# **ProACT™ Adjustable Continence Therapy for Men**

# **About the ProACT™ Therapy**

The ProACT™ Adjustable Continence Therapy for Men is a minimally invasive surgical treatment option for men who have stress incontinence as a result of a radical prostatectomy or transurethral resection of the prostate. The procedure to place the ProACT balloons is approximately 30 minutes in duration. Once the ProACT device is implanted, the device can be tailored to the patient's individual needs during following office visits. After implant, urination will occur normally without manual manipulation at anytime.

#### **ProACT Procedural Animation**





#### **ProACT Balloons**

Home

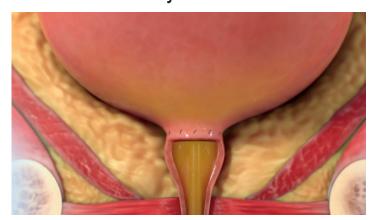
FAQs

Each ProACT implant consists of a medical-grade silicone balloon and titanium filling port connected by tubing. The balloons are implanted on either side of the bladder neck and the port is placed under the skin of the scrotum to be easily accessible by a urologist for adjustments. The ports are approximately the size of a No. 2 pencil eraser and placed in a discreet location unnoticeable by others.

## Over 10,000 patients have been implanted with ProACT.

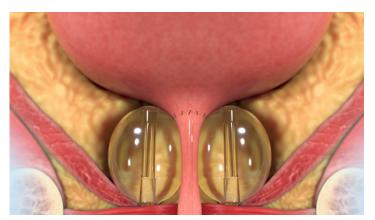
## How does the ProACT™ Therapy work?

#### **After Prostatectomy**



The prostate provides support to the bladder by restricting the flow of urine through two valves. After prostate surgery, the valves that prevent the flow of urine during times of strain may have been damaged or removed.

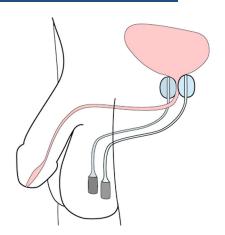
## **After ProACT™ Placement**



The ProACT balloons are implanted where the prostate was removed to help replace the support it provided. The devices support the bladder by providing pressure that keeps the bladder outlet closed during moments of physical activity.

# What makes this therapy adjustable?

Adjustments to the balloons may begin four to six weeks after balloon placement. At an adjustment visit in the office, the urologist will place a small needle through the skin into the port to adjust the size of the balloons. Patients typically experience optimal results after 3-4 adjustment visits.



# Advantages of the ProACT™ Therapy

- Easily adjustable to meet continence needs.
- Allows for natural urination without the need to activate or deactivate a pump.
- Placed in a minimally invasive procedure involving only two small incisions.
- Long-term treatment option for incontinence.
- Covered by Medicare.

Potential risks associated with this procedure can include: injury to the bladder or urethra during implantation procedure, movement of the devices from their intended location, damage to the tissue of the bladder or the urethra caused by the device, or infection.

# **Additional Resources**

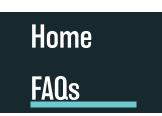
ProACT Patient Brochure Uromedica, Inc. 🗹

## **Contact Form**

[Site's Contact Form]

# How do I know the ProACT Therapy is right for me?

The ProACT Therapy may be right for you if you have failed conservative therapy for your stress incontinence, are more than 12 months after prostate surgery, and are seeking a minimally invasive surgical treatment option. The ProACT Therapy may be appropriate if you are seeking a long-term, customizable solution for your incontinence needs.



# How many men have been implanted with ProACT?

This therapy had been commercially available outside the USA since 2002 and has been available within the USA since 2015. To date, over 10,000 men have been implanted with ProACT.

#### What should I expect after ProACT implantation?

After your ProACT surgery, your doctor will adjust your device in a brief office visit to better suit your needs. These adjustments are intended to improve your continence. You may see an improvement right away, although it could take multiple adjustments to reach maximum effectiveness.

## Will my partner notice my ProACT implant?

The ProACT balloons are placed entirely in your body. The ports are placed underneath the skin of your scrotum to allow access for adjustments. The ports are approximately the size of a No. 2 pencil eraser; only you will know that they are there.

## What clinical data is there for the ProACT therapy?

The ProACT Therapy received FDA approval in 2015 with proven efficacy and safety data. To date, there are over 40 publications about the effectiveness, safety, and long-term durability of the ProACT therapy.

#### What if ProACT does not work for me?

If you see no improvement with ProACT, the devices can be removed at any time. The balloons are deflated and removed in an office setting in a minimally invasive procedure. After the ProACT is removed, you can be re-implanted with ProACT or pursue other therapy options.

## Is the ProACT Therapy covered by my health plan?

If your urologist determines that the ProACT therapy is an appropriate treatment option for you, the physician's office staff can work with you and your health plan to determine your coverage. The ProACT therapy is covered by Medicare.

# FAQ Section with Optional Comparison Questions

#### How do I know the ProACT Therapy is right for me?

The ProACT Therapy may be right for you if you have failed conservative therapy for your stress incontinence 12 months after prostate surgery and are seeking a minimally invasive surgical treatment option. The ProACT Therapy may be appropriate if you are seeking a long-term, customizable solution for your incontinence needs.

# Home FAQs

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#### What if I am only mildly incontinent, is the ProACT therapy a reasonable option?

The ProACT Therapy is indicated for all severities of incontinence. The adjustable nature of this device allows for your urologist to tailor the treatment to your degree of incontinence. If over time, your incontinence severity changes, your urologist will be able to increase the volume of the balloon to provide more support for your bladder and urethra.

## Can I be implanted if my sling or Artificial Urinary Sphincter (AUS) failed?

If a previous sling or AUS failed, you and your urologist can still consider the ProACT Therapy. The location the ProACT balloons are placed is different than where your sling or AUS was placed. The ProACT balloons are placed closer to your bladder neck, in the place where your prostate was removed. The sling is placed underneath your urethra and the three components of AUS are in different areas than the intended ProACT locations. Published results of ProACT implantation following other incontinence surgical treatments are available.

## What is the difference between a male sling and ProACT?

A male sling is a long strip of woven polypropylene mesh that is used to compress or reposition your urethra. Mesh devices require an invasive surgery for placement and may require extensive surgery to remove.

The ProACT device is made of medical grade silicone, not polypropylene mesh. Each device consists of a small balloon which is attached by tubing to a filling port placed under the skin of the scrotum. ProACT does not require additional surgery to adjust. The size of the balloons can be increased or decreased to better meet your needs. The adjustments can be performed in under 10 minutes in your doctor's office.

## What is the difference between an artificial urinary sphincter (AUS) and ProACT?

The artificial urinary sphincter is a device consisting of three main components: a cuff to constrict the urethra, a pressure regulation balloon, and a pump with tubing connecting these components. The implant procedure for an AUS is more complex and invasive than the insertion of ProACT. The AUS cannot be adjusted post-operatively to your needs and removal of this device requires an extensive surgery. The AUS requires you to manipulate a pump located in your scrotum every time you need to urinate.

ProACT can be tailored to your incontinence severity. The physician injects fluid into the port of the balloon in a brief office adjustment. With ProACT, you will be able to urinate naturally. No patient manipulation is required.