

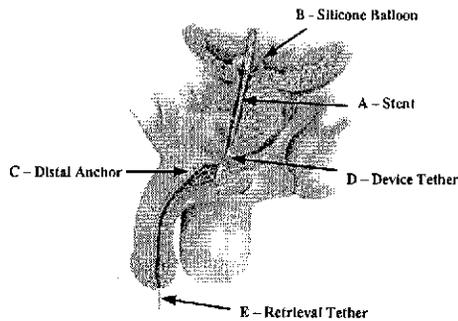
## Instructions for Use of The Spanner™ and the Surveyor™

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician.

### DEVICE DESCRIPTION OF THE SPANNER™ AND ACCESSORIES

The Spanner™ Temporary Prostatic Stent ("the Spanner") is a sterile, single use device made of silicone elastomer positioned in the prostatic urethra, extending from the bladder to the proximal side of the external sphincter (Figure 1, A). The interior lumen provides a conduit for urine to flow from the bladder to the external sphincter during urination.

Figure 1: Spanner Stent (positioned in prostatic urethra)



The Spanner is inserted and positioned tactilely using a detachable insertion tool. The stent is held in the bladder by an inflatable balloon (B) on its proximal end and a soft distal anchor (C) on the distal end. The distal anchor is attached to the stent by the device tethers (D). 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 (E) which provides for the deflation of the balloon and withdrawal of the stent.

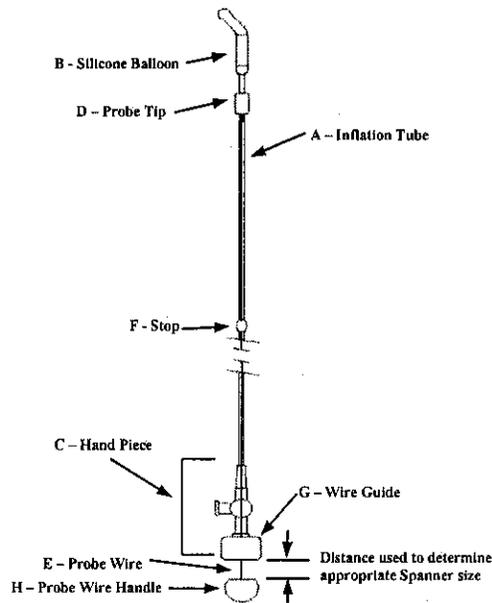
Spanner size selection is enabled by the use of an accessory, the Surveyor urethral measurement device. The stent and insertion tool are provided together in a sterile package. The Spanner is available in 20F diameter, 6 sizes (lengths 4, 5, 6, 7, 8, and 9 cm), and straight or coude-tip versions.

### Surveyor

The Surveyor™ (Figure 2) is designed to assess the length of the urethra from the bladder neck to the distal side of the external sphincter in order to select the appropriate Spanner size. The Surveyor is provided with a coude-tip. The Surveyor is sterile and packaged separately.

The Surveyor consists of an inflation tube (Figure 2, A) with a balloon (B) on the proximal end and a hand piece (C) on the distal end. A lumen extends from an inflation port stopcock on the hand piece to the balloon, and is used to inject fluid to inflate the balloon. A short probe (D) encircles the inflation tube and slides along the tube length between the balloon and a stop (F). A probe wire (E) is attached to the probe tip; it extends along the length of the Surveyor through the stop and wire guide (G), where it is attached to a probe wire handle (H).

Figure 2: Surveyor Device



**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.

**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).

**PRECAUTIONS**

- Improper selection of device size could result in acute urinary retention (AUR), device migration, incontinence, or patient intolerance.
- If the device migrates or clotting occurs, AUR may develop during use of the Spanner.
- The Spanner and Surveyor are to be used only by or under the direction of a physician who is qualified by training and experience to use the device.
- Appropriate patient education, training, and monitoring by a qualified health care professional are required for safe patient use.
- Safety and effectiveness in patients with median lobe enlargement, bladder or pelvic tumors, or prior pelvic irradiation therapy has not been established.
- The Spanner has not been evaluated for use with MRI. If a MRI is needed, the Spanner should be removed.
- Safety and effectiveness has not been evaluated for use immediately following treatment with transurethral microwave thermotherapy (TUMT) without prior catheterization during the initial post-treatment period.
- The Spanner and Surveyor are packaged sterile and for single use only. The devices should not be re-

- sterilized. Re-sterilization may degrade device materials resulting in device failure.
- Sterile water should be used for balloon inflation. Use of saline or ionic solutions may compromise balloon drainage at the time of removal.
  - Do not use petroleum based lubricants with the device. Use of these lubricants may degrade device materials resulting in device failure.
  - The Spanner patient contact surfaces are silicone rubber. If your patient has a known allergy or sensitivity to silicone, do not use the Spanner.

**ADVERSE EVENTS**

Men enrolled in this evaluation were post-TUMT patients. The events reported may reflect the cumulative effects that characterize the TUMT healing process as well as the presence of the Spanner. The Spanner clinical trial included 100 subjects who used the Spanner to improve 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 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 I shows the number and percentage of post-TUMT Spanner subjects that experienced an event at least once for events that occurred in at least 3% of the the Spanner subjects. All 100 Spanner subjects were included in the analysis.

**Table I: Rates of All Urological Adverse Events**

Event	Spanner N (%)	Total Number of Events
Micturition Burning	69 (69.0%)	70
Bleeding/Hematuria	61 (61.0%)	68
Urinary Frequency	44 (44.0%)	47
Urgency		
Perineal Pain	26 (26.0%)	29
Bacteriuria	21 (21.0%)	23
Pain/Discomfort/Spasm	19 (19.0%)	21
Symptomatic UTI	15 (15.0%)	16
Urinary Retention	10 (10.0%)	12*
Urinary Retention with no reported migration or clotting	5 (5.0%)	
Urinary Retention associated with migration	3 (3.0%)	
Urinary Retentions associated with clotting	2 (2.0%)	
Urinary Incontinence	8 (8.0%)	8
Pain - Trauma Activated	7 (7.0%)	8
Irritation of Bladder/Urethra from device contact	6 (6.0%)	6
Ulceration/Trauma of Urethra/Bladder	4 (4.0%)	4
Ejaculation Failure	4 (4.0%)	4
Dyspareunia - Painful Sex	4 (4.0%)	4
Elevated PVR	3 (3.0%)	3
Urinary hesitation	3 (3.0%)	3

\* This includes two retention events that occurred after Spanner removal.

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

Other urological adverse events that occurred in less than 3% of subjects in the investigation included: difficulty in micturition, post void dribble, urethral irritation, pruritus, mucosal tingling, migration not associated with retention, Spanner expulsion, Foley expulsion, bladder calculus, hemospermia, epididymitis, penile swelling, phimosis, penile pain, ejaculation disorder, testicular pain, bladder discomfort, and urethritis. 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.

To assess the severity of the reported events, urological adverse events that required treatment were reviewed. Rates of urological adverse events requiring treatment were comparable for the Spanner and SOC subjects. Table 2 shows the number and percentage of Spanner subjects that experienced an event which required treatment for events that occurred in at least 3% of the the Spanner subjects. All 100 Spanner subjects were included in the analysis.

**Table 2: Rates of Urological Adverse Events Requiring Treatment**

Event	Spanner N (%)	Total Number of Events
Bacteriuria	16 (16.0%)	17
Symptomatic UTI	13 (13.0%)	14
Urinary Retention	10 (10.0%)	12*
Urinary Retention with no reported migration or clotting	5 (5.0%)	
Urinary Retention associated with migration	3 (3.0%)	
Urinary Retentions associated with clotting	2 (2.0%)	
Micturition Burning	9 (9.0%)	9
Pain/Discomfort/Spasm	7 (7.0%)	8
Urinary Frequency Urgency	5 (5.0%)	5
Perineal Pain	5 (5.0%)	5

\* This includes two retention events that occurred after Spanner removal.

Other urological adverse events requiring treatment that occurred in less than 3% of 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.

## SUMMARY OF CLINICAL STUDIES

### Purpose

Safety and effectiveness of The Spanner™ Temporary Prostatic Stent ("the Spanner") was evaluated in a prospective, randomized, multi-center clinical investigation.

### Methods

The investigation compared use of the Spanner to a Standard of Care (SOC) control group during the post-TUMT recovery period. Patients were randomized *after* the Foley catheter was removed, 3-10 days post-TUMT, and successful completion of a voiding trial. The Spanner:SOC randomization ratio was 1:1 for the first 147 enrolled subjects and 2:1 thereafter. Patients in the Spanner group used the Spanner to manage lower urinary tract symptoms (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. A total of 186 patients were enrolled in the investigation at nine clinical centers in the United States. Primary study endpoints were reduction in post-void residual level (PVR) and reduction in LUTS (as indicated by the International Prostate Symptom Score – ‘IPSS’). 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 and other secondary endpoints were monitored. Study subjects were followed at 1, 2, and 4 weeks during the Spanner indwelling period and 1 and 4 weeks after the point of Spanner removal.

### Results

A total of 186 subjects were enrolled and randomized at nine (9) clinical centers, with 100 subjects (54%) randomized into the Spanner group and 86 (46%) into the Standard of Care group. Table 3 depicts the number of subjects participating in each follow-up evaluation.

Visit Type	Spanner	SOC
Visit 3 (7 days post Insertion)	89	81
Visit 4 (14 days post Insertion)	86	81
Visit 5 (28 days post Insertion and Spanner Removal)	82	78
Visit 6 (7 days post Removal)	82	78
Visit 7 (28 days post Removal)	82	77

The primary efficacy endpoint of the trial, IPSS score, was analyzed by comparing the mean at visits 3 and 4 to the baseline value, and computing a change score (using last value carried forward for missing data). All 100 Spanner patients and 86 Standard of Care patients were included in the analysis, with an improvement from baseline of 7.28 points in the Spanner group and 4.42 points in Standard of Care. The Spanner group was statistically improved compared to Standard of Care with a difference of 2.86 points ( $p=0.019$ ).

The primary safety endpoint, post void residual (PVR), was analyzed by comparing the mean at visits 3, 4 and 5 to the baseline value, and computing a change score (using last value carried forward for missing data). All 100 Spanner patients and 86 Standard of Care patients were included in the analysis, with a mean *decrease (improvement)* from baseline of 6.5 ml in the Spanner group and a mean *increase* of 28.6 ml in the Standard of Care group. The Spanner group was significantly improved compared to Standard of Care ( $p=0.001$ ).

IPSS and PVR values presented by visit (Table 4 and Table 5), demonstrate superiority ( $p<0.05$ ) in the Spanner group versus Standard of Care at Visits 3 and 4 for PVR and at Visit 3 for IPSS. All 100 Spanner patients and 86 Standard of Care patients were included in the analyses.

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**Table 4: IPSS Change from Baseline by Visit**

Time Period	Spanner Mean +/- SD (Range)	SOC Mean +/- SD (Range)	p- value*
Visit 1 (Baseline)	22.7+/- 5.4 ( 10, 34)	22.1+/- 5.0 ( 13, 35)	N/A
Visit 3 (change from Visit 1)	-6.6+/- 9.1 (-27, 14)	-3.6+/- 7.3 (-31, 13)	0.047
Visit 4 (change from Visit 1)	-8.0+/- 9.1 (-30, 16)	-5.3+/- 8.2 (-35, 12)	0.084
Visit 5 (change from Visit 1)	-9.1+/- 9.5 (-29, 15)	-7.7+/- 7.9 (-35, 10)	0.290
Visit 6 (change from Visit 1)	-11.9+/- 9.1 (-30, 10)	-9.8+/- 8.0 (-35, 6)	0.179
Visit 7 (change from Visit 1)	-14.1+/- 8.9 (-31, 9)	-12.3+/- 7.8 (-35, 2)	0.234

\* Multiply adjusted using the permutation resampling method of Westfall and Young (1993)

**Table 5: PVR Change from Baseline by Visit**

Time Period	Spanner Mean +/- SD N (Range)	SOC Mean +/- SD (Range)	p- value*
Visit 1	83.1+/-65.7 ( 0, 347)	86.9+/-98.8 ( 0, 641)	N/A
Visit 2 (Baseline)	60.0+/-62.3 ( 0, 291)	60.3+/-88.9 ( 0, 641)	N/A
Visit 3 (change from Visit 2)	-7.7+/-63.0 (-166, 199)	32.2+/-89.8 (-365, 511)	0.001
Visit 4 (change from Visit 2)	-5.0+/-70.4 (-190, 214)	40.0+/-93.3 (-328, 417)	0.001
Visit 5 (change from Visit 2)	-6.7+/-65.6 (-190, 263)	13.6+/-80.6 (-341, 275)	0.099
Visit 6 (change from Visit 2)	9.1+/-71.3 (-190, 204)	12.8+/-76.8 (-337, 229)	0.736

\* Multiply adjusted using the permutation resampling method of Westfall and Young (1993)

**PATIENT COUNSELING INFORMATION**

Patient counseling is the responsibility of the treating physician. AbbeyMoor Medical provides a Patient Information Booklet to assist the physician in discussing The Spanner and Surveyor with the patient. It is recommended that the subjects in this book including the insertion and removal of the Spanner, the risks, sexual activity, and other options be discussed with the patient. It is AbbeyMoor Medical's recommendation that the Patient Information Booklet be provided to the patient in a timely manner.

**HOW SUPPLIED**

The Spanner and Surveyor are packaged and sold separately.

One (1) Spanner is packaged sterile in a peel-away pouch with Instructions for Use (IFU) and an Emergency Removal Card included.

One (1) Surveyor and Spanner Selector Card are packaged sterile in a peel-away pouch with an IFU included.

The Spanner and Surveyor are provided ethylene oxide (EO) sterilized.

Materials required but not included:

- 10cc Luer-tip syringe
- Water based lubricant (i.e. KY Jelly)
- Lidocaine Jelly
- Sterile Water

**INSTRUCTIONS FOR USE**

**Caution:** Before using any sterile packaged product, carefully inspect the package and device for any damage which may compromise sterility or use.

**Use the Surveyor to select the appropriate size**

**Spanner**

The appropriate Spanner size is determined using the Surveyor, a tool designed to assess the distance from the bladder neck to the distal side of the external sphincter, which corresponds with where the Spanner resides *in situ*.

1. Lubricate the tip of the Surveyor with a water soluble lubricant (e.g., sterile lubricating jelly or topical anesthetic).
2. Inject a topical anesthetic into the urethra.
3. Insert the Surveyor into the urethra and advance it until the proximal tip is located in the bladder.
4. Inject 5cc sterile water and close stopcock.

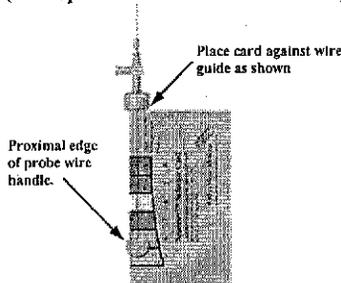
**Caution:**

- Failure to close the stopcock valve will allow the balloon to deflate, potentially resulting in an inaccurate Spanner size selection.
- Use the recommended inflation volume to ensure accurate selection of Spanner size.

5. Apply gentle traction on the Surveyor to seat the balloon on the bladder neck.
6. Ask the patient to relax while continuing to apply gentle traction to the Surveyor, then advance the probe tip until it gently abuts the patient's external sphincter.
7. Confirm sphincter location by repeating step 6.
8. Once confirmed, the Spanner size is determined by comparing the distance between the wire guide and the probe wire handle with the Spanner selector card (Figure 3). This distance represents the distance from the bladder neck to the bottom of the external sphincter. The Spanner selector card indicates the appropriate size to use.

**Caution:** If the probe wire handle does not indicate a size, the patient is not a candidate for receiving the Spanner.

**Figure 3: Spanner Selector Card and Device Size Table**  
(Note Spanner Size 8cm selection shown)



Color Code	Device Size
[Dark Grey]	4 cm
[Medium Grey]	5 cm
[Light Grey]	6 cm
[White]	7 cm
[Dark Grey]	8 cm
[Medium Grey]	9 cm

9. Following size selection, open the stopcock and wait 15 seconds until the balloon is completely drained.
10. Withdraw the Surveyor.

**Prepare the Spanner**

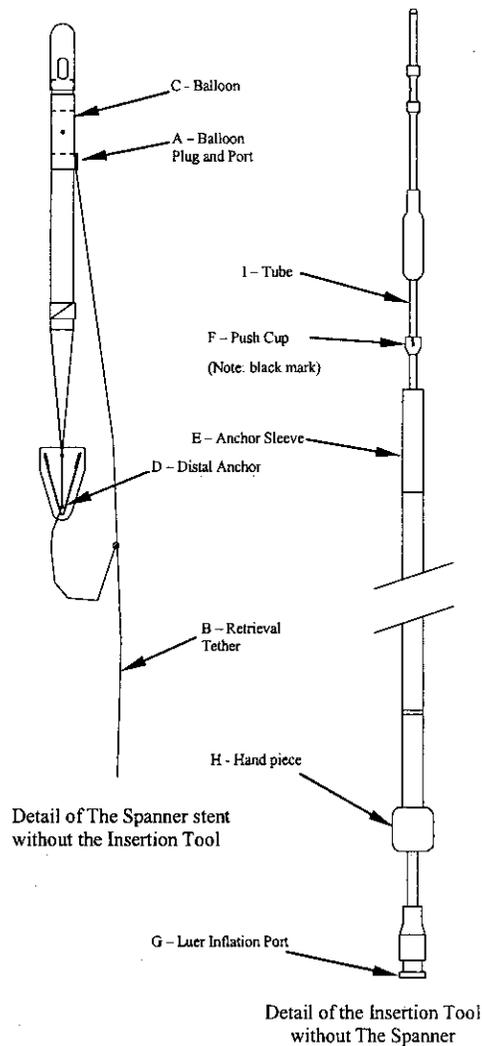
(Refer to Figure 4 for a detailed diagram of the Spanner and Insertion Tool components.)

1. Separate the Spanner stent from the Insertion Tool.
2. Verify that the balloon plug (A) is properly seated in the balloon plug port.
3. Partially fill the stent lumen with sterile lubricant.
4. Replace the stent onto the insertion tool.
5. Conduct a balloon inflation pre-test as follows:
  - a. Inject approximately 5cc sterile water into the inflation port.

**Caution: If the balloon does not fully inflate, do not use the device.**

- b. Pull the black retrieval tether (B) to drain the balloon.
- c. Massage the balloon (C) lightly to remove the residual water and fully replace the balloon plug (A).

**Figure 4: The Spanner and Insertion Tool Detail**



6. Retract the distal anchor sleeve (E) until the push cup (F) is visible. Fill the anchor sleeve lumen with lubricant.
7. Insert the tip of the distal anchor (D) under the black mark on the push cup (F).
8. Wrap the distal anchor around the insertion tool tube (I).
9. Advance the wrapped anchor into the anchor sleeve until the anchor is covered.

10. Align the black retrieval tether along the body of the insertion tool. Be very careful to ensure that the black retrieval tether is not wrapped around the body of the insertion tool to avoid inadvertent or premature removal of the balloon plug.

The Spanner is now prepared for insertion.

#### **Insert the Spanner**

##### ***Caution:***

- Proper placement of the device and correct balloon inflation volume are essential for device function. Misplacement or incorrect inflation volume may result in inadequate stenting of the prostate. If this occurs the patient may experience difficult urination, increased post void residual (PVR) or AUR. Incontinence may occur if stent extends through the external sphincter.
  - The balloon must be in the bladder prior to inflation. Inflation of the balloon while in the urethra may be painful.
  - Sterile water should be used for balloon inflation. Use of saline or ionic solutions may compromise balloon drainage at the time of removal.
  - Do not use petroleum based lubricants with the device. Use of these lubricants may degrade device materials resulting in device failure.
11. Advance the Spanner slowly into the urethra until the balloon is positioned in the bladder. Do not use excessive force to insert the Spanner. If unexpected resistance is encountered, do not continue insertion without first determining the cause of the resistance and taking remedial action.
  12. Use a luer syringe to inject 5cc sterile water into the inflation port (G).
  13. Apply gentle traction to position the balloon in the bladder neck.
  14. Release the anchor by holding the metal luer (G) steady while withdrawing the plastic hand piece (H). You may feel the anchor release from the insertion tool.

***Caution:*** Pushing the metal luer to release the anchor will incorrectly position the Spanner in the urethra.

15. Continue to withdraw the insertion tool using the plastic hand piece. The Spanner should deploy easily from the Insertion Tool. If separation of either the distal anchor or the hand piece does not occur with gentle traction the device should be removed by pulling the black tether, waiting 15-20 seconds to allow the balloon to deflate, and then withdraw the device.
16. The black retrieval tether may be left extended beyond the meatus. If left extended, it should be trimmed 2" beyond meatus with penis on stretch to compensate for the possibility of erectile function and to prevent retraction of tether.

#### **Discharge the Patient**

1. Conduct a trial void to verify patient can urinate adequately.
2. Instruct the patient not to pull on the black retrieval tether as this could deflate the balloon and dislodge the Spanner.

***Caution:*** Pulling the black tether may result in the patient experiencing an AUR event.

3. Instruct the patient on the signs of developing retention and other potential adverse events. At the onset of relevant symptoms the patient should consult his urologist or caregiver.
4. Provide the patient with emergency contact information and Emergency Removal Card. Instruct the patient that

- if he requires emergency care the caregiver must be informed that the patient is wearing The Spanner.
- Instruct the patient that removal of The Spanner should be performed by or under the supervision of a physician.

**Remove The Spanner**

- If tether is indwelling, it may be beneficial to have the patient urinate immediately prior to device removal to help position the retrieval tether near the meatus. Retract the tip of the penis slightly to locate and grasp the retrieval tether. Note: If the retrieval tether cannot be located manually, urethroscopy may be required to locate and grasp the retrieval tether.
- Remove the device by gently pulling on the black retrieval tether until you feel the plug release from the balloon then stop pulling. Wait 15-20 seconds to allow balloon to deflate.
- Resume pulling on the black retrieval tether until stent is removed. Do not use excessive force during device removal. If unexpected resistance is encountered determine the cause of the resistance and take remedial action.

**Caution:**

- If excessive resistance is felt during Spanner removal, balloon deflation may not have occurred. Removal of the device should be completed under cystoscopic guidance.
  - If balloon rupture occurs during removal, cystoscopy should be performed to assure that all balloon fragments have been removed from the urinary tract.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

**PATIENT INFORMATION**

A Patient Information Booklet is available to assist the physician in counseling the patient about this device. Patient Information Booklets are provided with the initial device order and additional copies are available from AbbeyMoor Medical. A patient Emergency Removal Card is included with this IFU.

For additional information contact:

**AbbeyMoor Medical, Inc.**  
 501 East Soo Street  
 Parkers Prairie, MN 56361 USA  
 1-888-528-9073 FAX 1-218-338-6710

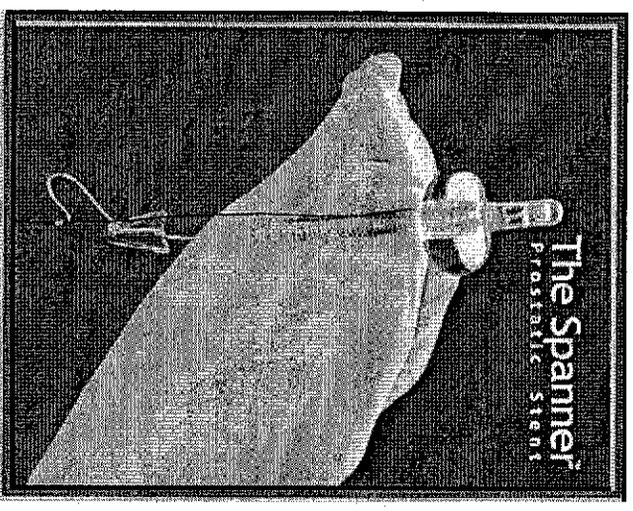
**International Symbols Glossary**

	Caution, Consult Accompanying Documents
	Sterilization using ethylene oxide
	Do Not Reuse
	Manufacturer
	EU Authorized Representative
	CE Marking of Conformity
	Catalogue Number
	Batch Code
	Use By

PN 3007035 Rev C  
 Effective Date: ##/##/##



## Patient Information Booklet



*This booklet is for men and their families regarding the use of The Spanner™. It contains important information about the Spanner device. Please review this booklet and discuss your questions with your doctor.*

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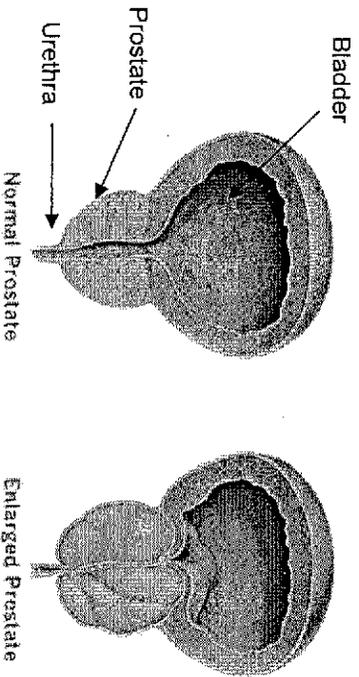
PN 1007/335 Rev A Effective Date: ##/##

## Glossary of Terms

- Bladder** – The organ in the body where urine is retained until it is expelled from the body through the urethra.
- Catheterization** – Insertion of a thin tube by way of the urethra into the bladder to allow urine to drain.
- External Sphincter** – A circular band of muscle that encircles the urethra. This muscle acts as a valve to start and stop the flow of urine.
- Incontinence** – Uncontrolled leaking of urine.
- Meatus** – The opening or passage to the male urethra.
- Pelvic MRI** – A noninvasive procedure performed to obtain detailed images of the structure of the pelvic region.
- Penis** – Male sexual organ which is also used during urination.
- Perineum** – The area between the scrotum and the anus.
- Prostate Gland** – A male organ that surrounds the urethra at the base of the bladder and secretes a fluid that is a major part of semen.
- Prostatic Urethra** – The part of the male urethra that spans the length of the prostate.
- Scrotum** – The pouch of skin that contains the testes.
- Stent** – A tube used to open an obstructed pathway within the body.
- Supra Pubic Catheterization** – A thin tube inserted through an incision in the lower abdomen to the bladder which allows urine to drain.
- Urethra** – The tube that extends from the bladder to the exterior of the body that urine passes through.
- Urinary Retention** – The inability to urinate.
- Urinate** – To pass or discharge urine.

## What Is The Spanner™ And What Is It Used For?

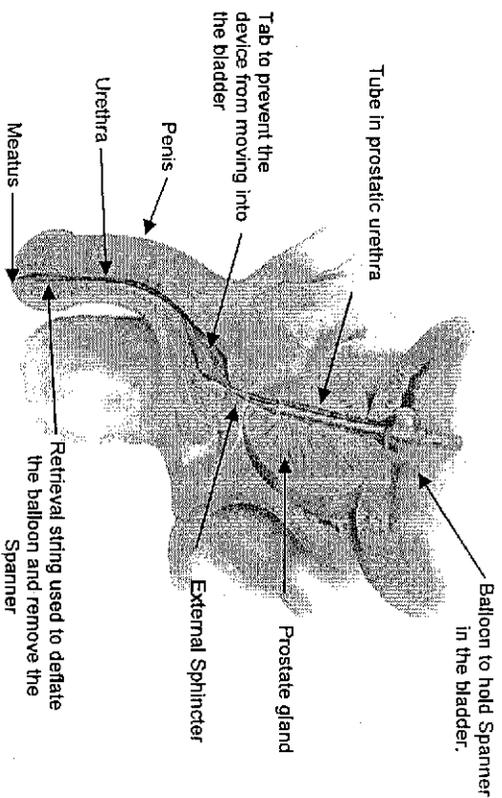
When you urinate your urine passes from your bladder through your urethra and out of your penis. You are able to start urinating because your brain tells your bladder to squeeze, while at the same time telling a valve, called the external sphincter to open. The bladder pushes the urine out of your body through your urethra, which is a tube that extends from your bladder to the tip of the penis. Often the reason that men cannot easily urinate is because their prostate gland, which surrounds the urethra, enlarges and blocks the flow of urine. (See figures below)



Common treatments for an enlarged prostate use heat to reduce it size. During the healing period, your prostate may swell and further block your urethra. You will need a catheter for the first few days after your treatment for your enlarged prostate. The Spanner is used after this catheter is removed. The Spanner is a medical device called a stent. The Spanner stent allows some men to urinate more comfortably as they recover from treatment for their enlarged prostate.

It works this way: the Spanner has a small tube that is placed in a man's urethra which keeps the prostate from blocking (or pressing on) the urethra.

The picture below shows a Spanner inside the body.



The Spanner has a tube with a small balloon near the tip which stays inside the bladder. This balloon is used to keep the Spanner in place. The tube allows urine to flow from the bladder through the portion of the urethra that the enlarged prostate gland is blocking. It holds the urethra open even though the prostate is pressing on it. The tube *does not* go through the sphincter because if it did you would not be able to stop your urine from draining from your bladder. This is called incontinence or the accidental loss of urine. There are soft strings that do go through the sphincter, but they will not affect urination or cause accidental loss of urine.

A soft tab connected to the strings is located at the other end of the stent. This tab keeps the stent from moving into the bladder.

A retrieval string is tied to the Spanner, and is used to drain the balloon when it is time to remove the Spanner.

**With the Spanner in place, when you want to go to the bathroom your body will function as it normally should. It will start and stop urination as normal. Your urine will flow through the Spanner's tube and out of your body.**

Alternative therapies for the temporary management of urine flow, after the catheter is removed, include:

- No catheterization
- Re-catheterization
- Clean Intermittent Catheterization (CIC)
- Supra Pubic Catheterization (SP Tube)
- Medication



### How does The Spanner go in?

- The Spanner is inserted into your penis using an insertion device (introducer). Before inserting the stent, your doctor may put a numbing gel into the urethra through the tip of your penis to help make you comfortable.
- The Spanner is advanced until the tip is inside the bladder. (Fig. 1)
- The balloon is then inflated with sterile water. (Fig. 2)
- The insertion device is then removed (Fig. 3), leaving the stent correctly positioned in the prostatic urethra.

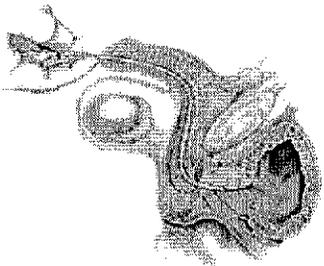


Fig 1

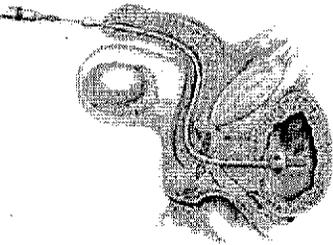


Fig 2

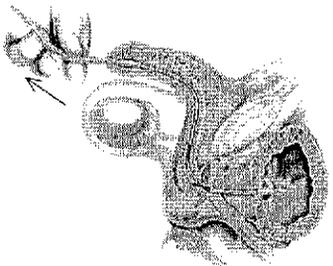


Fig 3

Your doctor may trim the retrieval string so that it is visible and extending beyond the tip of the penis. It is important not to pull on the string. Pulling the string will allow the Spanner to move out of the urethra.

**Caution:** Pulling the black string may cause the device to move out of place resulting in the inability to urinate. If this happens contact your doctor promptly or go to an emergency room.

### What is it like to wear the Spanner?

Most men tolerate the stent very well, but some men have found it to be uncomfortable.

Compared to how you felt before the treatment for your enlarged prostate and having the Spanner inserted, it is possible that you will experience one or more of the following while wearing the Spanner:

- Feel like your bladder is emptying more completely.
- Be able to urinate without starting and stopping repeatedly.
- Have an improved stream.
- Be able to start urination easier.

And, you may:

- Have slight discomfort or burning sensation at the tip of penis during urination.
- Feel some amount of discomfort or pain in your perineum (the area under and behind your scrotum).
- Find it difficult to postpone urination and may have to go to the bathroom more frequently in the first few days of stent wear.

- Experience mild or moderate pain or discomfort during an erection.

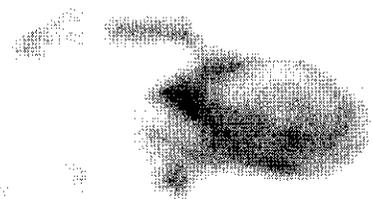
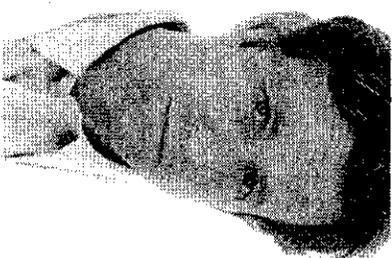
The risks of wearing the stent are detailed in the section below titled "What Risks Are Associated with Use of the Spanner and What Should I Do If They Occur?"

### How do I know the Spanner is working properly?

You can tell the stent is working because you feel like you are adequately emptying your bladder and are reasonably comfortable.

**Caution:** If you are frequently urinating only small amounts, your urination pattern has recently worsened, or you feel pressure in your bladder, the Spanner may not be helping with your urinary problems. You should contact your doctor immediately.

If you feel the Spanner needs to be removed for any reason, consult your doctor.



## Can I have sex with the Spanner in place?

Wearing the Spanner does not preclude sexual activity. Of those men who engaged in sexual activity with the Spanner in place some reported mild or moderate pain or discomfort lasting less than 1 hour. The Spanner may interfere with erectile function and you may feel mild to moderate pain during an erection.



## How Does the Spanner Come Out?

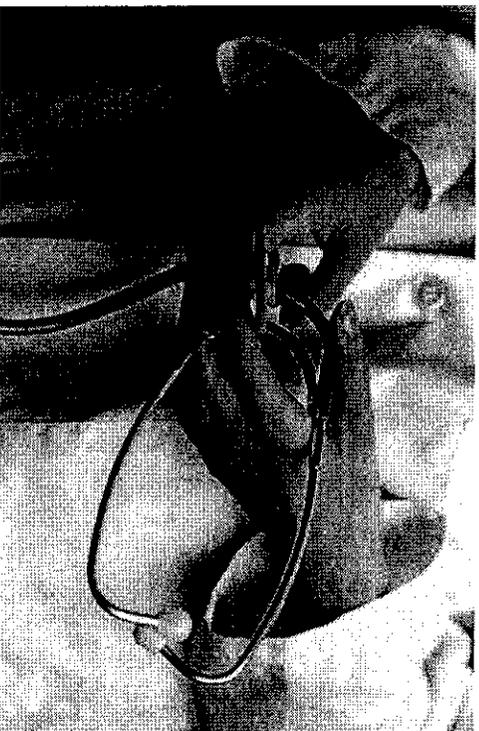
**Caution:** The Spanner must be removed by or under the supervision of a doctor. Removal of the Spanner by others may result in urinary retention or injury.

The doctor pulls the stent out using the retrieval string. Do not be concerned if you do not see the string. It is common for it to move into the urethra. Your doctor will still be able to take the stent out.

After locating the string, your doctor will gently pull on it. The string is connected to a plug that keeps the water in the balloon. When the plug is pulled, the water will drain out of the balloon. Once the balloon is empty, your doctor gently pulls the stent out.

## Is Insertion or Removal of the Spanner Painful?

You may feel brief and temporary discomfort during insertion or removal of the Spanner. The doctor may use a numbing jelly in your urethra to make you more comfortable. Most Spanner patients experience mild or no pain upon insertion or removal of the device.



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## What Risks are Associated with the Use of the Spanner and What Should I do if they Occur?

The following guidelines will help you decide what to do for problems that may occur with use of the Spanner.

**Important Note:** If you go to an emergency room or consult a doctor other than the doctor who inserted the Spanner, take your emergency removal card with you. If you do not have your emergency removal card available, bring this booklet. It will provide useful information to the doctor or other staff who are caring for you.

**Caution:** The Spanner has not been evaluated for use with Magnetic Resonance Imaging (MRI). If a MRI is needed, the Spanner should be removed.

**Caution:** The Spanner patient contact surfaces are silicone rubber. If you have a known allergy or sensitivity to silicone please notify your doctor.

## What do I do if I experience any of the following?

- Bleeding or blood in the urine.  
Insertion or removal of the Spanner may cause a small amount of bleeding or blood in the urine. This is most likely to occur in the 24-48 hours after the device is inserted or removed. A small to moderate amount of blood coming from your penis, or noticing blood-tinged (pink or brown tint) urine in the 24-48 hours after the Spanner is inserted or removed is expected to occur in some men.

### What to do:

Drinking plenty of water will help flush out any blood. If you see a lot of blood coming from your penis, or in your urine at any time, contact your doctor promptly or go to an emergency room for evaluation.

- Pain or discomfort.  
You may experience pain in the area under and behind your scrotum, penis, or bladder while wearing the Spanner. A burning sensation at the tip of the penis during urination may also occur. These symptoms are most likely to occur in the period immediately following insertion.

What to do.

If these symptoms occur, they should be mild to moderate in severity. This type of discomfort or pain should generally subside within a few days. If mild to moderate pain continues longer, consult your doctor. Severe pain associated with wearing a Spanner is not expected. If severe pain occurs, contact your doctor promptly or go to an emergency room.

- Urgency or frequency of urination.

You may experience urgency or frequency when the Spanner is in place due to irritation of the bladder or urethra by the Spanner.

What to do.

If these symptoms are intolerable or persist beyond a few days after the Spanner is inserted, consult your doctor.

- Persistent frequency or urgency of urination, burning with urination, foul smelling urine, or fever.

These are all potential symptoms of a urinary tract infection.

What to do.

If one or all of these symptoms occur consult your doctor promptly.

If a urinary tract infection is present, it can be treated with antibiotics.

**Caution: If left untreated, a urinary tract infection can lead to more serious problems.**

- Inability to urinate, urinating only small amounts, or a feeling of full bladder after urinating.

These could be signs that the Spanner device is not functioning properly and is preventing you from getting urine out of your bladder.

What to do.

If any of these symptoms occur, or if for any other reason you suspect the Spanner is not working properly and is preventing you from urinating, **contact your doctor immediately or go to an emergency room.** This condition can generally be remedied by simply removing the Spanner.

**Caution: If this condition is present, and not corrected, it could lead to more serious problems.**

- Device moves or comes out.

While unlikely, it is possible that the Spanner device may move from its proper position and out of the urethra.

What to do.

If you suspect this has occurred, *do not* try to remove the Spanner yourself even if a portion of the device is visible at the tip of your penis. Promptly consult your doctor or go to an emergency room.

In the event that the device does come all of the way out, place it into a closeable plastic bag.

Thoroughly wash your hands and all surfaces the device came into contact with and contact your doctor.

- Urinary Incontinence (involuntary loss of urine or leaking urine).  
Urinary incontinence may occur with use of the Spanner and may be an indication that the Spanner is not properly positioned in your urethra.

What to do.

If you experience urinary incontinence while wearing the Spanner, inform your doctor.

**If you experience any other problem that you believe is associated with use of the Spanner, contact your doctor right away.**



### Useful Contact Information

For **non-emergency** inquiries relating to patient care or problems with the Spanner, please contact:

Name:

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Phone Number:

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Address:

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For **emergency** inquiries relating to patient care or problems with the Spanner, please contact:

Name:

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Phone Number:

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Address:

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