Are you worried about unwanted urine loss?

Learn about a clinical research study on an investigational device for women with stress urinary incontinence.

For more information, contact your local clinic.

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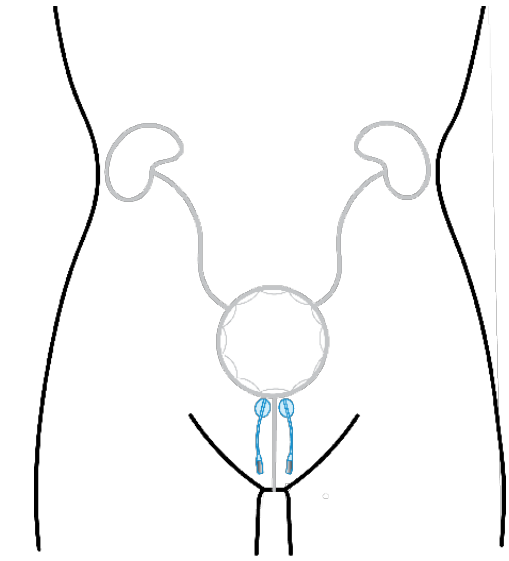
UROMEDICA

What is stress urinary incontinence?

Stress urinary incontinence is the involuntary leakage of urine during physical strain such as coughing, sneezing, or other activity. This condition may arise from intrinsic sphincter deficiency. Intrinsic sphincter deficiency is the weakening of the muscles that prevent unwanted urine loss during physical activity.

This trial for the Adjustable Continence Therapy for Women (ACT) is an investigative treatment option for women suffering from stress urinary incontinence.The procedure is minimally invasive and involves the implant of two silicone balloons on either side of the urethra near the bladder. The balloons provide pressure and support to the muscles preventing urine loss. The study doctor may increase the volume of the balloon in an office setting to meet your individual needs.



About the ACT Trial

PURPOSE

The Adjustable Continence Therapy for Women (ACT) is a clinical investigation evaluating the safety and effectiveness of the ACT devices in improving stress urinary incontinence. The knowledge gained from this trial may help others in the future.

RISKS

The study team will discuss all trial risks with you and answer any additional questions you may have.

TIME

Your participation is expected to last 12-months from the date of implant with potential for continued follow-up for five years.

What Should I Expect?

If you are interested and meet the criteria to participate in the trial, you will undergo a series of assessments to evaluate your physical and bladder health for the implant surgery.

The implant is a minimally invasive surgery and you will be able to leave the same day. Six weeks after the surgery, your study doctor will be able to adjust the volume of the device(s) to meet your individual needs.

To evaluate your continence, you will complete a pad test requiring you to perform a set of exercises and fill out questionnaires at select visits. The study team will discuss with you the study assessments required at each visit.

Study Visit Guide

	Enrollment	Implant *(Day 0)*	6-Weeks	3-Month	6-Month	9-Month	12-Month	Annual Visits*	Trial Exit
Office Visit									
Physical Exam									
Medical & Incontinence History									
Medication Use									
Pregnancy & Urine Test									
Implant Surgery									
Pad Weight Test									
Cystoscopy & Urodynamics									
Questionnaires									

*Annual visits up to five-years may be required

How to Participate

You may be eligible to participate in this clinical research study if you are an adult female who:

- Demonstrates stress urinary incontinence with primary intrinsic sphincter deficiency
- Failed at least six months of previous conservative (e.g. pelvic floor muscle exercise) or surgical treatment(s) for stress urinary incontinence
- Can undergo implant surgery
- Is not pregnant
- Does not have diabetes

Note: These are not the only criteria for participation in this study. Additional criteria may exclude you from the study. A member of the study team will help determine if you meet all the requirements to participate.

Want to Learn More?

Contact

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ACT

ACT UM08 Brochure V1.0_28May2020