2 Device Description

The Zenflow System consists of a Delivery System and a Spring Implant. The Spring Implant is available in three sizes: 15, 18, and 21mm. The Zenflow Spring Implant and Delivery System is supplied sterile and is for single use only.

Accessories available separately and utilized with the Zenflow System include the following:

- Zenflow Spring Scope (supplied sterile and for single use only)
- Camera Control Unit
- Implant Retrieval Device (supplied sterile and for single use only)

2.1 Spring Implant

The Spring Implant is an electropolished and passivated nickel titanium alloy (nitinol) implant. The implant is constructed from a single wire strand formed into ring elements connected by spine sections. Implant sizes range between 15 mm – 21 mm in length to accommodate prostate lengths between 25 mm – 45 mm. The ends of the implant have rounded balls to minimize tissue trauma and assist in grasping the device. The device is designed to be easily removable and can be retrieved at any time after deployment, as described in Section XV of the Instructions for Use.

Figure 1: Zenflow Spring Implant Sizes – 15 mm, 18 mm, 21 mm (Note: images are not to scale)

2.2 Delivery System

The Zenflow Delivery System consists of a handle and a catheter shaft. The Spring Implant is designed to be straightened and to reside within a lumen of the 11.5 Fr Delivery System catheter for insertion. When inflated, a compliant balloon at the distal end of the catheter is designed to anchor and position the Delivery System during Implant delivery.

2.3 Principles of Operation

Prior to treatment, a urologist will use cystoscopic visualization via the Zenflow Scope to confirm the prostatic urethral length. The physician then selects the appropriate size of Spring

Implant among the three sizes ranging from 15 mm to 21 mm in length for implanting in the patient's prostatic urethra.

The Delivery System and Spring Scope provide the physician the ability to deploy, retract, and release the Implant under direct visualization. To prepare for deployment, the Spring Implant is retracted into the Delivery System Shaft by pulling the trigger, then inserted into the Spring Scope's central lumen. Under cystoscopic guidance, the Delivery System is advanced into the bladder. The balloon is inflated with air and the Delivery System is retracted to engage the bladder neck. Tension is applied to the Delivery System to ensure a stable position at the bladder neck throughout deployment of the Spring Implant. Pulling the handle trigger repeatedly advances the Implant out of the shaft and into the prostatic urethra. Once the Implant has fully exited the Delivery System shaft, the physician will check the position of the implant via cystoscopic visualization. The Spring Implant is considered ideally placed when the most proximal ring is positioned distal to the bladder neck and the most distal ring is positioned proximal to the External Urethral Sphincter (EUS). If the position is not optimal, the physician can use the directional selector switch to retract the Implant into the Delivery System, reposition, and deploy once again.

Once the Spring Implant position is acceptable, the physician releases the Implant from the Delivery System by actuating the unlock knob and the Delivery System trigger. Following release, tension can be released, the balloon is deflated, and the Delivery System is detached from the Spring Scope followed by removal from the patient.

The Zenflow Spring Implant is designed to be a permanent implant but can be repositioned or removed by the physician. For device repositioning or removal after final release, the operator should follow the directions for removal found in the Instructions for Use.

3 Study Description

3.1 Study Design

This is a prospective, randomized, open-label, parallel-group post-market clinical trial (PMCT). The overall objective of this PMCT is to compare the effectiveness, durability, and patient-centered outcomes of the Zenflow Spring System versus Tamsulosin in men who are not on active therapy with moderate to severe LUTS/BPH. This PMCT is designed to collect information on the performance of the Spring System during the implant procedure, short term follow-up (1 and 3 months) and long-term follow-up (6 and 12 months) to assess improvement in clinical outcome measures, return to activities and satisfaction with treatment, and any device or Tamsulosin related adverse events. Any implant related reinterventions or removals or cessation or dose alteration of Tamsulosin therapy will also be captured in the post-market clinical trial. Eligible patients will be entered into this PMCT and randomized 1:1 to receive either treatment with the Spring System or Tamsulosin. Each patient randomized will be assigned a PMCT

number. To assure patient confidentiality, information identifying specific patients will not be collected, but will be maintained separately by the study coordinator to allow for patient follow-up.

Eligible participants who consent to participate will be randomized in a 1:1 ratio to one of the following treatment arms:

1) Zenflow Spring System (provided by manufacturer)
2) Medical therapy with Tamsulosin 0.4 mg orally once daily (billed to insurance as standard-of-care)

Randomization will be computer-generated and stratified by study site.

Patients will be followed at 1, 3, 6, and 12 months following initiation of assigned therapy. Patients in the Medical Therapy arm will be allowed to crossover to receive the Zenflow Spring System after at least 3 months of follow-up. An overview of the study design is provided in the Figure below. The complete Schedule of Assessments from baseline through study completion is provided in Section 5.4.

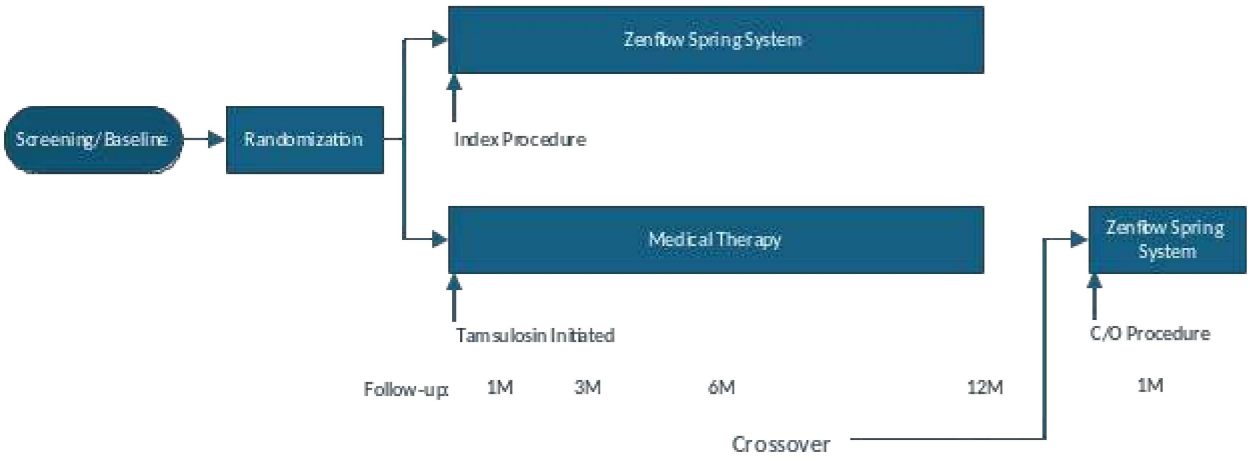

Figure 2: Study Schematic

3.2 Number of Patients and Institutions

This post-market clinical trial will enroll, randomize, and treat 110 patients at up to 20 institutions.

3.3 Study Duration

It is expected that patients will be entered into the post-market clinical trial over a 24-month

period. Patients will be followed for 12 months. Further follow up past 12 months will be at the discretion of the site and patients will be consented appropriately.

3.4 Crossover

Patients randomized to the Tamsulosin therapy arm will be allowed to crossover to receive treatment with the Zenflow Spring System after 1) their 3-month follow-up assessments are completed, 2) the patient's symptoms are confirmed to continue to warrant treatment; and 3) the patient continues to meet the study enrollment criteria. No crossover will be permitted beyond 30 days after completion of the 12-month follow-up. Patients who elect crossover and have a successful placement of the Spring Implant will be followed for 1 additional month and then will exit the study.

3.5 Study Population

Patients will be selected based on the criteria set forth in the Instructions for Use for the Zenflow Spring System and the additional criteria listed below.

3.5.1 Zenflow Spring System Criteria

All patients must meet the Zenflow Spring System IFU labeling requirements as follows in order to be enrolled in the study:

Indications for Use: The Spring® Implant and Delivery System is indicated for the treatment of obstructive lower urinary tract symptoms secondary to benign prostatic hyperplasia (BPH) in men with prostatic urethral lengths between 25mm and 45mm and prostate sizes between 25cc and 80cc.

Contraindications: Use of the Spring® Implant and Delivery System is contraindicated in the following conditions:

- Patients with a previous laser prostatectomy, hyperthermia, brachytherapy, or invasive treatment to the prostate or pelvis area
- Patients with acute urethral stricture disease, meatal stenosis, or bladder neck stricture – either current or recurrent
- Patients with active urolithiasis
- Prostate cancer or previous external or internal gamma radiation therapy for prostate or proximal urethral cancer
- Known allergy to nickel, titanium, or stainless steel
- Patients with urinary tract infections (UTIs)
- Patients with acute infection (acute urethritis, acute prostatitis, acute epididymitis)
- Patients with hematuria with an undiagnosed cause
- Patients with an existing prostatic foreign body
- Urinary incontinence due to an incompetent external sphincter

Additional Patient Selection Considerations:
A thorough clinical evaluation should be performed on all patients presenting for treatment for BPH as recommended by the American Urological Association (AUA) Guidelines for the Management of BPH, considering factors such as:

- Overactive bladder
- Obstructive intravesical median prostatic lobe, including Intravesical Prostatic Protrusion (IPP) greater than 10mm
- High bladder neck with absence of lateral lobe encroachment
- Patients with uncontrolled coagulopathy or patients on anticoagulant therapy who cannot safely temporarily suspend treatment in order to undergo the Spring Implant procedure

Patients with the above contraindicated conditions or additional patient selection conditions must be excluded from this study.

3.5.2 Additional Study Criteria

In addition to the above labeling requirements, patients must also meet all the following criteria to be eligible for enrollment in this study:

Inclusion Criteria

1. Moderate to severe LUTS, defined as an International Prostate Symptom Score (IPSS ≥ 8)
2. Not actively taking any medication indicated for BPH, defined as current use of:
    a. Alpha-adrenergic antagonists (Alpha Blockers) within 2 weeks of baseline IPSS assessment
    b. 5-alpha reductase inhibitors (5ARI) within 6 months of baseline IPSS assessment
    c. PDE5 daily use (on demand use is permitted)
3. Ability to provide informed consent and comply with study procedures and follow-up schedule

Exclusion Criteria

Participants who meet the following criteria will be excluded:

1. Known, previous adverse reaction to use of alpha-adrenergic antagonists (e.g., Tamsulosin)
2. Neurologic conditions affecting bladder function, including but not limited to:
    a. Multiple sclerosis
    b. Parkinson’s disease
    c. Neurogenic bladder or other conditions causing non-obstructive voiding dysfunction