

# Post-Market Study to Assess iTind Safety in Comparison to UroLift

NCT04757116

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	Olympus Corporation of the Americas
<b>Enrollment</b>	206 participants

## Key Eligibility Criteria

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### Inclusion (8)

- Diagnosis of lower urinary tract symptoms presumed to be secondary to benign prostatic enlargement causing bladder outlet obstruction for which treatment is recommended
- Willing and able to provide informed consent
- Males  $\geq$  50 years of age or older
- PSA  $<$  4 ng/dl, ng/ml or if the PSA is 4 - 10 ng/dl, ng/ml, prostate cancer must be ruled out to the satisfaction of the Principal Investigator (PI) by local standard of care methods within prior 6 months
- Prostate volume up to 75 cc (inclusive) documented by cross-sectional imaging (TRUS, MRI, etc.). Results from standard of care imaging may be accepted up to 6 months prior to Screening if the subject was not on 5-alpha reductase inhibitors (5ARIs) at that time

... and 3 more (see full listing online)

### Exclusion (18)

- History of prostate cancer or suspected, should be ruled out to the satisfaction of the PI by local standard of care methods within prior 6 months
- Confirmed or suspected bladder cancer within the last 2 years
- History of acute bacterial prostatitis within the last 2 years
- Median lobe obstruction of the prostate as confirmed by cross-sectional imaging
- PSA value  $>$  10 ng/dl, ng/ml

... and 13 more (see full listing online)

## Locations (18 total)

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Mayo Clinic Arizona, Phoenix, Arizona, United States  
Arizona Urology Specialists, Tucson, Arizona, United States  
Urology Associates of Central California, Fresno, California, United States  
... and 15 more locations

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<https://clinicaltrials.gov/study/NCT04757116>

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