

## SUMMARY OF SAFETY AND EFFECTIVENESS DATA

### I. GENERAL INFORMATION

Device Generic Name: Stent, urethral, prostatic, semi-permanent

Device Trade Name: The Spanner™ Temporary Prostatic Stent

Applicant's name and address: AbbeyMoor Medical, Inc.  
501 East Soo Street  
Parkers Prairie, MN 56361

Premarket Approval Number: P060010

Date of Panel Recommendation: None

Date of Notice of Approval  
To the Applicant: December 14, 2006

### II. INDICATIONS FOR USE

The Spanner™ is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-treatment catheterization.

### III. CONTRAINDICATIONS

The Spanner™ is contraindicated for use in patients with:

- Positive urine culture or active urinary tract infection,
- History of symptomatic urinary tract disease such as urethral stricture, bladder stones, or other significant urological conditions (e.g., gross hematuria) that could affect the function of the stent,
- Surgery altering the normal uro-genital anatomy or abnormal urethral anatomy that affects the function of the lower urinary tract, or
- A prostatic urethral length less than 4 cm or greater than 9 cm (combined length from the top (proximal side) of the bladder neck to the bottom (distal side) of external sphincter).

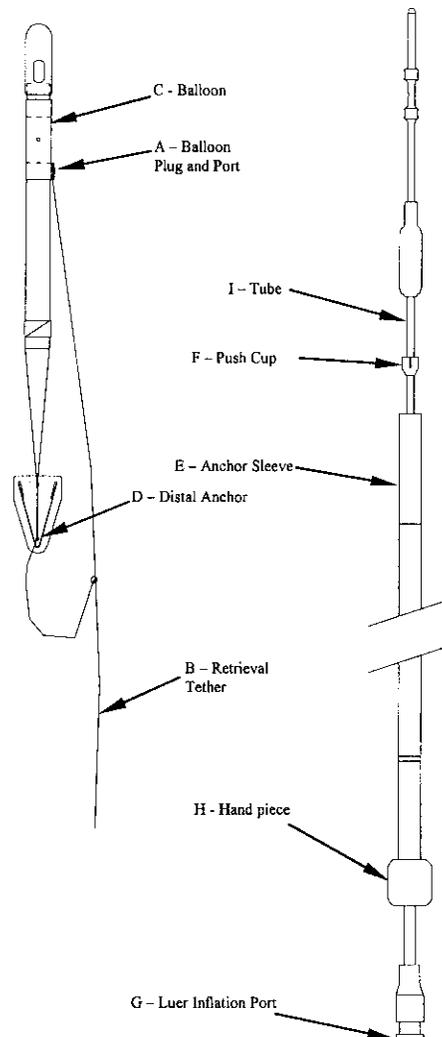
### IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in The Spanner™ Temporary Prostatic Stent physician's Instruction for Use.

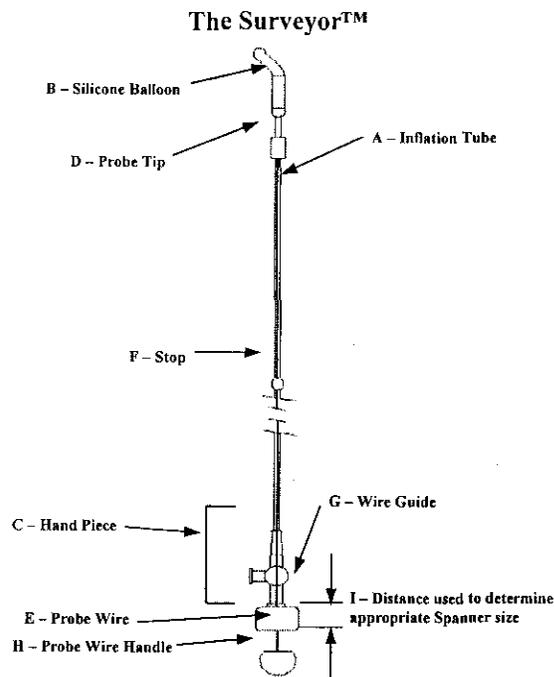
## V. DEVICE DESCRIPTION

The Spanner™ Temporary Prostatic Stent (“The Spanner™”) is a sterile, single use device made from silicone elastomer designed to facilitate volitional voiding urination following minimally invasive treatment for BPH following the typical initial catheterization period. The stent portion is positioned in the prostatic urethra, extending from the bladder to the proximal side of the external sphincter. The interior lumen provides a conduit for urine to flow from the bladder to the external sphincter during urination. The stent is held in the bladder by an inflatable balloon on its proximal end and a soft distal anchor on the distal end. The distal anchor is attached to the stent by the device tethers. The tethers traverse the external sphincter, with the anchor positioned on the distal side of the sphincter to prevent migration toward the bladder, while allowing normal sphincter function to occur. The stent is removed using the retrieval tether, which provides for the deflation of the balloon and withdrawal of the stent. To facilitate device insertion, the stent is mounted on a sterile, single use insertion tool. The stent and insertion tool are provided together in a sterile package. The Spanner™ is available in 20 Fr diameter, six lengths (4, 5, 6, 7, 8, and 9 cm), and straight or coudé-tip versions.

**The Spanner™ and Insertion Tool**



The Surveyor™ is a sterile, single use device accessory to The Spanner™ used to select the appropriate size The Spanner™. The Surveyor™ is used to assess the distance from the top (proximal side) of the bladder neck to the bottom (distal side) of the external sphincter. This distance corresponds to the distance from The Spanner™ balloon to the distal anchor when The Spanner™ resides *in situ*. The Surveyor™ consists of an inflation tube with a balloon on the proximal end and a hand piece on the distal end. A small probe slides along the Surveyor™ inflation tube through the length of the pendulous urethra to the level of the bottom (distal side) of the external sphincter. Components of the Surveyor™, external of the patient, replicate the position of the probe relative to the bottom of the external sphincter. The appropriate The Spanner™ size is identified using a selector card in conjunction with the Surveyor™.



## VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative practices and procedures to The Spanner™ use include Foley catheterization, clean intermittent self-catheterization, suprapubic catheterization, and no catheterization.

## VII. MARKETING HISTORY

AbbeyMoor, Inc. received CE Mark certification for The Spanner™ in July 2003. The Spanner™ has not been withdrawn from marketing in any country for reasons relating to device safety and effectiveness.

## VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The Spanner™ clinical trial included 100 subjects who had undergone transurethral microwave thermotherapy (TUMT) to treat their BPH and who used The Spanner™ to manage their urinary symptoms and urine flow after removal of their post-treatment urinary catheter. There were 658 adverse events reported during the course of the study; 385 events were reported by 99 The Spanner™ subjects and 273 events were reported by 80 Standard of Care (SOC) subjects.

There were 5 serious adverse events reported during the course of the study. The four events in The Spanner™ group were gross hematuria due to initiating anticoagulation therapy, congestive heart failure, and preexisting abdominal aortic aneurysm (all unrelated to the device), and urinary tract infection requiring hospitalization (possibly related to the device). The one serious adverse event reported in the Standard of Care group was congestive heart failure. There were no deaths reported.

Table 1 shows the number and percentage of subjects that experienced an event at least once.

**Table 1: Urological Adverse Events (with more than 3% event rate)**

Event	The Spanner™ N=100		Standard of Care N=86	
	N (%)	# Events	N (%)	# Events
Micturition Burning	69 ( 69.0% )	70	52 ( 60.5% )	55
Bleeding/Hematuria	61 ( 61.0% )	68	50 ( 58.1% )	51
Urinary Frequency Urgency	44 ( 44.0% )	47	40 ( 46.5% )	40
Perineal Pain	26 ( 26.0% )	29	11 ( 12.8% )	12
Bacteriuria	21 ( 21.0% )	23	17 ( 19.8% )	21
Pain/Discomfort/Spasm	19 ( 19.0% )	21	16 ( 18.6% )	16
Symptomatic UTI	15 ( 15.0% )	16	10 ( 11.6% )	12
Urinary Retention	10 ( 10.0% )	12*	13 ( 15.1% )	17
Urinary retention with no reported migration or clotting	5 ( 5.0% )		12 ( 14.0% )	
Associated with migration	3 ( 3.0% )		na	
Associated with clotting	2 ( 2.0% )		1 ( 1.2% )	
Urinary Incontinence	8 ( 8.0% )	8	6 ( 7.0% )	6
Pain - Trauma Activated	7 ( 7.0% )	8	na	na
Irritation of Bladder/Urethra from device contact	6 ( 6.0% )	6	na	na
Ulceration/Trauma of Urethra/Bladder	4 ( 4.0% )	4	0 ( 0.0% )	0
Ejaculation Failure	4 ( 4.0% )	4	0 ( 0.0% )	0
Dyspareunia - Painful Sex	4 ( 4.0% )	4	0 ( 0.0% )	0
Elevated PVR	3 ( 3.0% )	3	3 ( 3.5% )	3
Urinary Hesitation	3 ( 3.0% )	3	0 ( 0.0% )	0
Hemospermia	1 ( 1.0% )	1	6 ( 7.0% )	6

\* Includes two retention events that occurred after The Spanner™ removal

Other urological adverse events that occurred in less than 3% of The Spanner™ subjects in the investigation included difficulty in micturition, post void dribble, urethral irritation, pruritus, mucosal tingling, migration not associated with retention, The Spanner™ expulsion, Foley

expulsion, bladder calculus, epididymitis, penile swelling, phimosis, penile pain, ejaculation disorder, testicular pain, bladder discomfort, and urethritis.

In the Standard of Care group, the following adverse events occurred in less than 3% of subjects: post void dribble, difficulty in micturition, penile swelling, phimosis, penile pain, pruritus, urine flow decreased, drainage lumen occlusion, rash - genital, nocturia, and renal pain.

Non-urological adverse events experienced by at least 3% of The Spanner™ subject included constipation, vomiting, and influenza-like symptoms.

The majority of adverse events (> 75%) for both groups occurred during weeks 1-4 following randomization. Adverse events that occurred following removal of The Spanner™ included: bleeding/hematuria, urinary/frequency/urgency, urinary retention, elevated PVR, perineal pain, pain/discomfort/spasm, micturition burning, bacteriuria, and symptomatic UTI.

Table 2 shows the number and percentage of subjects that experienced an event which required treatment.

**Table 2: Urological Adverse Events Requiring Treatment (with more than 3% event rate)**

Event	The Spanner™ N=100		Standard of Care N=86	
	N (%)	# Events	N (%)	# Events
Bacteriuria	16 (16.0%)	17	9 (10.5%)	10
Symptomatic UTI	13 (13.0%)	14	10 (11.6%)	11
Urinary Retention <sup>#</sup>	10 (10.0%)	12*	13 (15.1%)	17
Urinary retention with no reported migration or clotting	5 (5.0%)		12 (14.0%)	
Associated with migration	3 (3.0%)		na	
Associated with clotting	2 (2.0%)		1 (1.2%)	
Micturition Burning	9 (9.0%)	9	5 (5.8%)	5
Pain/Discomfort/Spasm	7 (7.0%)	8	2 (2.3%)	2
Urinary Frequency Urgency	5 (5.0%)	5	4 (4.7%)	4
Perineal Pain	5 (5.0%)	5	2 (2.3%)	2

\* Includes two retention events that occurred after The Spanner™ removal

Other urological adverse events requiring treatment that occurred in less than 3% of The Spanner™ subjects in the investigation included bleeding/hematuria, elevated PVR, migration not associated with retention, Foley expulsion, irritation of bladder/urethra from device contact, epididymitis and testicular pain.

In the Standard of Care group, the following adverse events requiring treatment occurred in less than 3% of subjects: bleeding/hematuria, elevated PVR, urinary incontinence, drainage lumen occlusion, rash - genital, difficulty in micturition, renal pain, penile swelling, phimosis, and urine flow decreased.

Urinary retention occurred in 10 The Spanner™ subjects and 13 Standard of Care subjects. Device migration occurred in 5 The Spanner™ subjects leading to urinary retention in 3 subjects.

Clot blockage of The Spanner™ resulted in urinary retention in 2 subjects. Urinary retention was not associated with serious adverse effects.

Bladder and urethral cystoscopy revealed no significant differences in overall findings between the treatment and control groups.

## **IX. SUMMARY OF PRECLINICAL STUDIES**

Non-clinical laboratory studies were performed on The Spanner™ and Surveyor™ and included design verification, material safety, package integrity, shelf life, and sterilization validation. Results of these studies, briefly summarized below, demonstrate that The Spanner™ and Surveyor™ designs are suited for their intended use.

### **Design Verification/Mechanical Testing**

Design verification testing (DVT) was carried out on the combined The Spanner™ Stent/Insertion Tool, The Spanner™ and Insertion Tool individually, and the Surveyor™. Modifications made to the device to improve the design and its manufacturability after initial DVT was completed, were evaluated using a Change Risk Analysis (CRA) procedure. Testing conducted as part of the DVT and CRA included:

- Simulated use testing to demonstrate The Spanner™ Stent/Insertion Tool assembly can be reliably inserted, inflated, deployed, and removed. Testing to show that The Spanner™ balloon inflates, maintains volume, resists rupture, and deflates reliably, and that the Insertion Tool reliably uncouples from The Spanner™.
- Mechanical tests (bending, stiffness, static load, and tensile force) to demonstrate that the device provides adequate strength and flexibility when subjected to the pressures and forces anticipated for device insertion, deployment, usage, and removal.
- Attachment force testing to demonstrate that the material bonds provide sufficient strength to withstand the forces anticipated in the intended clinical environment.
- Testing to demonstrate that The Spanner™ is able to resist pullout, similar to a Foley catheter.
- Testing to demonstrate that that the Surveyor™ balloon inflates, maintains volume, resists rupture, and deflates reliably.
- Compatibility testing to demonstrate that the device materials and performance are not likely to degrade in the presence of urine for the duration of the specified intended use.

The testing evaluated the mechanical integrity of key bonds and components as well as the functional aspects of the device. The testing provided reasonable assurance that The Spanner™, Insertion Tool, and Surveyor™ will function as expected and provided a foundation to evaluate future modifications to the device.

### **Material Safety**

The Spanner™ is constructed from silicone elastomer reinforced with stainless steel wire in the stent and distal anchor. The tethers consist of nylon suture material. The materials used to

construct The Spanner™ are commonly used in commercially available urological devices. Biomaterial safety testing of representative samples of the finished, sterilized device was conducted in accordance with ISO 10993 - *Biological evaluation of medical devices, Part 1 - Evaluation and tests* and in consideration of the FDA Blue Book memo (G95-1) *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*.

Cytotoxicity, sensitization, and acute intracutaneous reactivity tests were performed for both The Spanner™ stent and Insertion Tool mounted together. The following biomaterial tests were performed on The Spanner™ stent alone: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, two and four-week muscle implantation studies. Testing for the Surveyor™ consisted of cytotoxicity, sensitization, and acute intracutaneous reactivity. These tests were conducted according the ISO protocols and the results showed no adverse effects.

### **Packaging, Shelf Life, and Sterilization Testing**

The Spanner/Insertion Tool and Surveyor™ devices are sterilized using a validated gaseous ethylene oxide (EO) sterilization process that provides a sterility assurance level (SAL) of at least  $10^{-6}$ ; the devices are labeled for single use only. EO residuals have been demonstrated through testing to be within acceptable limits.

Effects of aging on The Spanner™, Insertion Tool, and Surveyor™ devices and package configurations have been evaluated with samples aged (via a combination of real time and accelerated aging) of the packaged The Spanner™/Insertion Tool and Surveyor™. These studies were conducted under simulated distribution and handling conditions. The testing confirmed the sterility and integrity of the packaging for 2 years for The Spanner™/Insertion Tool and 3 years for the Surveyor™. However, the functional shelf testing of the devices was conducted on samples that included material differences in key components. The Spanner™/Insertion Tool and the Surveyor™ are approved for a shelf-life of 6 months. This shelf life may be increased once functional testing using the approved protocols is completed.

## **X. SUMMARY OF CLINICAL STUDIES**

### **Study Design**

The study was a multi-center, prospective, controlled, randomized clinical investigation designed to evaluate the safety and effectiveness of The Spanner™ to manage lower urinary tract symptoms (LUTS) and bladder emptying after TUMT treatment after an initial period of catheterization. Study participants were male patients older than 45 years of age that had undergone TUMT treatment for BPH.

The investigation compared use of The Spanner™ to a Standard of Care (SOC) control group during the post-TUMT recovery period. Subjects planning TUMT to treat their BPH were screened after signing the informed consent (Visit 1). These subjects completed their scheduled TUMT procedure and discharged with a Foley catheter. At 3-10 days post-TUMT, patients returned for removal of the Foley catheter (Visit 2). At this visit subjects performed a voiding

trial after catheter removal and only those who were successful (PVR  $\leq$  250 mL with a mean voided volume of at least 100 mL) were considered enrolled. Patients were randomized after removal of the Foley catheter and a successful voiding trial.

Patients in The Spanner™ group used The Spanner™ to manage LUTS and bladder emptying for a period of 28 days after removal of their post-treatment Foley catheter. Patients in the SOC group were sent home with no catheter or stent after removal of their post-treatment Foley catheter, as this is the current standard of care. Study subjects were followed at 1, 2, and 4 weeks during The Spanner™ indwelling period and 1 and 4 weeks after the point of The Spanner™ removal. SOC subjects were evaluated at the same time points.

The Spanner™:SOC randomization ratio was 1:1 for the first 147 enrolled subjects and 2:1 thereafter. A total of 186 subjects [100 (54%) The Spanner™ and 86 (46%) SOC] were randomized at 9 clinical sites.

### Study Endpoints

The primary effectiveness endpoint was the reduction in LUTS as indicated by the International Prostate Symptom Score (IPSS). For the IPSS analysis the baseline (pre-TUMT) score was assessed at Visit 1 and the follow-up score is the average of the IPSS values at Visit 3 (7 days after randomization) and Visit 4 (14 days after randomization). IPSS values at Visits 3 and 4 were averaged.

The primary safety endpoint was post-void residual (PVR). For the PVR analysis the baseline PVR level was assessed at Visit 2 following removal of the Foley catheter (post-TUMT), and the follow-up PVR level is the average of the abdominal ultrasound readings taken at Visits 3 (7 days after randomization), Visit 4 (14 days after randomization), and Visit 5 (28 days after randomization). PVR values at Visits 3, 4, and 5 were averaged.

The investigational plan hypothesized that the reduction in PVR levels in The Spanner™ group would be non-inferior to that in the SOC group and that the reduction in IPSS in The Spanner™ group would be superior to that in the SOC group. Adverse events were also monitored, along with other secondary endpoints (uroflowmetry, quality of life, device satisfaction, sexual function, and cystoscopy).

### Eligibility Criteria

#### Inclusion Criteria:

- Age > 45 years
- IPSS > 13
- The subject has undergone (TUMT) treatment for BPH
- Ability and willingness to sign the Informed Consent Form
- Willing and able to complete the follow-up protocol requirements

#### Exclusion Criteria:

- Evidence of active urinary tract infection or positive urine culture at Visit 1

- Signs and symptoms of active urinary tract infection when the Foley catheter is removed 3-10 days after the TUMT procedure
- Post-void residual urine > 250 ml at Visit 1
- Voided volume less than 100 ml on the Visit 1 uroflow test
- Current, recent, or symptomatic urinary tract disease including urethral stricture, bladder stones, and other significant urological conditions
- Surgery altering the normal uro-genital anatomy or abnormal urethral anatomy that affect the function of the lower urinary tract
- Previous minimally invasive therapy or surgery for BPH
- History of neurogenic bladder or conditions associated with neurogenic bladder, including spinal cord injury, multiple sclerosis, or Parkinson's disease
- Gross hematuria when the indwelling catheter is removed 3-10 days post TUMT, or in the 24 hours prior to catheter removal
- Unsuccessful trial void when the indwelling catheter is removed 3-10 days post TUMT (to be considered a successful trial void, the PVR must be < 250 ml with a voided volume of at least 100 ml)
- Known or suspected prostate cancer
- Prior pelvic irradiation therapy
- Prostatic urethral length > 5.4 or < 2.4 cm
- Any change in prostate specific medications such as alpha-blockers or other medications for BPH within the 30 days prior to the TUMT procedure, including initiating or discontinuing treatment or a change in the medication dosage
- Intravesical enlargement of the median lobe of the prostate

#### Follow-up Examination Schedule

- Visit 1: Subjects planning TUMT to treat their BPH were screened after signing the informed consent. At this visit, relevant patient and medical history and data from laboratory testing, PVR, IPSS, and uroflow were collected. Subjects completed their scheduled TUMT procedures and were discharged with a Foley catheter.
- Visit 2: At 3-10 days post-TUMT, patients returned for removal of the Foley catheter. Subjects performed a voiding trial after catheter removal and only those who were successful (PVR  $\leq$  250 mL with a mean voided volume of at least 100 mL) were considered enrolled. Patients were randomized after removal of the Foley catheter and successful voiding trial. Adverse events and data from laboratory testing, voiding diaries, PVR, and uroflow were collected. Patients randomized into The Spanner™ group had the device inserted. Patients in the SOC group were sent home with no catheter or stent.
- Visit 3: At 7 days following randomization, subjects returned for follow-up. Adverse events and data from laboratory testing, voiding diaries, IPSS, PVR, a patient satisfaction questionnaire, and uroflow were collected.

- Visit 4: At 14 days following randomization, subjects returned for follow-up. Adverse events and data from laboratory testing, voiding diaries, IPSS, PVR, a patient satisfaction questionnaire, and uroflow were collected.
- Visit 5: At 28 days following randomization, subjects returned for follow-up. The Spanner™ was removed for subjects in The Spanner™ group. Adverse events and data from cystoscopy, laboratory testing, voiding diaries, IPSS, PVR, a patient satisfaction questionnaire, and uroflow were collected.
- Visit 6: At 35 days following randomization (7 days after The Spanner™ removal), subjects returned for follow-up. Adverse events and data from laboratory testing, voiding diaries, IPSS, PVR, and uroflow were collected.
- Visit 7: At 56 days following randomization (28 days after The Spanner™ removal), subjects returned for follow-up. Adverse events and data from laboratory testing, voiding diaries, IPSS, and uroflow were collected.

Demographic and Baseline Data

Table 3 provide relevant demographic data for subjects in The Spanner™ and Standard of Care groups.

**Table 3: Patient Demographics**

	The Spanner™ N=100	Standard of Care N=86	p-value
	Mean±SD (Range) or N (%)	Mean±SD (Range) or N (%)	
African American	3 (3.0%)	3 (3.5%)	0.800
Caucasian	72 (72.0%)	64 (74.4%)	
Hispanic	24 (24.0%)	19 (22.1%)	
Other	1 (1.0%)	0 (0.0%)	
Age	68.3±8.8 (49.0, 86.0)	68.4±8.1 (47.0, 88.0)	0.935
Height (inches)	69.9±2.7 (62.0, 76.0)	68.5±3.6 (60.0, 83.0)	0.424
Weight (pounds)	169±36.8 (130, 382)	191±36.0 (118, 275)	0.439

Tables 4-5 provide relevant baseline data for subjects in The Spanner™ and Standard of Care groups.

**Table 4: Patient Baseline Characteristics prior to TUMT (Visit 1)**

	The Spanner™ N=100	Standard of Care N=86	p-value
	Mean±SD (Range)	Mean±SD (Range)	
PSA (ng/mL)	4.3±4.5 (0.3,25.0)	2.5±2.3 (0.2,11.6)	0.005
IPSS	22.7±5.4 (10,34)	22.1±5.0 (13,35)	0.446
PVR (mL)	83.1±65.7 (0,347)	86.9±98.8 (0,641)	0.756
Q <sub>max</sub> (mL/s)	12.0±5.3 (2.8,27.2)	12.4±5.8 (3.8,34.0)	0.675
Quality of Life	4.3±1.2 (1,6)	4.3±1.1 (2,6)	0.781

**Table 5: Patient Baseline Characteristics after TUMT Treatment (Visit 2)**

	<b>The Spanner™</b> N=100	<b>Standard of Care</b> N=86	p-value
	Mean±SD (Range)	Mean±SD (Range)	
IPSS	not collected	not collected	
PVR (mL)	60.0±62.3 (0,291)	60.3±88.9 (0,641)	0.984
Q <sub>max</sub> (mL/s)	8.9±4.2 (3.3,29.0)	9.2±5.4 (2.0,39.0)	0.691
Quality of Life	not collected	not collected	

## Results

A total of 186 subjects [100 (54%) The Spanner™ and 86 (46%) SOC] were randomized at 9 clinical sites. Table 6 shows the number of subjects evaluated at each follow-up visit.

**Table 6: Patient Accountability**

	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7
<b>The Spanner™</b>	100	89	86	82	82	82
<b>Standard of Care</b>	86	81	81	78	78	77

The number of subjects that were consented but failed the voiding trial at visit 2 was 31. Of these 31 subjects, 23 were excluded from study participation and 8 subjects were inappropriately enrolled into the trial (4 The Spanner™ and 4 Standard of Care).

### Primary Effectiveness

For the primary effectiveness endpoint, the baseline (pre-TUMT) IPSS score was assessed at Visit 1 and the follow-up score is the average of the IPSS values at Visit 3 and Visit 4. The observed improvements from baseline were 7.28 points in The Spanner™ group and 4.42 points in the SOC group. The Spanner™ group was statistically improved compared to SOC by 2.86 points ( $p = 0.019$ ).

IPSS analyzed by visit demonstrate superiority ( $p < 0.05$ ) in The Spanner™ group versus SOC at Visit 3 (see Table 7).

**Table 7: IPSS Change from Baseline by Visit**

Time Period	<b>The Spanner™</b> N=100	<b>Standard of Care</b> N=86	p-value
	Mean±SD	Mean±SD	
Visit 1	22.7±5.4	22.1±5.0	N/A
Visit 3 (change from 1)	-6.6±9.1	-3.6±7.3	0.047
Visit 4 (change from 1)	-8.0±9.1	-5.3±8.2	0.084
Visit 5 (change from 1)	-9.1±9.5	-7.7±7.9	0.290
Visit 6 (change from 1)	-11.9±9.1	-9.8±8.0	0.179
Visit 7 (change from 1)	-14.1±8.9	-12.3±7.8	0.234

IPSS continued to decrease at each subsequent visit for both groups. However, the differences between the two groups were not statistically significant after Visit 3 both before (Visits 4 and 5) and after (Visits 5 and 6) removal of The Spanner™.

### Primary Safety

For the primary safety endpoint, PVR was assessed at Visit 2 following removal of the Foley catheter (post-TUMT), and the follow-up PVR was the average of the abdominal ultrasound readings taken at Visits 3 (7 days after randomization), Visit 4 (14 days after randomization), and Visit 5 (28 days after randomization). A mean *decrease (improvement)* from baseline of 6.5 mL was observed in The Spanner™ group and a mean *increase* of 28.6 mL in the SOC group. The Spanner™ group was significantly improved compared to SOC (p=0.001).

PVR values analyzed by visit demonstrated superiority (p<0.05) in The Spanner™ group versus SOC at Visits 3 and 4 (see Table 8).

**Table 8: Post Void Residual Change from Baseline by Visit**

Time Period	The Spanner™ N=100	Standard of Care N=86	p-value
	Mean±SD	Mean±SD	
Visit 1	83.1±65.7	86.9±98.8	N/A
Visit 2 Pre-Insertion Baseline	60.0±62.3	60.3±88.9	N/A
Visit 3 (change from 2)	-7.7±63.0	32±89.8	0.001
Visit 4 (change from 2)	-5.0±70.4	40.0±93.3	0.001
Visit 5 (change from 2)	-6.7±65.6	13.6±80.6	0.099
Visit 6 (change from 2)	9.1±71.3	12.8±76.8	0.736

At Visit 5, the PVR Standard of Care group decreased and difference between the two groups was not statistically significant. The PVR in The Spanner™ group increased after The Spanner™ was removed (Visit 6). The difference between The Spanner™ and Standard of Care group was not statistically significant at Visit 6. PVR was not evaluated at Visit 7.

Refer to section VIII for a description of the adverse events that occurred in the clinical trial in patients who used The Spanner™.

## **XI. CONCLUSIONS**

The preclinical data adequately characterized the material safety of The Spanner™ and its accessories, and provided reasonable assurance that The Spanner™, Insertion Tool, and Surveyor™ mechanically will function as expected and that the package integrity is adequate under expected handling to maintain sterility.

The U.S. multi-center clinical investigation compared the use of The Spanner™ to a standard of care group (no stent) following typical removal of their post-TUMT urinary catheter. The Spanner™ reduced post-void residuals and improved lower urinary tract symptoms (2.86 point difference in mean IPSS) compared to the control group who were not using a catheter or stent. Based on the results of the clinical trial it was concluded that The Spanner™ provided

modest patient benefits while introducing an acceptable amount of risk, when used during the period following typical catheterization immediately following TUMT. The safety and effectiveness of using The Spanner™ rather than a traditional urinary catheter immediately following TUMT was not evaluated.

The clinical trial evaluated the safety and effectiveness of The Spanner™ in patients following treatment with several different approved TUMT devices. Other minimally invasive treatments for BPH use different types of energy (microwave, radio frequency, optical) to produce the same post-treatment necrotic process as their primary mechanisms of action. Like TUMT, these treatments also produce temporary edema causing retention or worsening of lower urinary tract symptoms. Therefore, it was concluded that the results of the clinical trial would be applicable to other minimally invasive therapies for BPH, such as other transurethral microwave thermotherapy (TUMT), transurethral needle ablation (TUNA), and interstitial laser coagulation (ILC).

Together the clinical and non-clinical test results provided a reasonable assurance that The Spanner™ and its accessories are safe and effective when used as intended and in accordance with the instructions for use.

## **XII. PANEL RECOMMENDATIONS**

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Gastroenterology and Urology Devices Advisory Panel, an FDA advisory committee for review, for review and recommendation, because the information in the PMA substantially duplicates information previously reviewed by this panel.

## **XIII. CDRH DECISION**

Based upon its review of the PMA, CDRH concludes that these data, the labeling requirements and post-approval requirements provide a reasonable assurance that The Spanner™ Temporary Prostatic Stent and the Surveyor™ are safe and effective when used in accordance with the Instructions for Use.

FDA issued an approval order on December 14, 2006.

The applicant's manufacturing facility was inspected August 17, 2006 and was found to be in compliance with the Quality System Regulation (21CFR 820).

## **XIV. APPROVAL SPECIFICATIONS**

Instructions for Use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling.

Post-approval Requirements and Restrictions: See approval order.