



PROACT™

ProACT™ Adjustable Continence Therapy for Men



URO *Get more from life* MEDICA

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Glossary

(Alphabetical)

Benign Prostatic Hyperplasia (BPH): The prostate gland commonly becomes enlarged as a man ages. This condition is called BPH. As the prostate enlarges, it may squeeze the urethra and decrease the flow of the urinary stream.

Bladder Compliance: the ability of the bladder to stretch in response to an increase in volume of urine.

Contrast Solution: a substance (often containing iodine) that appears dark on X-rays. It is introduced into the body to increase the contrast between an internal body part and its surrounding tissue on the X-ray image.

Detrusor (Bladder) Instability or Overactivity: With an unstable or overactive bladder, you feel strong, sudden urges to urinate.

MR-conditional: A patient with an MR-conditional device may be safely scanned in an MR (or MRI) system only under certain, specific conditions that are defined in the device labeling.

Radiotherapy: a treatment involving the use of high-energy radiation. It is commonly used to treat cancer.

Serious Adverse Event: an adverse event that results in death, is life threatening, causes inpatient hospitalization or prolongation of existing hospitalization, causes a congenital anomaly/birth defect, results in permanent impairment of a body function or permanent

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damage to body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Stress Urinary Incontinence: the involuntary loss of urine during actions—such as coughing, sneezing, and lifting—that put abdominal pressure on the bladder.

Urge Incontinence: the involuntary loss of urine following an overwhelming urge to urinate that cannot be halted.

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What is the purpose of the ProACT device?

The purpose of the ProACT Adjustable Continence Therapy for Men is to treat adult men who have developed **stress urinary incontinence** after prostate surgery.

Your prostate surgery may have caused a weakening or loss of control of your ability to retain urine.

Most men with incontinence are conservatively treated using absorbent products such as pads, adult diapers, and bed protection. Right after surgery, a condom catheter, indwelling catheter, or penile clamps may be used.

You may be a candidate for treatment with the ProACT device if:

1. Your stress urinary incontinence has persisted for at least 12 months after your prostate surgery, and
2. You have not adequately responded to conservative treatments.

Your doctor feels you might benefit from a surgical procedure to implant two devices called the ProACT Adjustable Continence Therapy for Men.

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Description of the ProACT device

The ProACT devices are comprised of two inflatable silicone balloons. These balloons are placed inside your body at the opening of your bladder (called the “bladder neck”) to help improve your stress continence.

Each balloon has tubing connected to a small port. These ports are placed under the skin in your scrotum.

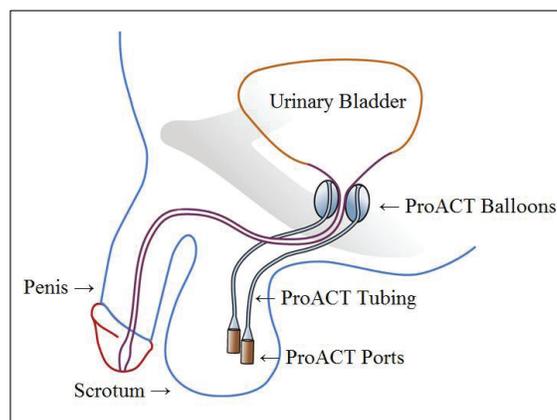


Figure 1 - ProACT Device Placement

After your ProACT surgery, your doctor will be able to use these ports to adjust your devices in the clinic. These adjustments are intended to improve your continence. You may see an improvement right away, although it could take six months or longer to reach maximum effectiveness. It is also possible that you will not see any improvement.

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When should the ProACT device not be used (contraindications)?

The ProACT may not be suitable for you if you have any one of the following:

- an active systemic or urinary tract infections,
- incontinence due to **detrusor (bladder) instability or over activity**,
- primarily urge incontinence,
- reduced **bladder compliance**,
- residual urine volume greater than 100 cc after urinating,
- presently receiving **radiotherapy**,
- plan to receive **radiotherapy** within the next six months,
- have received **radiotherapy** within the last six months,
- suspected bladder cancer,
- unsuccessfully treated bladder stones,
- a bleeding disorder.

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Procedure Information*Implantation Procedure*

If you decide to be implanted with the ProACT devices, the procedure will be performed in a same-day surgery center or operating theater. You will be under anesthesia for the procedure. The procedure will take about 30 minutes.

Two small incisions will be made in the skin between your scrotum and your rectum. The incision locations are indicated by the dotted lines in the figure below.



Figure 2 - ProACT Incision Locations

Using X-ray imaging, your surgeon will place two devices next to your bladder. The balloons will be inflated with a small amount of fluid to secure their position. One or two stitches per side will be required to complete your surgery. A catheter will be inserted in your penis to ensure you are able to drain your bladder of urine. The catheter will be removed before you leave the hospital.

You may be fully or partially continent immediately after your operation because of tissue swelling. However, after the swelling has diminished (usually over about 4 weeks),

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your incontinence may return. This is quite normal. Your doctor will be able to adjust your device in the clinic. The adjustment procedure is described below.

Follow-up Adjustment Procedure

After your ProACT surgery, your doctor will be able to use the ports in your scrotum to adjust your devices in the clinic, which should improve your continence.



Figure 3 - Adjustment of a ProACT Balloon

Your doctor will spray your scrotum with a numbing solution. Your doctor will then insert a needle through the skin of your scrotum into a small port on each of the ProACT balloons to inject some fluid. You may experience a dull ache during the adjustment.

After each adjustment, you may have immediate improvement in your continence, although it could take six months or longer to reach maximum effectiveness. It is also possible that you will not experience any improvement.

ProACT is a continuously adjustable device. Adjustments may be performed over multiple years to try to meet your changing needs.

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Alternative Procedures

ProACT is not the only therapy available to treat your stress urinary incontinence. If you wish to pursue an alternative therapy, please contact your doctor. Your doctor can tell you about alternative treatments, such as a mesh sling or artificial urinary sphincter (AUS).

Mesh sling: Strips of synthetic mesh are used to create a pelvic sling under your urethra. The sling is supported by your pelvic bones. The sling may help keep your urethra closed by creating pressure on its underside.

AUS: An AUS is made of up a cuff, a pump, and a fluid-filled balloon, all connected with tubing. The fluid-filled cuff (like a blood pressure cuff) is implanted around your urethra to prevent you from leaking urine. To urinate, you activate the pump implanted under the skin of your scrotum. This opens the cuff around your urethra. Once you are done urinating, the cuff will then re-close around your urethra to prevent you from leaking urine.

You should understand that if you choose to have the ProACT devices implanted and if they were to fail, the devices would be removed on an outpatient basis and an alternative procedure could then be performed to treat your stress incontinence.

It is not known if failed ProACT therapy will affect the chance of success with a subsequent alternative therapy such as a mesh sling or artificial urinary sphincter.

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Warnings and Precautions*Warnings:*

- The balloons in this device are filled with an iodine-based fluid. If you are or may be allergic to iodine, then your physician can substitute iodine with saline. Failure to do this may result in a severe allergic reaction.

Precautions:

- You will be given pre-operative antibiotics before you have your surgery to reduce the possibility of post-operative infections.
- Infections are usually easily treated with antibiotics. An infection of the device will generally require a removal of the device (explantation).
- You will be exposed to x-ray radiation during the implantation procedure.
- The long-term safety and effectiveness of ProACT therapy are unknown.

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Benefits and Risks*Benefits*

The benefits of the ProACT device for the treatment of stress urinary incontinence can vary from person to person. You may see a reduction in your total urine leakage each day, the number of pads you use per day, and the number of leaks you have per day. If you achieve one or more of these possible benefits from ProACT therapy, you may feel this improves your overall quality of life.

The ProACT surgery is minimally invasive. The surgery can be done without an overnight stay in the hospital. The ProACT balloons' volume can be adjusted from time to time in an attempt to meet your changing needs.

Please refer to the Clinical Study section on page 13 for information on the effectiveness results observed in the ProACT clinical study.

Risks

ProACT implant surgery carries risks from the surgical procedure, including the risk of infection and the risks associated with anesthesia. In addition, there is a risk that your implant surgery may be unsuccessful. For example, your ProACT devices may fail to function as intended or your incontinence may not improve or may get worse. If this happens, you may need additional surgery to remove or replace your ProACT device. Discuss these possibilities with your doctor.

The main risks associated with the ProACT device and surgical procedure are the following:

1. *Worsening of Incontinence*

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Worsening incontinence is an increase in the severity, frequency, or volume of urine leakage. In the ProACT clinical study, worsening of incontinence was reported based on any of the following: a patient's perception that their incontinence increased, their doctor's visual evaluation, or a measured increase in leakage in a 24-hour pad weight test. In the ProACT clinical study, worsening of incontinence related or possibly related to the ProACT device or procedure was reported by 29% of patients.

2. *Pain or discomfort*

Pain is physical suffering or discomfort. Approximately 28% of the patients in the ProACT clinical study reported pain or discomfort related, or possibly related, to the ProACT device or procedure.

3. *Perforation*

Perforation is when a surgical tool is accidentally passed into the bladder or urethra during the ProACT implant surgery. If a perforation of your urethra occurs, a ProACT balloon cannot be implanted until your urethra heals. Perforation occurred in 15% of patients during the ProACT clinical study.

4. *Migration*

Migration is the movement of the ProACT balloons away from the urethra where they were originally placed. If migration occurs, it may cause the return of your incontinence. Migration may need to be resolved with surgery to remove your ProACT devices.

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Approximately 19% of patients in the clinical study had one or both of their ProACT balloons migrate and approximately 11% of the patients in the study had their ProACT device(s) removed because of migration.

5. *Erosion*

Erosion is when the tissue next to any part of your ProACT device is "worn away" by contact with the device. It is possible for the ProACT device to erode into your bladder, urethra, rectum, or scrotal tissue. If an erosion occurs, symptoms may include pain, redness of skin, tenderness, fever, or exposure of the device through your skin. If an erosion of your ProACT device occurs, please consult your doctor immediately. Approximately 9% of patients in the ProACT clinical study reported an erosion. Approximately 6% of patients experienced an erosion that resulted in an explant of one or more ProACT devices.

6. *Infection*

Infection can happen after the surgical procedure to place the ProACT devices inside your body. Your doctor will try to lower your risk of infection by giving you antibiotics before and after your operation and by flushing (washing out) the surgical site with antibiotics during surgery. The following conditions increase the risk of getting an infection: diabetes, a spinal cord injury, open sores, an existing skin infection near the incision site, or an existing urinary tract infection.

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Approximately 7% of patients in the ProACT clinical study developed one or more urinary tract infections related or possibly related to the device or procedure.

7. *Urination Problems*

These four types of urination problems were reported as related to the device or procedure in the ProACT clinical study:

- 15% reported Retention: the inability to completely empty the bladder,
- 9% reported Urgency: the compelling urge to urinate,
- 8% reported Frequency: the need to urinate more often than usual, even after having recently urinated,
- 8% reported Difficulty Urinating: a general term, which may include any of the symptoms above.

8. *Allergic Reaction*

Allergic reactions may occur if you have sensitivity to the antibiotics that were used during the ProACT procedure or if you have an allergy to the contrast (iodine) solution contained in your ProACT balloons.

In the ProACT clinical study, 1.3% of patients experienced an allergic reaction related, or possibly related, to the device or procedure.

9. *Other*

Please see the Adverse Effects section on page 14 for a more complete summary of the risks and adverse events observed in the ProACT clinical study.

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Clinical Study

A clinical study was performed to determine the safety and effectiveness of ProACT. In this study, 123 mild, moderate, and severely incontinent men were implanted with ProACT.

Effectiveness Results:

The study showed that 46% of the men were considered successful because ProACT reduced their 24-hour urine leakage by 50% or more. Men were considered failures if they had worsening or lesser improvement of their incontinence, had their devices removed (even if the devices were replaced), missed too many clinic visits, died (for reasons unrelated to ProACT), or withdrew from the study before 18 months after their surgery.

On average, men in the study experienced reductions in the number of pads they used per day and their number of incontinent episodes per day. They also experienced an increase in their quality of life.

As stated above, success rate with a first implant of ProACT is 46%. Many patients elected to have a ProACT reimplant after a failure of their first device. The success rate among those reimplanted patients was 29% at the end of the study (18 months after their first implant).

Safety Results:

The study showed a 2.4% rate of serious adverse events and an 80% rate of non-serious adverse events related or possibly related to the ProACT device or the ProACT surgery. There were no study-related deaths. You can find a summary of the non-serious adverse events observed in the study in the next section.

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Adverse Effects

After 18 months of patient follow-up, the study showed a 2.4% rate of **serious adverse events** related or possibly related to the ProACT device or the ProACT surgery. One patient experienced each of the following three serious adverse events: urinary retention, low heart rate, and ulcerative colitis. There were no study-related deaths.

You can find a summary of the non-serious adverse events observed through 24 months in the ProACT clinical study in the table below. These events were reported as related or possibly related to the ProACT device or procedure.

Adverse Event	Percentage of Patients with the Adverse Event (%)
Total	79.7%
Pain or discomfort	26.8%
Worsening Incontinence	28.5%
Device Migration	18.7%
Inability to empty bladder	15.4%
Perforation	15.4%
Device Failure	14.6%
Device Leakage	12.2%
Difficulty urinating	8.1%
Erosion	8.9%
Urinary urgency	8.9%
Urinary frequency	8.1%
Urinary Tract Infection	6.5%
Reddening of the skin	4.9%
Device Clogged	2.4%
Blood in Urine	2.4%
Skin Hardening	2.4%
Abdominal pain	1.6%
Allergic Reaction to Antibiotic	1.6%
Bladder spasm	1.6%

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Inflammation of tissue	1.6%
Procedural failure	1.6%
Low heart rate from anesthesia	0.8%
Asymptomatic heart murmur	0.8%
Bruising of the scrotum	0.8%
Decreased stream	0.8%
Device Kinking	0.8%
Doesn't feel empty after urinating	0.8%
Drainage from site	0.8%
Bruising of skin	0.8%
Urine leakage while sleeping	0.8%
Fever 100 degrees	0.8%
Needed catheter more than 24 hours	0.8%
Increased incontinence due to urge	0.8%
Infection at surgical site	0.8%
Infection and hardening in scrotum	0.8%
Infection in scrotum	0.8%
Hernia	0.8%
Minor bleeding at incision site	0.8%
Not passing urine through catheter	0.8%
Numbness at incision site	0.8%
Numbness at the end of penis	0.8%
Other (no improvement in patient's incontinence)	0.8%
Fluid in the lungs	0.8%
Pus discharge from catheter	0.8%
Urine remained in bladder after urination	0.8%
Scrotal incision opened	0.8%
Minor stroke	0.8%
Swelling on right side, between scrotum and rectum	0.8%
Sores in colon	0.8%
Urine dribbling	0.8%

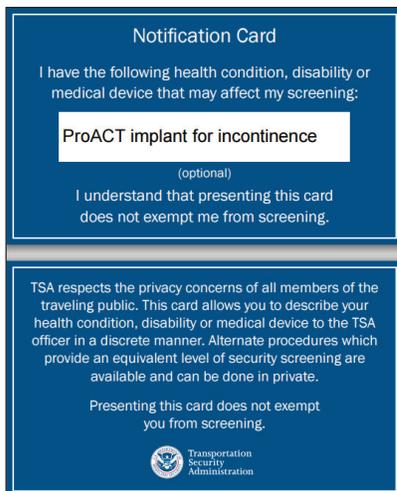
Table 1 – Non-Serious Adverse Events in the ProACT Study that were related or possibly related to the ProACT device or procedure.

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Travel

The ProACT device contains metal (titanium and platinum-iridium), which may be detected by security screening equipment. While traveling by airplane, you'll need to inform the U.S. Transportation Security Administration's (TSA) officer about the presence of the implants prior to TSA security screening.

You can use TSA's Notification Card to communicate discreetly with security officers. However, showing this card or other medical documentation will not exempt you from additional screening. You may print the notification card (example pictured below) from the TSA website (<http://www.tsa.gov/traveler-information/notification-card>) with a statement about your ProACT implant for your incontinence.



The image shows a blue TSA Notification Card. The top section contains the text: "Notification Card", "I have the following health condition, disability or medical device that may affect my screening:", a white box with "ProACT implant for incontinence" and "(optional)" below it, and "I understand that presenting this card does not exempt me from screening." The bottom section contains: "TSA respects the privacy concerns of all members of the traveling public. This card allows you to describe your health condition, disability or medical device to the TSA officer in a discrete manner. Alternate procedures which provide an equivalent level of security screening are available and can be done in private." and "Presenting this card does not exempt you from screening." The TSA logo is at the bottom.

Figure 4 - Example TSA Notification Card

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MRI Safety Information

Before having an MRI, you should let your doctor know that you have an implanted medical device that is classified as "**MR-conditional.**" You can be safely scanned in an MR system only under certain specific conditions, which are described below.

Be sure to share the following information with your doctor or MRI technician before having an MRI scan:



Non-clinical testing demonstrated that the ProACT system is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 10,000-Gauss/cm (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system

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- Under the scan conditions defined, the ProACT device is expected to produce a maximum temperature rise of 1.6°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

Artifact Information

In non-clinical testing, the image artifact caused by the ProACT device extends approximately 10-mm from the ProACT device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

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When to Call Your Doctor

If you have trouble urinating, your incontinence symptoms worsen, or if you have severe pain, please call your doctor immediately.

You may use the space on the following page to fill in the contact information you may need:

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	Name	Contact Information
<p>Doctor who performed your ProACT surgery:</p>		
<p>Your family doctor:</p>		
<p>Nurse hotline:</p>		
<p>Manufacturer of ProACT:</p>	<p>Uromedica, Inc.</p>	<p>1840 Berkshire Lane North Plymouth, Minnesota 55441 Telephone: (763) 694 - 9880 Fax: (763) 694 - 9945 info@uromedica-inc.com www.uromedica-inc.com</p>