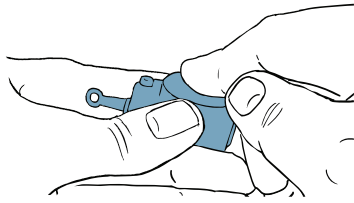


IMPORTANT INFORMATION

Before Procedure

Test your dexterity in pressing the blue rubber mold of the pump button to see if you can or have any difficulty with using the device.



Test your dexterity by also placing the blue rubber mold of the pump button in your pants pocket and pressing it to see if you can or have any difficulty with using the device.

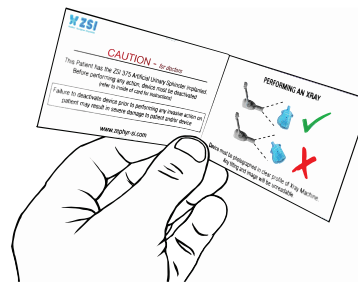


After Procedure

1. You will continue to be incontinent and use pads for 2 months until the device is activated by your doctor.
2. It is normal that your scrotum may be swollen and/or sensitive with discomfort for a month or two.
 - If the discomfort persists, contact your doctor
 - If there is severe pain, inflammation and/or leakage from your incisions, it is important to contact your doctor promptly. You might have an infection.
3. The device is implanted well under the skin and none of its components will ever be visible.
4. The device is activated two months after the operation, at which time you will visit your doctor and he will firmly press the activation button located just above the pump button.
 - The goal is to be dryer than before the implantation.
 - Some patients have either no need for the use of pads or a substantial reduction in the number used per day.
 - After the activation most patients have a social continence.
5. It is perfectly normal to experience minor leakages when straining your body through minor or major physical activity such as playing sports, working out, certain postures and coughing. This is normal. The cuff has a constant pressure on the urethra that cannot adapt to sudden muscular strains, as in the case of coughing.

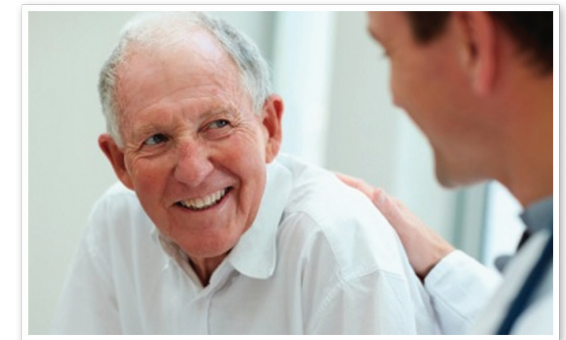
6. It is strongly recommended that you do not ride bicycles, motorbikes and/or horses (only if a special saddle or seat is provided). Such activities create an external pressure on the cuff and urethra and can cause temporary and/or lasting injury to both.
7. Take care when sitting. Any surface is ok as long as the sitting position does not add excessive pressure on the cuff, as pressure on it can aspirate it and cause a small amount of leakage when you stand up. When the pressure is removed, the cuff will inflate again as per normal. Just remember that no sitting position should be putting pressure around the area of your perineum.
8. Neither the device nor the cuff will interfere with your sexual libido and/or your erection.
9. The device has been designed to be discrete and undetectable to MRI and Airport scanners.
10. The device has a minimum life of 30 000 cycles, or on average, 7 to 10 years. Of course it can work for much longer.
11. If you notice that there is an increase of leakage, it might mean that the device has lost a bit of pressure or simply that, due to the individual differences of every man's urethra, it might require a little more pressure. This is perfectly normal. You should contact your doctor and he will inject saline solution into the device until the pressure is right.
12. If, for whatever reason, you need to introduce a catheter into your urethra, the cuff must be emptied and the device deactivated. If not, there is a risk of injuring the urethra and/or cuff. The injury is almost certain if the device is not deactivated.

Ask to be given the Zephyr 'Pocket Card' which you should carry around with you to present to doctors if the case arises that some procedure should be performed on your pelvic area.



YOUR SOLUTION FOR INCONTINENCE

ZSI 375 ARTIFICIAL URINARY SPHINCTER



PATIENT MANUAL

More information at: www.zephyr-si.com

Local Distributor

ZEPHYR Surgical Implants

Route des Jeunes 4 - 1227 Acacias (Geneva) Switzerland
Tél : + 41 22 327 1026 / Fax : + 41 22 327 1027
Email : contact@zephyr-si.com / www.zephyr-si.com



1 - ANATOMY

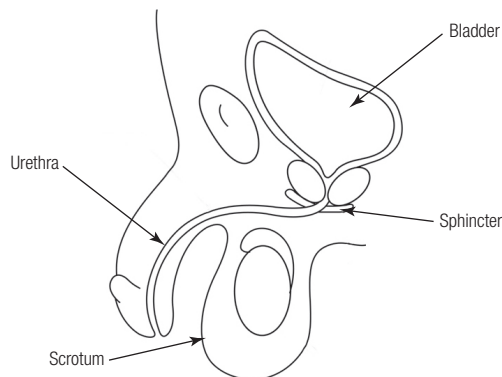
The **Bladder** is the organ containing urine.

The **Intrinsic Sphincter** is a muscle around the urethra.

By compressing the urethra the sphincter holds the urine in the bladder and prevents incontinence. When the sphincter releases the urethra, the bladder can empty itself.

The **Urethra** is the canal that flushes the urine out of the body from the bladder.

The **Scrotum** is the pouch containing the testis.

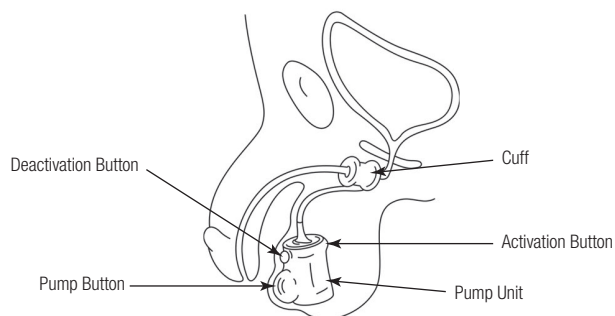


2 - THE ARTIFICIAL SPHINCTER ZSI 375

The artificial urinary sphincter ZSI 375 is a medical device implanted in the body. It works like an intrinsic sphincter.

The **Cuff** is placed around the urethra.

The **Pump Unit** is placed in the scrotum.

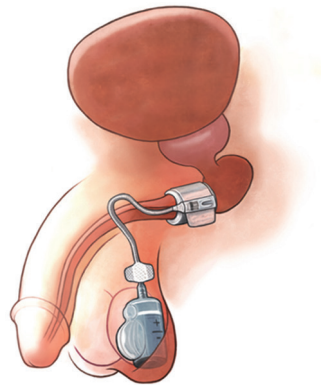


Not to be touched by patients

The **Deactivation Button** is a small button found on the upper part of the Pump Unit just above the Pump Button.

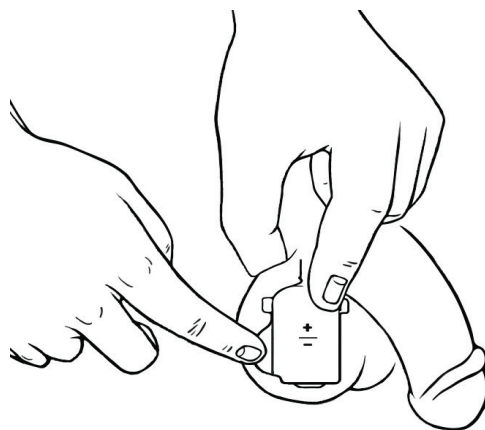
The **Activation Button** is a small button placed on the upper part of the Pump Unit at the opposite end of the Deactivation and Pump Button.

3 - FUNCTIONING OF THE ARTIFICIAL URINARY SPHINCTER ZSI 375



The patient is continent as the cuff compresses the urethra.

3.1 - HOW TO URINATE?



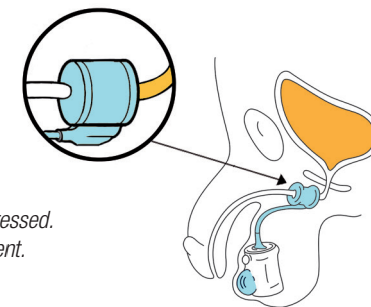
With one hand hold the Pump Unit in the scrotum with the Pump Button forward.

With the index finger of the other hand press and release the Pump Button once.

The Cuff deflates, decompressing the urethra.

The Cuff needs 2-3 minutes to automatically re-inflate and compress the urethra once again.

3.2 - THE HYDRAULIC CIRCUIT

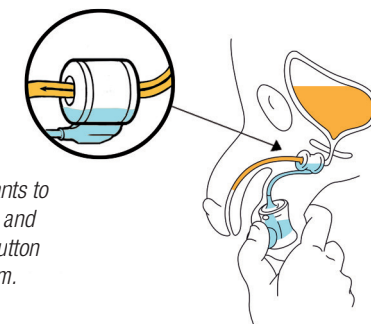


Step 1

The cuff is inflated.

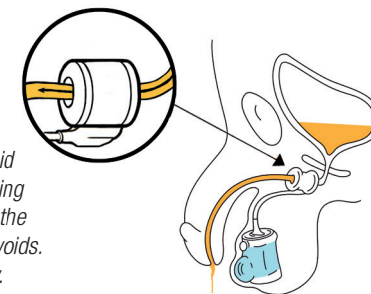
The urethra is compressed.

The patient is continent.



Step 2

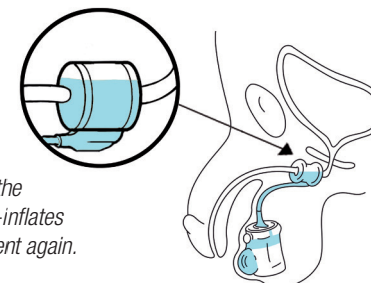
When the patient wants to urinate, he squeezes and releases the pump button located in the scrotum.



Step 3

The unit pulls the fluid out of the cuff releasing the pressure around the urethra. The patient voids.

The bladder is empty.



Step 4

Within 2-3 minutes the cuff automatically re-inflates

The patient is continent again.