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LIVING WITH

INFORMATION FOR PATIENTS

Adjustable Artificial Sphincter

Restoring continence

VICTO is an adjustable artificial urinary sphincter, offered as a reliable solution to treat male stress urinary incontinence. It consists of three preconnected components: a control pump, a pressure regulating balloon and a urethral cuff. All three components form a coherent hydraulic system that simulates the natural function of your sphincter.

This leaflet aims to provide you, as a patient, with all the information and insight for the implant you will receive or have already received. To enhance your experience in living with VICTO, you will find following information:

- Information about the components of VICTO and how they work
- How to use the implant correctly
- Informations about outpatients interventions to adjust the system pressure
- Important information and answers on FAQs

() What is male Stress Urinary Incontinence?

Urinary incontinence is a complex condition that affects millions of men. This pathology is often associated with a diminished quality of life, threatening lifestyle both in social or work activities and affecting selfesteem.

Stress urinary incontinence is one type of involuntary urine loss, associate to a deficiency in the urinary sphincter to maintain the urine in the bladder while exerting some pressure on it, such us coughing, sneezing, laughing, or exercising. This could be caused, for example, by a previous prostate treatment like prostatectomy.

VICTO components

THE CUFF

The circumferential urethral cuff is placed around the urethra, exerting pressure to keep it close and guarantee continence.



How VICTO works

Once VICTO is activated 4-6 weeks after the implantation, it maintains the urine passage closed. Only when you wish to micturate, you manipulate the control pump in the scrotum manually, the urethra is opened and micturition is possible.



THE PRESSURE REGULATING **BALLOON**

The pressure regulating balloon, also known as "reservoir", is placed in the abdomen and regulates the pressure of the cuff, depending on the amount of fluid within the system.

Continent status Cuff is closed and urine passage is blocked Micturition status Cuff is opened to empty the bladder

THE PUMP

The control pump is placed inside the scrotum, and by squeezing it using your fingers, you can open the urethral cuff so you can urinate and empty your bladder.





How to use VICTO

1 Open the urethral cuff for micturition

To empty your bladder properly, palpate the pump located in your scrotum and grab it from the flat faces with your thumb and forefinger. Then squeeze the pump firmly. After releasing the pump, the cuff will open to enable micturition. A single stroke of the pump is enough to decompress your urethra.

The hydraulic mechanism of the implant closes the cuff automatically and reaches the maximum set pressure after about 2 minutes. Enough time to completely empty the urine stored in your bladder.



Rapid closure function

If a faster cuff closure is required, this can be achieved, using the "Rapid Closure Function" of the implant. Therefore, locate the two palpable nubs or protrusions on the sides of the pump neck and press just above them for about 5-10 seconds to fully close the urethra. This mechanism should not be used after every time you empty your bladder, just in circumstances where you have no time to wait for the automatic closure.



3 Activation, Adjustment & Deactivation of VICTO

The activation of your VICTO is performed as an outpatient intervention in a minimally invasive procedure, normally around 4 to 6 weeks after the implantation surgery, depending on the individual healing process.

To increase the system pressure your doctor will inject 4 ml of fluid into the implant via the port on the pump.

If urinary continence is not achieved by the activation of the device, future adjustments can be performed by injection of additional amount of fluid to increase the pressure the cuff induces to the urethra.

• To deactivate VICTO correctly, the doctor has to remove 7 ml of the fluid from your device within an outpatient intervention. For the reactivation, the doctor must reinject into the implant, the same amount of fluid which was removed previously. VICTO must only be deactivated by medical staff.



Please inform your doctor, that more information can be found on our webpage

www.promedon-upf.com/victo

Must knows

Device Identification Card

This card contains important information about your implanted device. It must be completed by the surgeon and given to you after the surgery, before leaving the hospital. We recommend you take care of this card and carry it with you, as it is useful in case of an emergency.

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www.victosphincter.com/talktovourpatier

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Your personal implant card contains important information that you might need for many years. Please hand it over to the doctor whenever a medical intervention is necessary.



Medical interventions

Physicians and healthcare professionals should be informed about your VICTO implant. This is especially important for interventions where a catheter or another instrument must be inserted into the urethra. If a surgery is performed via the urethra without prior deactivation of VICTO, serious injury to the urethra or damage to the implant is possible. Such damage may require the surgical removal of the implant.

When should a doctor be contacted?

As with any other medical device, there is always the possibility of complications, infections, or side effects. If any of the following occurs, please contact your doctor immediately:

- Unusual or prolonaed pain

Frequently asked questions FAQ

Below are questions that are frequently asked about "Living with VICTO". If you have any further questions or special medical concerns, please contact your doctor.

Can I ride a bicycle?

Check with your doctor before riding a bicycle after your surgery.

Will VICTO affect sexual activity?

VICTO should not have a negative effect on sexual activity. Nevertheless, it would be good for you to inform your partner about your implant, so they understand the device, e.g., where the control pump is located and how it works.

What about activities that put extra pressure on my body?

We recommend you coordinate all sports and other activities with your doctor.

Is magnetic resonance imaging (MRI) possible?

VICTO is MR conditional, it means imaging is safe for scans under static magnetic field of 1.5T and 3T. This information can be found in your Device Identification Card.

• Do I have to pay particular attention to anything during airport security checks?

No, the small amount of metal in the implant will not trigger an alarm at the airport.





Notes