alone seeing an estimated 299,010 new cases and over 35,250 deaths. In total, ACS further estimates that 1 in 44 men will die of prostate cancer.[1]

As such, early detection and treatment of prostate cancer is vitally important, with prostate biopsies having become a widely accepted and frequently used method for its detection. In particular, transrectal biopsies are the most common method of ultrasound prostate biopsy, with millions of procedures performed each year across North America and Europe.[2] Unfortunately, the procedure also poses a significant (5-7%) risk of infection. Published data from a 9-year global prevalent study of infection in urology stated the risk of infection (5-7%), with severe infection requiring hospitalization being seen in 1-3% of patients and fatal events reported in 0.1-1.3% of (transrectal) biopsies.[3] Additionally, systematic transrectal biopsies have been shown to frequently under sample or even miss cancers in parts of the prostate that are often more difficult to access, including the anterior, lateral peripheral zone, and apex.[4]

Even though TRUS has been the most common system for performing prostate biopsies since 1989, Thomas J. Polascik, MD, urologic oncologist, says it poses serious risks, even for relatively healthy men.

1/44

men estimated to die of prostate cancer[1]

5-7%

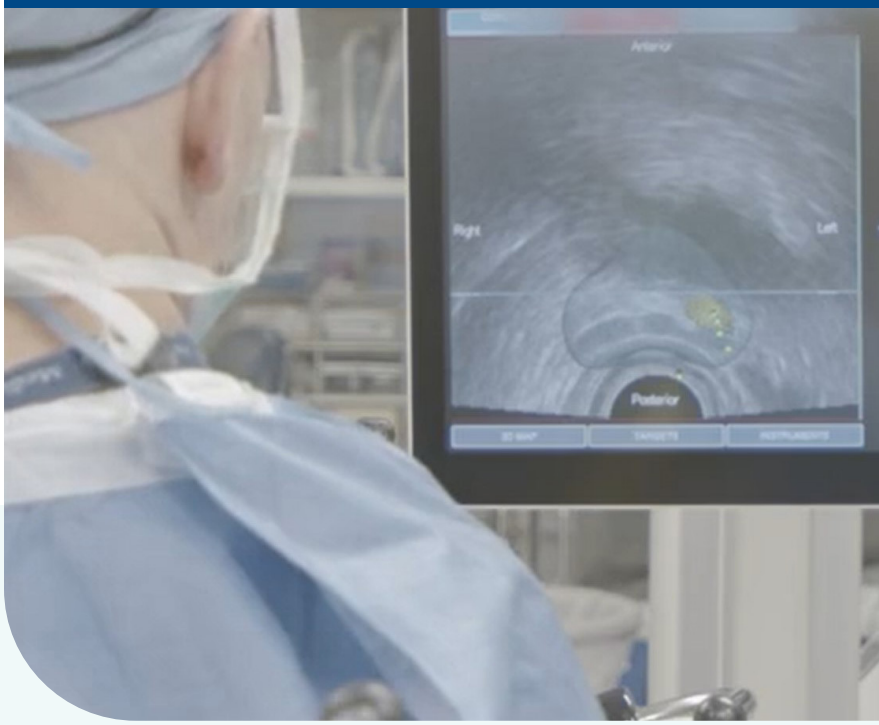
patients face risk of infection[3]

1-3%

patients with severe infection requiring hospitalization

"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..."[5]

Thomas J. Polascik, MD



1 Key Statistics for Prostate Cancer – American Cancer Society: https://www.cancer.org/cancer/types/prostate-cancer/about/key-statistics.html
2 Schmeusser B. Levin B. Lama D. & Sidana A. (2022). Hundred years of transperineal prostate biopsy. Therapeutic Advances in Urology. https://doi.org/10.1177/17562872221100590
3 Alidjanov J. F. Cai T. Bartoletti R. Bonkat G. Bruyère F. Köves B. Kulchavenya E. Medina-Polo J. Naber K. Perepanova T. Pilatz A. Tandogdu Z. Bjerklund Johansen T. E. & Wagenlehner F. M. (2021). The negative aftermath of prostate biopsy: prophylaxis complications and antimicrobial stewardship: results of the global prevalence study of infections in urology 2010-2019. World Journal of Urology 3423–3432. https://doi.org/10.1007/s00345-021-03614-8
4 Das C. J. Razik A. Sharma S. & Verma S. (2019). Prostate biopsy: when and how to perform. Clinical Radiology 853–864. https://doi.org/10.1016/j.crad.2019.03.016
5 In Detecting Prostate Cancer, Which Biopsy Procedure is Best? (Duke Health): https://physicians.dukehealth.org/articles/detecting-prostate-cancer-which-biopsy-procedure-best

16,941 participants

A 2020 meta-analysis of **16,941 participants** across **90 randomized controlled trials** reported **significantly reduced infectious complications** (including sepsis, fever, and urinary tract infections) compared to transrectal biopsy.[8]

In contrast, statistics have shown the transperineal prostate biopsy to have various improved clinical advantages when compared to the transrectal approach.

A recent literature review showed that the rate of sepsis after transrectal biopsy is substantial, with post-biopsy sepsis rates developing in up to 1.5% of patients and up to 9.1% of patients with antimicrobial-resistant rectal flora.[6] Meanwhile, various clinical studies have recently demonstrated the potential of transperineal biopsies to significantly decrease infection rates, with a recent study reporting infective complications as low as 0-1%.[7] Similarly, a 2020 meta-analysis of 16,941 participants across 90 randomized controlled trials reported significantly reduced infectious complications (including sepsis, fever, and urinary tract infections) compared to transrectal biopsy.[8]

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.

Statistically, 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.[9] This is critical, given that anterior tumors constitute roughly 20% of all prostate tumors.[10] 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.[11,15]

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6 EXIT from Transrectal prostate biopsies (TREXIT): sepsis rates of transrectal biopsy with rectal swab culture guided antimicrobials versus freehand transperineal biopsy: https://www.nature.com/articles/s41391-021-00438-w

7 Comparing outcomes of transperineal to transrectal prostate biopsies performed under local anesthesia: https://pubmed.ncbi.nlm.nih.gov/35505694/

8 Pradere B. Veeratterapillay R. Dimitropoulos K. Yuan Y. Omar M. I. MacLennan S. Cai T. Bruyère F. Bartoletti R. Köves B. Wagenlehner F. Bonkat G. & Pilatz A. (2021). Nonantibiotic strategies for the prevention of infectious complications following prostate biopsy: a systematic review and meta-analysis. The Journal of Urology 653–663. https://doi.org/10.1097/JU.0000000000001399

9 Schouten M. G. van der Leest M. Pokorny M. Hoogenboom M. Barentsz J. O. Thompson L. C. & Fütterer J. J. (2017). Why and where do we miss significant prostate cancer with multi-parametric magnetic resonance imaging followed by magnetic resonance-guided and transrectal ultrasound-guided biopsy in biopsy-naïve men? European Urology. https://doi.org/10.1016/j.eururo.2016.12.006

10 Żurowska A. Pęksa R. Bieńkowski M. Skrobisz K. Sowa M. Matuszewski M. Biernat W. & Szurowska E. (2023). Prostate cancer and its mimics-a pictorial review. Cancers. https://doi.org/10.3390/cancers15143682

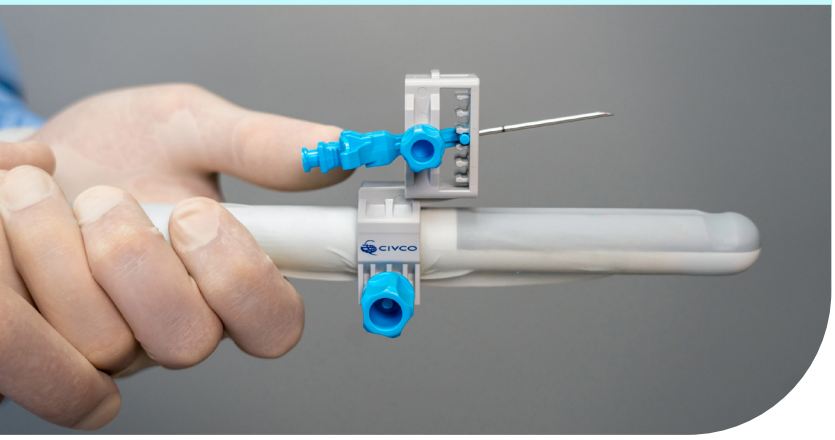
11 NHS England: "The Trexit initiative: transperineal prostate biopsies under local anaesthetic" https://nhsaccelerator.com/news-item/trexit-initiative-transperineal-prostate-biopsies-local-anaesthetic/

12 Freehand transperineal prostate biopsy case series and review support widespread use: https://www.urologytimes.com/view/freehand-transperineal-biopsy-case-series-and-review-support-widespread-use

As evidenced, transperineal prostate biopsies offer numerous clinical advantages, including a reduced risk of complications and improved tissue sampling in all prostate zones. The last few years have seen this technique receive heightened recognition across medical communities worldwide, with increasing numbers of urologists and patients embracing the method's benefits.[12]

One method of performing transperineal biopsies that has gained momentum in recent years is the freehand, minimal access transperineal prostate biopsy, [13] which offers an even more targeted approach than typical transperineal biopsies, such as grid-based biopsies, minimizing perineal puncture sites compared to grid-based solutions[14] while also decreasing negative outcomes such as infection and patient pain.[14]

The clinical advantages of transperineal prostate biopsies – and in particular, freehand trasperineal prostate biopsies - **can now be further optimized with TP Pivot Pro™, CIVCO's cutting-edge solution designed to revolutionize the TP biopsy process.** TP Pivot Pro is the first transperineal biopsy guide to grant access to the full prostate gland, thanks to its unique pivoting function, which allows needle angulation of +/- 20 degrees from the initial parallel path, enabling sampling access of the entire prostate, including the anterior zone where prostate cancer is frequently diagnosed, without the need to remove the needle from the guide or patient.



Additionally, **TP Pivot Pro** also improves stability through secure attachment to a range of biplane probes that helps ensure needle visualization, as the needle is kept within the imaging plane. Together, these features allow for both easier access to varying anatomies and more control during the procedure, enabling clinics to achieve better workflow.

In the quest to combat prostate cancer, early detection is paramount. While traditional transrectal biopsies come with innate risks and limitations, the freehand minimally invasive transperineal biopsy offers a safer, more precise alternative with easier access to all zones of the prostate. Statistics confirm its clinical advantages, and when performed with revolutionary tools designed with clinicians, by clinicians, like **TP Pivot Pro**, healthcare facilities can achieve improved efficiencies and improved clinical outcomes for their patients through the approach.

13 Urkmez A. Demirel C. Altok M. Bathala T. K. Shapiro D. D. & Davis J. W. (2021). Freehand versus grid-based transperineal prostate biopsy: a comparison of anatomical region yield and complications. The Journal of Urology 894–902. https://doi.org/10.1097/JU.0000000000001902

14 Ngu I. S. Ngooi M. S. Ng H. K. Tee K. T. L. Loo C. H. & Lim M. S. (2023). Freehand transperineal prostate biopsy with a coaxial needle under local anesthesia: experience from a single institution in malaysia. Cancer Pathogenesis and Therapy 33–39. https://doi.org/10.1016/j.cpt.2022.12.001

15 Trexit: A 'Clean Break' from Transrectal Prostate Biopsies - Medscape - May 09, 2019: https://www.medscape.com/viewarticle/912823