

THE ARTIFICIAL URINARY SPHINCTER:

A TREATMENT FOR POST- PROSTATECTOMY URINARY INCONTINENCE



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Introduction

Severe urinary incontinence (involuntary leakage of urine) following prostate surgery is a *rare* event, occurring in only about 5% of men following radical prostatectomy for prostate cancer and in an even smaller percentage of men who have undergone prostate surgery for a benign process. It is often the result of loss of the function of the urinary sphincter that can occur as a consequence of removal of the prostate gland. If incontinence does occur following prostate surgery, it can be devastating to your quality of life—affecting your psychological, emotional, and sexual well-being. It often causes loss of self-esteem, depression, and avoidance of a healthy, productive, and active lifestyle.

Fortunately, for the small percentage of men rendered severely incontinent after prostatectomy, there is a solution. The Artificial Urinary Sphincter (AUS), manufactured by American Medical Systems, offers a great opportunity for cure and has enormous potential in significantly improving the quality of life of men suffering from this debilitating condition. The goal is for *you* to control your bladder and not have your bladder control you.

The AUS provides you with simple, discreet control over bladder storage and emptying. Implanted entirely within the body, the device mimics the function of a healthy sphincter muscle by keeping the urethra closed until you want to urinate. No parts are visible once the AUS is implanted.

The AUS implant is a fluid-filled device consisting of three components: a *cuff* implanted around the urethra, a *pressure-regulating balloon* implanted in the retropubic space (area behind the pubic bone adjacent to the bladder), and a *control pump* implanted in the scrotum. The cuff of the AUS gently pinches the urethra closed, preventing urine from passing. When you want to urinate, you simply squeeze and release the control pump that is conveniently situated in the scrotum, transferring fluid from the cuff to the pressure-regulating balloon. The cuff opens, allowing urine to flow through the urethra. Within several minutes, the pressure-regulating balloon automatically returns the fluid to the cuff to once again pinch off the urethra.

The AUS, first developed in 1972, has been used successfully for over 40 years and has been implanted in thousands of men. Over the years, refinements and device improvements have further improved this device. It is a time-tested and proven treatment for incontinence after prostatectomy and is considered to be the “gold standard” by urologists. Many men are *completely* continent after an AUS implant, and others will experience only minor dribbling with very strenuous exercise or exertion, perhaps requiring one small pad per day. The overall patient satisfaction rate exceeds 90%.

Patient Selection

In order to be the right candidate for the AUS, certain criteria should be met. Your incontinence should be on the basis of a weakened or damaged sphincter and not on the basis of bladder over-activity. The incontinence should be present for at least 6 months before considering the AUS, because spontaneous improvement often does occur for some time after prostatectomy. You obviously need to be sufficiently motivated to receive such an implant, and its use demands good manual dexterity in order to operate the control pump. You also need an adequate capacity bladder, sufficient urinary flow rate with ability to empty the bladder, and sterile (uninfected) urine. Prior to consideration for an AUS implant, sophisticated urinary testing is thus imperative. The evaluation entails *urodynamics and cystoscopy*, which can be done in the office.

Patient Evaluation Prior to Consideration for AUS: Urodynamics and Cystoscopy

Urodynamics is a study whereby simultaneous measurements of bladder and abdominal pressures, urinary flow rates and pelvic floor muscle activity of the bladder and urethra during the filling and emptying phases of urination are obtained and recorded on a computer. This highly sophisticated method of correlating pressure testing is invaluable in the evaluation of men with incontinence after prostatectomy.

You will initially be asked to empty your bladder into a special commode that records your urinary flow. After numbing your urethra with anesthetic jelly, a tiny catheter is inserted into the bladder. A tiny catheter is inserted in the rectum and two patch electrodes, similar to an EKG test, are placed adjacent to the anus to monitor the pelvic floor muscles. As your bladder is slowly filled, you will be asked to describe how your bladder feels. Bladder sensation, pressure, and capacity will be recorded. You will be asked to strain and cough, and empty your bladder after it is full. The entire test will be recorded on the computer, and you are encouraged to observe it on the screen as it is occurring. Every aspect will be explained as the evaluation is being performed. The last part of the testing is *cystoscopy*, at which time the urethra is numbed with anesthetic jelly and a tiny lighted instrument is used to view the urethra, sphincters, and bladder on a monitor that you will be able to see.

After the evaluation has been completed, the results of the study will be reviewed with you and a management plan will be formulated. This study will be able to determine if you are an appropriate candidate for the AUS.

Implantation of the Artificial Urinary Sphincter

Implantation of the AUS is a surgical procedure that requires anesthesia. It generally takes about one hour or so to perform and is done on an outpatient basis. The conventional operation is performed with your legs in stirrups and requires two incisions, one in the abdomen and the other in the *perineum* (area between scrotum and anus). In 2001 Dr. Steve Wilson and I devised an innovative technique for AUS implantation via a single scrotal incision technique. This technique affords numerous advantages over the dual incision abdominal-perineal approach. The scrotal incision technique can be performed in the *supine* position (lying on your back vs. legs in stirrups), requires only one small incision in the scrotal sac, and the implant can be achieved significantly faster. The surgery is easier, healing is faster, and discomfort is less.

It is important to know that the AUS will not be activated—and thus will not be functional—for a 6-week period of time. This will avoid excessive pressure on the urethra that could undermine the healing process. Activation is a simple 5-minute process that is done in the office, involving minimal discomfort.

The Surgical Process

The surgery is usually done in the CAS (Center for Ambulatory Surgery) located on the third floor of the Hackensack University Medical Center Mediplex building. You will need to arrive several hours before the actual surgery because certain preparations need to be made. An intravenous line is placed so that appropriate fluids and antibiotics can be administered, and support stockings are placed to help prevent clotting within the leg veins. The anesthesiologist will meet with you to discuss which type of anesthesia is safest and best for you. I will meet with you and answer any last minute questions, after which you are transported to the operating room. Your family will be shown the surgical waiting area, where they can relax comfortably. This is the room where I will join them after the operation is finished.

After completion of the AUS implant, you will be transported to the Recovery Room, where you will be carefully monitored. Once you are awake and alert, you will be transferred back to a room where you can be visited by your family members or friends. Once you are ambulatory and are able to tolerate food, you can be discharged home.

Post-Operative Considerations

Once you arrive home, it is recommended that you spend as much time off your feet as possible. On the day following surgery, you may resume non-strenuous activities. It is important that you do not strain during bowel movements or engage in any heavy lifting or physically exertional activities for several weeks after AUS placement.

You will have a scrotal pressure dressing placed before you leave the operating room. I will generally want to remove it 2-3 days following the implant. Please place an ice pack on top of the dressing for the first several days to reduce the swelling. Twenty minutes on, twenty minutes off is satisfactory. Once the dressing is removed, you will likely observe swelling, bruising, and perhaps spotting of blood. The swelling and bruising may involve the penis, scrotum, perineum, and lower abdomen. Once the swelling abates (usually within a few days), it is a good idea to gently pull the pump down into as low a position in the scrotum as possible a few times per day to help permanently position the pump into as easily accessible a position as is possible. After removal of the pressure dressing, it is recommended that you wear an athletic supporter or jockey type shorts to immobilize the testicles and scrotum. This will no longer be necessary after several weeks. Remember that you will remain incontinent until the AUS is activated and until activation, you will need to continue to wear protection.

You may resume your regular diet and medications immediately. You may bathe or shower after removal of the dressing. Gently pat dry the incision after bathing. The sutures used to close the scrotal skin will dissolve on their own, generally in about 2 weeks.

You may have a sore throat from the breathing tube used by the anesthesiologist. This will go away spontaneously, but cold, soft foods such as yogurt and ice cream can be very soothing.

You will be sent home with prescriptions for antibiotics and a narcotic pain medicine. It is absolutely imperative that you complete the antibiotic course to prevent infection. You may take the pain medication on an "as needed" basis. Please do not drive or operate machinery while on the pain medication. Narcotics have side effects including constipation, nausea, and causing an ill-at-ease feeling. If this is the case with you, you may be better off with an over-the-counter anti-inflammatory such as Advil or Motrin. The combination of undergoing an operative procedure and taking narcotic medication frequently leads to an unpleasant inability to move your bowels. Everyone taking a narcotic should thus begin taking a stool softener, such as Colace, immediately after the surgery. Colace can be purchased at any pharmacy without a prescription and is dosed at 100 mg. twice daily. Even with the Colace, you may still require a supplemental Dulcolax rectal suppository or Milk of Magnesia or alternative cathartics.

It may be advisable to order and wear a *MedicAlert* bracelet to inform health care personnel that you have an AUS implant in the event of a medical emergency. If you were rendered unconscious or unable to express yourself, *MedicAlert* would “speak for you”, informing emergency medical staff that you have a prosthetic device. The MedicAlert Foundation can be reached at www.medicalert.org.

Frequently Asked Questions

Who manufactures the Artificial Urinary Sphincter?

American Medical Systems, Inc.
104700 Bren Road West
Minnetonka, Minnesota 55343
1-800-328-3881
www.visitAMS.com

Will insurance cover this device?

Medicare has a national coverage policy for incontinence control devices, which includes the AUS. Most commercial health insurers also cover the AUS when it is deemed medically necessary for the patient. Our billing and insurance staff will work with your insurance carrier to verify coverage and insurance payment levels.

How effective is the Artificial Urinary Sphincter?

More than 90% of patients with the AUS have greatly improved continence, many of whom achieve complete urinary control with no need for pads and the remainder of whom have occasional, minor stress incontinence with vigorous activities, requiring typically one small pad per day.

Does the AUS need to be measured to my body?

The pump is “one size fits all”, but the cuff is sized to the circumference of your urethra to achieve a proper fit. The reservoir comes in a variety of pressures. The higher the pressure of the reservoir, the tighter is the closure of the urethra. The tighter the closure of the urethra, the better is the continence, but also the greater the chance of urethral pressure damage. So a trade-off must be achieved in order to achieve the necessary occlusive pressure to achieve continence while minimizing potential damage to the urethra. In practical terms, this usually translates into a 61-70 cm. pressure reservoir for most men, and a 51-60 cm. pressure reservoir for men who have received pelvic radiation.

What are alternatives to the AUS, assuming that behavioral techniques and pelvic floor muscle exercises have failed?

1. Absorbent pads and garments
2. Penile compression clamps
3. External collecting devices (condom catheters)
4. Urethral bulking agents
5. The male sling

The first three items are external, bulky, mechanical means of coping with—not treating—the problem. Urethral bulking agents have fared poorly and the male sling is a relatively new modification of an old procedure that achieves results far inferior to those possible with the AUS.

What are the potential risks and complications associated with AUS implantation?

Complications occur in only a very small percentage of patients. The vast majority of patients are extremely satisfied with the AUS implant, which is often the only hope for those suffering from severe incontinence following prostatectomy.

Infection: As with any surgery, an infection can develop after an AUS implant. Every step will be taken to reduce the likelihood of an infection—including intravenous antibiotics before the implant, topical antibiotics to flush the surgical site during the implant, and oral antibiotics after the implant. Additionally, a lengthy scrub with antiseptic is performed prior to the operation, meticulous surgical technique is used, and antibiotic ointment is placed on the incision. If an infection occurs and does not respond to antibiotics, it may be necessary to remove the AUS. This is an extremely rare occurrence.

Erosion: This is a breakdown of the urethral tissue next to the cuff component. It is generally treated with cuff removal to allow for urethral healing prior to consideration for cuff replacement at a later date. Erosion most often occurs when a catheter is placed into the urinary bladder by health care personnel uninformed that the AUS device is in place. The delicate urethra, pinched closed by the inflated cuff surrounding it, is traumatized and damaged by catheter placement. This situation can be avoided by deactivating the AUS prior to catheterization. This is one of the reasons that a Medic-Alert card and bracelet are useful considerations.

Mechanical Malfunction: The AUS is extraordinarily effective and reliable, but it is a mechanical device that can ultimately malfunction. The seven-year malfunction rate requiring an operation for repair is approximately 10%. It is not possible to predict how long an AUS will function in an individual patient. As with any biomedical prosthesis, this device is subject to wear, component disconnection, component leakage, and other mechanical problems that may lead to the device not functioning as intended, and may ultimately require additional surgery to replace the device.

Tissue Atrophy: This situation can result from the long-term pressure effect of the cuff on the urethra. Essentially, the urethra shrinks down from being squeezed by the cuff, resulting in some degree of worsening of urinary control. When this happens, it generally requires repositioning of the cuff to a new urethral location.

Pain: Discomfort in the groin, penis, and scrotum is expected immediately after surgery and during the period when you first use your device. There have been very rare cases of chronic pain associated with implantation of an AUS.

Migration and Extrusion: These are *extremely* rare occurrences. Migration is the movement or displacement of components within the body space in which they were originally implanted. Extrusion occurs when a component moves to an abnormal location outside of the body.

Summary

The AUS is an extraordinarily well-engineered medical prosthesis that has an excellent track record in terms of effectiveness, safety and reliability. Although there is no means of totally replacing our natural sphincter system, the AUS is presently the only device that serves to “mimic” this system, providing consistent results in the treatment of incontinence following prostatectomy. Both my patients and I have experienced extreme satisfaction and gratification with the restoration of urinary control as a result of the AUS implant.

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