

ACT[®]

Adjustable Continence Therapy for Women



Post-operatively Adjustable Treatment for
Recurrent Female Stress Incontinence

URO MEDICA The Balloon Company

Not intended for distribution to a United States audience.

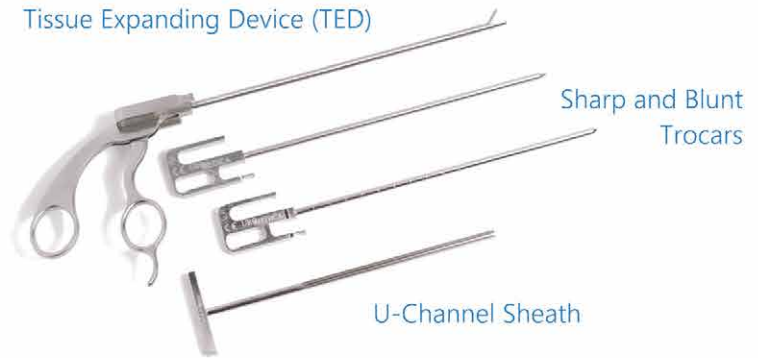
SUI and ACT

Stress urinary incontinence (SUI) is a common and disturbing complication of intrinsic sphincter deficiency (ISD) following childbirth or hysterectomy. ACT (Adjustable Continenence Therapy) is a minimally invasive long term implant designed to treat female patients who have SUI from ISD after failed previous incontinence treatments, like bulking agents or slings.^{1,2,3}

Adjustable Balloon Volume



Reusable, Sterizable Surgical Tools



Simple Implantation Procedure

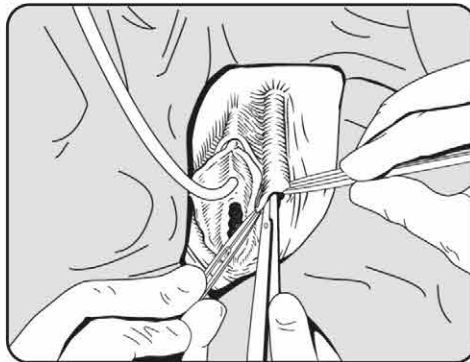
Minimally Invasive, Takes 15-30 minutes, Easily Reversible

No absorption, No bone anchors or fixation sutures, No abdominal or vaginal incisions

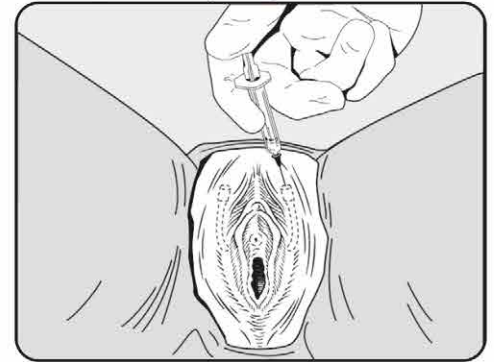
1) Balloon Implantation



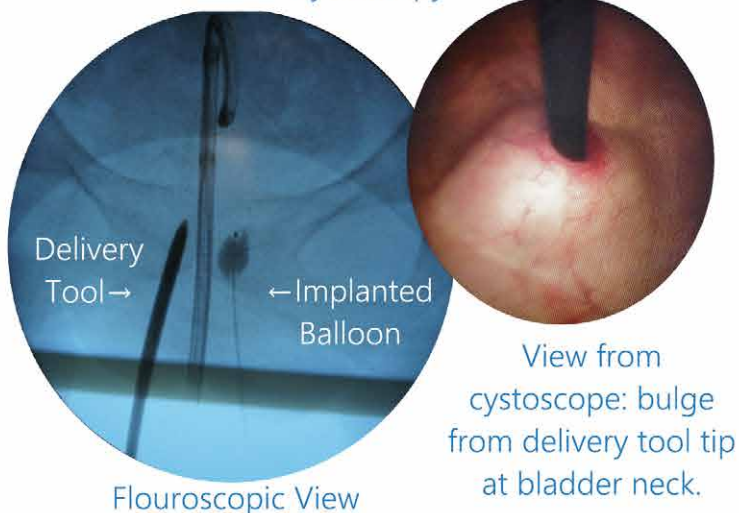
2) Port Placed in Labia



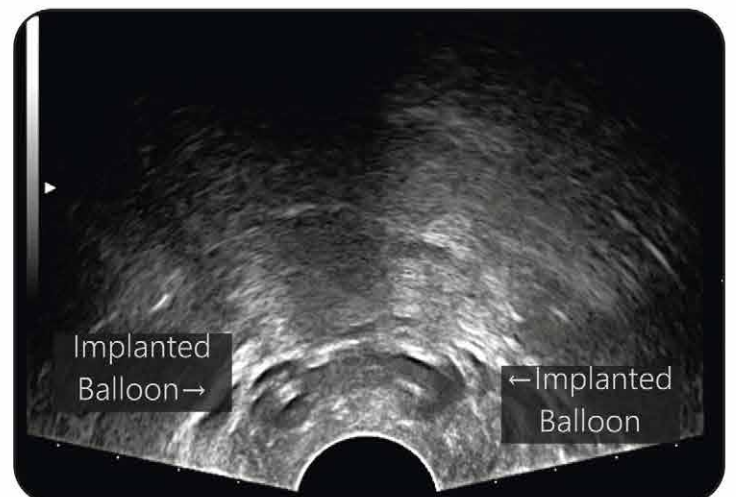
3) Post-op Adjustment



Visualization using Fluoroscopy and Flexible Cystoscopy⁴



Visualization using Transvaginal Ultrasonography⁵

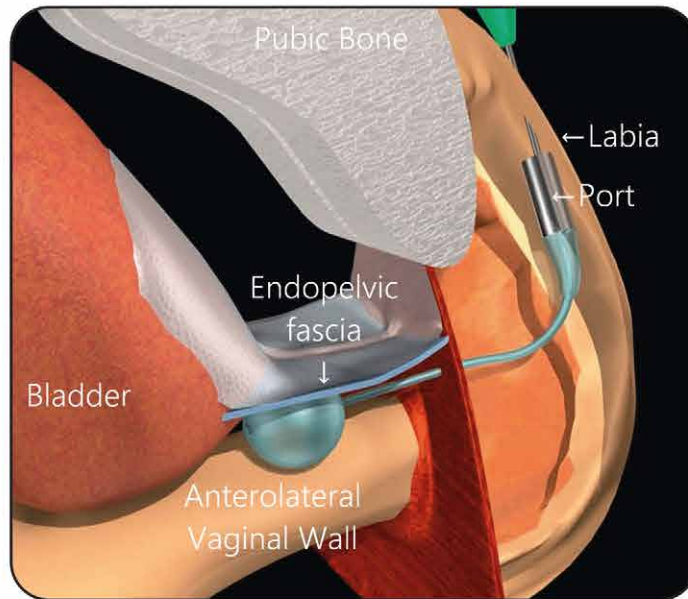


How ACT Works

The ACT device consists of two post-operatively adjustable balloon implants placed via a perineal approach bilaterally in a periurethral position at the bladder neck. The implant procedure is minimally invasive and may be performed with local anesthesia.

ACT Placement

Self-sealing titanium ports attached via tubing to each balloon are placed superficially in the fatty tissue of the labia majora, minimizing patient discomfort and allowing for post-operative volume adjustment.^{1,6}



Increasing the balloon volumes will increase coaptation of the urethra which will improve continence.⁶ Adjustments can be made post-operatively without anesthesia on an outpatient basis to best meet the needs of the patient.

Device Design

Self-sealing Port

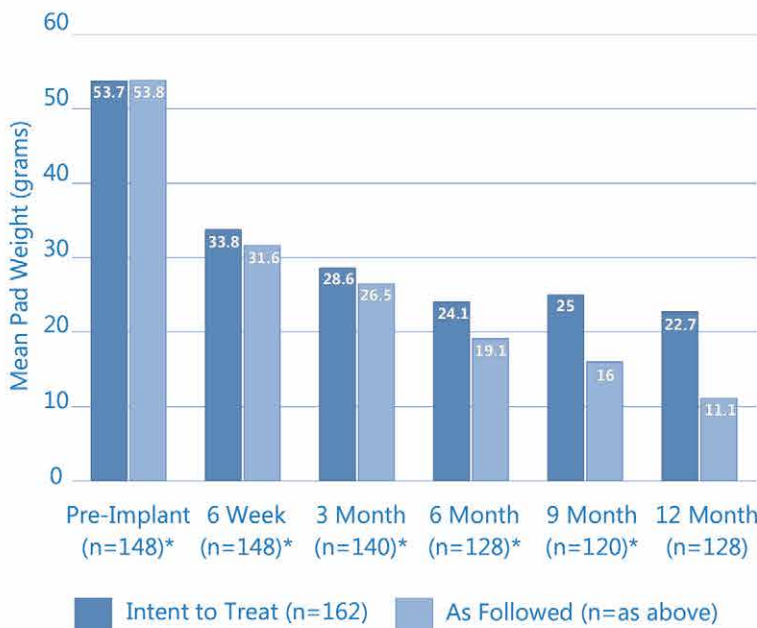
Flexible Bi-lumen Tubing

Durable Balloon Shell

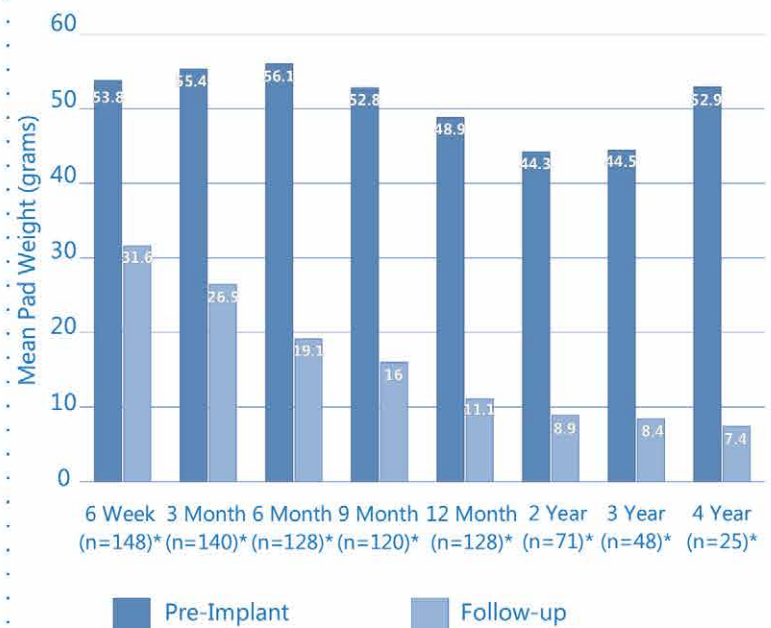


Patient Outcomes

Provocative Pad Weight Reduction
ACT Study^{1,3}



Pad Weight Reduction Durability
ACT Study^{1,3}



* Pad weight change from pre-implant: $p < 0.001$ for ITT and As Followed, Wilcoxon Signed Ranks

* As Followed Analysis, matched data $p < 0.001$, Wilcoxon Signed Ranks

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, 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.

Sources

- 1 Galloway NT, Aboseif SR, Sassani P, Franke EI, Nash SD, Slutsky JN, Le Tu M, Pommerville PJ, Baum NH, Sutherland SE. "Five Years Follow-up of Adjustable Continence Therapy (ACT) in the treatment of Recurrent Female SUI". OJU, 2013, 3, 132-137. doi:10.4236/oju.2013.32025. Published Online May 2013 (<http://www.scrip.org/journal/oju>).
- 2 Aboseif SR, Sassani P, Franke EI, Nash SD, Slutsky JN, Baum NH, Le Tu M, Galloway NT, Pommerville PJ, Sutherland SE. "Treatment of moderate to severe female stress urinary incontinence with the adjustable continence therapy (ACT) device after failed surgical repair". WJU (2011 Apr) Vol 29, No2, p249-253 Electronic Publication:2010-10-20. Journal code:8307716.E-ISSN:1433-8726.L-ISSN:0724-4983
- 3 Kocjancic E, Crivellaro S, Ranzoni S, Bonvini D, Grosseti B, Frea B. "Adjustable Continence Therapy for Severe Intrinsic Sphincter Deficiency and Recurrent Female Stress Urinary Incontinence: Long-Term Experience". J Urol. 2010 Jul 17. Epub ahead of print J of Urol Vol 184, 1017-1021 (Sep2010) DOI: 10.1016/j.juro.2010.05.024
- 4 B. Vayleux, F. Luyckx, S. Thélu, J. Rigaud, O. Bouchot, G. Karam, L. Le Normand. Poster, "Functional results of the Adjustable Continence Therapy in women, and new way for balloon positioning". Nantes University Hospital, Hôtel Dieu, France.
- 5 Crivellaro Simone, Palazzetti Anna, Abbinante Maria, Martinez Bustamante Louis Guillermo, Elena Finotto, Frea Bruno. Video, "Over the Wire Stepper-Guided Ultrasound ACT Positioning". Azienda Ospedaliero Universitaria "Santa Maria della Misericordia" di Udine. May 2011.
- 6 Wachter J, Henning A, Roehlich M, Marszalek M, Rauchenwald M, Madersbacher S. "Adjustable Continence Therapy for Female Urinary Incontinence: A Minimally Invasive Option for Difficult Cases". Urol Int 2008;81:160-166

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