ProACT Adjustable Continence Therapy for Men

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Device Overview

Urinary incontinence is one of the more prevalent post-prostatectomy adverse effects and can significantly impact patients' quality of life. [1] Several conservative and surgical treatment options are available depending on severity and specific patient needs. There are a variety of devices, with different modes of action, utilized for surgical treatment including bulking agents, synthetic slings, artificial sphincters, and compressive balloon systems. [1] ProACT adjustable continence therapy (UroMedica) is a minimally invasive, passive therapy for post-prostatectomy stress urinary incontinence (SUI) consisting of two silicone balloons (implanted and adjusted in the outpatient setting) that apply pressure to the bladder neck helping prevent leakage. [2] Key device elements listed by the manufacturer include adjustability of the ballons to "meet individual and changing incontinence needs", the absence of need for patient manipulation, and the device being placed in a minimally invasive procedure in the outpatient setting. [2]

Actions for Consideration

PARTNER

ENGAGE SUBJECT MATTER EXPERTS

Key team members may include urologists specializing in prostatectomy and men's incontinence, OR leadership, a reimbursement specialist, and quality.

CONSIDER GUIDELINES FOR USE

With multiple options available for treatment, consider criteria for appropriate indications and populations for use.

UNDERSTAND CONCERNS

Leverage a physician champion as a peer liaison. Consider connecting with facilities who have already adopted to understand barriers encountered.

CONNECT

SEEK CLINICAL IMPACT

Include review of current treatment options utilized (with outcomes) and an assessment of available evidence for device's potential to impact outcomes and/or satisfaction.

CONDUCT ANALYSIS

Include potential clinical impact, cost, reimbursement considerations, possible impact to case mix, and physician interest and/or hesitancy.

DETERMINE POPULATION

Consider specific population needs, varying risk levels, contraindications, approved indications for use, and specialty guidelines.

COMMUNICATE

EDUCATE AND TRAIN

Ensure supplier engagement. Consider observation at available training centers and/or hands on at home facility with supplier rep support. Include education for staff on pre/post care and patient instructions.

PLAN AHEAD

Communicate initiative with ample notice to allow for dialogue and closed loop feedback. Consider trialing if consensus not attained in analysis.

FOLLOW-UP FOR FEEDBACK

Consider reconvening 90 days post implementation to discuss progress, barriers, and celebrate successes. Report metrics regularly.

Professional Society Statements & Clinical Practice Guidelines

American Urological Association (AUA), Society of Genitourinary Reconstructive Surgeons (GURS), and Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction (SUFU)

Incontinence After Prostate Treatment: AUA/GURS/SUFU Guideline (2019; Amended 2024) is intended to assist clinicians in the management of patients with incontinence after treatment for localized prostate cancer and includes the following in relation to adjustable balloon devices:

"Clinicians may offer adjustable balloon devices to non-radiated patients with mild to severe stress urinary incontinence after prostate treatment."

"In patients with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, clinicians should offer artificial urinary sphincter over male slings or adjustable balloons."

Found here. [3]

Clinical Evidence

There are multiple studies available regarding the use of ProAct for the treatment of male stress incontinence after prostatectomy. A sample is included below.

A 2019 systematic review and meta-analysis by Angulo et. al. aimed to compare the safety and efficacy of adjustable incontinence therapy (ProACT) and adjustable transobturator male systems (ATOMS).
The devices were evaluated for "dryness status", satisfaction, durability, complications, and improvement of symptoms.
Population, Intervention, Comparator, Outcomes, and Study Design (PICOS) criteria were utilized for search criteria which included retrospective and prospective single center and multi-center case series (n=41).
They concluded that both devices appear safe and effective. "However, taking into account the statistical summary of effect size ATOMS is a more efficacious alternative compared to ProACT with higher dryness, improvement and patient satisfaction rates, lower explant rate, and higher durability."
Limitations included the high heterogeneity in studies, variability in criteria to report complications, and the absence of controlled randomized studies. [4]

Clinical Evidence cont'd

A 2019 systematic review and meta-analysis by Larson et. al. aimed to evaluate the efficacy of adjustable balloon devices/adjustable incontinence therapy (for male SUI), as well as the "safety profile" and rates of adverse events. The literature search was conducted utilizing an online software tool, Covidence, with search terms "adjustable continence: balloons or device or therapy or implant," "ProACT," "Uromedica," "periurethral balloons," and "implantable continence balloons" (n=19 studies and 1264 patients). They concluded that adjustable balloon devices are effective and safe for the treatment of male SUI. In addition, "given the minimal invasiveness of the therapy, adjustable balloon devices may be a serious option as a first-line treatment in nonirradiated patients with stress urinary incontinence who are not ideal candidates for the artificial urinary sphincter" and that further evidence is needed to determine which patients would benefit the most from these devices.
Limitations included variability in type of absorbent pads, discrepancies in pad change habits, irregularity in follow up ranges, heterogeneity among patients included, varying surgical techniques, and differing methods for complication management. [5]

A 2019 multicenter retrospective study by Agro et. al. aimed to assess the safety and efficacy of ProAct. Patients with a minimum of 24 month follow up, after implantation of ProACT for postoperative SUI, were included (n= 240). Pad weights at 24 hours and records of intraoperative, as well as long-term, complications were utilized for evaluation. They concluded that ProAct was a safe and effective option for male SUI after prostate surgery, that the minimal invasiveness of the procedure "justifies its use" before more invasive procedures, and that most complications were grade I or II being "typically managed in an office setting." Limitations were not listed for this study. [6]

FDA Approval

ProACT received FDA PMA approval (#P130018) in 2015 as indicated for:

"...the treatment of adult men who have stress incontinence arising from intrinsic sphincter deficiency of at least twelve months duration following radical prostatectomy or transurethral resection of the prostate (TURP) and who have failed to respond adequately to conservative therapy." Found here. [7]

Clinical Insights: Healthtrust Physician Advisors

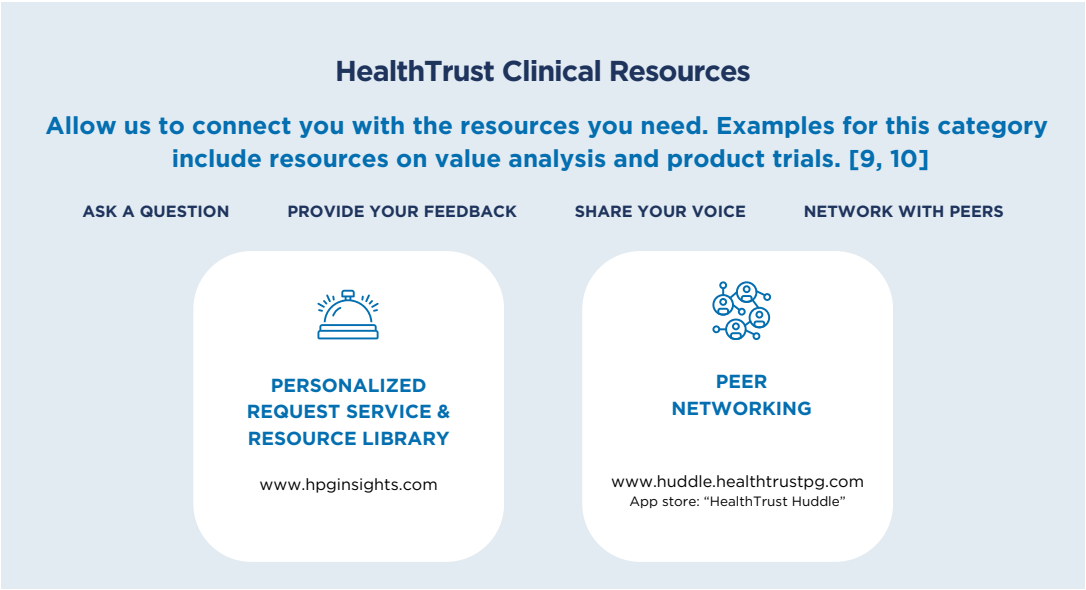
A panel of urologists, specializing in prostatectomy and men's incontinence, shared the following insights in regard to ProACT. [8]

Physician Insights

- **This is a relatively new device; therefore, many centers may not offer this yet.**
- **Education may be needed in order for physicians to include ProACT in all options presented to patients.**
- **ProACT Adjustable, AMS 800 Artificial Urinary Sphincter, and the Advance XP Male Sling System are each distinct devices, with differing indications for use, to be utilized in varying patient populations.**
- **Appears "relatively easy" to place.**
- **Potential complications may include balloon migration, infection, urethral injury, urinary retention, and patient discomfort.**

Summary

1. ProAct is a minimally invasive, passive therapy for post-prostatectomy SUI consisting of two silicone balloons (implanted and adjusted in the outpatient setting) that apply pressure to the bladder neck helping prevent leakage.
2. Available evidence supports ProACT as a safe and effective treatment for SUI after prostatectomy, with some studies suggesting further follow up may be needed to best determine benefit in specific populations.
3. Collaboration with subject matter experts, supplier engagement in training/education, connecting with peers currently utilizing, and development of criteria for use are important considerations for successful implementation.



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