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Uromedica Inc.
1840 Berkshire Lane North
Plymouth, MN 55441
USA
Tel: +1-763-694-9880
Fax: +1-763-694-9945
www.uromedica-inc.com
e-mail: info@uromedica-inc.com



Patient Guide to
Minimally Invasive Treatment for
Female Stress Urinary Incontinence



You are receiving this brochure because your doctor has diagnosed your condition as stress incontinence and thinks ACT® may be appropriate for you. This brochure provides more information about stress incontinence and the ACT procedure. After reading this information, please discuss any questions or concerns you have with your doctor

Stress Incontinence is Widespread and Treatable

Stress incontinence is the unintentional loss of urine that occurs when pressure is put on the bladder by coughing, sneezing, laughing, lifting something heavy or even getting out of bed. For women, the most common causes of stress incontinence are childbearing and hysterectomy, which may weaken the tissue that supports the bladder neck and urethra (tube that empties urine from the bladder). It is difficult to pinpoint the number of women affected by stress incontinence, because often they do not report it. However, results of one study suggest that 20.8% of women over the age of 15 have experienced stress incontinence¹.

ACT Can be an Effective Solution to a Frustrating Problem

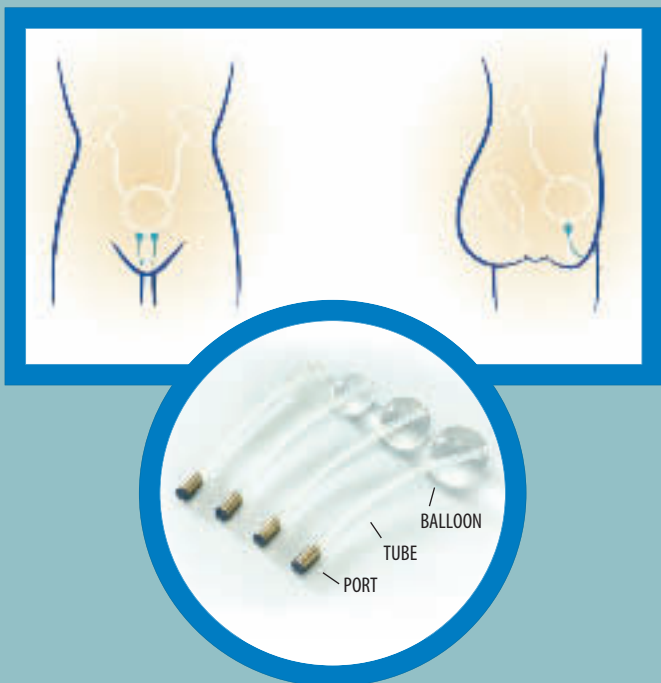
Treatments for stress incontinence include exercises to strengthen the pelvic floor muscles, medications, bulking agents and surgery. However, even if other treatments such as bulking agents or sling surgery have not been effective for you, Adjustable Continence Therapy (ACT) can still be considered.

ACT is a small device implanted on each side of the bladder neck (see illustration). At one end, there is a small balloon filled with fluid. Each balloon is connected to a tube with a titanium port at the end of it. The balloons press on the bladder neck to restrict the accidental flow of urine. However, when you need to urinate, the normal bladder contractions will push urine out, allowing you to pass urine in the normal way. The amount of pressure the balloons exert can be adjusted by adding or removing fluid through the ports. The complete system is implanted within your body and once implanted, no one but you will know it is there.

ACT has been used in more than 1,000 women in Europe, Canada and Australia. It is currently being studied in the United States in a Food and Drug Administration clinical study. Results of a previous study suggest that 24 months after surgery, 82% of patients are dry or much improved².

The ACT Procedure

The ACT procedure is minimally invasive and lasts approximately 30 minutes. The procedure will be performed in the hospital, and you will be given a local or general anesthetic. Using X-ray imaging, two balloon devices will be implanted—one on each side of the bladder neck. Your surgeon will examine the position of the balloons to ensure correct placement. The balloons will be inflated with fluid to secure their position. The titanium ports will lie beneath the surface of the skin. A urethral (Foley) catheter will be inserted after surgery, but it will be removed prior to discharge, when you are able to pass urine on your own.





Post-Operative Care

- Your doctor may prescribe medication such as antibiotics for you to take.
- You will need to keep the area where the stitches are located as clean and dry as possible, while the stitches are healing. If you wear pads, they will need to be changed regularly.
- Avoid bicycling, exercise and heavy lifting for the first 3-4 weeks after the procedure.
- Refrain from sex for the first 3-4 weeks after the procedure.
- Once your stitches are healed and the swelling is gone, you may resume normal activities, including exercise, bicycling and sex.

Post-Surgical Adjustments

In the first few days after the surgery, you may be completely dry. However, during the next 2-4 weeks you may leak again. This is completely normal and is to be expected. Your doctor can adjust the fluid levels in the balloons to reduce



the leaking. When an adjustment is needed, the tissue near the port will be numbed with a local anesthetic and then a small needle will pass through the skin to the port to add or remove fluid from the balloons. During the adjustment phase, you should see improvement over your pre-surgery state, but it may take 3-4 adjustments over the course of 2-3 months to achieve the desired effectiveness.

Possible Side Effects

The potential risks with this procedure are similar to those for other surgical treatments for stress urinary incontinence. These include, but are not limited, to the following:

Tissue perforation (tear)

Device migration

Tissue erosion/infection at the implant site

Device failure

Non-response to treatment

Post-operative urgency, frequency, or retention

If an infection occurs at the implant site, it can be treated with antibiotics. If the device migrates, changes can be made to improve the positioning. If a more serious side effect occurs (e.g. perforation, migration), ACT can be completely removed. Please ask your doctor any questions you may have about the procedure.

Conditions That May Affect ACT

ACT is not appropriate for all patients with stress incontinence. If you have any of the following conditions, you should talk with your doctor about whether or not ACT is suitable for you:

Bleeding disorders

Bladder cancer

Bladder stones

Recent or upcoming radiotherapy (patients who have had radiation therapy may have lower success rates with ACT)

Severe constipation (i.e. if you regularly are unable to go to the bathroom for several days in a row)

When ACT Should be Postponed

Pregnancy

Urinary tract infection

Any condition requiring regular use of a rigid urinary tract scope

References

¹ Maral, I., Ozkardes, H. Peskircioglu, L., and Ali Bumin, M. Prevalence of stress urinary incontinence in both sexes at or after age 15 years: a cross-sectional study. *J Urol*:165, 408–412 (2001).

² Kocjancic, E, *European Prospective Multi-centre Experience with Adjustable Continence Therapy (ACT®) Periurethral Prosthetic Implantation: Results at 12 to 24 Months, presented at 34th International Continence Society (ICS) Annual Meeting, Paris, August 23-27, 2004.*

