2nd Most commonly diagnosed cancer among men worldwide

5th Leading cause of cancer death among men worldwide

One Million Prostate biopsies performed each year in the US

Background
- Early detection to Prostate cancer is vital and screenings are performed by testing for prostate-specific antigen (PSA) levels with levels higher than 2.5 ng/mL for men in their 40s indicating prostate cancer.
- PSA is collected through transrectal or transperineal biopsies.
- The process involves retrieving at least 12 core samples from different regions of the prostate and histologic analysis of the tissue

Needs Statement
Urologists need a method with a low task-load index for reducing procedural time to decrease patient discomfort and enable the use of both transperineal and transrectal approaches

User Needs and Design Requirements
- Should maintain the clinician's accuracy and obtain high-quality cores
- Biopsy time should be <13 minutes with 1 minute per core retrieval time
- Should not increase the existing cognitive burden on clinicians
- Post-biopsy cores should be traceable to their sample region within the patient
- Should not require more than 20 procedures for clinicians to become proficient

Prostate Biopsy Workflow

User Needs and Design Requirements
- Procedural time: 15 Min
- requires localised anaesthesia
- higher rate of infection

Procedural time: 30 Min
- requires general anaesthesia, increasing patient discomfort
- lower rate of infection

Testing Pathway
- Allow Correlation Between Sampled Region and Biopsy Collection Order
- Enable Core Visualization Mid-Procedure
- Confirm Core Cutting Quality
- Verify Procedural Accuracy
- Confirm Faster Procedural Time

Pinnacle enables seamless core collection without unnecessary gun removals, lowering patient pain and ultimately benefiting patient outcomes