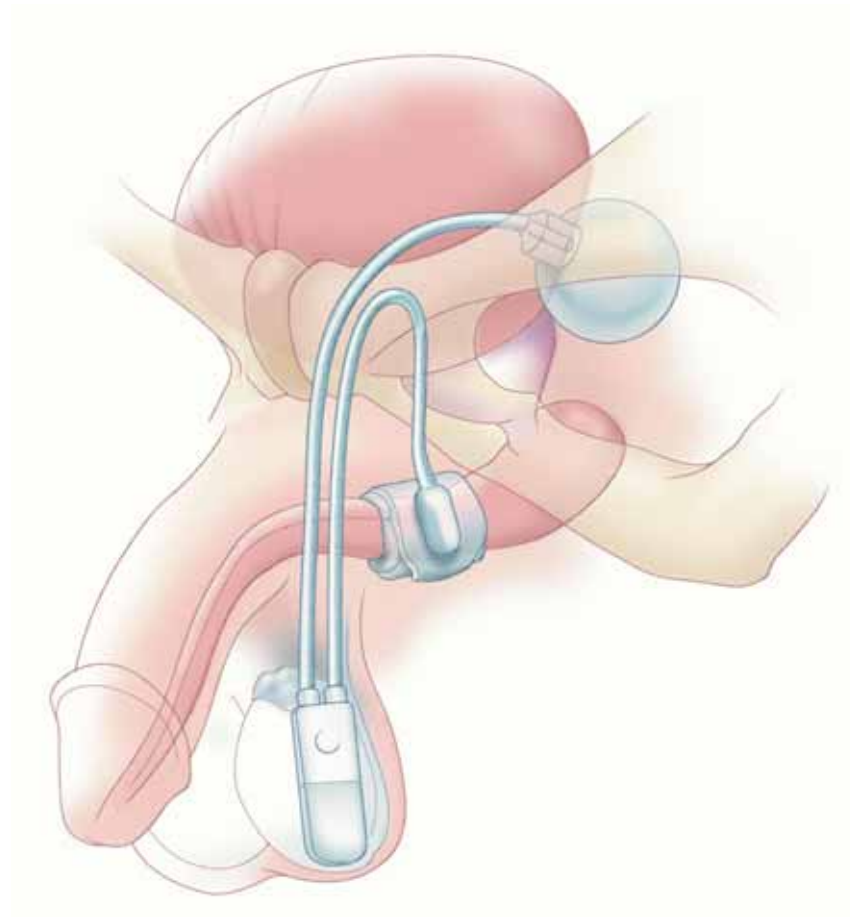


# Male Continence Training

**AMS™ 800**

**Artificial Urinary Sphincter**

# AMS Sphincter 800™



# AMS Sphincter 800™

The AMS Sphincter 800 is the Gold Standard, time-tested surgical solution for control of **moderate to severe** stress urinary incontinence.

# AMS Sphincter 800™

## Patient Selection – Good Candidates

- Good manual dexterity
- Good mental capacity
- Incontinent for at least 6 months (varies)
- Good Urodynamic results
  - Bladder capacity of at least 200cc (average adult = 300-500)
  - Urine flow greater than 10ml/second
  - Low urine residuals – can void completely
- Desire to be dry or nearly dry outweighs fears
- Men
  - Women and children not approved in the USA

# AMS Sphincter 800™

## Patient Selection – Poor Candidates

- Detrusor instability
  - Should be resolved prior to AUS surgery
- Poor Urodynamic results
  - Could identify abnormalities that could jeopardize the efficacy of the AUS
- Limited physical or mental abilities

# AMS Sphincter 800™

## Contraindications

- Chronic urinary tract infections
- An irreversible obstructed urinary tract
- Patients with irresolvable detrusor hyperreflexia
  - Bladder contractions override sphincteric resistance resulting in incontinence
- Unstable urethral stricture disease or a urethral diverticulum at the potential cuff site

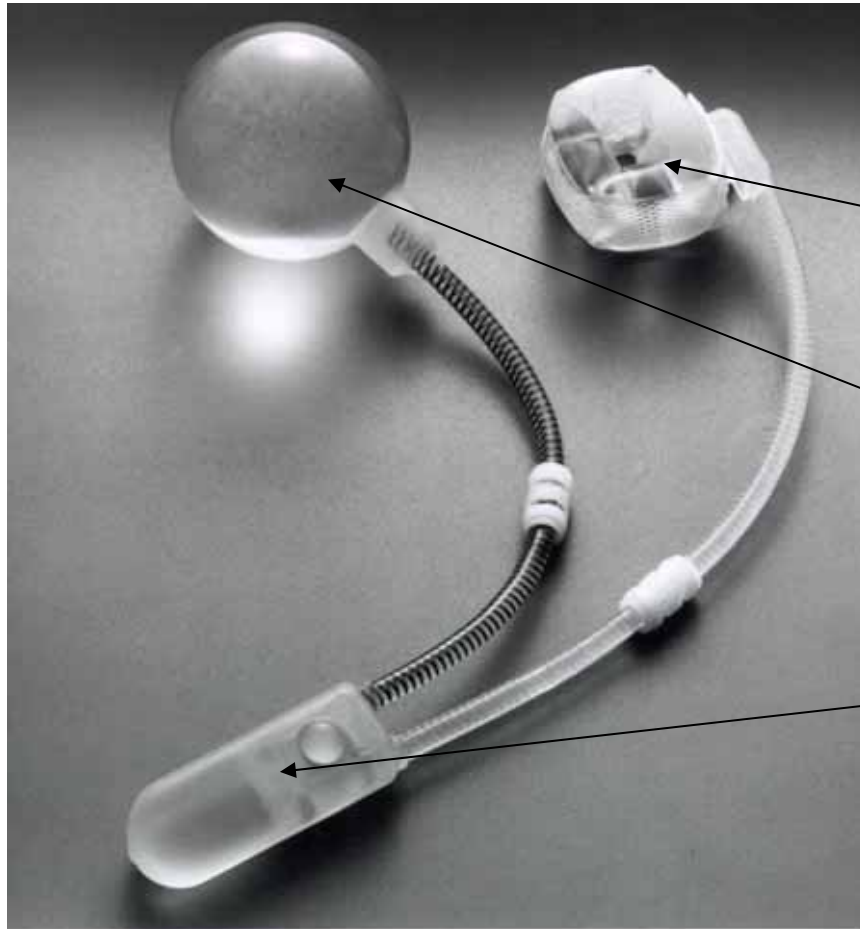
# AMS Sphincter 800™

## History

- Created by Brantley Scott in 1972
- Device Updates
  - Narrow backed cuff
  - KRT
  - Quick Connectors
  - Y Connector
  - Deactivation Button



# AMS Sphincter 800™



**Three components:**

**Cuff**

**Pressure  
Regulating  
Balloon**

**Pump**



# AMS Sphincter 800™

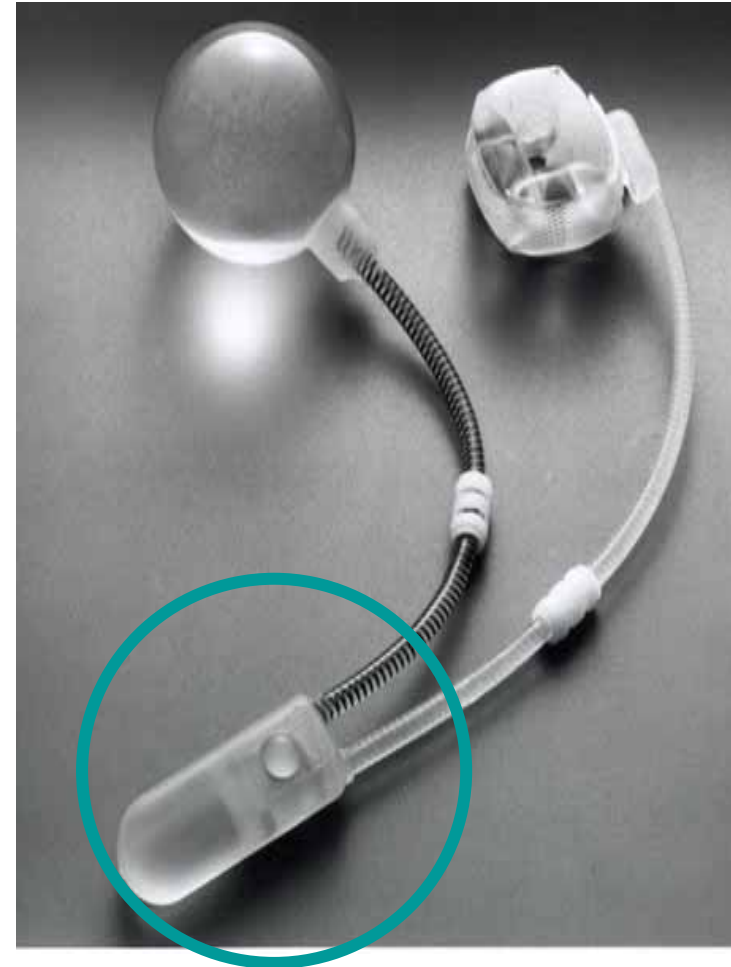
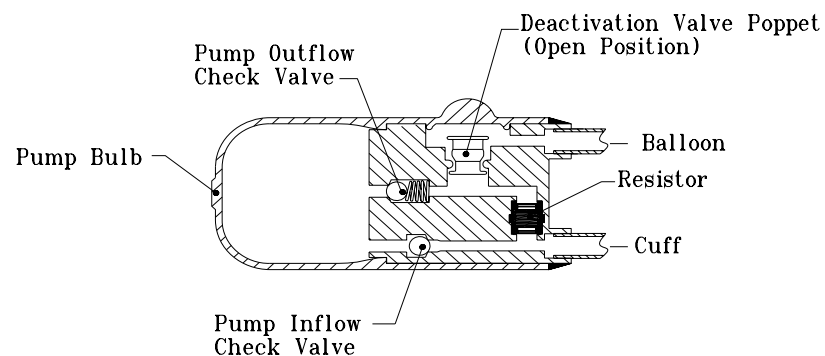
## Loaner Kit Contents

- Control Pump
- Pressure Regulating Balloon
  - 51-60cm, 61-70cm, 71-80cm
- Occlusive Cuff
  - 4.0-7.5 (.5 increments), 8.0-11.0 (whole increments)
- Accessory Kit
  - Quick Connect™ Sutureless Connectors
  - Suture Tie Connectors
  - 30cm lengths of tubing (2)
  - Blunt tip needles
  - Cuff sizer
  - Y-Connector
- Operating Room Manual
- AMS Quick Connect Assembly Tool
- Patient Information Guide (PIF Form)

# AMS Sphincter 800™

## Control Pump

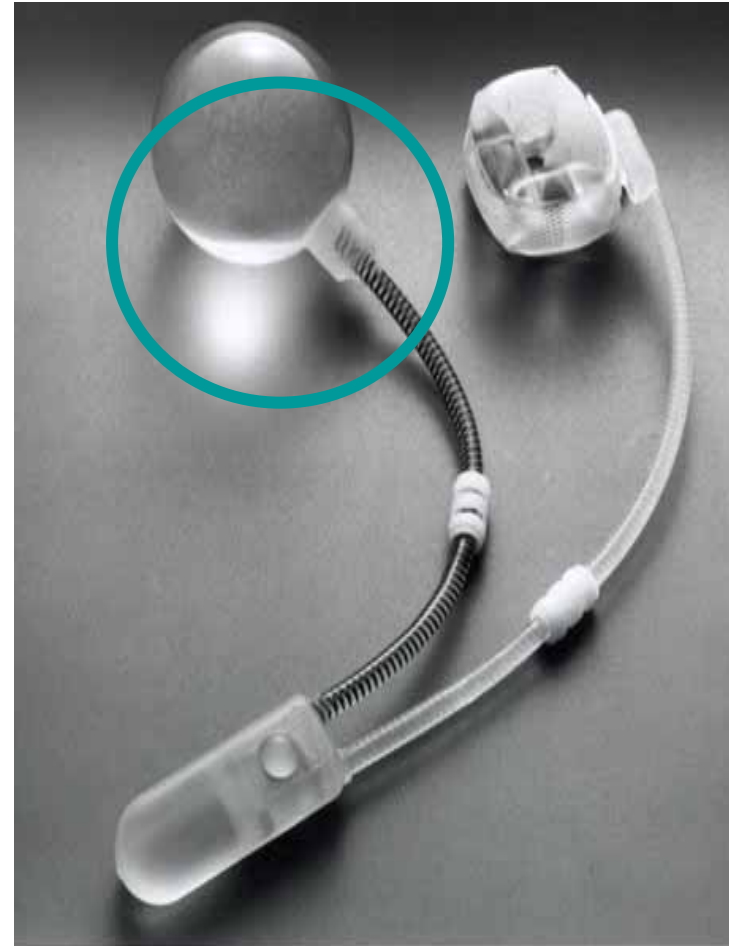
- Regulates the flow of fluid between the Cuff and PRB
- Deactivation Button
  - Allows patient to heal for 6 weeks prior to activation



# AMS Sphincter 800™

## Pressure Regulating Balloon (PRB)

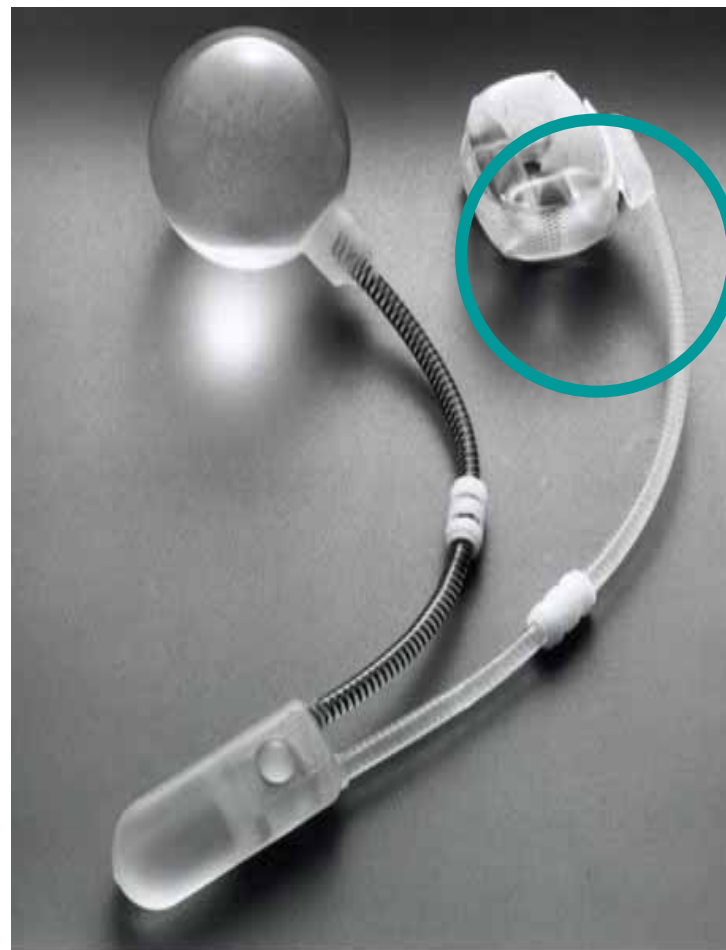
- 3 Pressures
  - 51-60cm H<sub>2</sub>O
    - Traditionally used for radiated patients but latest data shows 61-70 is ok
  - **61-70cm H<sub>2</sub>O**
    - Standard/most used
  - 71-80cm H<sub>2</sub>O
    - Used with bladder neck cases or occasionally on revisions for persistent incontinence



# AMS Sphincter 800™

## Occlusive Cuff

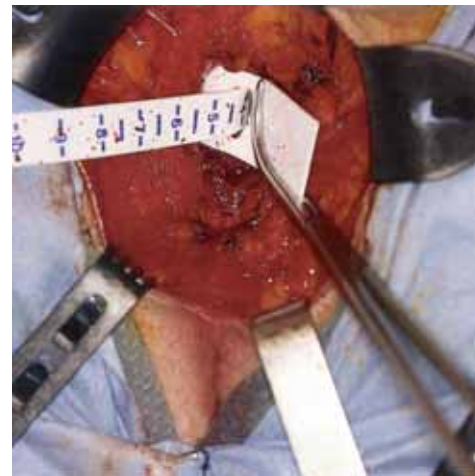
- 4.0 – 7.5 (.5 increments)
- 8.0 – 11.0 (whole increments)



# AMS Sphincter 800™

## AMS Cuff Sizer

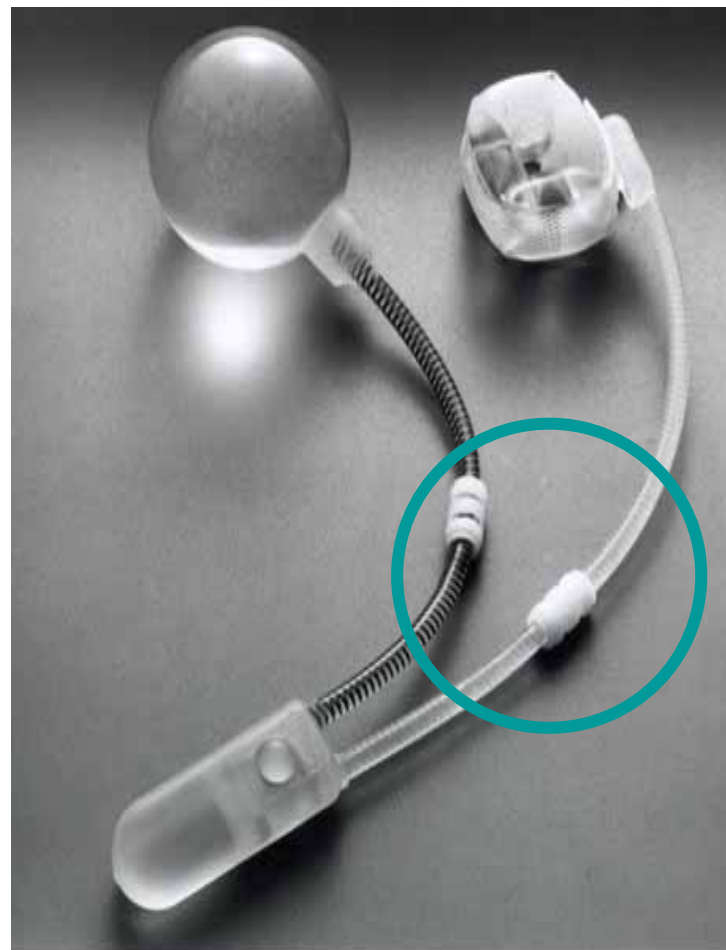
- Determines which size cuff
  - $<4.0 = 4.0$
  - $4.0 - 4.5 = 4.5$
- 2cm wide plane must be created around the urethra to accommodate the cuff
- It's best to remove Catheter prior to measuring
- Too tight = retention
- Too loose = incontinence



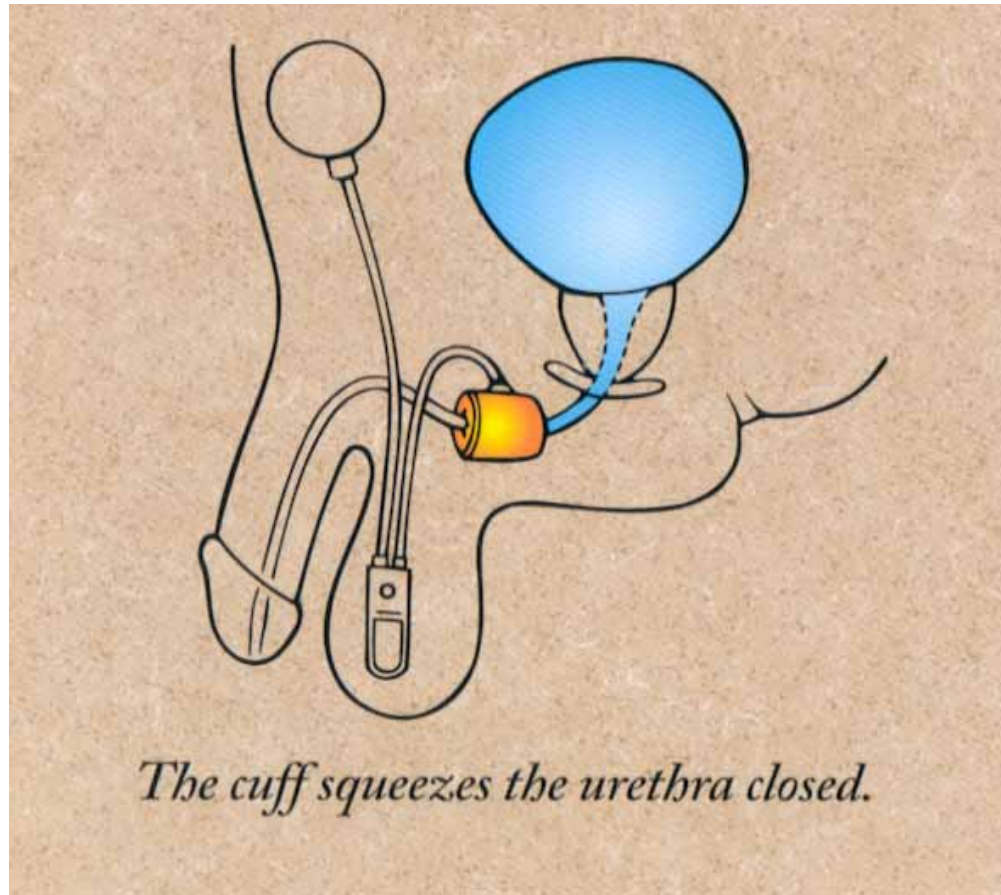
# AMS Sphincter 800™

## Quick Connectors

- Interlocking plastic connectors
- Connected with the AMS Quick Connector tool

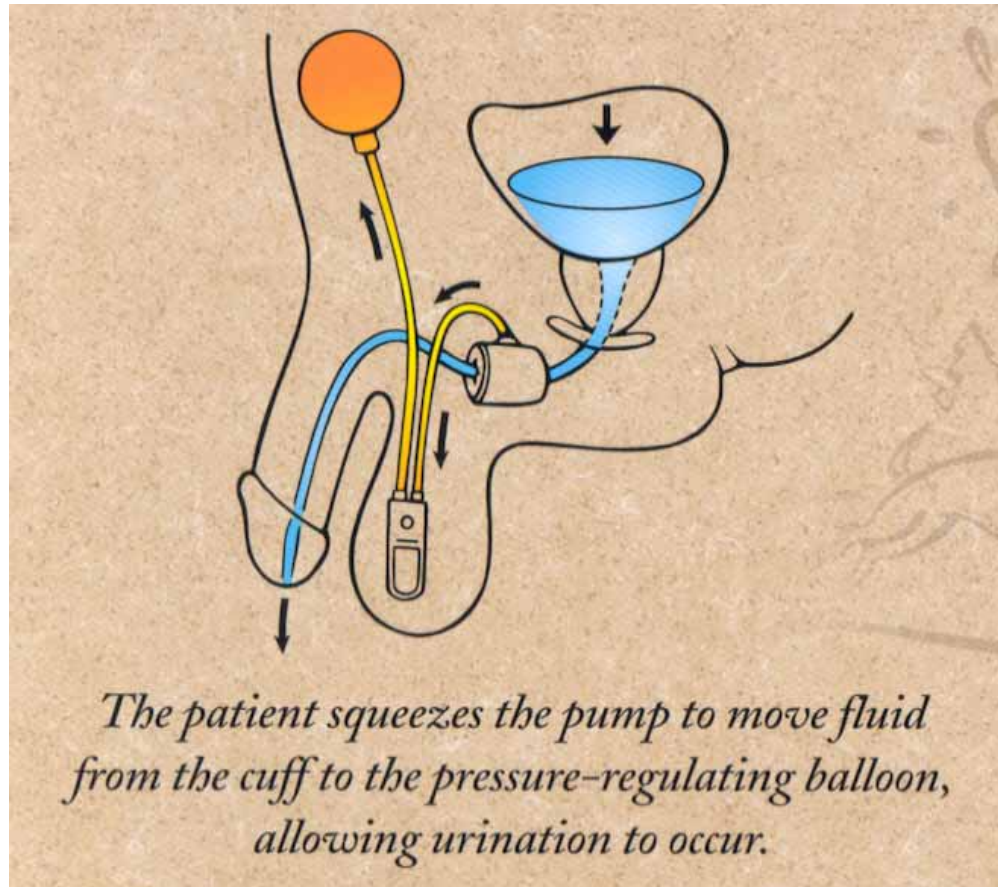


# AMS Sphincter 800™





# AMS Sphincter 800™





# AMS Sphincter 800™



# AMS Sphincter 800™

## Cuff Placement

- Males
  - Bulbous urethra is most common
  - 4.0 or 4.5cm cuff most common
  - Bladder neck placement used in young men and those who need frequent catheterization (8.0-11.0 for adults)
- Females and Children
- Bladder neck is only option (6.0-8.0cm)
  - Children will need revisions due to their growth

# AMS Sphincter 800™

## Contrast Media

- “Radiocontrast Substances”
- Iodine based
- Various types and dilution chart on page 8 of OR Manual
- Normal saline is the recommended isotonic solution to use

# AMS Sphincter 800™

## Contrast Media - Pros

- Allows X-ray of AUS to help diagnose malfunction
- Habit

# AMS Sphincter 800™

## Contrast Media - Cons

- It's expensive
- Frequently requires last minute scrambling for the right type
- Improper mixing by surgical staff can result in a non-isotonic solution and fluid loss
- Unknown potential for iodine allergies
- Nominal benefit
  - X-rays are seldom conclusive – 10ccs in PRB can look normal
  - Any malfunction must be corrected surgically
  - Kinks in tubing are very rare since introduction of KRT

# AMS Sphincter 800™

AMS 800™ Surgical Procedure

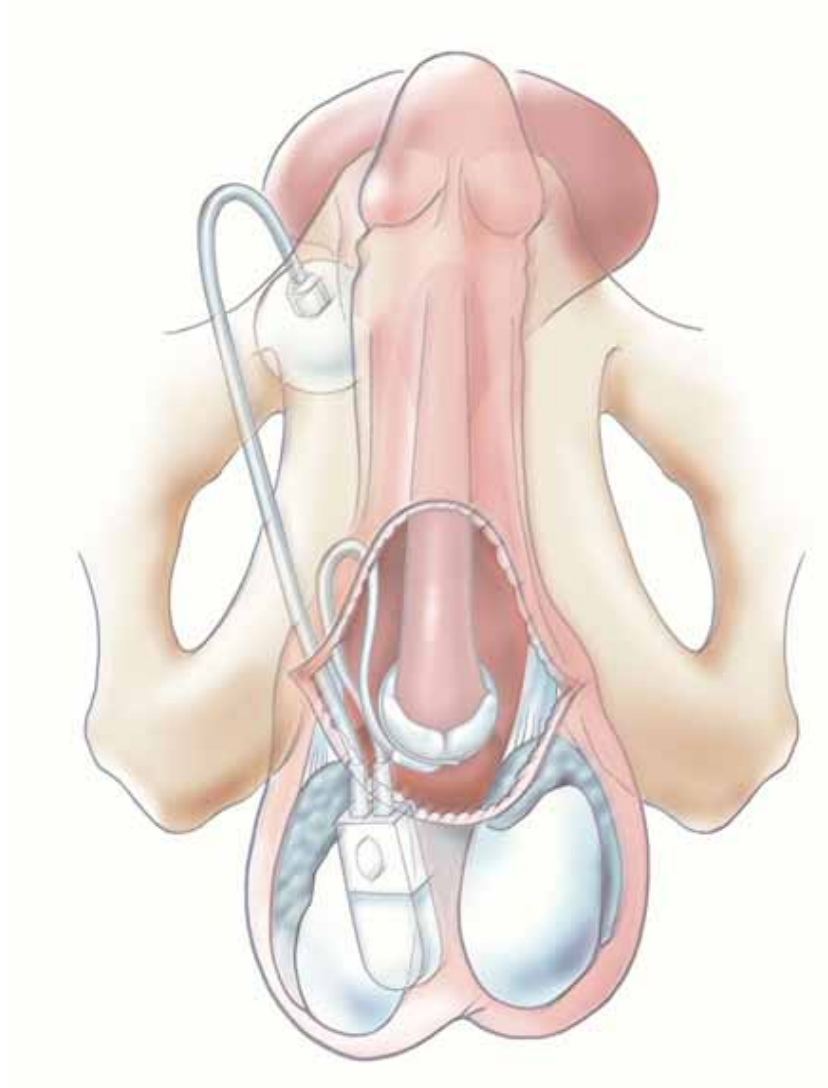
Dr. Steven Wilson

University of Arkansas

# AMS Sphincter 800™

## **The Transverse Scrotal Approach**

*A New Technique for  
a Proven Surgical Method*



# AMS Sphincter 800™

## Drawbacks of the Perineal Approach

- Time consuming
  - 1-1.5 hours
- Blind dissection
- Healing of perineal incision is uncomfortable for patients
- Incision site in close proximity to rectum
  - Potentially greater risk of infection



# AMS Sphincter 800™

## Questions about the TVS approach

- Is the cuff in the same place?
- Is the exposure equivalent?
- Is the PRB placement easy?
- Can you explant and/or reimplant from this incision?
- Is double cuff placement possible?

# AMS Sphincter 800™

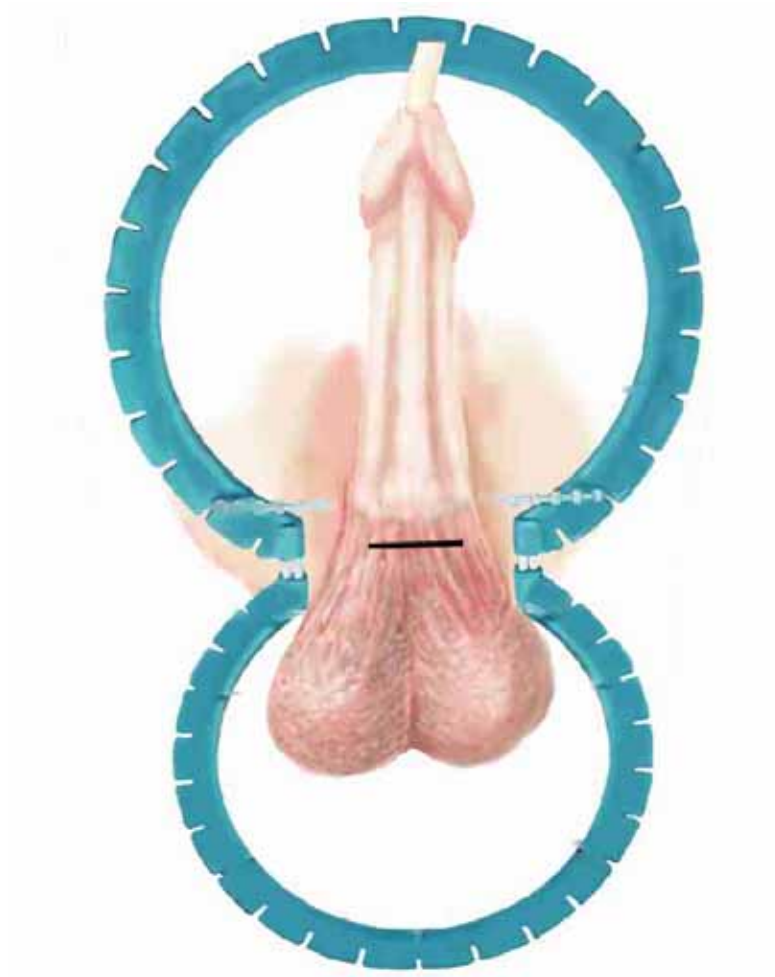
## Critical Success Factors to the TVS approach

- Positioning of the patient
  - Low lithotomy position



# AMS Sphincter 800™

Incision



# AMS Sphincter 800™

## Critical Success Factors to the TVS approach

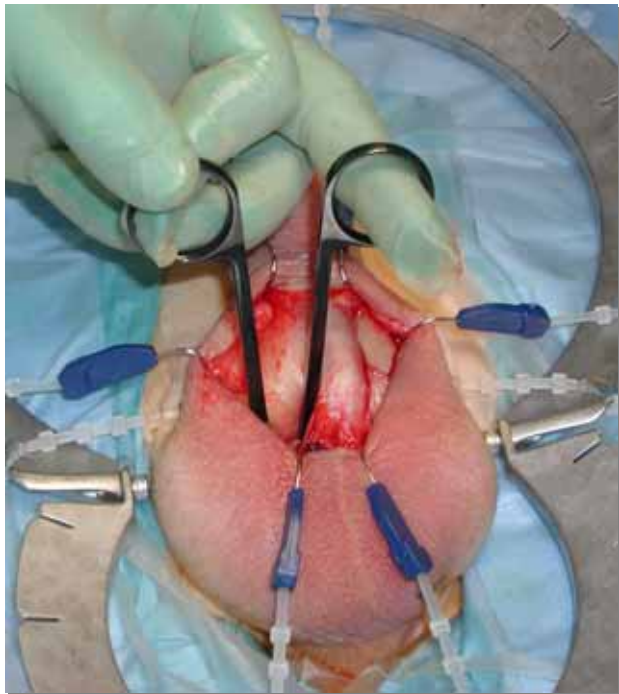
- Exposure using a self retaining retractor (Scott/Wilson)
  - Tight hooks at 9:00 & 3:00
  - Looser hooks at 11:00, 1:00, 5:00 & 7:00



# AMS Sphincter 800™

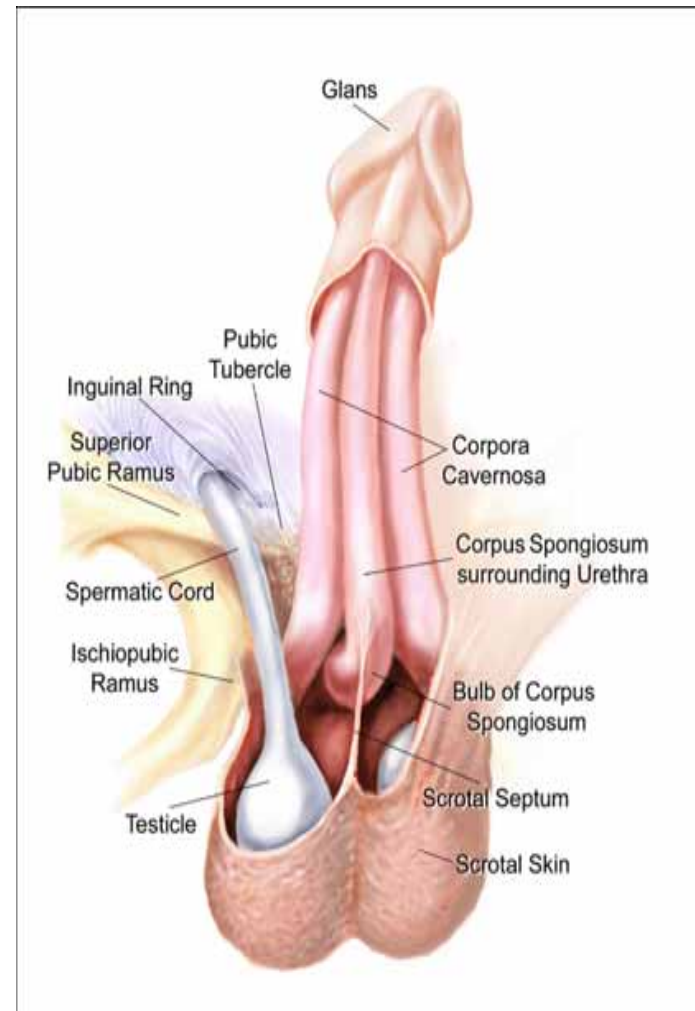
Critical Success Factors to the TVS approach

- Proximal exposure to Ischial Tuberosity



# AMS Sphincter 800™

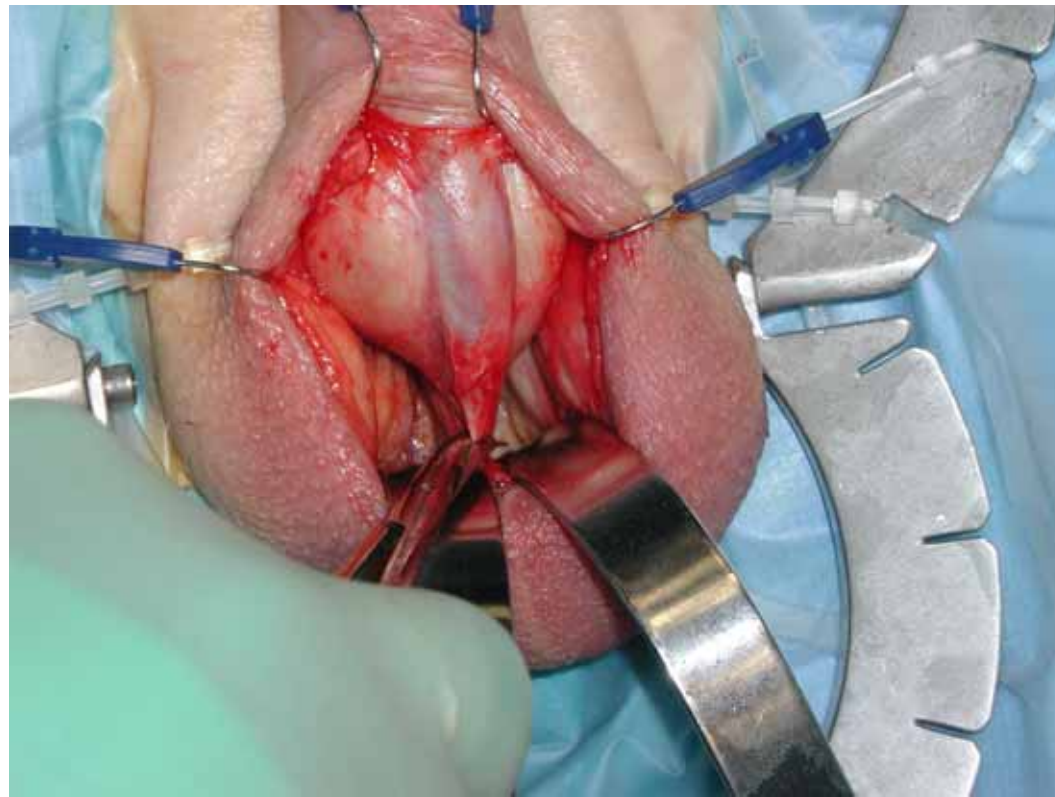
Scrotal Septum is isolated





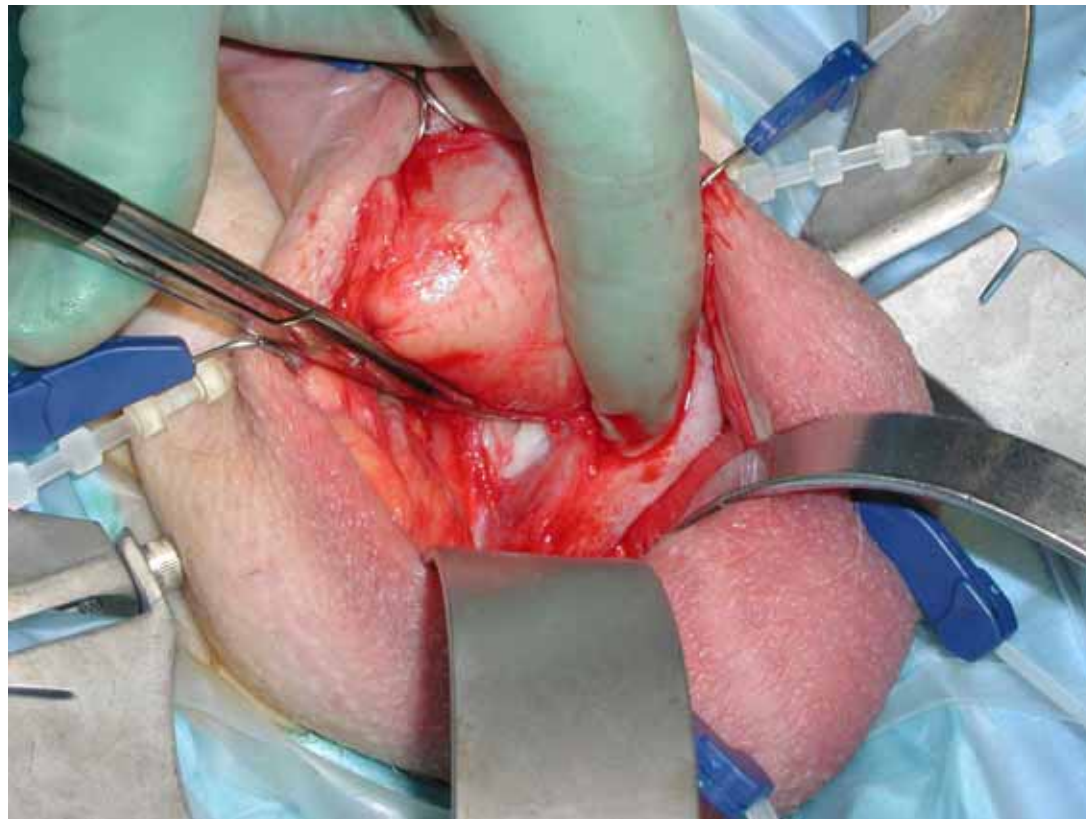
# AMS Sphincter 800™

Taking down the Scrotal Septum



# AMS Sphincter 800™

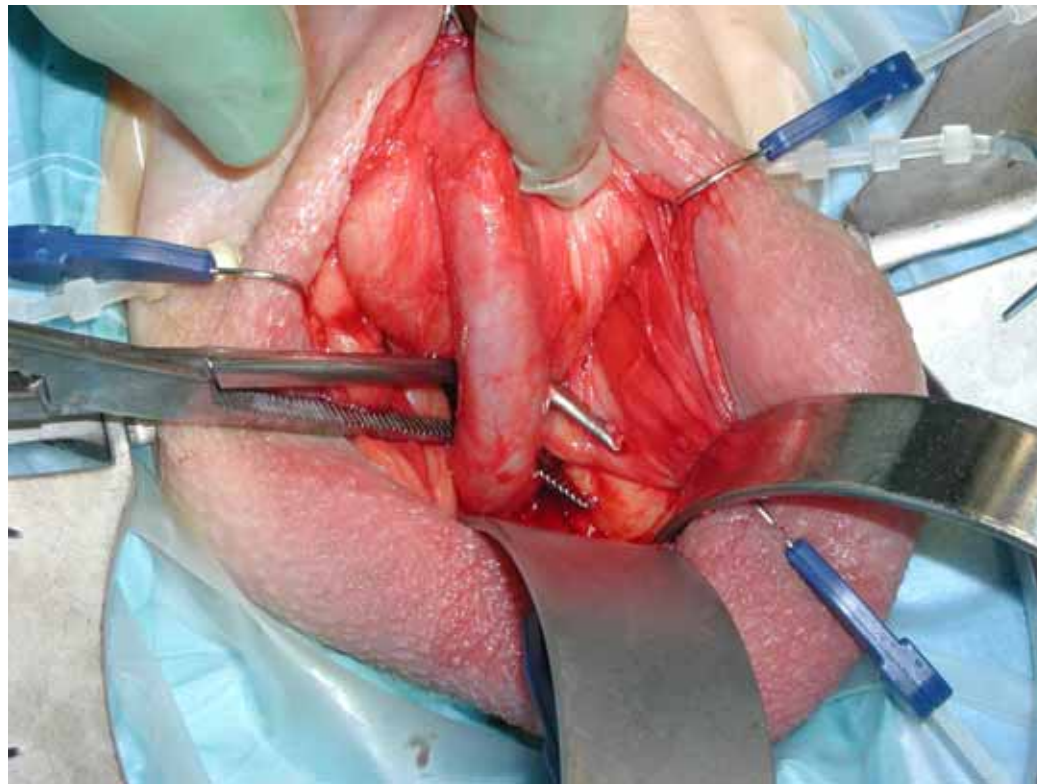
Dissection of Buck's Fascia





# AMS Sphincter 800™

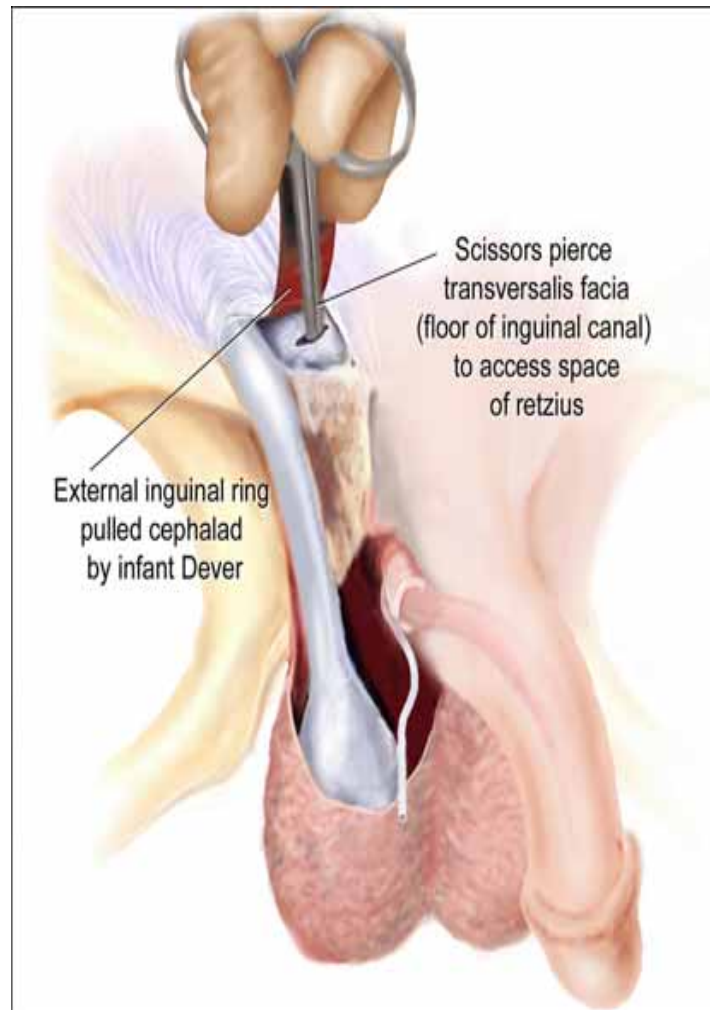
## Urethral Dissection



# AMS Sphincter 800™

## Pressure Regulating Balloon Placement

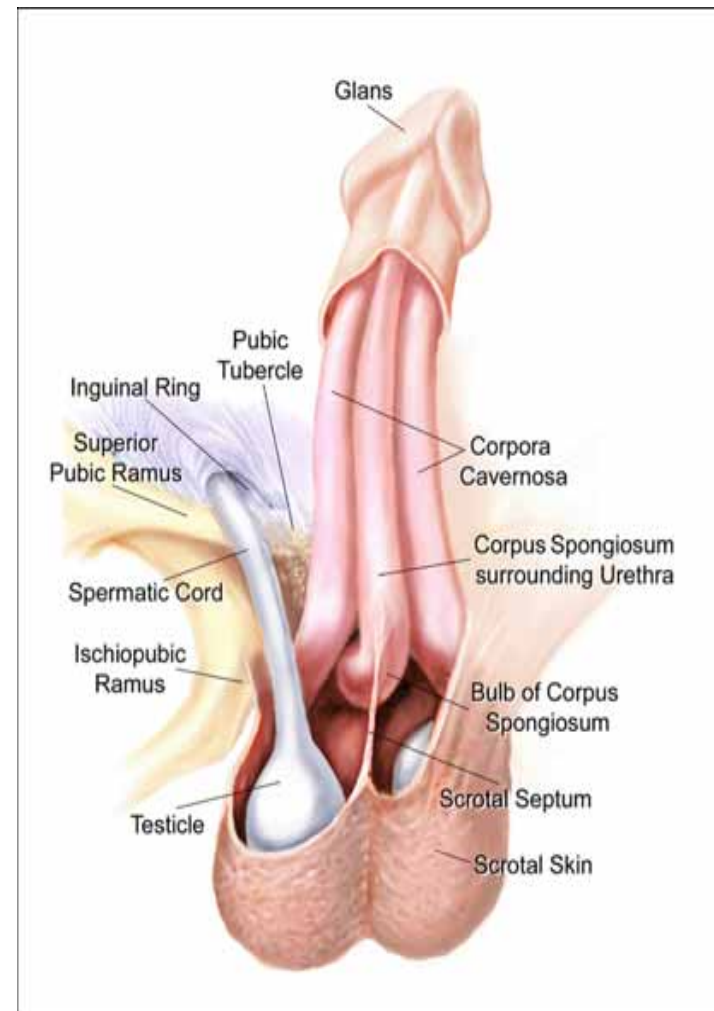
- Identification of external inguinal ring
- Puncture of the transversalis fascia medial to the cord



# AMS Sphincter 800™

## Alternate Pressure Regulating Balloon Placement

- External inguinal ring is located
- Finger dissection is used to develop a pouch beneath the rectus muscle
- After placement, the opening is narrowed with a suture



# AMS Sphincter 800™

## TVS approach Summary

- Great time savings
  - Mean operative time of 35 minutes (20-52)
- Simpler dissection and easier urethral exposure
- Elimination of discomfort related to healing of perineal incision
- Easier PRB placement
  - Less distance and greater exposure to inguinal ring

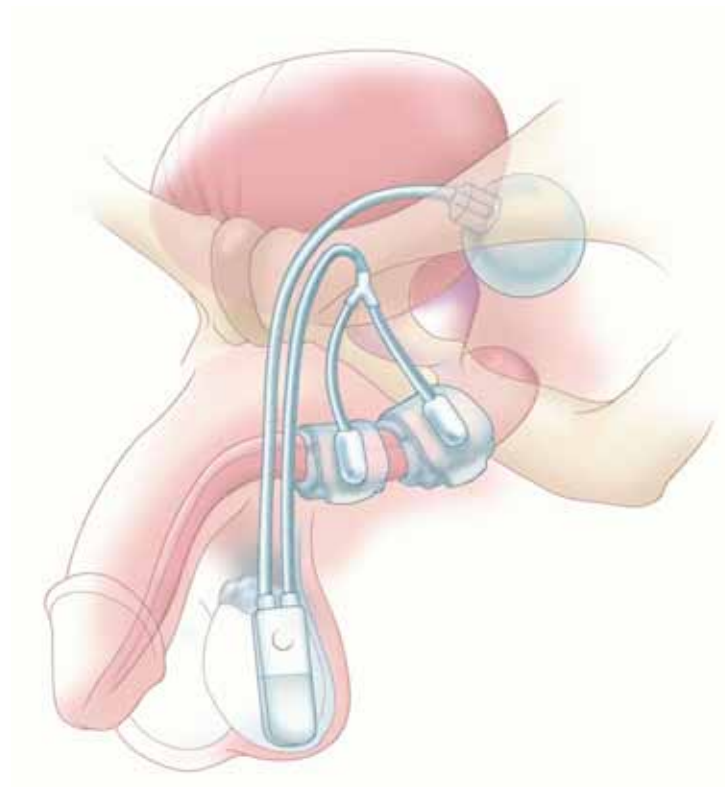
# AMS Sphincter 800™

## TVS approach Summary (continued)

- Easier pump placement in all patients, particularly the obese population
- Revisions are simpler
  - Single incision, greater exposure to all components for explant/implant
- Comparable clinical outcomes
  - Dr. Wilson's 2 year data
- ❖ Step-by-step guide on pages 18-20 in OR Manual

# AMS Sphincter 800™

AMS 800 Double Cuff For Severe Incontinence



# AMS Sphincter 800™

## Addition of a Second Cuff

- Measure width for both cuffs
  - Don't just measure the first and assume the second will be the same
  - Urethra width narrows the closer to the head of the penis
- Second cuff site is selected either proximal or distal to original site
- Leave 1-2cm gap between cuffs to prevent wear
- Add 2cc to system for new cuff
- If original cuff has been in place for over 3 yrs, consider replacing it when adding the second cuff

# AMS Sphincter 800™

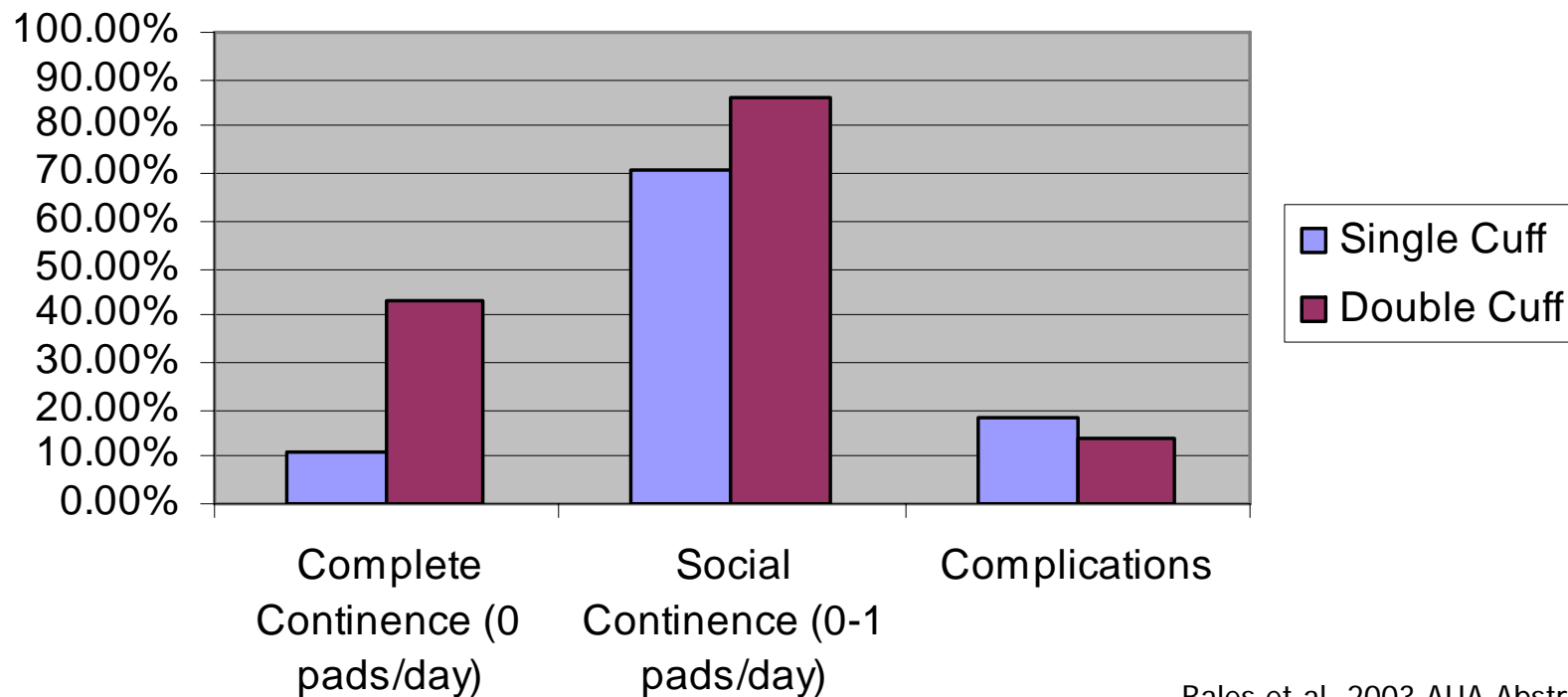
## AMS 800 Double Cuff Is The Treatment of Choice For Severe Incontinence

- Why not give the severe patient the best chance of being dry?
- Long-term Experience With The Double-Cuff
  - Dr. John Mulcahy, Order #0556 (51 AUS in '03 – 21 DC)
  - N = 95
  - Follow up = 9 years
  - PPD before surgery = 6-10
  - PPD after surgery = 0-1 in 90% of patients



# AMS Sphincter 800™

## Comparison of Outcomes Following Single and Double Cuff AUS Implantation



# AMS Sphincter 800™

## Results

# AMS Sphincter 800™

- 90% of male patients reported satisfaction with the AMS 800™
- 92% of male patients would have the AMS 800™ placed again
- 80% of males were socially continent using 0-1 pad per day at 7 years
- For over 30 years, the AMS Sphincter 800™ has been the gold standard to treat urinary incontinence

# AMS Sphincter 800™

**“Artificial sphincter implantation is clearly the treatment of choice for postprostatectomy urinary incontinence. 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 it does this at a cost comparable to collagen injections and with a reasonable safety profile.”**

Drogo K. Montague, M.D.  
Cleveland Clinic  
Urology, 2000

# AMS Sphincter 800™

- *“Long-Term Analysis of the Durability of the AMS 800: A Review of 323 Cases”*

- Daniel S. Elliott, M.D.  
David M. Barrett, M.D.

- *Journal of Urology*  
Vol. 159, 1206-1208 April  
1998

## *Conclusions:*

- Excellent long-term solution and increased continence in correctly selected patients with urinary incontinence
- At a mean 68.8 months (5.7 yrs), 72% of patients had original sphincter without revision surgery

# AMS Sphincter 800™

- “The Long-Term Outcome of Artificial Urinary Sphincter”

- R. Mundy, M.D.

- *Urology* Vol. 56, 600-603 2000

## Conclusions:

- The AUS is an effective long-term treatment for male incontinence
- 92% of patients were continent at 10 years
- Device survival was 66% at 10 years

# AMS Sphincter 800™

Myth	Reality
Big Surgery	58% of patients are day cases
Costly	Comparable to bulking agents
High Erosion Rate	3.6%
High Infection Rate	2.3%
Mechanical Failures	4.4%

# AMS Sphincter 800™

## Complications



# AMS Sphincter 800™

## Intraoperative Urethral Perforation

- Inject methylene blue dye or diluted betadyne into the urethra to identify lacerations
- 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 consider implanting lower PRB.
- Deactivate for a longer period of time (8-12 weeks)
- Come back later if perforation is too large

# AMS Sphincter 800™

## Intraoperative Bladder Perforations

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

# AMS Sphincter 800™

## Persistent Incontinence

- Bladder capacity adequate?
- Severe bladder spasms?
- More pumps to empty cuff/ cuff atrophy
- Fluid loss/Cuff coaptation

# AMS Sphincter 800™

## Urethral Atrophy

- Persistent incontinence is the primary reason for revision (6-9%)
- Revision options
  - Increase balloon pressure
    - Increases risk of erosion
  - Downsize cuff size
    - 4.0 cm is smallest
    - Increase risk of erosion
  - Add a second cuff
    - Uses increased length of compression rather than increasing pressure

# AMS Sphincter 800™

## Infection

- No erosion: Mulcahy salvage protocol an option
- Erosion: ALL components must be removed

# AMS Sphincter 800™

## Erosion

- Indications
  - Hematuria
  - Burning on urination
  - Abnormal swelling of scrotum
  - Retention
- No infection: Remove and plug tubing
- No infection and erosion of one cuff of a double cuff system: Possible to convert to a single cuff system (Order #0559)
- Leave 18 Fr. Foley in place for 3 weeks
- Attempt re-implantation in 6 months

# AMS Sphincter 800™

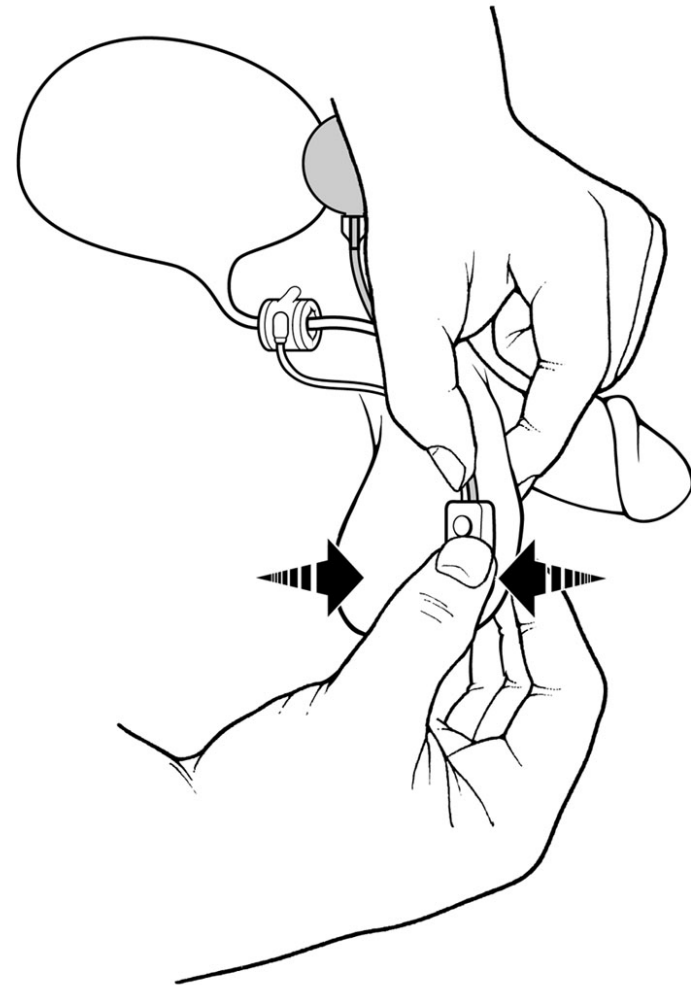
## Diagnosing a Malfunction

- Cycle the device
  - Confirm proper function
  - Confirm device is activated
- Cystoscopy
- X-Ray if contrast media used
- Surgical Exploration

# AMS Sphincter 800™

## Sticky Poppets

- Grasp the tubing above the pump
- DO NOT hold the upper half of the pump while attempting to deactivate
- Page 24 in OR Manual





# AMS Sphincter 800™

AMS 800 = Opportunity

- The Gold Standard
- Over 65,000 cases in 32 years
- Very high patient satisfaction rate
- Great opportunity for growth
- Still a lot of interest
- TVS Approach