

# Pivotal Study of Voro Urologic Scaffold

NCT06873581

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Status	RECRUITING
Phase	Phase 3
Sponsor	Levee Medical, Inc.
Enrollment	266 participants

## Key Eligibility Criteria

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### Inclusion (23)

- Male  $\geq$  45 years of age of any race and ethnic group
- Diagnosed with prostate cancer and scheduled for radical prostatectomy
- Gleason Grade Group 4 or lower
- Prostate size less than 80 grams, as measured by Magnetic Resonance Imaging (MRI)
- Able and willing to provide written consent to participate in the study

... and 18 more (see full listing online)

### Exclusion (13)

- Malignant tumors with known bladder neck or urethral sphincter invasion or metastatic disease confirmed via baseline assessments (example [e.g.,] Multiparametric magnetic resonance imaging [mpMRI], bone scan)
- History of urinary incontinence, including stress or urge urinary incontinence
- Demonstration of SUI, such as positive 1 hour pad weight test or participant reported incontinence episodes
- Currently treated with medications to treat overactive bladder (OAB)
- Post void residual  $>200$  milliliter (ml) or  $> 25$  percentage (%) total volume(= voided volume + residual volume)

... and 8 more (see full listing online)

## Locations (20 total)

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Mayo Clinic, Phoenix, Arizona, United States  
Academic Urology, Sun City, Arizona, United States  
UCLA Urology, Los Angeles, California, United States

... and 17 more locations