

If Initial Stress Urinary Incontinence Interventions Have Failed: **ACT!**



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ACT[®]

Adjustable Continence Therapy

Not intended for distribution to a United States audience.

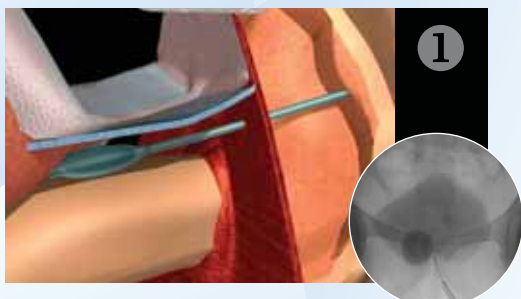
Treatment for Patients with Stress Urinary Incontinence Who Have Not Responded to Other Interventions



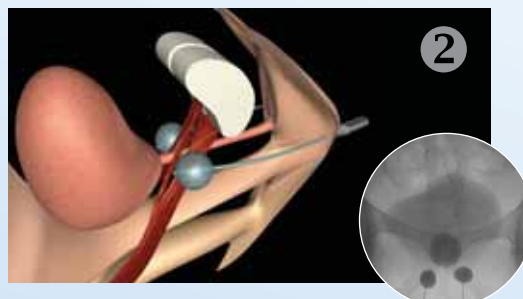
Adjustable Contenance Therapy (ACT®) is a minimally invasive urological implant designed to treat female patients who have stress urinary incontinence (SUI) arising from intrinsic sphincter deficiency (ISD) with or without hypermobility of the bladder neck or urethra. ACT can be an effective treatment for female patients who have recurrent stress incontinence after other therapies (e.g. bulking agent injections, sling placements or other procedures) have failed.

Though sub-urethral tapes have proven very effective in many patients, both with urethral hypermobility as well as ISD, there is a percentage of patients (10–15%) that will fail these procedures.¹ Complications include problems such as voiding difficulties and urinary retention, de-novo detrusor overactivity, irritative voiding symptoms or urethral injuries and erosion of the urethra or vaginal wall.² **ACT® may be a solution for this challenging group of patients.**

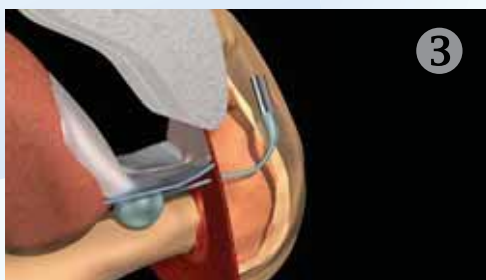
Overview of the ACT Procedure



1 A foley catheter (filled with contrast) is placed in the bladder. Two post-operatively adjustable balloon implants are placed via perineal approach in the vesico vaginal space at the bladder neck.



2 Balloon implants are initially inflated with 1–2 ml of an isotonic (sterile water and contrast) solution.



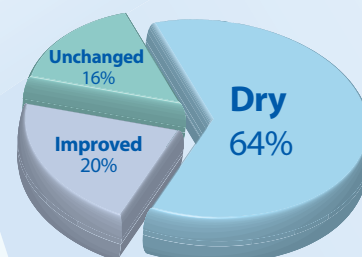
3 Titanium ports (attached via discrete tubing to each balloon) are placed in the labia majora.



4 After 4–6 weeks the adjustment process can be started. Balloon volume can be increased with 0.5–1 ml every 2 weeks until the desired level of continence is reached.

Published Clinical Results

ACT is an appropriate treatment recommendation for female patients who have SUI arising from ISD with or without hypermobility of the bladder neck who have not responded to other interventions. Results from two clinical studies (67 patients with a mean follow-up of 3 years and 25 patients with a mean follow-up of 1 year) found that 78–84% of patients were dry or significantly improved with ACT.^{3,4} Quality of life (QOL) scores also improved from 35.2 +/- 20.7 at baseline to 69.9 +/- 24.6 at 36 months.³



Clinical Outcomes⁴

Nonsurgical Adjustability to Maximize Clinical Efficacy



ACT 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).

Bulking has been shown to produce poor long-term efficacy with SUI patients⁵ and requires repeated procedures to achieve even modest solutions.⁶ In addition, a percentage of these patients will form periurethral masses within 12–18 months post-injection.⁷ Likewise, while sub-urethral slings have shown a high cure rate at a mean follow-up of three months,² therapeutic efficacy has also been shown to decrease within five years.^{1,8,9}



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

Benefits of ACT

- Effective for SUI with ISD component in female patients
- Minimally invasive (short) implant procedure (typically takes 20–40 minutes)
- Non-surgical, post-operative adjustability
- Subcutaneous port offers easy access for adjustments in balloon volume
- Can be removed/reversible procedure
- No patient handling/manipulation required (as with Artificial Urinary Sphincters)
- No systemic migration (as with injectables)
- Is not absorbed like particulate bulking agents
- Three lengths to meet your individual patient needs (7, 8 and 9 cm)

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 ACT Technical Manual for complete indications, contraindications, warnings, precautions and instructions for use.

Citations

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- ² Segal JL et al. The efficacy of the tension free vaginal tape in the treatment of five subtypes of stress urinary incontinence. *Urogynecol J.* 2006(17);120-124.
- ³ Kocjancic E, Carone R, Bodo G, et al. 36 Month Follow-up with Adjustable Continence Therapy (ACT) in Female Stress Incontinence Due to Intrinsic Sphincter Deficiency (ISD) [abstract]. Taken from: International Continence Society (Montreal). 2005;624.
- ⁴ Stecco A et al. Can MRI predict which patients are most likely to benefit from percutaneous positioning of volume-adjustable balloon devices? *Urologia Internationalis.* 2006(76);240-246.
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- ⁶ McGuire EJ. Urethral bulking agents. *Clin Pract Urol.* 2006;3(5);234-235.
- ⁷ Madjar S et al. Periurethral mass formations following bulking agent injection for the treatment of urinary incontinence. *J Urol.* April 2006(175);1408-1410.
- ⁸ Kuuva N, Nilson CG. Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women. *Acta Obstet Gynecol Scand.* 2006;85(4);482-7.
- ⁹ Koops SES et al. What determines a successful tension-free vaginal tape? A prospective multicenter cohort study: Results from the Netherlands TVTdatabase. *Am J Obst Gynecol.* 2006;194;65-74.



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