Adjustable Continence Therapy for Women

Post-operatively Adjustable Treatment for Recurrent Female Stress Incontinence

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 Continence 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.\textsuperscript{1,2,3}

**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 Cystoscopy\textsuperscript{4}

Visualization using Transvaginal Ultrasonography\textsuperscript{5}
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\(^{1,3}\)

<table>
<thead>
<tr>
<th>Time</th>
<th>Mean Pad Weight (grams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Implant (n=148)*</td>
<td>53.3</td>
</tr>
<tr>
<td>6 Week (n=148)*</td>
<td>33.8</td>
</tr>
<tr>
<td>3 Month (n=140)*</td>
<td>28.6</td>
</tr>
<tr>
<td>6 Month (n=128)*</td>
<td>26.5</td>
</tr>
<tr>
<td>9 Month (n=120)*</td>
<td>24.3</td>
</tr>
<tr>
<td>12 Month (n=128)</td>
<td>19.1</td>
</tr>
</tbody>
</table>

As Followed (n=as above)

- Intent to Treat (n=162)
- As Followed

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

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

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<tr>
<td>6 Month (n=128)*</td>
<td>56.1</td>
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<tr>
<td>9 Month (n=120)*</td>
<td>57.7</td>
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<tr>
<td>12 Month (n=128)</td>
<td>58.3</td>
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<tr>
<td>2 Year (n=71)*</td>
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<td>3 Year (n=48)*</td>
<td>54.5</td>
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<tr>
<td>4 Year (n=25)*</td>
<td>57.2</td>
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</tbody>
</table>

Pre-Implant

Follow-up

* 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


For more information, contact:

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