Introducing a post-operatively *adjustable* first-line treatment for male stress incontinence

UROMEDICA *Get more from life*

PROACT™

Adjustable Continence Therapy for Men

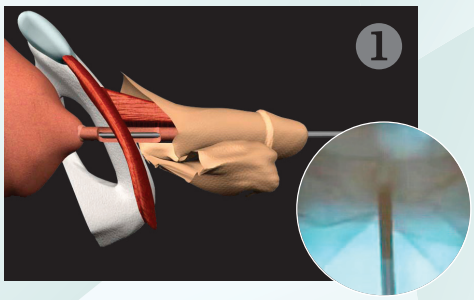
Not intended for distribution to a United States audience.

High Prevalence of Post-Prostectomy Stress Incontinence

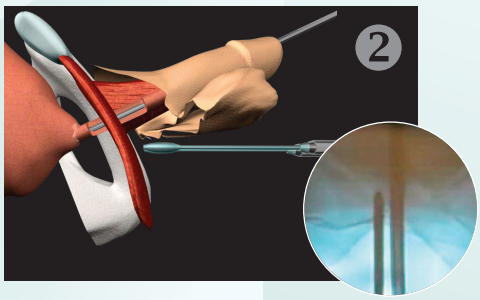
In 2002, an estimated 679,000 men were diagnosed with prostate cancer worldwide, many of whom would require a radical prostatectomy.[1] Recurrent stress urinary incontinence (SUI) is often a disturbing complication following this surgical removal of the prostate.

SUI affects thousands of men worldwide who find themselves in an embarrassing situation after sneezing, laughing, coughing or exercising. Prevalence estimates of post-prostatectomy stress incontinence vary from 6-69%, depending on the method used to measure incontinence and surgeon skill. Retrospective physician studies typically report lower incontinence rates than patient-reported outcomes.[3]

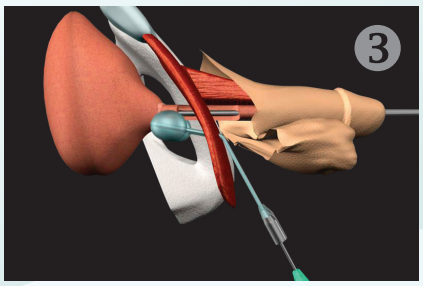
Overview of ProACT Procedure



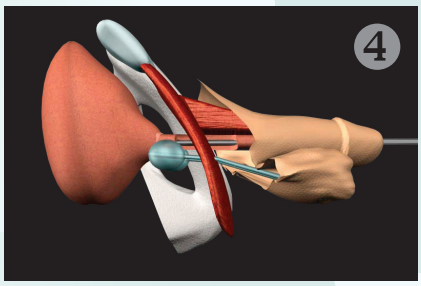
A rigid cystoscope is inserted under general or spinal anesthesia to visualize the bladder neck.



The pelvic floor is perforated next to the urethra in the cephalad and lateral direction.



Two post-operatively adjustable balloon implants are placed via perineal approach bilaterally in a periurethral position at the bladder neck or at the apex of the prostatic remnant.



Titanium ports (attached via discrete tubing to each balloon) are placed in the scrotum, allowing for subcutaneous, post-operative volume adjustment.

SIGNIFICANT COST TO SOCIETY

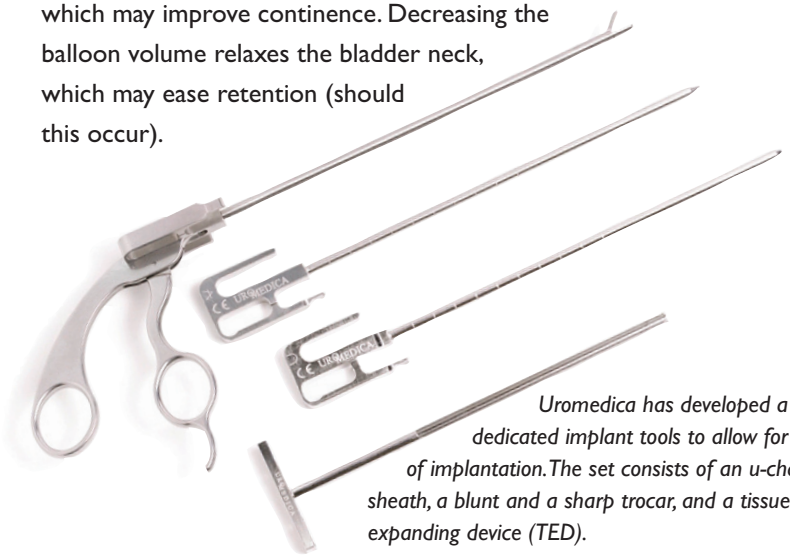
Compared to men without SUI, the presence of SUI increases the annual expenditures per male yearly from $3,204 to $7,702.[4]

Benefits of ProACT

- Effective for post-prostatectomy SUI
- Minimally invasive (short) implant procedure (typically takes 15-30 minutes)
- Non-surgical, post-operative adjustability
- Subcutaneous port offers easy access for adjustments in balloon volume
- Can be removed easily/reversible procedure
- No bone anchors or fixation sutures required (as with male slings)
- No patient handling/manipulation required (as with Artificial Urinary Sphincters)
- No systemic migration (as with injectables)
- Is not absorbed like particulate bulking agents
- Two lengths to meet your patient's individual needs (12 cm and 14 cm)
- Appropriate for both moderate and severe incontinence (male slings not suggested for severe incontinence)[6]

Nonsurgical Adjustability to Maximize Clinical Efficacy

ProACT offers a simple way to post-operatively adjust the therapy to best meet the individual patient's needs. Balloon volume may be easily increased or decreased through the subcutaneous port. Increasing the balloon volume increases the coaptation of the urethra and lifts the bladder neck, which may improve continence. Decreasing the balloon volume relaxes the bladder neck, which may ease retention (should this occur).



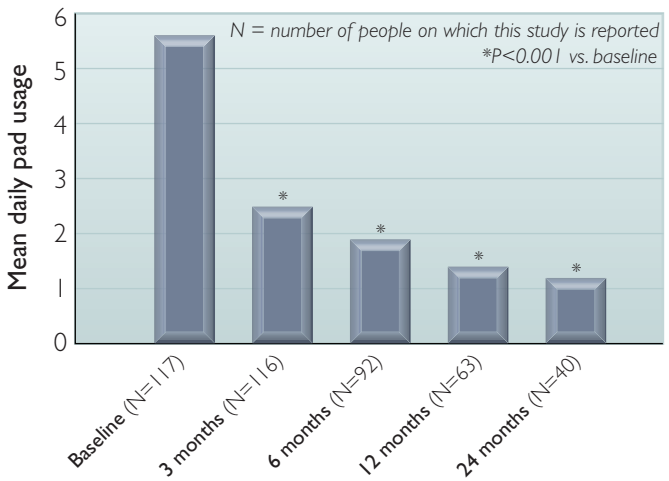
Uromedica has developed a set of dedicated implant tools to allow for ease of implantation. The set consists of an u-channel sheath, a blunt and a sharp trocar, and a tissue expanding device (TED).

Clinical Results

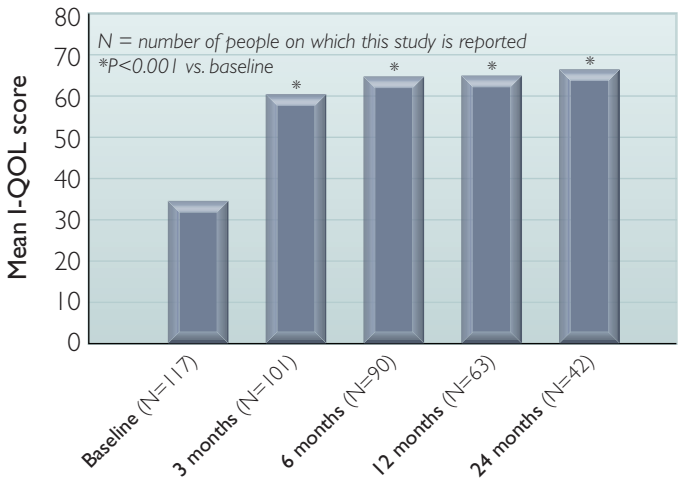
ProACT is an appropriate treatment recommendation for post-prostatectomy incontinent patients resulting from radical prostatectomy for prostate cancer or transurethral resection of the prostate (TURP) for benign prostatic hyperplasia (BPH). In a clinical study, ProACT Therapy produced "durable outcomes equivalent or better than other minimally invasive treatments for incontinence after prostatectomy." After a mean follow-up of 13 months, 67% of men were dry and 92% were significantly improved.[5]

"The promising results reported here suggest that this may be an appropriate, effective and durable first-line treatment to offer men with stress urinary incontinence after prostatectomy."[5]

Pad Usage: Decrease in Daily Pad Usage



I-QOL: Improved Quality of Life Within Three Months



Participants also reported using fewer security pads [chart 1] and a higher QOL (quality of life) [chart 2] after ProACT Device implant.[5]

Safety Information for Physicians

The potential risks with this procedure are similar to those for other surgical treatments for SUI. These include, but are not limited to, tissue perforation (tear); device migration; post-operative urgency, frequency or retention; tissue erosion/infection at the implant site; device failure; and non-response to treatment.

Review the ProACT Technical Manual for complete indications, contraindications, warnings, precautions and instructions for use.

Citations

[1] Parkin DM, Bray F, Ferlay J, Pisani P. Global Cancer Statistics, 2002. *CA Cancer J Clin.* Mar 2005:55;74–108.

[2] Stanfor JL, et al. Urinary and sexual function after radical prostatectomy for clinically localized prostate cancer. *JAMA.* Jan 19, 2000:283(3);354–360.

[3] Wei JT, et al. Prospective assessment of patient reported urinary continence after radical prostatectomy. *J Urol.* Sep 2000:164;744–748.

[4] Stothers L, et al. Urologic Diseases in America Project: Urinary Incontinence in Males—Demographics and Economic Burden. *J Urol.* Ap 2005:173;1302–08.

[5] Hübner WA, Schlarp OM. Treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy. *Br J Urol.* Sep 2005:96(4);587–94.

[6] Castle EP, et al. The male sling for post-prostectomy incontinence: mean follow-up of 18 months. *J Urol.* May 2005:173;1657–60.

PROACT™

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This device is not commercially available in the United States. Available in selected markets outside the United States only.

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