

ACT
Adjustable Continence Therapy for Women
Uromedica, Inc.

Patient Information Leaflet - Australia

Please read all information carefully.

1. Device Name, Description, Materials, and Model Numbers

ACT Adjustable Continence Therapy for Women is an implantable prosthetic that is intended to treat adult women who have developed stress urinary incontinence. Silicone tubing connects an expandable silicone balloon with a titanium port that is used by your physician for post-operative adjustment. The balloon contains a radiopaque platinum-iridium alloy marker which allows the device to be viewed under x-ray.



Figure 1 - ACT Implants

The ACT devices are placed through two small incisions in your labia. A delivery tool is inserted through the incision and guided next to your bladder. An ACT device is delivered through the tool and inflated with a small amount of fluid. This process is repeated on the other side of your urethra. The adjustment ports are placed underneath the skin of your labia and the incisions are closed using 1-2 stitches for each incision.

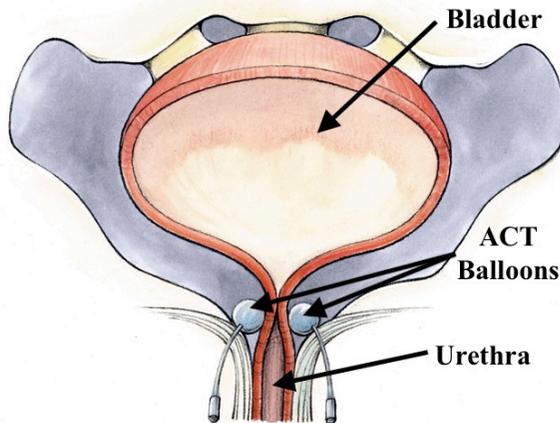


Figure 2 - Diagram Depicting Positioning of ACT Implants

Table 1 – ACT International Model Numbers

Model Number	Device Length	Description
800016-01	5 cm	ACT Patient Kit: Two (2) prosthetic implants
800016-02	6 cm	ACT Patient Kit: Two (2) prosthetic implants
800016-03	7 cm	ACT Patient Kit: Two (2) prosthetic implants
800016-04	8 cm	ACT Patient Kit: Two (2) prosthetic implants
800016-05	9 cm	ACT Patient Kit: Two (2) prosthetic implants
800021-01	5 cm	ACT Revision Kit: One (1) prosthetic implant
800021-02	6 cm	ACT Revision Kit: One (1) prosthetic implant
800021-03	7 cm	ACT Revision Kit: One (1) prosthetic implant
800021-04	8 cm	ACT Revision Kit: One (1) prosthetic implant
800021-05	9 cm	ACT Revision Kit: One (1) prosthetic implant

2. Intended Use and Indication

Intended Use

The ACT prosthetic implant device is intended, via initial and post-operative volume adjustments, to increase urethral coaptation at the bladder neck to eliminate unwanted urine loss.

Indication

The ACT system is a permanent implant designed for the correction of stress urinary incontinence in adult female patients.

3. Intended Performance

ACT is intended to improve your incontinence symptoms. Improvement is defined as a 50% reduction in incontinence symptoms from baseline. The devices are intended to have a lifetime of at least 10 years.

4. Potential Adverse Events

Potential adverse events from the ACT system, the attendant equipment and supplies, or the implant procedure include:

Allergic Response

Anesthetic risks

Device Calcification

Device Malfunction

Device Wear

Erosion of the device at the bladder, labia, urethra, or vagina

False Channel Creation

Intraoperative perforation (e.g. bladder, urethra, vagina)

Pain or Discomfort

Procedure/adjustment not able to be completed

Prosthetic Infection

Prosthetic Migration

Urinary Complications (e.g. Urinary Difficulty, Frequency, or Urgency, Worsening Incontinence*)

Urinary Retention

Urinary Tract Infection

Vascular Complications (e.g. Bleeding, Hematoma, Induration, Inflammation)

Wound Infection

* “Worsening Incontinence” includes subjective patient-perceived worsening.

5. MRI (Magnetic Resonance Imaging) Safety Information



MR Conditional

Non-clinical testing demonstrated that the ACT system is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 5,000-Gauss/cm (50-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the ACT system is expected to produce a maximum temperature rise of 1.5°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the ACT system extends approximately 10-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

6. Post-Operative Care

The patient is usually discharged on the day of the surgery. Your physician will ensure that you can void spontaneously prior to discharge from the surgical facility. Most surgeons choose to send their patients home with a course of antibiotics. Adjustments of the ACT therapy may begin six weeks after the ACT implantation procedure. During an adjustment, your physician will adjust the volume of fluid in your ACT balloons. Multiple adjustments may be required to achieve the desired level of continence. The devices can be adjusted to a maximum volume of 8mL each. In the meantime, you may need to continue using absorbent pads.

Avoid undue strenuous activity immediately post-operatively as directed by the physician. Failure to do so could lead to device migration.

Contact your physician if you experience redness, swelling, or drainage of the incision site, experience a return of incontinence symptoms, or are unable to urinate.

Review the MRI information above and understand the impact that ACT might have on travel security screenings (titanium and radiopaque components).

7. Serious Incidents

Any serious incident that occurs in relation to the ACT device should be reported to Uromedica (see back page of this leaflet for contact information) and to the Therapeutic Goods Administration (<https://www.tga.gov.au/>)

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