

# Fundación IVO Registry for Patients Undergoing Sling or Artificial Urinary Sphincter After Prostate Cancer Treatment

NCT02901392

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Status	RECRUITING
Sponsor	Fundación Instituto Valenciano de Oncología
Enrollment	400 participants

## Plain Language Summary

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This study tracks outcomes for men who receive surgery (either a sling device or an artificial urinary sphincter) to treat bladder leakage (urinary incontinence) that developed after prostate cancer treatment such as surgery or radiation.

**\*\*You may be eligible if...\*\***

- You are a male over 18 years old
- You have experienced stress urinary incontinence (leaking urine when coughing, sneezing, or exercising) for at least 12 months after prostate cancer treatment
- Your incontinence has been confirmed by a pad test and bladder function testing
- You have agreed to have the incontinence surgery device implanted

**\*\*You may NOT be eligible if...\*\***

- You have not had incontinence for at least 12 months
- Your leakage is not confirmed by the required testing
- You are unwilling to provide consent

This registry helps doctors understand how well these surgical devices work long-term for men dealing with this common side effect of prostate cancer treatment. Talk to your doctor to see if this trial is right for you.

## Key Eligibility Criteria

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### Inclusion (8)

- The subject has agreed to be treated with the male Incontinence surgery devices
  - The subject is willing and able to give valid informed consent.
  - The subject is > 18 years of age.
  - The subject has confirmed stress urinary incontinence for at least 12 months after prostatectomy or radiotherapy.
  - It has been confirmed the stress urinary incontinence with 24-Hour Pad Weight test
- ... and 3 more (see full listing online)

### Exclusion (11)

- The subject has an active urinary tract infection or active skin infection in region of surgery
  - The subject has serious bleeding disorders
  - The subject has unstable bladder neck stricture disease
  - The subject has Neurogenic bladder condition that is not treatable or controllable by pharmacological or alternative methods.
  - The subject has Detrusor-external sphincter dyssynergia.
- ... and 6 more (see full listing online)

## Locations (1 total)

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Argimiro Collado, Valencia, Spain  
<https://clinicaltrials.gov/study/NCT02901392>

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