ProACT
Adjustable Continence Therapy for Men
Uromedica, Inc.

Patient Information Leaflet - Australia

Please read all information carefully.

1. Device Name, Description, Materials, and Model Numbers

ProACT Adjustable Continence Therapy for Men is an implantable prosthetic that is intended to treat adult men who have developed stress urinary incontinence after prostate surgery. Silicone tubing connects an expandable silicone balloon with a titanium port that is used by your physician for post-operative adjustment. The balloon contains a radiopaque platinum-iridium alloy marker which allows the device to be viewed under x-ray.

Figure 1 - ProACT Implants

The ProACT devices are placed through two small incisions underneath your scrotum. A delivery tool is inserted through the incision and guided to the location your prostate was removed or resected. A ProACT device is delivered through the tool and inflated with a small amount of fluid. This process is repeated on the other side of your urethra. The adjustment ports are placed underneath the skin of your scrotum and the incisions are closed using 2-3 stitches for each incision.

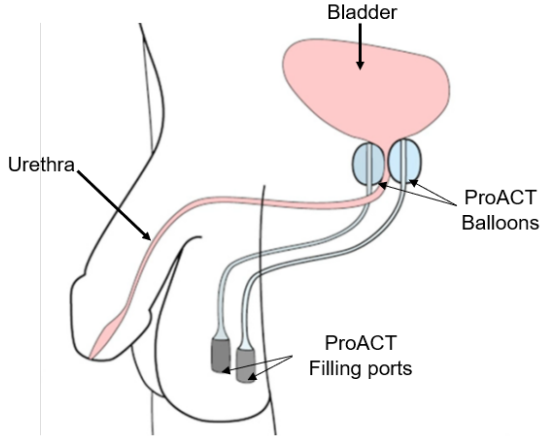

Figure 2 - Diagram Depicting Positioning of ProACT Implants

Table 1 – ProACT International Model Numbers

Model Number	Device Length	Description
800018-01	12 cm	ProACT Patient Kit: Two (2) prosthetic implants
800018-02	14 cm	ProACT Patient Kit: Two (2) prosthetic implants
800022-01	12 cm	ProACT Revision Kit: One (1) prosthetic implant
800022-02	14 cm	ProACT Revision Kit: One (1) prosthetic implant

2. Intended Use and Indication

Intended Use

The ProACT prosthetic implant device is intended, via initial and post-operative volume adjustments, to increase urethral coaptation at the bladder neck or at the apex of the prostate to eliminate unwanted urine loss.

Indication

The ProACT system is designed to provide a permanent implant for the correction of urinary incontinence in male patients post prostatectomy and who have either de novo (no prior surgery) or recurrent (failed prior surgery) stress urinary incontinence.

3. Intended Performance

ProACT is intended to improve your incontinence symptoms. Improvement is defined as a 50% reduction in incontinence symptoms from baseline. The devices are intended to have a lifetime of at least 10 years.

4. Potential Adverse Events

Potential adverse events from the ProACT system, the associated equipment and supplies, or the implant procedure include:

Allergic Response
Anesthetic risks
Device Calcification
Device Malfunction
Device Wear
Erosion of the device at the bladder, perineum, rectum, scrotum, or urethra
False Channel Creation
Intraoperative perforation (e.g. bladder, rectum, urethra)
Pain or Discomfort
Procedure/adjustment not able to be completed
Prosthetic Infection
Prosthetic Migration
Urinary Complications (e.g. Urinary Difficulty, Frequency, or Urgency, Worsening Incontinence*)
Urinary Retention
Urinary Tract Infection
Vascular Complications (e.g. Bleeding, Hematoma, Induration, Inflammation)
Wound Infection

* “Worsening Incontinence” includes subjective patient-perceived worsening.

5. MRI (Magnetic Resonance Imaging) Safety Information

MR Conditional

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

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 5,000-Gauss/cm (50-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the ProACT system is expected to produce a maximum temperature rise of 1.5˚C after 15-minutes of continuous scanning (i.e., per pulse sequence).

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

6. Post-Operative Care

The patient is usually discharged on the day of the surgery. Your physician will ensure that you can void spontaneously prior to discharge from the surgical facility. Most surgeons choose to send their patients home with a course of antibiotics. Adjustments of the ProACT therapy may begin six weeks after the ProACT implantation procedure. During an adjustment, your physician will adjust the volume of fluid in your ProACT balloons. Multiple adjustments may be required to achieve the desired level of continence. The devices can be adjusted to a maximum volume of 8mL each. In the meantime, you may need to continue using absorbent pads or condom catheters.

Avoid undue strenuous activity immediately post-operatively as directed by the physician. Failure to do so could lead to device migration.

Contact your physician if you experience redness, swelling, or drainage of the incision site, experience a return of incontinence symptoms, or are unable to urinate.

Review the MRI information above and understand the impact that ProACT might have on travel security screenings (titanium and radiopaque components).

7. Serious Incidents

Any serious incident that occurs in relation to the ProACT device should be reported to Uromedica (see back page of this leaflet for contact information) and to the Therapeutic Goods Administration (https://www.tga.gov.au/)

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Uromedica, Inc.
1840 Berkshire Lane North
Plymouth, MN 55441, USA
+1 (763) 694 9880
info@uromedica-inc.com

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