PROACT™

Adjustable Continence Therapy for Men

Post-operatively Adjustable Treatment for Male Stress Incontinence

RX Only

Not for distribution to a United States audience.

Get more from life

URO MEDICA

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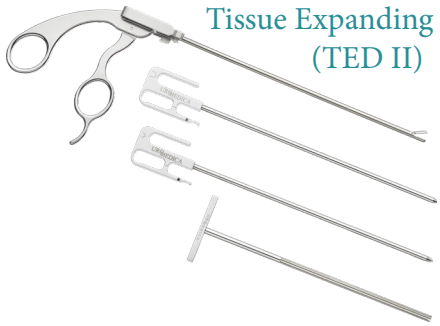
SUI and ProACT

Stress urinary incontinence (SUI) is a disturbing complication following radical prostatectomy for prostate cancer or transurethral resection of the prostate (TURP) for benign prostatic hyperplasia (BPH). SUI affects thousands of men worldwide, who find themselves in embarrassing situations after sneezing, laughing, coughing, or exercising. The ProACT system is intended for use in male patients with post-prostatectomy stress urinary incontinence (SUI) due to any level of intrinsic sphincter deficiency with or without previous surgical treatment of SUI.[1,2]

Adjustable Implants

Reusable, Sterilizable Surgical Tools



Tissue Expanding Device (TED II)

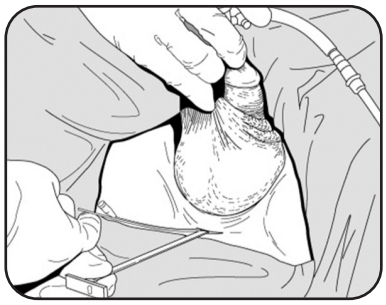
Sharp and Blunt Trocars

U-Channel Sheath

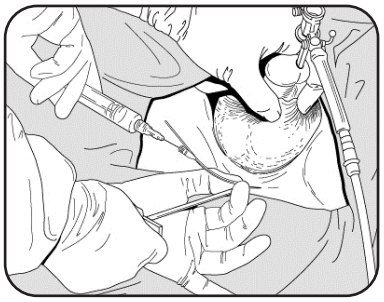
Simple Implantation Procedure

Minimally invasive. Takes approximately 30 minutes to implant. Easily reversible. No absorption. No bone anchors. No fixation sutures. No pump to manipulate.

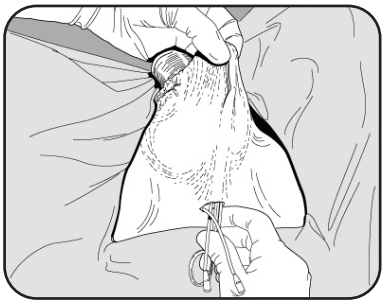
1. Balloon Implantation



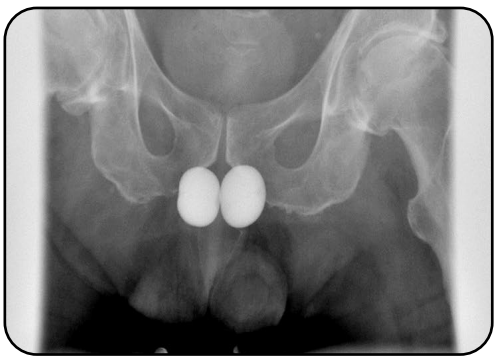
2. Initial Balloon Filling



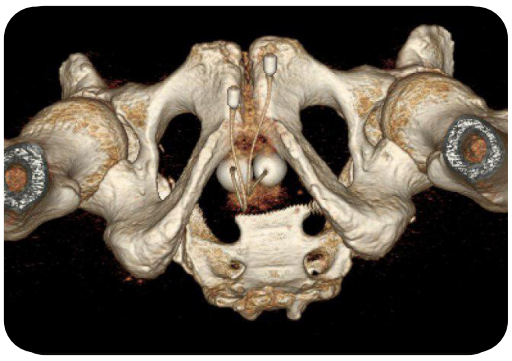
3. Ports Placed in Scrotum



Visualization using Fluoroscopy[3]



Placement of the Balloons

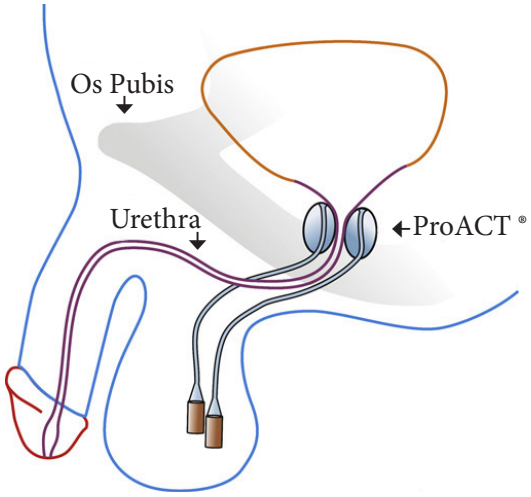


How ProACT Works

The ProACT device consists of two post-operatively adjustable balloon implants placed bilaterally in a periurethral position at the bladder neck or at the apex of the prostatic remnant.

ProACT Placement[4]

Self-sealing titanium ports attached via tubing to each balloon are placed subcutaneously in the scrotum and allow for post-operative volume adjustments.



Increasing the balloon volume increases coaptation of the urethra which improves continence.[5]

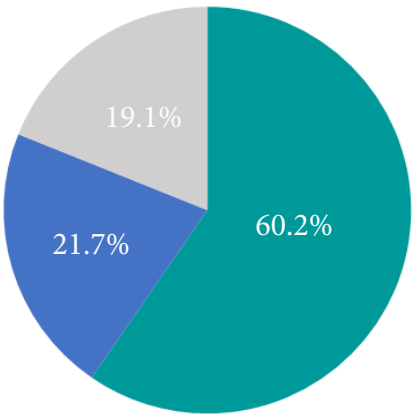
Adjustments can be made long-term to meet each individual patient's needs. A maximum of 8 mL can be placed in each balloon.

Device Design

Durable Balloon Shell | Flexible Bi-lumen Tubing | Self-sealing Port

Patient Outcomes

Pooled proportion estimate of dry and greater than 50% improved patients (19 studies and 1,264 patients)[6]



Adjustable continence therapy (ProACT) for the treatment of male stress urinary incontinence: a systematic review and meta-analysis[6]

Results (Average Study Length: 3.6 Years)	
"Dry" or >50% Improved Estimate	81.9%
Average IQOL Point Increase (relative percent increase)	31 (66%)

Meta-Analytic Estimates of Common Adverse Events	
Balloon Migration	6.5%
Perforation During Implant	5.3%
Device Failure, Leakage	4.1%
Balloon Erosion	3.8%
Infection	2.2%
Retention	1.5%
Overall Revision Rate for All Causes	22.2%

Safety Information for Physicians

The common risks with this procedure include: tissue perforation, device migration, post-operative urgency, frequency or retention, tissue erosion/infection at the implant site, device failure, and non-response to treatment. Most device-related adverse events are resolved with explant of the device in a short, office procedure.

Review the ProACT Instructions for Use for complete indications, contraindications, warnings, and precautions.

Sources

1. Kjaer L, et al. Adjustable Continence Balloons; Clinical results of a new minimally invasive treatment for male urinary incontinence. Scand J Urol Nephrol. 2012; 46(3): 196-200.
2. Roupret M, et al. Management of Stress Urinary Incontinence Following Prostate Surgery with Minimally Invasive Adjustable Continence Balloon Implants: Functional Results from a Single Center Prospective Study. J Urol. 2011; 186: 198-203.
3. Nestler S, Thomas C, Neisius A, Rubenwolf P, RoosF, Hampel C, Thüroff JW. Long term results of ProACT primary and repeat implantation for treatment of stress urinary incontinence in men. World J Urol. 2019 Jun;37(6): 1173-1179.
4. Bauer R, et el. Post-prostatectomy Incontinence: All About Diagnosis and Management. Eur Urol. 2009; 55(2): 322-333.
5. Utomo E, et al. Urodynamic effects of Volume-adjustable Balloons for Treatment of Post-prostatectomy Urinary Incontinence. Urol. 2013; 81(6): 1308-1314.
6. Larson T, Jhaveri H, Yeung LL. Adjustable continence therapy (ProACT) for the treatment of male stress urinary incontinence: A systematic review and metaanalysis. Neurourol Urodyn. 2019 Nov;38(8):2051-2059.

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