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**PROACT™**  
Adjustable Continence Therapy for Men 

## Patient Guide to Minimally Invasive Treatment for Male Stress Urinary Incontinence



*You are receiving this brochure because your doctor has diagnosed your condition as stress incontinence and thinks ProACT™ may be appropriate for you. This brochure provides you with more information about stress incontinence and the ProACT procedure. After reading this information, please discuss any questions or concerns you have with your doctor.*

### **Stress Incontinence is Widespread and Treatable**

Stress incontinence is the unintentional loss of urine that occurs when pressure is put on the bladder by coughing, sneezing, laughing, lifting something heavy or other daily activities. For men, incontinence is most often seen after prostate surgery, if there was damage to the nerves or the external bladder outlet valve (sphincter). Men have two sphincters, so this is not always a problem. However, when a man's prostate gland is operated on, part or all of the internal sphincter is removed, so if the external sphincter is damaged, incontinence may result. Incontinence may be experienced by 5% - 30% of men after prostatectomy. Stress incontinence lasting beyond one year affects less than 5% of them<sup>1</sup>.

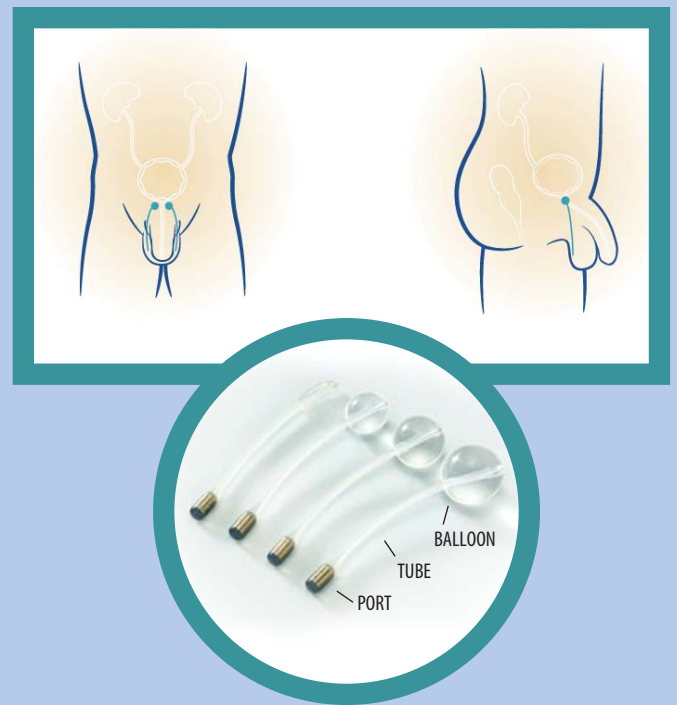
### **ProACT Can be an Effective Solution to a Frustrating Problem**

Treatments for stress incontinence include exercises to strengthen the pelvic floor muscles, medication and surgery. If at least 6 months have passed after prostate surgery, and exercises and medications have not been satisfactory, ProACT Adjustable Continence Therapy can be considered.

ProACT is a small device implanted on each side of the urethra, close to the bladder neck, near the area where the prostate used to be (see illustration). At one end of the device is a small balloon filled with fluid. Each balloon is connected to a tube with a titanium port at the end of it. The balloons press on the urethra to restrict the accidental flow of urine.

However, when you need to urinate, the normal bladder contractions will push urine out, allowing you to pass urine in the normal way. The amount of pressure the balloons exert can be adjusted by your physician by adding or removing fluid through the ports. The complete system is implanted within your body and once implanted, no one but you will know it is there. There is no need for you to manipulate any part of the device.

ProACT has been used in more than 2,000 men in Europe, Canada and Australia. It is currently being studied in the United States in a Food and Drug Administration clinical study. A previous study reported that after implant surgery, 67% of male patients are dry and 92% of male patients were significantly improved (average follow-up of 13 months)<sup>2</sup>.





### **ProACT Can be an Effective Alternative to More Invasive Surgeries**

Male sling surgery can be a complicated procedure. Once a male sling has been implanted, it cannot be adjusted without additional surgery, and it cannot be easily removed if the therapy fails. In addition, male sling surgery has a 28% failure rate by the third year after surgery, according to a recent study<sup>3</sup>.

Artificial Urinary Sphincter surgery also is a complex surgery. If there are problems with the artificial sphincter, it cannot be adjusted or removed without another surgery. This therapy also requires a certain level of manual dexterity that not every patient will have.

The ProACT procedure is relatively simple to perform and can be adjusted easily or removed if the therapy is not satisfactory.

### **The ProACT Procedure**

The ProACT procedure is minimally invasive and lasts approximately 30 minutes. The procedure will be performed in the hospital, and you will be given a local or general anesthetic. Using X-ray imaging, two balloon devices will be implanted—one on each side of the bladder neck. Your surgeon will examine the position of the balloons to ensure correct placement. The balloons will be inflated with fluid to secure their position. The titanium ports will lie beneath the surface of the skin. A urethral (Foley) catheter will be inserted after surgery, but it will be removed prior to discharge, when you are able to pass urine on your own.

### **Post-Operative Care**

- Your doctor may prescribe medication such as antibiotics for you to take.
- You will need to keep the area where the stitches are located as clean and dry as possible, while the stitches are healing. If you wear pads, they will need to be changed regularly.

- Avoid bicycling, exercise and heavy lifting for the first 3-4 weeks after the procedure.
- Refrain from sex for the first 3-4 weeks after the procedure.
- Once your stitches are healed and the swelling is gone, you may resume normal activities, including exercise, bicycling and sex.

## Post-Surgical Adjustments

In the first few weeks after the surgery, you may be completely dry. However, during the next 2-4 weeks you may leak again. This is completely normal and is to be expected. Your doctor can adjust the fluid levels in the balloons to reduce the leaking. When an adjustment is needed, the tissue near the port will be numbed with a local anesthetic and then a small needle will pass through the skin to the port to add or remove fluid from the balloons. During the adjustment phase, you should see improvement over your pre-surgery state, but it may take 3-4 adjustments over the course of 2-3 months to achieve the desired effectiveness.

## Possible Side Effects

The potential risks with this procedure are similar to those for other surgical treatments for stress urinary incontinence. These include, but are not limited to, the following:

- Tissue perforation (tear)
- Device migration
- Post-operative urgency, frequency or retention
- Tissue erosion/infection at the implant site
- Device failure
- Non-response to treatment

If an infection occurs at the implant site, it can be treated with antibiotics. If the device migrates, minor changes can be made to improve the positioning. If a more serious side effect occurs (e.g. perforation, migration), ProACT can be completely removed. Please ask your doctor any questions you may have about the procedure.

## Conditions That May Affect ProACT

ProACT is not appropriate for all patients with stress incontinence. If you have any of the following conditions, you should talk with your doctor about whether or not ProACT is suitable for you:

- Bleeding disorders
- Bladder cancer
- Bladder stones
- Recent or upcoming radiotherapy (patients who have had radiation therapy may have lower success rates with ProACT)
- Severe constipation (i.e. if you regularly are unable to go to the bathroom for several days in a row)

## When ProACT Should be Postponed

- Urinary tract infection
- Any condition requiring regular use of a rigid urinary tract scope

## References

- <sup>1</sup>Peyromaure, M., Ravery, V., and Boccon-Gibod, L. *The management of stress urinary incontinence after radical prostatectomy.* *BJU International*: 90, 155-161 (2002).
- <sup>2</sup>Hübner WA, Schlarp OM. *Treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy.* *BJU International*: 96, 587-594 (2005).
- <sup>3</sup>Singla et. al. *Feasibility of Artificial Urinary Sphincter after Male Sling Failure, presented at ICS 2005, Montreal.*