

# Optilume PoST AppRoval Clinical Evaluation of Andrology Parameters

NCT05383274

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Status	RECRUITING
Phase	Phase 4
Sponsor	Urotronic Inc.
Enrollment	34 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Male subjects between 22 and 65 years of age
- Subject diagnosed with a stricture in the anterior urethra that is able to be treated with the Optilume Urethral DCB in accordance with the approved Instructions for Use
- Subject is willing to provide written informed consent and comply with study required follow-up assessments
- Subject able to provide viable semen samples and baseline semen quality characteristics are above reference values based on below criteria (average of 2 samples):
- total sperm e39 million
- ... and 4 more (see full listing online)

### Exclusion (6)

- Subjects with a known hypersensitivity to paclitaxel or structurally related compounds
- Subjects with a history of vasectomy or other condition that may inhibit semen/sperm production or ejaculatory function
- Subjects currently taking 5-alpha reductase inhibitors, alpha-blockers, selective serotonin reuptake inhibitors, or hormone replacement therapy without appropriate washout
- Subject is unwilling to abstain or utilize a condom for 30 days after the procedure
- Subject is unwilling to utilize highly effective contraception for 6 months after the procedure if partner is of childbearing potential
- ... and 1 more (see full listing online)

## Locations (9 total)

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Arkansas Urology, Little Rock, Arkansas, United States  
Orlando Health, Orlando, Florida, United States  
Florida Urology, Tampa, Florida, United States  
... and 6 more locations