AMS Sphincter 800™

**Oclusive Cuff**
- Implanted around the urethra at the bladder neck or bulbous urethra
- Applies pressure circumferentially when inflated

**Pressure-Regulating Balloon**
- Implanted in the prevesical space
- Controls the amount of pressure exerted by the cuff

**Control Pump**
- Implanted in the scrotum
- Contains the resistor and valves for the transfer of fluid to and from the cuff
AMS Sphincter 800™

The cuff squeezes the urethra closed.
The device is implanted in the body and cannot be seen.

The cuff can be placed at the bulbous urethra or at the bladder neck.

The Sphincter allows the patient to control his/her urinary function.
The patient squeezes the pump to move fluid from the cuff to the pressure-regulating balloon, allowing urination to occur.
The fluid automatically returns from the pressure-regulating balloon to the cuff, restoring continence again.
AMS Sphincter 800™

Consists of three components:
- Cuff
- Pressure Regulating balloon
- Pump
Occlusive Cuff

Sizes include:

- 4.0cm
- 4.5cm
- 5.0cm
- 5.5cm
- 6.0cm
- 6.5cm
- 7.0cm
- 7.5cm
- 8.0cm
- 9.0cm
- 10.0cm
- 11.0cm
Pressure Regulating Balloon

3 Pressures:
51-60cm $H_2O$
61-70cm $H_2O$
71-80cm $H_2O$
Pressure Regulating Balloon Placement

- Look at:
  - Tissue quality
  - Cuff size
  - Activity level
  - Diagnosis
Patient Selection and Evaluation
Patient Selection Criteria

- Sterile Urine
- Incontinence due to an incompetent external sphincter
- Adequate manual dexterity
- Adequate mental capacity
- Incontinent present for at least 6 months
Patient Selection Criteria

- Bladder capacity of at least 200 cc
- Motivated patient
- Urine flow greater than 10 ml/sec
- Low residuals
Contraindications

- Chronic urinary tract infections
- An irreversibly obstructed urinary tract
- Patients with low-volume detrusor hyperreflexia, (bladder contractions override sphincteric resistance resulting in incontinence)
Contraindications

- Unstable urethral stricture disease or a urethral diverticulum at the potential cuff site
Patient Evaluation

- Patients with bladder neck contractures which have been incised should remain open for at least three months prior to implant and should easily accept passage of a 14Fr. Catheter (Urolume).
Patient Evaluation

- Distal or mid-bulbous urethral stricture disease or reconstruction may prevent implantation of the cuff at this level and an alternate site should be chosen.
- Visual inspection of urethral mucosa can indicate health and vascularity of the tissue, especially in radiated patients or post pelvic trauma.
Patient Evaluation

- **Urodynamics**

  Used to quantitate voiding function and identify anatomic abnormalities which could jeopardize the efficacy of the sphincter.
Surgical Procedure
Surgical Procedure
Surgical Procedure
Surgical Procedure

Blunt dissection is used to dissect the BC muscle away from the urethra.
Surgical Procedure

Exposed Urethra

Lateral retraction of muscle
Surgical Procedure
Surgical Procedure
Surgical Procedure
Surgical Procedure

2 cm wide plane must be created around the urethra to accommodate the cuff
Surgical Procedure

Prior to measuring, remove Foley Catheter
Surgical Procedure
Cuff Placement

In Males:

- Bulbous urethra placement most common. 4.0cm to 4.5cm most common.
- Bladder neck placement used in young men and those who need frequent intermittent catheterization. 8cm to 11cm most common size for adults.
Cuff Placement

In Females *(not approved in USA)*:

- Bladder neck placement only option. 6cm to 8cm most common
- Sizing critical, too tight a cuff will result in retention, too large a cuff will result in leaking
- A measurement of greater than 10cm uncommon

Approach-either:
- Transvaginal
- Abdominal
Cuff Placement

In Children: *(not approved in USA)*:
- Bladder neck placement only
- Cuff size 6cm to 8cm
- Revisions normally to lengthen pump tubing in scrotum or labia
Surgical Procedure

A midline or transverse incision is made through the rectus fascia to reach the prevesical space.
Surgical Procedure

Cuff tubing is passed from the perineal incision to abdominal incision
Surgical Procedure

Temporary connection is made from the cuff to the PRB to pressurize the cuff.
Surgical Procedure

Blunt dissection into scrotum for pump placement
Surgical Procedure
Surgical Procedure

Pump cycled and deactivated for 6-8 weeks.
Surgical Procedure

Video Presentation Overview
Transverse Scrotal Procedure for the AUS

Steven K Wilson, MD
Institute for Urologic Excellence
Van Buren AR
A New Approach for a Proven Surgical Solution

- Single incision
  - Faster, less infection risks
- No “blind spot” behind the urethra
- Mobile urethra, detached
  - Easier, Safer, and Faster
- Revisions are simpler
  - Single incision / Everything below
- Same successful results
- High interest by surgeons who saw it at AUA this year
Positioning

Patient Supine, Legs Abducted, Not Lithotomy
The Incision is Scrotal, The Exposure is Penile

High Transverse Scrotal

Move Scrotal Incision Onto Penis
Proper Hook Placement is Key to Exposuire

Place Hooks at 1, 5, 7, 11 o’clock To Stabilize incision

Place 3, 9 o’clock Hooks to expose
Dissect & Expose
By Replacing Hooks
Find Shiny Tunica

Exposure of Corpora is Key to Urethral Exposure

Move window
Expose Both Corpora
Exposure of Corpora is Key to Urethral Exposure

Pass Metz deep to proximal corpora, Place Infant Deaver in perforation

Repeat Metz Proximal Other Side
Exposure of Proximal Corpora Define Urethra

Pull Deavers Caudad Defining Septum
Incise Septum -- Urethral Exposure without Scrotal Dissection
Freely Mobile Urethra Because Supine, Not Lithotomy Position
Displace Scrotal Incision Over Inguinal Area

Palpate Pubic Tubercle

Push Finger into Inguinal Ring & Hook With Babcock

Reservoir Placement Through Scrotal Incision

Scissors pierce transversalis facia (floor of inguinal canal) to access space of retzius

External inguinal ring pulled cephalad by infant devier
Impact Of Transverse Scrotal Technique on AUS Sales

Surgeons Perceive the AUS Transverse Scrotal Technique to be Easy, Fast and Safe

- Surgical Prostheses
- Skill
- Prosthesis Surgeries
- Patient Presentation
- Surgeon Confidence
Y-Connector For Double Cuff Procedure
Double Cuff AUS Results

- 0-1 PPD: 90%
- 2+ PPD: 10%
Comparison of Outcomes Following Single or Double Cuff AUS Insertion

- Mean Pad Count Pre-Surgery: 7.7 pads/day
- Mean Age: 67 years
- n=56

Bales et al, 2003 AUA Abstract
Comparison of Outcomes Following Single or Double Cuff AUS Insertion

Bales et al, 2003 AUA Abstract
AMS Sphincter 800™

Y-Connector For Double Cuff Procedure

Urinary sphincter with 2 cuffs in tandem, 1 reservoir and 1 pump.
3-Way Connector

- Two in AMS 800 AUS Accessory Kit
- Plastic
- Bio-compatible
- MRI compatible
What’s New?
Dual-Cuff Implant
Dual-Cuff Surgical Options

- Adding New Cuff to Existing Cuff
- Removing Existing Cuff and Replacing with Two New Cuffs
- Placing Two New Cuffs
Adding New Cuff to Existing Cuff
Adding New Cuff to Existing Cuff

- Prepare and drape patient in normal manner for AMS 800 AUS procedure.
- Deactivate AMS 800 AUS.
- Insert Foley catheter to facilitate identification of urethra.
Adding New Cuff to Existing Cuff

- Make perineal incision.

- Implant second cuff approximately 1-2 cm distal to original cuff.
Adding New Cuff to Existing Cuff

- Make incision at cuff/pump tubing connection site.
- Locate white/clear tubing leading from original cuff to connection site.
- Using rubber shod clamps, clamp tubing on each side of original connector.
Adding New Cuff to Existing Cuff

- Cut out connector and discard connector.
- Route new tubing from perineal incision to cuff/pump tubing connection site.
  - Use tubing passer.
- Clamp.
Adding New Cuff to Existing Cuff

Add fluid to new cuff:

- Flush tubing.
- Connect syringe (15 gauge blunt needle/10cc sterile saline) to new cuff tubing.
- Remove clamp.
- Add 1cc of filling solution to new cuff.
- Clamp.
- Remove syringe.
Adding New Cuff to Existing Cuff

- Flush new cuff tubing.
- Attach 3-way connector to new cuff, then tie with suture.
  - Suture with a 3-0 non-absorbable polypropylene suture.

*NOTE: Care must be taken to ensure that there is no excessive tension on any of the 3 tubes leading to the connector to help avoid possible kinking.*
Adding New Cuff to Existing Cuff

- Flush original cuff tubing.
- Attach 3-way connector to tubing, then tie with suture.
- Flush pump tubing and 3-way connector.
- Attach 3-way connector to tubing, then tie with suture.
Adding New Cuff to Existing Cuff
Adding New Cuff to Existing Cuff

- Remove all clamps from tubing.
- Test system to confirm function.
- Deactivate system.
- Close incisions in normal manner.
Complications
Intraoperative Complications
Perforations

- Rectal wall perforation
- Male = Abandon placement, repair rectal wall, consider placing cuff around distal urethra
- Female = Abandon placement, repair rectal wall

Infection!
Intraoperative Complications

Perforations

- Urethral Perforation
  - Close defect with 4.0-5.0 absorbable suture and position cuff away from suture line
  - If repositioning not possible = place cuff over suture and implant lower PRB. Deactivate for a longer period of time
  - Come back later if perforation is too large

INFECTION!
Intraoperative Complications

Perforations

- Bladder
  - Repair in 2-3 layer closure
  - Re-position PRB on opposite side of perforation and continue with procedure
  - Rarely associated with infection
Intraoperative Complications
Perforations

- Vagina

- Repair with 3-0 or 4-0 absorbable sutures and continue placement around the bladder neck

Note: To limit risk of entering vagina, pack with betadine gauze
Intraoperative Complications
Perforations

- Scrotum or Labium
- Repair and re-position pump on opposite side
Intraoperative Complications

Perforations

- Bladder Neck
  - Repair with 3-0 or 4-0 absorbable suture
  - Continue cuff placement and deactivate at least 3 months
  - Rarely associated with infection
Post - op Complications

- Hematoma
- Retention
- Infection
- Mechanical malfunction
- Cuff erosion
- Recurrent or persistent incontinence
Persistent Incontinence

- Bladder capacity adequate?
- Bladder hyperreflexic?
- Stress Incontinence
- More pumps to empty cuff/ cuff atrophy
- Partial vs total incontinence
- Fluid loss/Cuff coaptation
Three Major Changes Circa 1989

- Narrow Backed Cuff
- Kink Resistant Tubing
- Quick Connect System
Out With The Old, In With The New

- Erosion: 8 Pre 1990, 5 Post 1990
- Mechanical Failure: 44 Pre 1990, 12 Post 1990
- Atrophy: 5 Pre 1990, 3 Post 1990
- No Re-operation: 33 Pre 1990, 82 Post 1990
Sometimes less is more!
Artificial sphincter implantation is clearly the treatment of choice for postprostatectomy urinary incontinence due to ISD... Only artificial urinary sphincter implantation is capable of offering most men with this complication the opportunity to achieve social continence for a reasonable time. Furthermore is does this at a cost comparable to collagen injections and with a reasonable safety profile.

Drogo K. Montague
Cleveland Clinic Foundation
Urology 55: 2-4, 2000
AMS Sphincter 800™ Results

Published results on patients achieving and maintaining social continence:

- Gundian et al. 90% J. Urology, 1989
- Marks et al. 95% J. Urology, 1989
- Perez et al. 85% J. Urology, 1992
- Singh et al. 96% J. Urology, 1992
- Litwiller et al. 84% J. Urology, 1996
AMS Sphincter 800™ Results

- 90% of male patients reported satisfaction with the AMS Sphincter 800™.
- 92% of male patients would have the AMS Sphincter 800™ placed again.
- 80% of males were socially continent using 0-1 pad per day at 7 years.
- For over 25 years, the AMS Sphincter 800™ has been the gold standard to treat urinary incontinence.
Conclusions

- Incontinence is not a life sentence.
- Incontinence can be treated effectively.
- Successful treatment options like the AMS Sphincter 800™ are available.
- Talk to your doctor about your options today!
Four Important Final Points

1. Always deactivate the system if the patient is going to be catheterized.
2. Always deactivate the system if the patient is going to be catheterized.
3. Always deactivate the system if the patient is going to be catheterized.
4. Always deactivate the system if the patient is going to be catheterized.