A Study to Assess the Safety and Effectiveness of the UrOActive® Artificial Urinary sPHincter (AUS)

NCT06968741

Status	RECRUITING
Phase	Not Applicable
Sponsor	UroMems SAS
Enrollment	140 participants

Key Eligibility Criteria

Inclusion (4)

- Male subjects aged e 22 years old
- Able to read, comprehend and willing to sign an informed consent form
- Primary diagnosis of stress urinary incontinence for at least 6 months, as assessed by the investigator
- Appropriate surgical candidate with no medical or mental condition that would interfere with study procedures or confound study outcomes as assessed by the investigator

Exclusion (4)

- Currently enrolled or plans to enroll in another investigational device or clinical drug trial or has completed an investigational study (for urinary incontinence) in the past 3 months prior to informed consent
- Poor candidate for surgical procedures and/or anesthesia, as determined by investigator
- Currently implanted with an Active Implantable Medical Device (AIMD)
- Symptoms or diagnosis of urge incontinence or mixed incontinence (MI) with a predominant urgency component, as assessed by the investigator

Locations (21 total)

University of California, Los Angeles, Los Angeles, California, United States
University of California, San Francisco, San Francisco, California, United States
Stanford University, Stanford, California, United States
... and 18 more locations