



USER MANUAL

PrecisionPoint[™] Transperineal Access System

for Use with the BK Ultrasound System

PrecisionPoint[™] Transperineal Access System

Background

The PrecisionPoint[™] Transperineal Access System (PPTAS) revolutionizes the methodology for obtaining prostate biopsies. This medical system takes full advantage of the transperineal path to more thoroughly sample all regions of the prostate including the anterior zone. Since the technique is free hand, the practitioner is not restricted to biopsy locations dictated by a grid configuration. The practitioner can freely maneuver the ultrasound probe to align the access needle to target the desired locations with certainty in a strategic and parallel direction.

The patented clamping mechanism allows the practitioner to use their existing BK ultrasound platform and cylindrical transrectal ultrasound transducer probe (0.7" - 0.85" BK #8658 or equivalent). Using a bi-plane linear ultrasound probe, one can adjust the position not only to probes of varying diameter, but also to any location along the shaft of the probe. An access needle press fits into the desired aperture of the sliding carriage allowing for a multitude of samples to be taken through a single puncture of the skin.

In addition, the PrecisionPoint[™] Transperineal Access System (PPTAS) minimizes the potential for infection, since passage of the biopsy needle avoids the rectal wall contaminants entirely. For the patient, this means no bowel prep or need to pre-medicate with antibiotics. The PPTAS enables the practitioner to perform the biopsy under local anesthesia in a time sensitive fashion.

Indications for the Procedure

- Transrectal ultrasound (TRUS) of the prostate is used to determine the dimensions and size of the prostate by an estimated volume using the Prostate Ellipsoid formula: Height (H) x Width (W) x Length (L) x pi/6.
- TRUS of the prostate can be combined with transperineal biopsy.

Contraindications for the Procedure

- Active infections of the prostate, perineum, rectum or urinary tract.
- Anticoagulants.

• Elevated Blood Pressure, defined as systolic over 200, or diastolic over 100.

Potential complications from the procedure

Infection:

Using the transperineal approach potentially eliminates the infection risk. No bowel prep or pre-procedure antibiotics are needed.

Bleeding at the biopsy site or gross hematuria immediately post-procedure:

Patient must adhere to pre-procedure guidelines/ instructions in regards to avoiding anticoagulants for 7 days

If excessive bleeding persists, it may require surgical intervention, i.e. endoscopic hemostasis and/or blood transfusion.

Urinary retention:

If the patient cannot void 6 hours after the procedure he should report to the nearest hospital emergency room for management.

Minor post-complications:

Hematospermia, mild to moderate discomfort

Minor post-procedure events may occur and last several weeks.

Self-limiting hematuria

PATIENT PREPARATION:

- 1. The patient should avoid Non-Steroidal Anti- inflammatory Drugs ("NSAIDS") for 7 days prior to the procedure.
 - a. The one exception for NSAIDS is Celebrex ("COX 2 inhibitor) which can be taken up to and on the day of the procedure.
 - b. Aspirin 325mg daily should also be avoided for 7 days prior to the procedure.
 - c. 81mg Aspirin once daily is allowed.
- 2. Bowel prep None required.
- Antibiotic Prophylaxis None required or follow institutional antibiotic administration policy.

ANESTHESIA, ANALGESIA OR SEDATION:

- Anxiolytics such as benzodiazepines can be given if deemed necessary.
- Topical Anesthesia can be used prior to insertion of the rectal probe by applying a small amount of Lidocaine Hydrochloride Jelly, USP, 2%, UROJET.
- Local Anesthesia can be used by injection of Lidocaine 1% through the needle guide using a 20g 6" spinal needle and bilateral instillation of 6cc – 10cc into the subcutaneous tissue, pelvic floor muscle and the fat plane between the pelvic floor muscle and the anterior capsule of the prostate. (Please see procedure below)

TECHNIQUE & DESCRIPTION OF PROCEDURE STEPS:

- 1. The patient is placed on the exam table in a dorsal lithotomy position with the scrotum elevated to expose the perineal skin.
- 2. The skin is prepped with Chlorhexidine solution or Povidone Iodine or equivalent.
- 3. A transducer cover (Civco # 610-1127 NeoGuard[™]) is filled with 2cc of ultrasound gel. The transducer cover is then fitted over the shaft of the bi-plane linear transducer probe (BK ProFocus 2202 ultrasound system, BK Transducer Probe #8658) halfway up the shaft being careful to evacuate any air bubbles that may be present in the gel surrounding the tip of the transducer probe. Using a clean, dry towel, wipe the proximal end of the ultrasound probe to remove any excess gel and continue to unroll the transducer cover until the entire ultrasound probe is covered. Secure with a rubber band if necessary.
- 4. Remove the PrecisionPoint[™] Transperineal Access System (PPTAS) from the sterile packaging and loosely clamped the device to the transducer, over the transducer cover, to an estimated location along the shaft of the bi-plane linear transducer probe.
- 5. Align center of the rails with midline of the sagittal transducer. Lock into place by compressing the bottom locking mechanism. The carriage with the access needle is <u>not</u> placed on the rail at this point.
- 6. A digital rectal examination is performed to examine the prostate and to relax the anal sphincter in preparation for the ultrasound probe.
- 7. Place gel on the tip of the transrectal ultrasound probe and insert the transducer into the rectum.
- 8. Transrectal scanning of the prostate for visualization of pathology and measurement of the prostate size is noted. The converse perineal skin location correlating with the mid-point between the urethra and the lateral edge of the prostate is noted. This will be the approximate location of the access needle engagement through the skin and subcutaneous tissue.
- 9. The height of the prostate will dictate which aperture on the carriage the access needle will be inserted.
 - a. Tall prostate use the upper apertures
 - b. Medium prostate use the center aperture
 - c. Short prostate use the lower apertures
- 10. Load the Carriage with the Perineologic Access Needle onto the rails of the rail/clamp assembly. The carriage with access needle is positioned at the neutral point of the rail to prevent the access needle from interfacing with the practitioner or the patient's tissue.

- 11. Loosely clamp the Rail/Clamp Assembly in its correct position on the ultrasound probe so that the access needle is midline to the sagittal transducer.
- 12. The PPTAS is then slid along the shaft of the probe so that the stabilization bars of the device merge with the skin slightly pushing the skin and subcutaneous tissue into the patient at a position where the prostate is centered on sagittal transducer. Once aligned, the clamp on the PPTAS is fully engaged, preventing rotation of the PPTAS and aligning the PPTAS in the correct orientation in relation to the transducers. This will ensure that the access needle and the biopsy needle will be continuously visualized during the entire procedure. This is critical to the proper alignment of the biopsy needle in relation to the procedure.
- 13. With the ultrasound probe tip rotated to the mid-point of the lateral axis, the approximate location where the access needle will be engaged is exposed and injected with 1% lidocaine using a 27-gauge needle with 1cc. One then rotates to the contralateral side in a similar fashion.
- 11. The block is accomplished by sliding the carriage with access needle puncturing the skin and just a few millimeters into the subcutaneous tissue.
- 12. The access needle will then guide the 20-gauge 6-inch biopsy needle to the desired location. The biopsy needle is advanced under direct ultrasound supervision, and the 1% lidocaine is injected along the path of subcutaneous tissue and the pelvic floor musculature and the fat plane between the pelvic floor muscle and the anterior capsule. You can articulate the ultrasound probe to access multiple prostate biopsies sites via one skin puncture.
- 13. Advancing the tip of the biopsy needle to the apical capsule and injecting a bolus of 6-8cc into this anatomic location will complete the block. One can visualize hydro dissection of the lidocaine within the pelvic floor musculature and the apical region between the capsule and pelvic floor of the prostate (spreading both anterior/posterior/lateral and medial). Thus, with each pass of the biopsy needle complete sensory block is achieved.
- 14. Care must be taken to avoid injecting into the dorsal vein complex and using a weight-based limit of 1% lidocaine.
- 15. These steps are repeated on the contralateral side. Once the block is complete, the carriage with access needle is advanced to the fully engaged position. Engagement of the access needle in conjunction with the pressure of the stabilization bars into the skin provides the needed stability for sampling any location of the prostate.
- 16. The resting position of the access needle is within the subcutaneous tissue just shy of the pelvic floor muscles and can be visualized in the sagittal plane.

PrecisionPoint[™] Transperineal Access System

- 17. The practitioner is now able to employ the ultrasound probe lateral or medial by pushing the probe in that direction. Assurance that biopsy needle will penetrate the prostate at the desired location is ensured by the inherent stability of the PrecisionPoint[™] Transperineal Access System as it interfaces with the skin and subcutaneous tissue plane and constant visualization of the tip of the access needle and the movement of the biopsy needle.
- 18. In order to sample locations anterior or along the posterior peripheral zone, one simply pulls up or pushes down on the ultrasound probe. In addition, a tilting motion of the probe as you push or pull may optimize the biopsy needle trajectory.
- 19. When sampling the lateral regions of the prostate, rotation with lateral push of the probe will facilitate ideal sampling of this important region.
- 20. Once adequate targeting of the right prostate is complete. The access needle is placed in the neutral position by pulling back on the tabs of the carriage. The probe is then rotated to the contralateral side.
- 21. Once completed the carriage is again brought back to the neutral position and the probe is removed from the patient. To disengage the device, the quick release flange portion of the clamp is deployed using a simple trigger finger flick.
- 22. At completion of the procedure, remove ultrasound probe with attached needle guide and biopsy needle.
- 23. Remove assembly from ultrasound probe by pulling on the release tab (on the clamping mechanism) and discard the Precision Point[™] Transperineal Access System into an appropriate biohazard and sharps container.

In situations where the prostate gland size is greater than 50 grams, the urologist may have limitations sampling both anterior and posterior regions of the prostate with one aperture selected on the carriage. For these scenarios, one naturally chooses a lower aperture for the posterior half of the prostate and begins with the right posterior quadrant, then rolls over to the left posterior quadrant to complete the entire posterior half of the prostate. Then the carriage is removed from the rail and the access needle is repositioned into an upper aperture to complete the anterior right and left. The user will replace the access needle into the same puncture site as the posterior position to insure utilization of the anesthetized tract.



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Patient Monitoring and Post-Procedure Instructions

At the completion of the biopsy, the patient will sit up slowly to the side of the bed and a post- procedure Blood Pressure will be obtained. If the patient begins to feel light-headed or dizzy, he will be placed supine for several minutes until feeling better.

The patient is instructed to notify his physician if he experiences any of the following:

- Temperature greater than 101⁰F during the first 72 hours after biopsy
- Excessive blood in urine or stool
- Inability to urinate

Warnings and Precautions

Discard and do not use previously opened or damaged devices.

- Use only devices that are packaged in unopened and undamaged containers.
- FOR SINGLE USE ONLY.
- Do not use if there is loss of sterility of the device.
- Do not re-sterilize.
- Do not use after expiration date.
- The Perineologic PrecisionPoint[™] Transperineal Access System is designed for use with a cylindrical style transrectal ultrasound transducer (0.7" to .85" diameter BK #8658 or equivalent) associated with a BK ProFocus ultrasound system.
- To aid in locking, avoid putting ultrasound gel on the probe in the area where the clamp will be placed.
- Do not use the Perineologic PrecisionPoint[™] Transperineal Access System with ultrasound transducers that do not fit into the Needle Guide Clamp or fail to be secured with the Needle Guide Clamp.
- The clamp on the PPTAS must be fully engaged to prevent the rotation of the PPBNG on the ultrasound probe and aligning the PPTAS in the correct orientation in relation to the ultrasound transducers. This is critical to the proper alignment of the biopsy needle in relation to the prostate gland image during the procedure.
- The clamp on the PPTAS, once engaged will prevent rotation of the PPTAS on the ultrasound probe. The user will align the PPTAS at the ultrasound probe at the midline position which is lined up with the sagittal transducer. This position will ensure proper alignment for accurate visualization of the access needle and the biopsy needle.

Appendix A – Ultrasound Imaging Examples

The PrecisionPoint[™] Transperineal Access System provides exquisite targeting accuracy as it works in synchrony with the ultrasound probe to which it is attached. The physician user can visualize the position of the access needle at all times as well as the trajectory of the biopsy needle which is inserted through the access needle. This combination of images ensures precise targeting of all areas of the prostate gland and allows for a systematic approach to sampling of all sections of the prostate gland, particularly the anterior or top of the prostate gland which is difficult by alternative methods. It also allows the physician to avoid sensitive structures, such as the urethra, during the prostate biopsy procedure. The attached figures demonstrate the accurate approach the PrecisionPoint[™] Transperineal Access System delivers.

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Ultrasound image, cross section of prostate gland Urethra Prostate Capsule Adenoma

Irology Associate

Figure 1 - Ultrasound image of the entire prostate gland and associated seminal vesicles together with the urethra bisecting the prostate gland. An adenoma of the prostate is located in the posterior section of the prostate. This is a sagittal view prior to the start of the prostate biopsy procedure.

Ultrasound axial image, cross section of prostate gland, for measurement of prostate volume.

Prostate Capsule

Urethra 🚥



Figure 2 - Ultrasound image in an axial view of the prostate gland, used to measure the size of the prostate prior to the start of the prostate biopsy procedure. Note the location of the urethra in the center of the image.

PrecisionPoint™ Biopsy Needle Guide

Ultrasound image, cross section of prostate gland – Access Needle Placement Access Needle Prostate Capsule Pelvic Floor Muscle Pelvic Floor Muscle State State

Figure 3 -Ultrasound image of the prostate gland demonstrating the placement of the access needle which is attached to the ultrasound probe. In this sagittal view, the physician user can visually assess the orientation of the access needle prior to the initiation of the biopsy procedure.

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Ultrasound image, cross section of prostate gland - Biopsy Needle Placement before Core Sampling - Sagittal View Access Needle Prostate Capsule Biopsy Needle Historical His

Figure 4 - Ultrasound image of the prostate gland demonstrating the orientation of the biopsy needle which has been inserted through the access needle prior to penetrating the prostate capsule for sampling. This is a sagittal view.





Figure 5 - Ultrasound image of the prostate gland demonstrating the biopsy needle deployed into the prostate capsule and obtaining a tissue sample. This is a sagittal view.



PrecisionPoint™ Biopsy Needle Guide



Figure 6 - Ultrasound image of the prostate gland demonstrating the accuracy in which the physician user can target the anterior (top) apical section of the prostate gland while avoiding the urethra. This sagittal image shows the biopsy needle deployed into the prostate capsule.

Ultrasound image, cross section of prostate gland-Anterior Section – Sagittal View Prostate Capsule Biopsy Needle



Figure 7 -Ultrasound image of the anterior (top) section of the prostate gland, sagittal view, biopsy needle deployed into the prostate capsule.



PrecisionPoint™ Biopsy Needle Guide

Ultrasound image, cross section of prostate gland-Anterior Section – Axial View

Figure 8 -Identical ultrasound image from Figure 7 of the anterior (top) section of the prostate gland, axial view, demonstrating the precise location of the biopsy needle position. Note surrounding perimeter of the prostate capsule and location of the urethra.

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PrecisionPoint[™] Biopsy Needle Guide

View

Urethra 💼

Prostate Capsule

Biopsy Needle



Figure 9 - Ultrasound image of the posterior (bottom) basilar section of the prostate gland, sagittal view, biopsy needle deployed into the prostate capsule.



PrecisionPoint[™] Biopsy Needle Guide

Ultrasound image, cross section of prostate gland-Posterior Basilar Section - Axial View Urethra 💼 Prostate Capsule Biopsy Needle \$1.8 52.6 m

Figure 10 - Identical ultrasound image from Figure 9 of the posterior (bottom) basilar section of the prostate gland, axial view, demonstrating the precise location of the biopsy needle position. Note surrounding perimeter of the prostate capsule and location of the urethra.

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