A prospective, randomized, controlled, blinded study to assess the Safety and Efficacy of the Butterfly Medical Prostatic Retraction Device in Benign Prostatic Hyperplasia (BPH) Patients.

Status: Recruiting

Eligibility Criteria

Sex: Male
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- men who are 50 to 80 years old - symptomatic BPH - additional criteria apply, study staff will review

Exclusion Criteria:

- known sensitivity to Nickel - current urinary retention - urinary stress incontinence - currently active bladder tumor or intravesical instillation - additional exclusion criteria related to prostate or urinary tract function (study staff will review)

Conditions & Interventions

Conditions:
Kidney, Prostate & Urinary
Keywords:
Clinics and Surgery Center (CSC), BPH (Benign Prostatic Hyperplasia), Lower Urinary Tract Symptoms (LUTS)

More Information

Description: The purpose of this study is to assess the safety and effectiveness of the Butterfly study device in reducing the symptoms that are associated with the BPH condition. Another purpose is to assess sexual function and quality of life following the use of the Butterfly study device. The Butterfly study device includes a metal (nitinol) implant that looks like a butterfly. The implant is inserted through the urethra - the tube that carries pee out of the body, and resides at the area of the prostate.
Study Contact: Maressa Twedt - twedt050@umn.edu
Principal Investigator: Deepak Agarwal
IRB Number: STUDY00017389