



## PrecisionPoint™ Transperineal Access System

Early intervention and diagnosis

Urology device that provides systematic and targeted transperineal prostate biopsies under local anaesthetic, transforming the prostate cancer pathway and improving the patient experience.

### What is the NHS Innovation Accelerator (NIA)?

- An award-winning national accelerator supporting committed individuals ('Fellows') to scale high-impact, evidence-based innovations across the NHS and wider healthcare system
- An NHS England initiative delivered in partnership with England's 15 Academic Health Science Networks (AHSNs) and hosted at UCLPartners
- Launched in 2015 to support the delivery of the Five Year Forward View, the NIA is highlighted in the NHS Long Term Plan, published in January 2019



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## What is it?

The PrecisionPoint Transperineal Access System™ (PP TAS) enables transperineal biopsies under local anaesthetic rather than general anaesthetic – as they have been undertaken to date.

This innovation can transform the standard of care for prostate biopsy practice in the NHS by both replacing the standard trans-rectal biopsy and enabling transperineal biopsies under local anaesthetic.

This CE Marked, FDA Approved medical device takes full advantage of the transperineal (TP) route to more thoroughly sample all regions of the prostate including those difficult to access with the transrectal approach. The PrecisionPoint system avoids the risks of infection associated with the transrectal approach because it uses 2 simple punctures of the perineal skin to access the prostate.

PrecisionPoint enables transperineal biopsies to be carried out in outpatient departments by Advanced Nurse Practitioners (ANP), optimising cancer diagnostic resources, reducing waiting lists and delivering safer and more effective prostate biopsies in a timely fashion. The transperineal biopsy technique is free hand, enabling the practitioner to easily target the desired locations with certainty and through a single puncture of the skin.

This low-cost disposable device represents a safer and more accurate method for urologists to detect potential prostate cancer at an earlier stage of the disease progression.

## What's the problem?

- There are 46,000 new prostate cancer diagnoses per year, equating to 60,000 prostate biopsies. The standard of care for prostate biopsies practice is outpatient transrectal biopsy (needle inserted via the rectum) under local anaesthetic (LA). This can result in missed-diagnosis, infection and sepsis. TRUS biopsies have limited access to the entire prostate meaning the anterior and apical regions are under-sampled and up to 25% of patients require a repeat biopsy.
- The alternative to TRUS biopsy is a Transperineal Biopsy in which the prostate gland is biopsied through the perineal skin. It offers a much cleaner biopsy with less risk of infection and can better sample all areas of the prostate which might contain cancer.
- In 2017 there were 35,000 transrectal (TRUS) biopsies each carrying a 1-2% risk of sepsis. By comparison, there were 15,500 transperineal biopsies with a <0.5% risk of sepsis.
- Data from Public Health England indicates that infectious complications are reported in 3-5% of patients having TRUS biopsies.

- Prostate biopsy-related sepsis accounts for 10% of hospital admissions for sepsis nationally, estimated to cost the NHS £7.7-11.1 million ([Batura et al., 2013](#)).
- Traditional transperineal mapping biopsies (with multiple needles inserted through the perineal skin) provide more effective sampling of the prostate and can virtually eliminate biopsy-related sepsis compared with TRUS biopsy. However, the current approach is impractical as a primary outpatient procedure because it requires complex equipment and general anaesthetic. This results in delays to treatment, causing breaches of the 31-62-day cancer pathway and resulting in high operating theatre costs.

#### What's the solution?

- By contrast, the PP TAS transforms prostate biopsy practice by enabling it to be delivered as a local anaesthetic outpatient procedure. It also provides a cost-effective alternative to TRUS biopsy.
- Precision Point biopsies enable effective Transperineal biopsies through two simple punctures under local anaesthetic in the outpatients and can be carried out by trained nurses and radiographers.

#### What's the evidence?

- To date over 4,500 Transperineal (TP) biopsies have taken place using the PrecisionPoint device. There are 48 Hospitals in the UK using the device, 6 in Europe and 15 throughout the rest of the world.
- Guy's and St Thomas' Hospital Foundation Trust stopped all transrectal biopsies in September 2017. This initiative has been called *Trexit* and the Precision Point became the preferred approach for diagnostic biopsy:
  - In Year 1, September 2017 - 2018, 678 TP biopsies were carried out. Historically, all TP biopsies have been done on General Anaesthetic Operating lists at a cost of approximately £767 per case, (**total cost £767 x 678 = £520,026**).
  - The costs of LA Outpatient TP biopsies are approximately £375 per case. Since the Guy's *Trexit*, 60% of patients had local anaesthetic TP biopsies with only 30% of patients requiring general anaesthetic and 10% intravenous sedation. 395 patients had LA biopsies at a total cost of £148,225. 283 patients required General Anaesthetic or sedation at a total cost of £217,061.
  - In Year 1 of the Guy's *Trexit* the cost to deliver 678 TP biopsies was £365,286, compared with a historical cost of £ 520,026, **an estimated saving of £157,740**.
  - To date in year 2, the need for General Anaesthesia or sedation has reduced further with 80% of patients having their TP biopsies under local anaesthetic.

- Routine General Anaesthetic biopsy lists have reduced from 6 per week to 2 – 3 per week freeing up operating lists and consultant time for other procedures.
- There has been only 1 case of sepsis, related to a urine infection post biopsy (0.15%)
- If the experience at Guy's and St Thomas' can be replicated nationally:
  - 70% of transperineal biopsies could be delivered in outpatients which would reduce the burden on operating lists and the need for general anaesthesia.
  - Waiting lists for TP biopsies should reduce benefitting the timed prostate pathway.
  - Nurses and Allied Health Care Professionals would deliver more of the biopsies freeing up doctors and consultants time for other activities.
  - The need for repeat biopsy would reduce by 10-20%.
  - Prostate Biopsy Related Sepsis complications would reduce by at least 50% with significant cost saving to the NHS and reduced risk of major complications.
  - The use of routine antibiotics would fall, reducing the risk of antibiotic resistance.
  - The NHS could be the first health care system in the world to stop transrectal biopsy delivering a UK Texit.

#### The evidence for transperineal biopsies

- [NICE Guideline NG131](#) has identified that general anaesthetic transperineal biopsies are a costly procedure and a significant resource issue nationally for hospitals.
- Freehand transperineal biopsies using the PrecisionPoint access system is a safe, tolerable and effective method for systematic and targeted biopsies in the outpatient setting ([Kum et al., 2018](#)).
- The use of ultrasound guided freehand transperineal prostate biopsy for the surveillance of prostate cancer is feasible and safe. Complications including systemic infection, urinary retention and haematuria or pain requiring physician or hospital intervention did not occur ([Dibianco et al., 2015](#)).
- Cancer detection rates using freehand transperineal biopsies are comparable to transrectal biopsy and eliminate the risk of infection ([Ristau et al., 2018](#)).

#### Regulatory requirements

- PrecisionPoint is FDA approved and a CE marked patented medical device.

## How can I adopt PrecisionPoint?

Monthly courses on Local Anaesthetic Transperineal biopsies using the PrecisionPoint device have been fully booked since commencement in August 2017. 160 Consultants have been trained with 70% of these now using the PrecisionPoint device regularly within their hospitals. In February 2018 the first Clinical Nurse Specialist Precision Point workshop was launched and to date 48 CNS' and Registrars have been trained. As a result, 33 of them are now performing Local Anaesthetic Trans Perineal biopsies using PrecisionPoint on a monthly basis.

If you would like to book onto either a Consultant or Clinical Nurse Specialist course, please contact [Emily.Jarrold@bxt-accelyon.com](mailto:Emily.Jarrold@bxt-accelyon.com) for current availability and more details of the course programme. BXT-Accelyon, the distributor of PrecisionPoint, is supporting the establishment of regional training centres, providing materials, videos and financial support to enable advanced nurse practitioners and urologists to use the device.

On average it takes 12-15 cases for nurse practitioners to achieve sufficient competence to undertake biopsies without direct supervision, demonstrating an acceptable learning curve and high generalisability. 20 regional champions have been identified across the cancer networks and will be trained by NIA fellow Rick Popert, to scale the procedure across the Cancer Networks.

The PrecisionPoint Transperineal Access System is supplied in boxes of 5 at a cost of £1,000 per box. In addition, a transducer cover kit at £110.40 (pack of 24) and 20-Gauge x 150mm Spinal Needles for £57.40 (box of 10) are also required. The price per device is £200 and is not discountable, with a minimum order of 5 devices.

### Training support

BXTAccelyon in conjunction with Mr Rick Popert run monthly PrecisionPoint Transperineal Access System work sessions every month at Guy's Hospital, London. Two course types are offered which run over either 1 day or 1.5 days. The first is aimed at clinicians, the other focused more towards advanced nurse practitioners. Both course types are designed for those individuals who are involved in the diagnosis and treatment of prostate cancer and are interested in changing the paradigm of outpatient prostate cancer diagnostics for transrectal prostate biopsies to transperineal biopsies.

For more information on cost-effectiveness and to move forward with adoption, please contact: [Rick Popert](mailto:rick.popert@gmail.com) on +44 77641 81971 or at [rick.popert@gmail.com](mailto:rick.popert@gmail.com)

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## Who else is using it?

The PrecisionPoint device is currently being used in hospitals in Ireland, Amsterdam, Australia, New Zealand, Switzerland, Hong Kong, Singapore, Kuwait and Germany. More than 48 UK Trusts have adopted Precision Point biopsies.

PrecisionPoint has also transformed practice in Guys' and St Thomas' hospital in the last two years, reducing cancer pathway breaches and waiting lists. Since March 29<sup>th</sup> 2019, all Trust across South East London Cancer Alliance have stopped conducting transrectal biopsies and moved to transperineal biopsies.

### South East London case study

In 2016 the South East London Cancer Alliance (SELCA) identified General Anaesthetic Trans Perineal Biopsy as the most significant contributory factor (27.5%) to delays in the diagnostic prostate cancer pathway. The outcomes from the pilot study on Local Anaesthetic Trans Perineal biopsy at Guys and St Thomas's Trust was presented to SELCA. As a consequence, NIA Fellow, Mr Rick Popert started training other Consultants within Guy's Hospital and the other 4 hospital sites across SELCA. A monthly training course was established at Guy's Hospital to provide the opportunity for Urology Consultants and Specialist Registrars from across the Network and other hospitals.

In September 2017 Guy's stopped all TRUS biopsies, the Precision Point System became the preferred approach for diagnostic biopsy. A Cancer Nurse Specialist in Urology at GSTT, was taught to do the LA TP biopsies and in a matter of weeks was carrying out the procedure independently. Subsequently SELCA took a lead in coordinating and training medical and nursing staff across the cancer alliance to undertake LA TPs. Within four months, all prostate biopsies were undertaken using the precision point approach.

## Endorsements

"Rick has provided outstanding clinical leadership to transform the South East London diagnostic prostate pathway. His vision, expertise and energy has supported the roll out of transperineal biopsies under local anaesthetic at all three South East London acute trusts!" - **Dr Kate Haire, Clinical Director, South East London Cancer Alliance**

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## Contact details



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