

The Spanner™
Prostatic Stent

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- **Patient Information Booklet**



This booklet is for men and their families regarding the use of

The Spanner™ Temporary Prostatic Stent.

It contains important information about the Spanner device. Please review this booklet and discuss your questions with your doctor.

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.

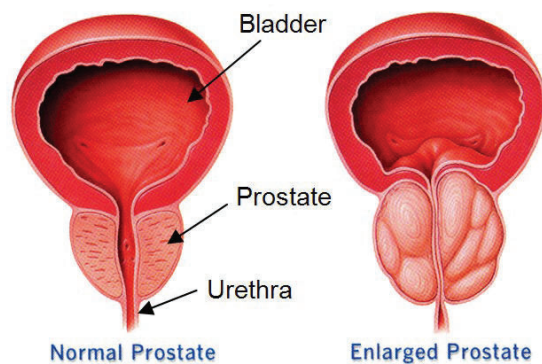
Urinary Retention – The inability to urinate.

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

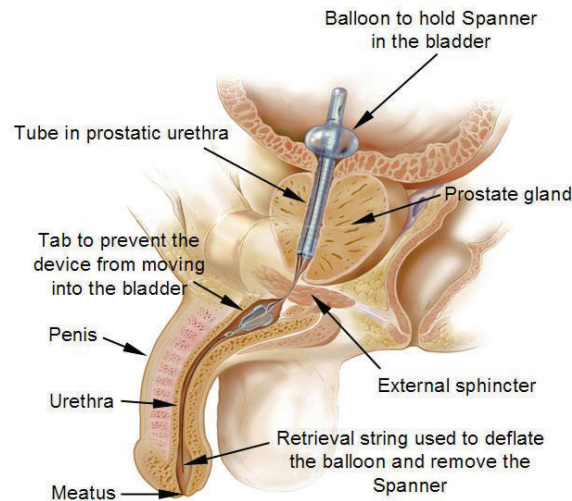
urethra and out of your penis. You are able to start urinating because your brain tells your bladder to squeeze, while at the same time telling a valve, called the external sphincter to open. The bladder pushes the urine out of your body through your urethra, which is a tube that extends from your bladder 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)



The Spanner is a medical device called a stent. The Spanner stent allows some men with an enlarged prostate to urinate more effectively. The Spanner stent can be placed in the prostatic urethra for up to 30 days, and the stent can be replaced after 30 days. Before each stent replacement, your physician will check to make sure that your bladder is adequately emptying.

How does it work?

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



When should The Spanner not be used? (Contraindications)

You should not be prescribed a Spanner if you have an active urinary tract infection. The Spanner stent should also not be prescribed if you have a history of certain urologic conditions or urologic surgery that could affect the function of the stent. Finally, the Spanner stent will not be placed by your physician if the length of your prostate is not compatible with the length of the stent.

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)



Fig 1



Fig 2



Fig 3

- The insertion device is then removed (Fig. 3), leaving the stent correctly positioned in the prostatic urethra.

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 your 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 on pages 11-14 in the section titled, "What risks are associated with the use of The Spanner and what should I do if they occur?"

How do I know The Spanner is working properly?

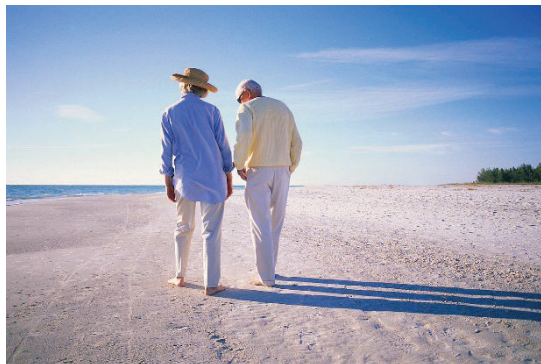
You can tell the stent is working because you feel like you are adequately emptying your bladder and are reasonably comfortable.

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.



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.



Notes:

Useful Contact Information

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

Name:

Phone Number:

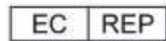
Address:

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

Name:

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Address:



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