



AMS Sphincter 800™ Urinary Prosthesis

AMS Sphincter 800™

Occlusive Cuff

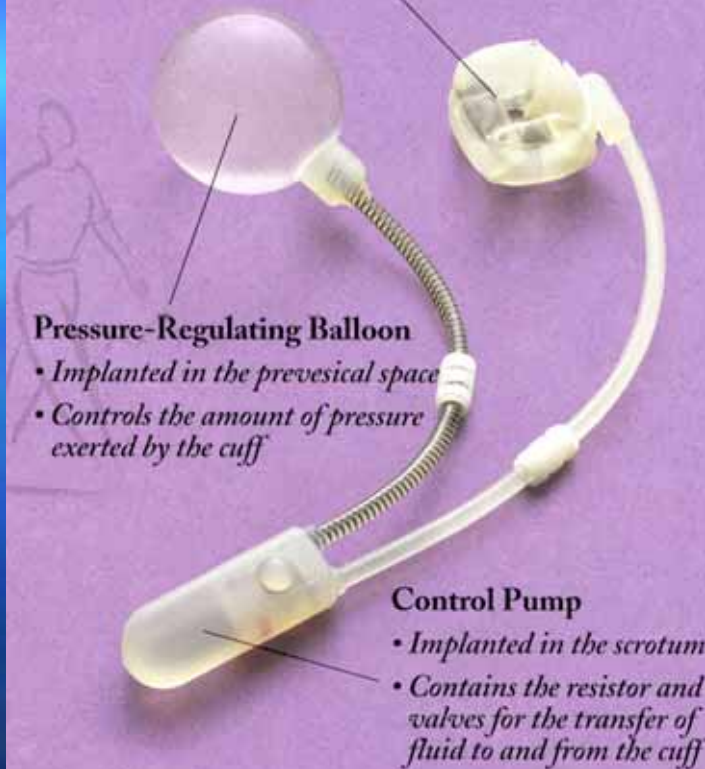
- *Implanted around the urethra at the bladder neck or bulbous urethra*
- *Applies pressure circumferentially when inflated*

Pressure-Regulating Balloon

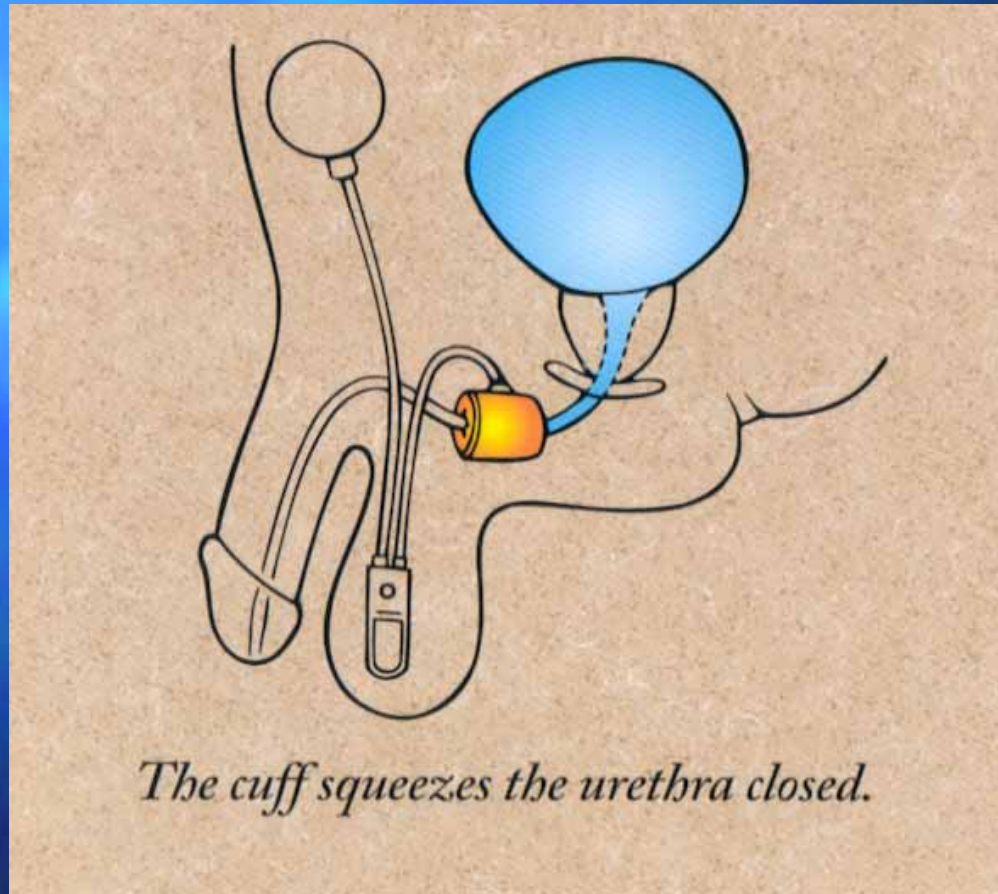
- *Implanted in the prevesical space*
- *Controls the amount of pressure exerted by the cuff*

Control Pump

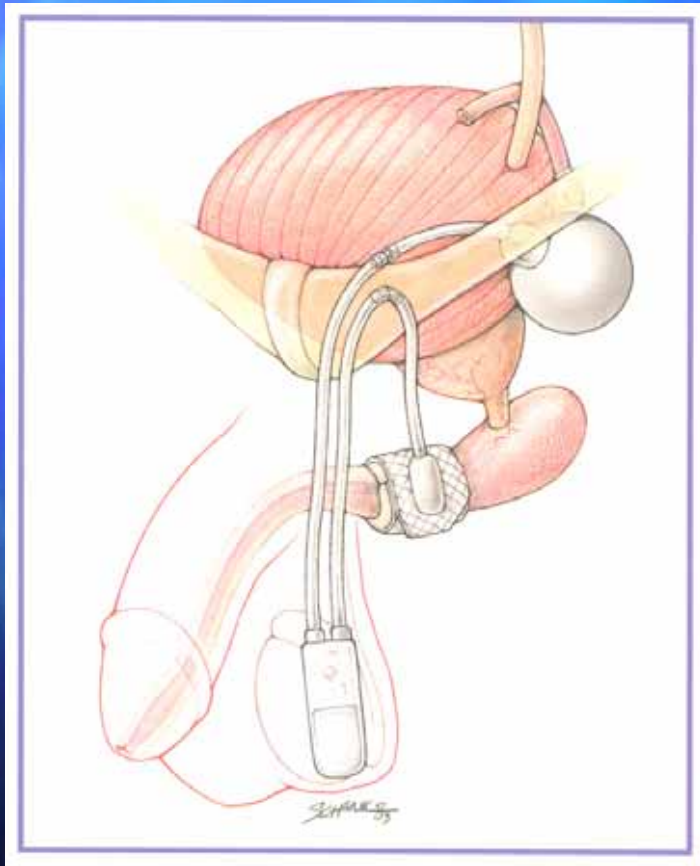
- *Implanted in the scrotum*
- *Contains the resistor and valves for the transfer of fluid to and from the cuff*



AMS Sphincter 800™

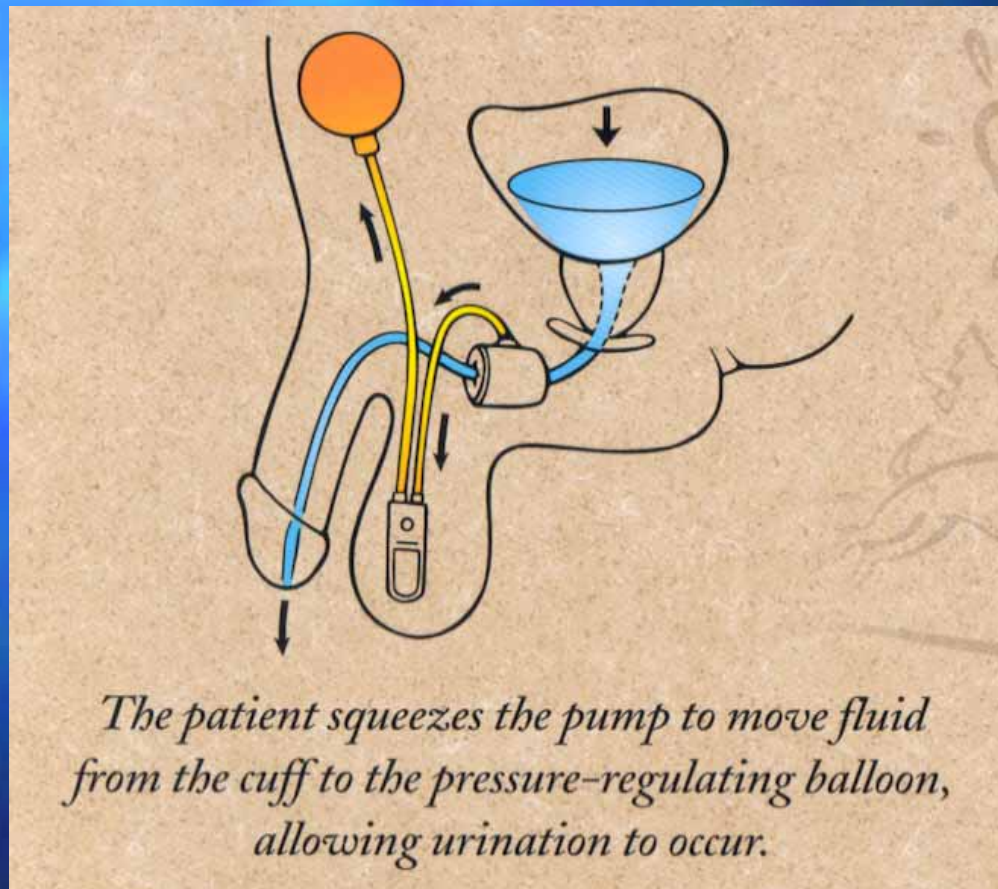


AMS Sphincter 800™

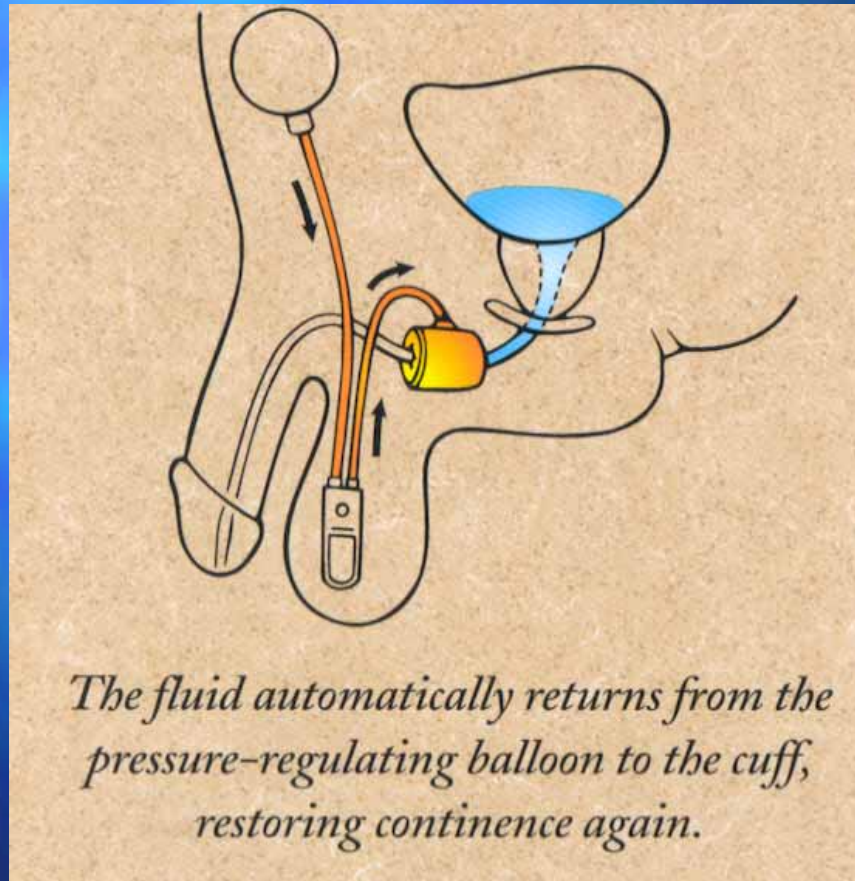


- The device is implanted in the body and cannot be seen.
- The cuff can be placed at the bulbous urethra or at the bladder neck.
- The Sphincter allows the patient to control his/her urinary function.

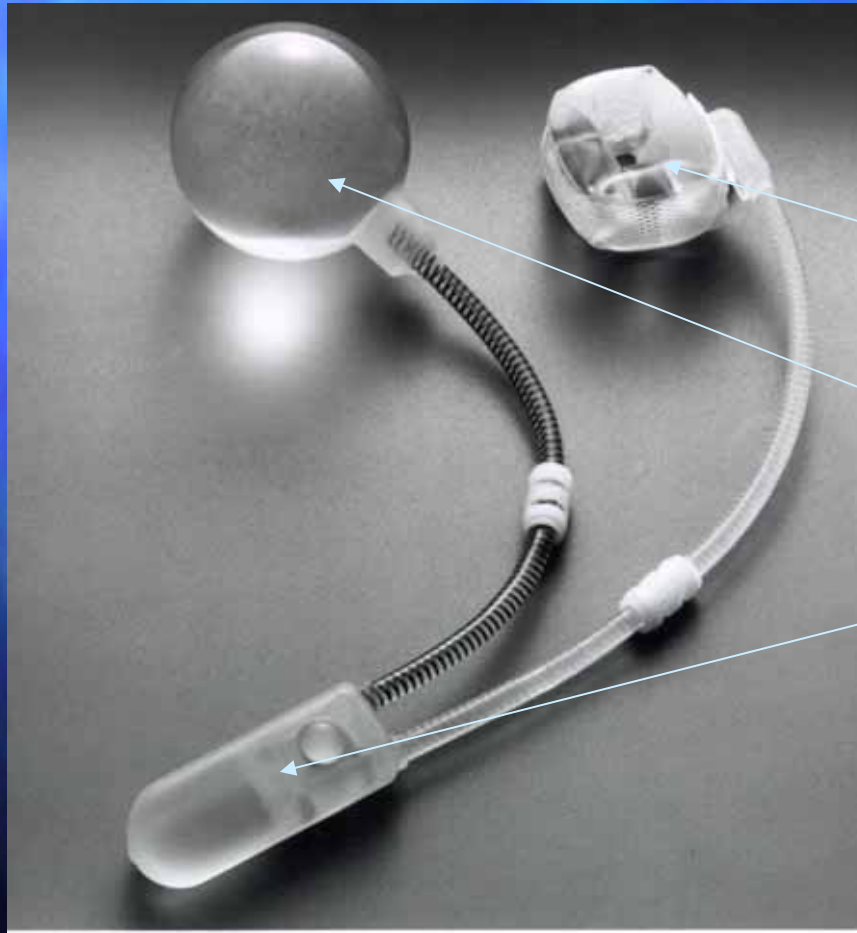
AMS Sphincter 800™



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Consists of three components:

Cuff

Pressure Regulating
balloon

Pump

Occlusive Cuff



Sizes include:

4.0cm	7.5cm
4.5cm	8.0cm
5.0cm	9.0cm
5.5cm	10.0cm
6.0cm	11.0cm
6.5cm	
7.0cm	

Pressure Regulating Balloon



3 Pressures:

51-60cm H₂O

61-70cm H₂O

71-80cm H₂O

Pressure Regulating Balloon Placement

q Look at:

- q Tissue quality
- q Cuff size
- q Activity level
- q Diagnosis



Patient Selection and Evaluation

Patient Selection Criteria

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

Patient Selection Criteria

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

Contraindications

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

Contraindications

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

Patient Evaluation

- q 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

- q 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
- q Visual inspection of urethral mucosa can indicate health and vascularity of the tissue, especially in radiated patients or post pelvic trauma

Patient Evaluation

q Urodynamics

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

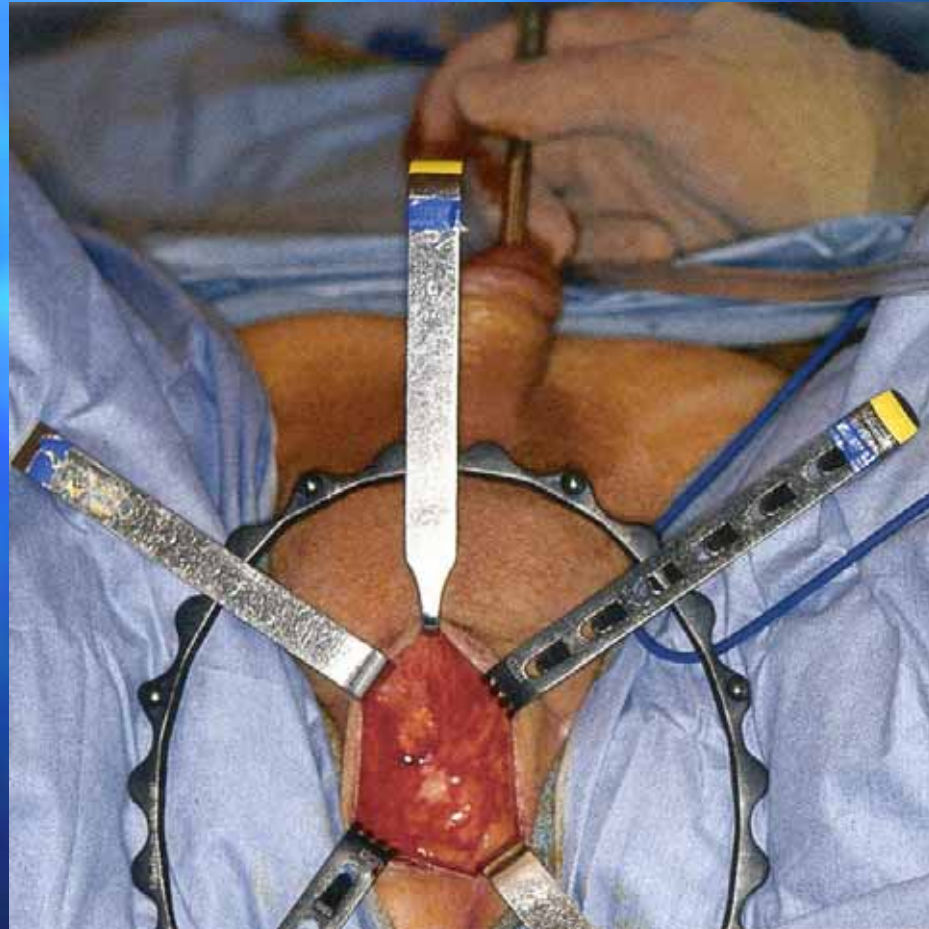
Surgical Procedure



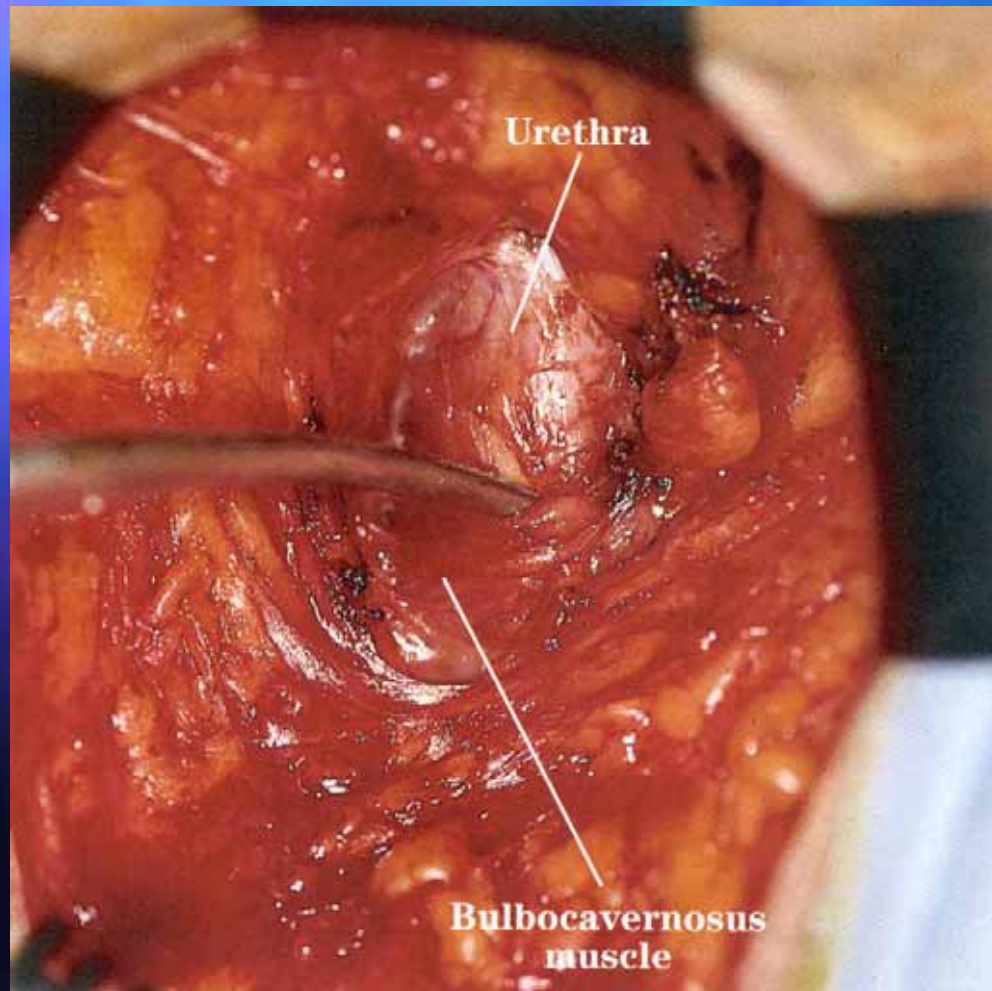
Surgical Procedure



Surgical Procedure

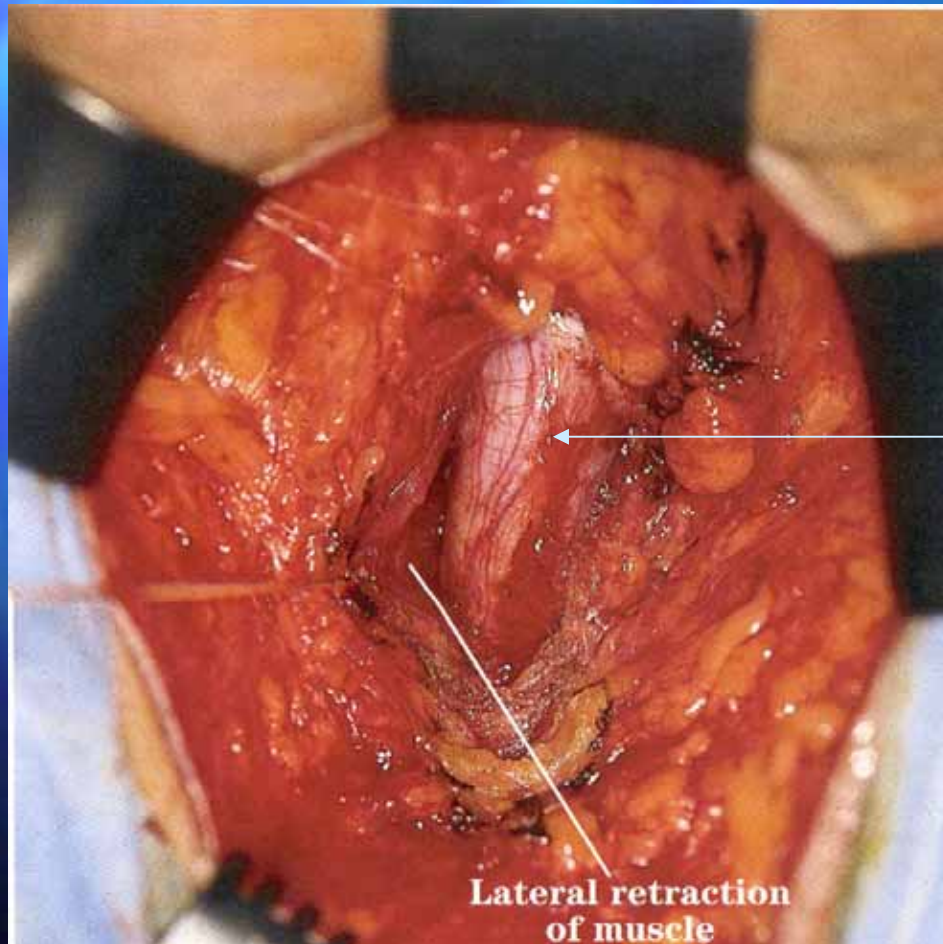


Surgical Procedure



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

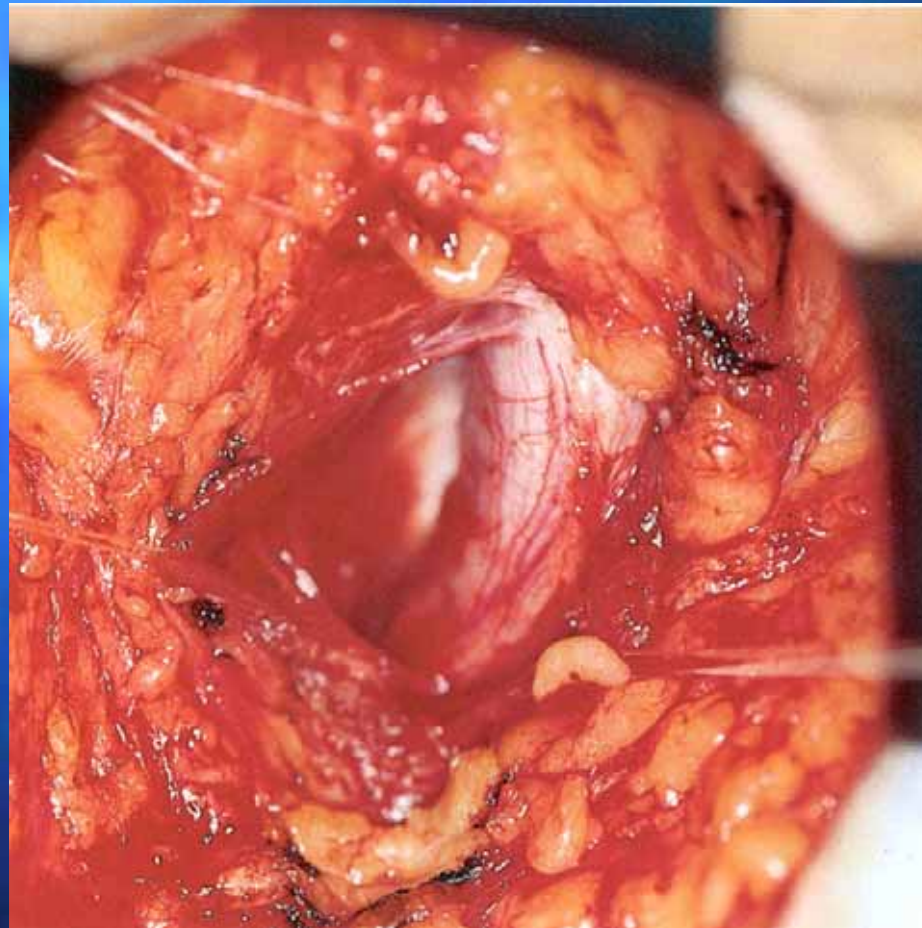
Surgical Procedure



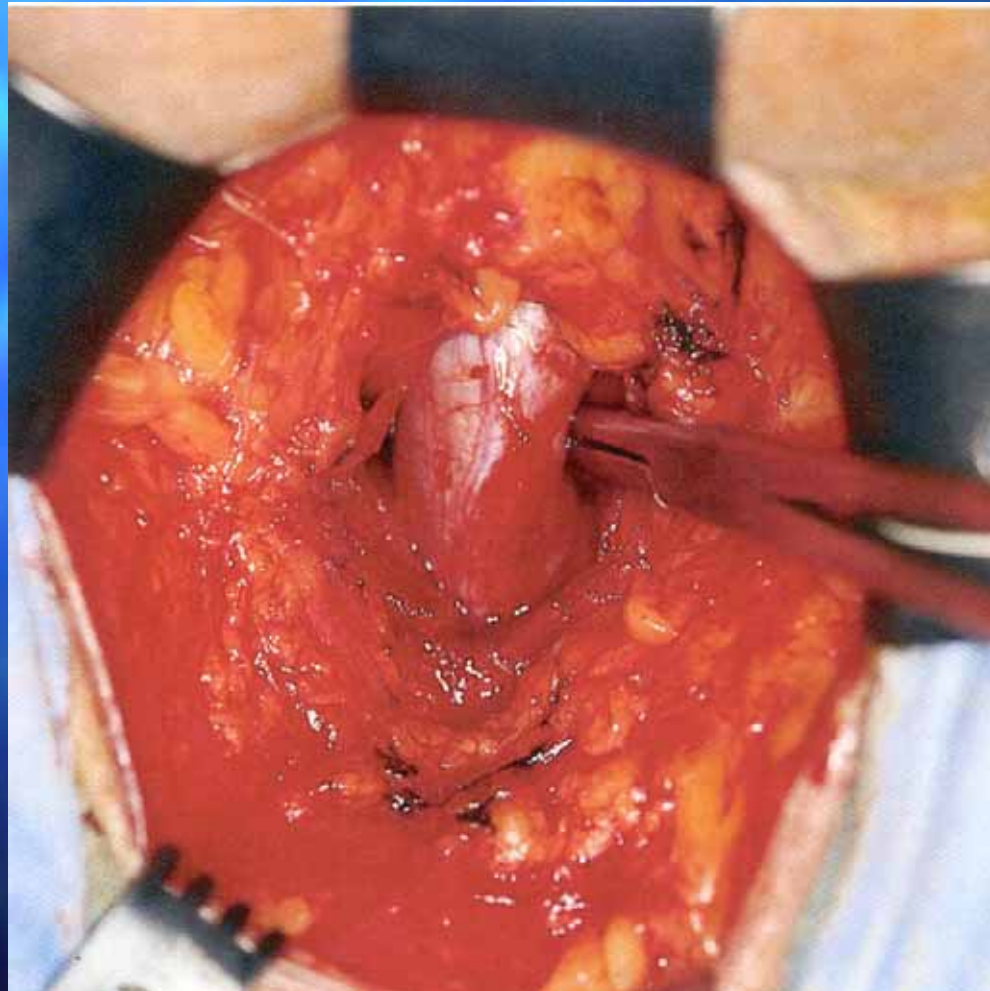
Exposed Urethra

Lateral retraction
of muscle

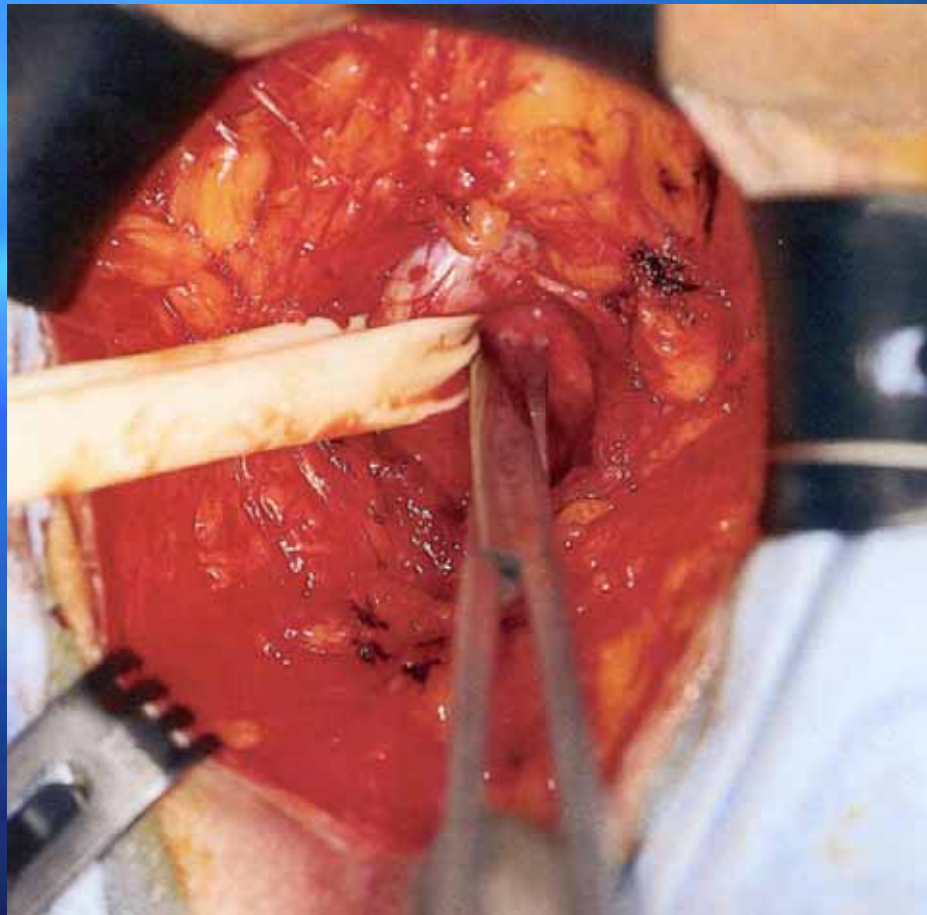
Surgical Procedure



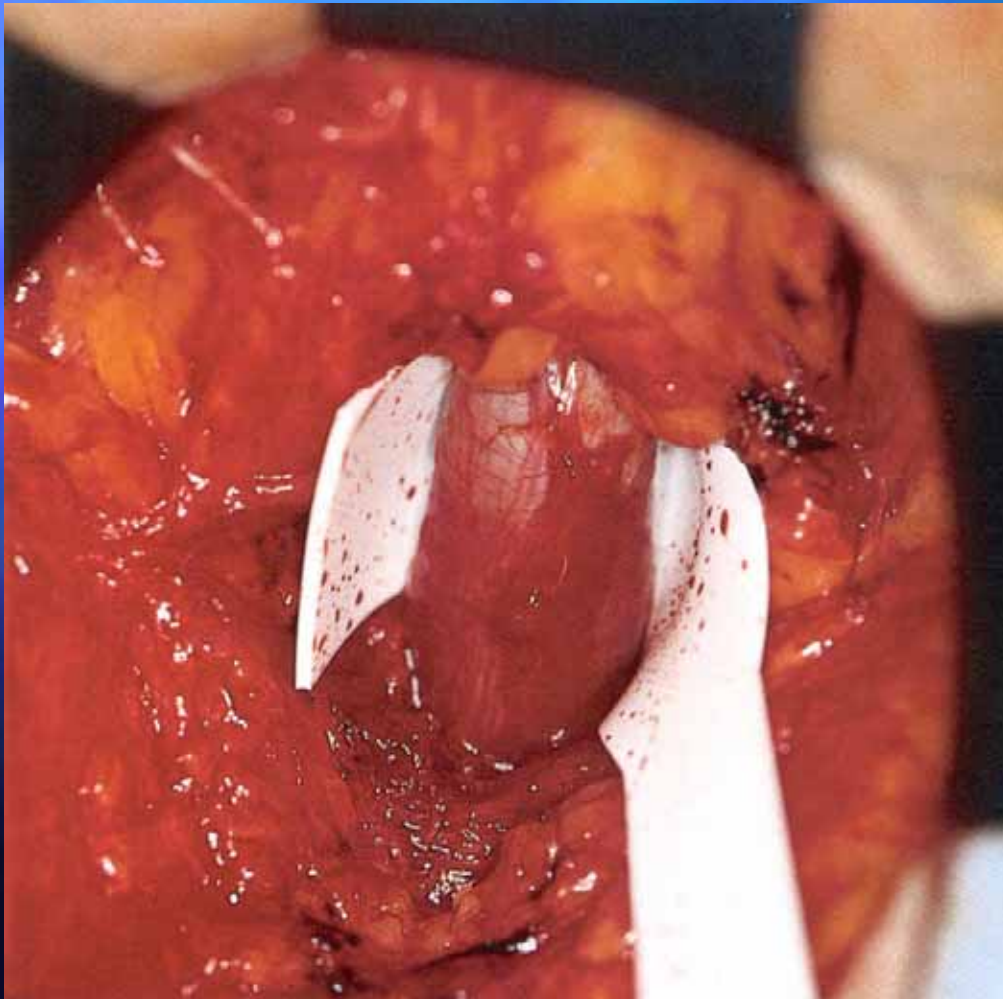
Surgical Procedure



Surgical Procedure

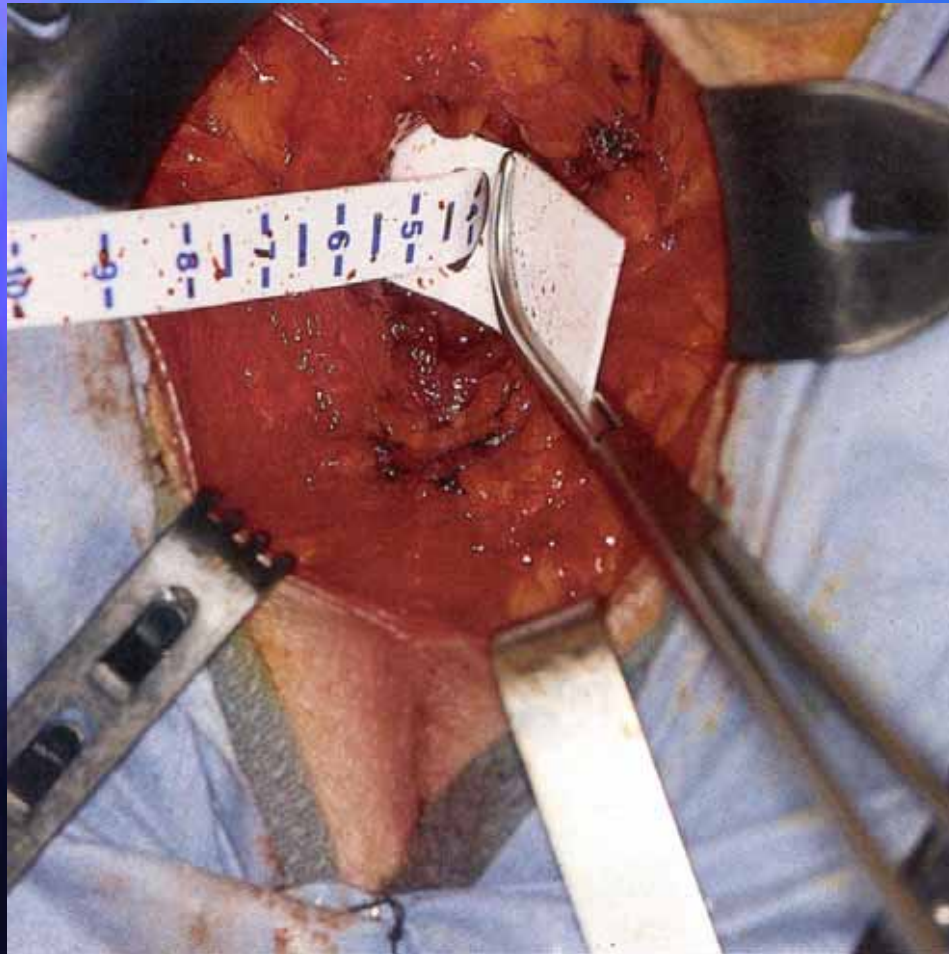


Surgical Procedure



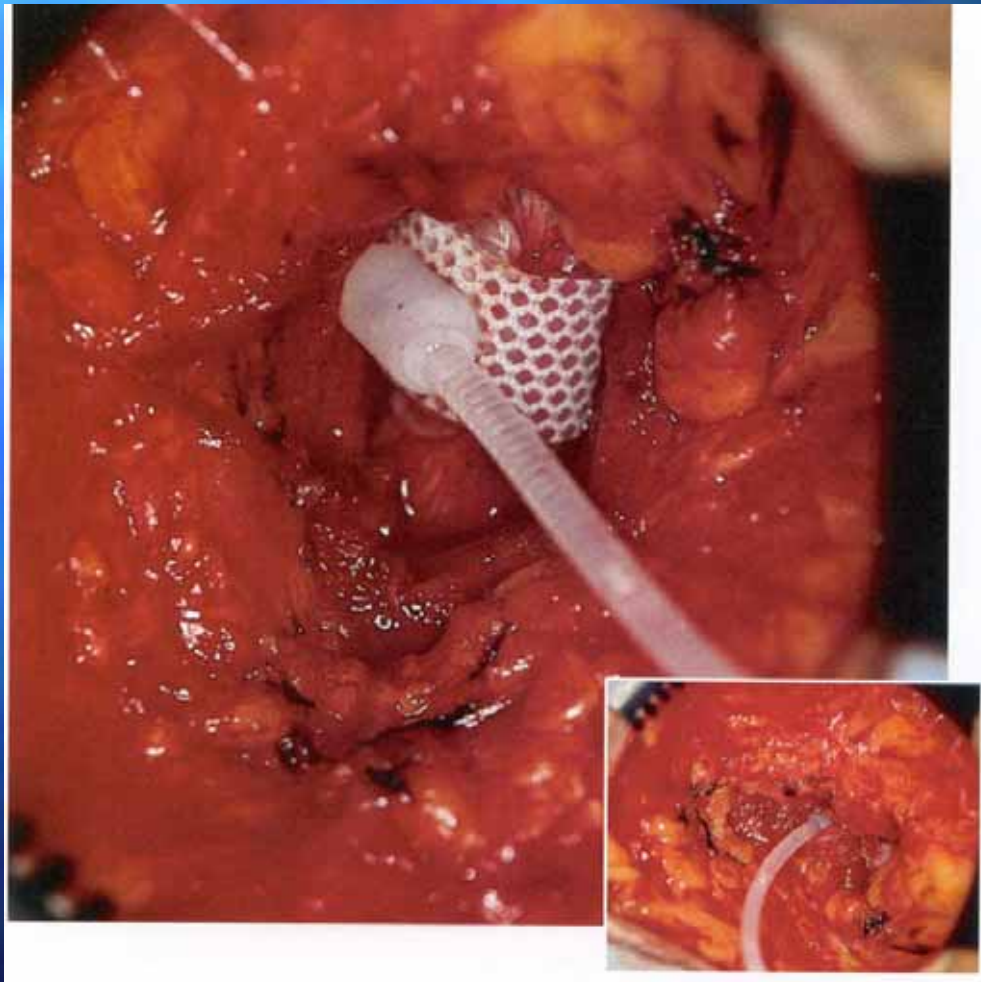
2 cm wide plane must be created around the urethra to accommodate the cuff

Surgical Procedure



Prior to measuring,
remove Foley Catheter

Surgical Procedure



Cuff Placement

q In Males:

- q Bulbous urethra placement most common. 4.0cm to 4.5cm most common
- q 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

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

Surgical Procedure



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



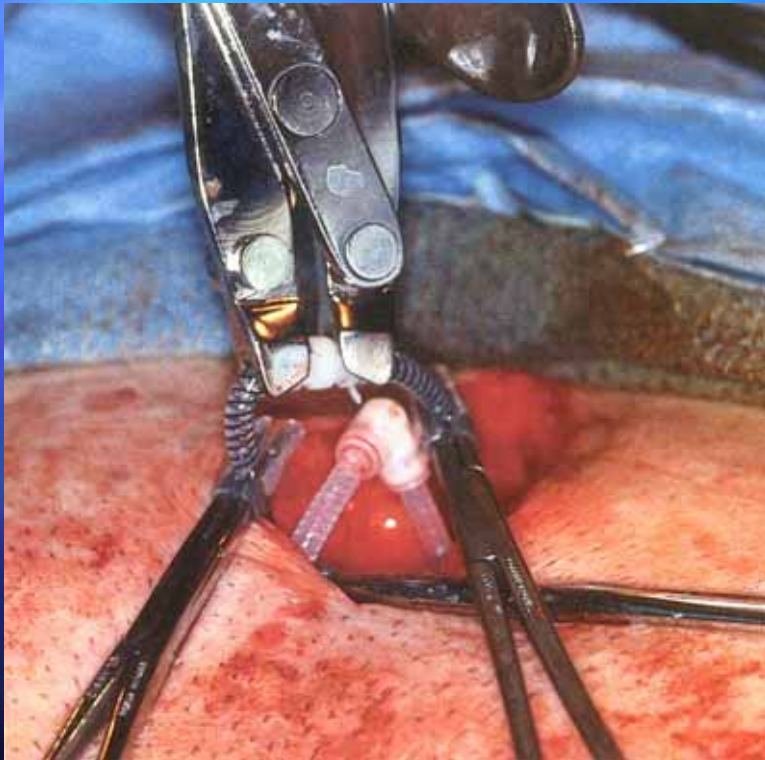
Temporary connection
is made from the cuff to
the PRB to pressurize
the cuff

Surgical Procedure

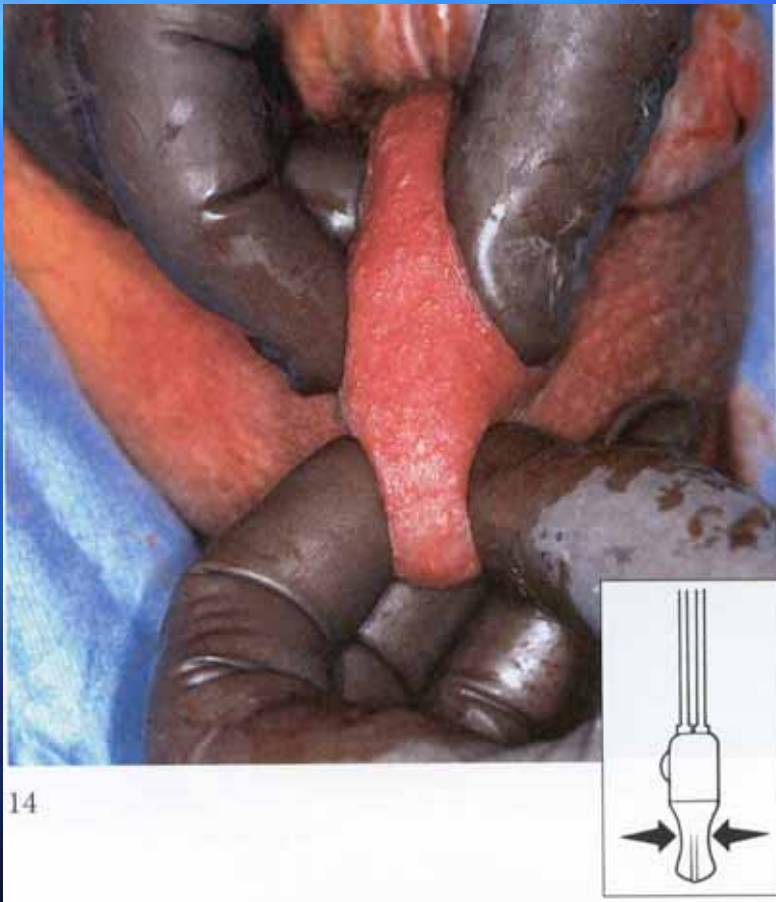


Blunt dissection into scrotum for pump placement

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

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

Positioning



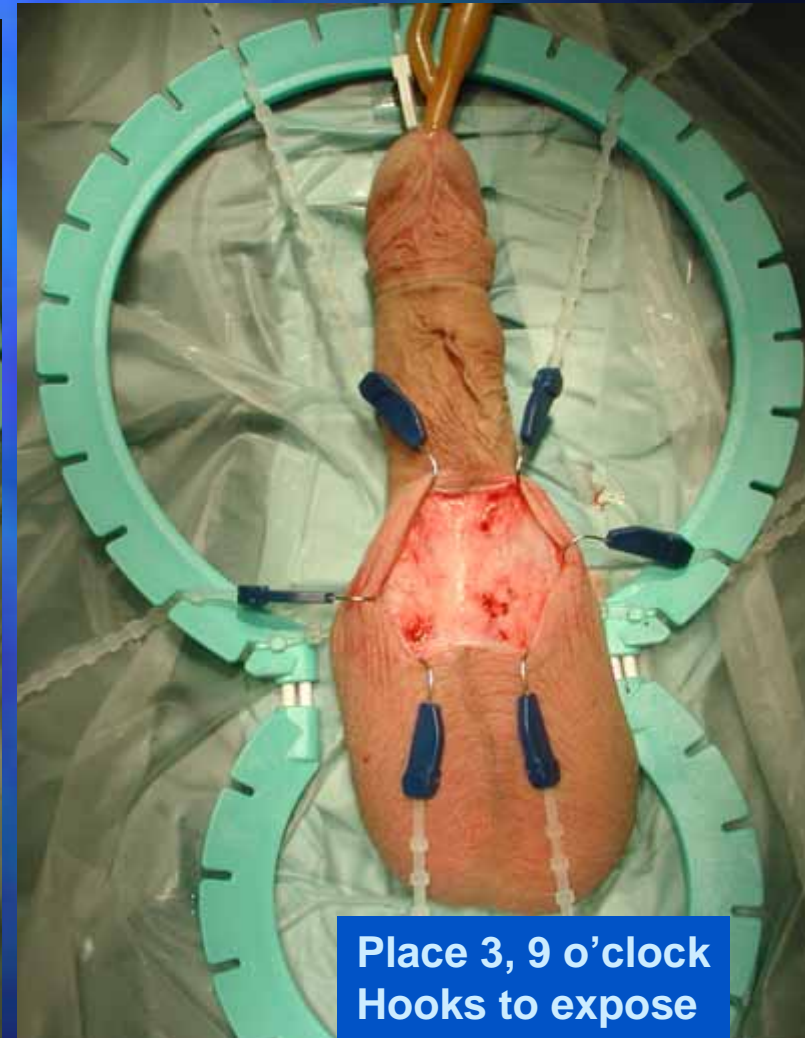
Legs Gently Abducted

q Patient Supine, Legs Abducted, Not Lithotomy

The Incision is Scrotal, The Exposure is Penile



Proper Hook Placement is Key to Exposuire



Exposure of Corpora is Key to Urethral Exposure



Move window



Expose Both Corpora

Exposure of Corpora is Key to Urethral Exposure

Deaver in Perforation

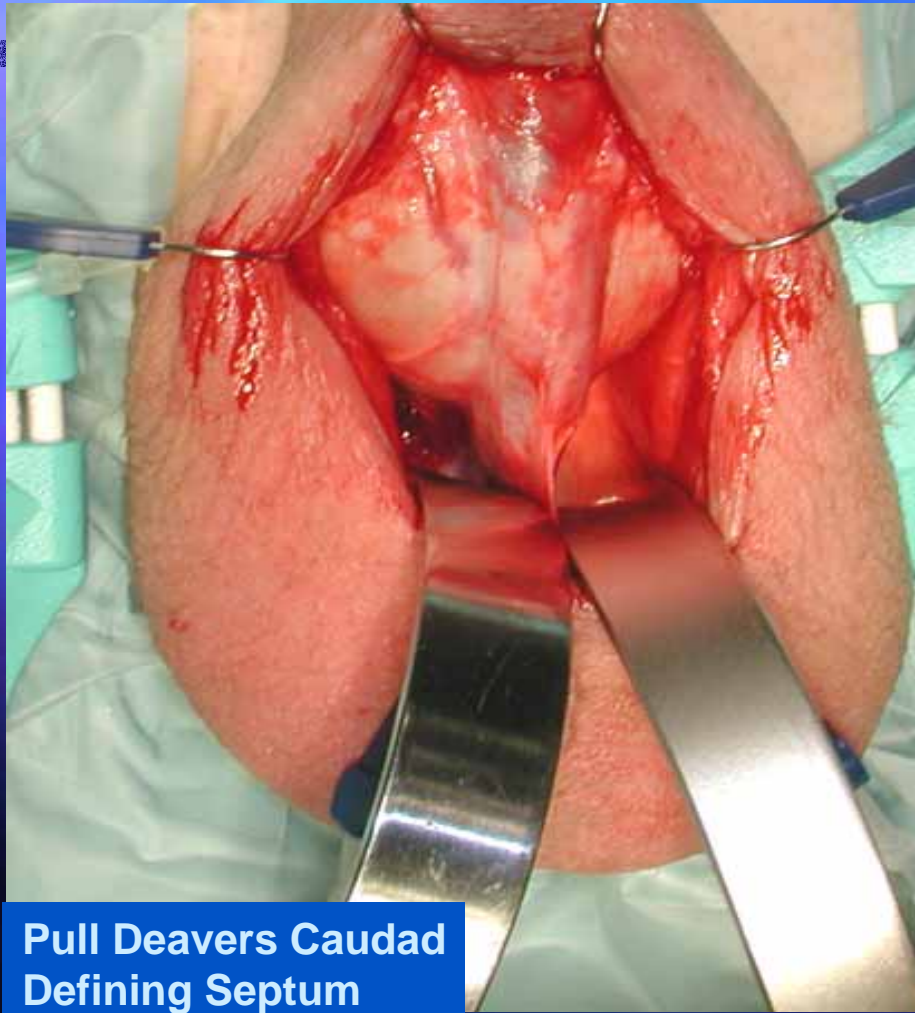


Repeat Metz Proximal
Other Side

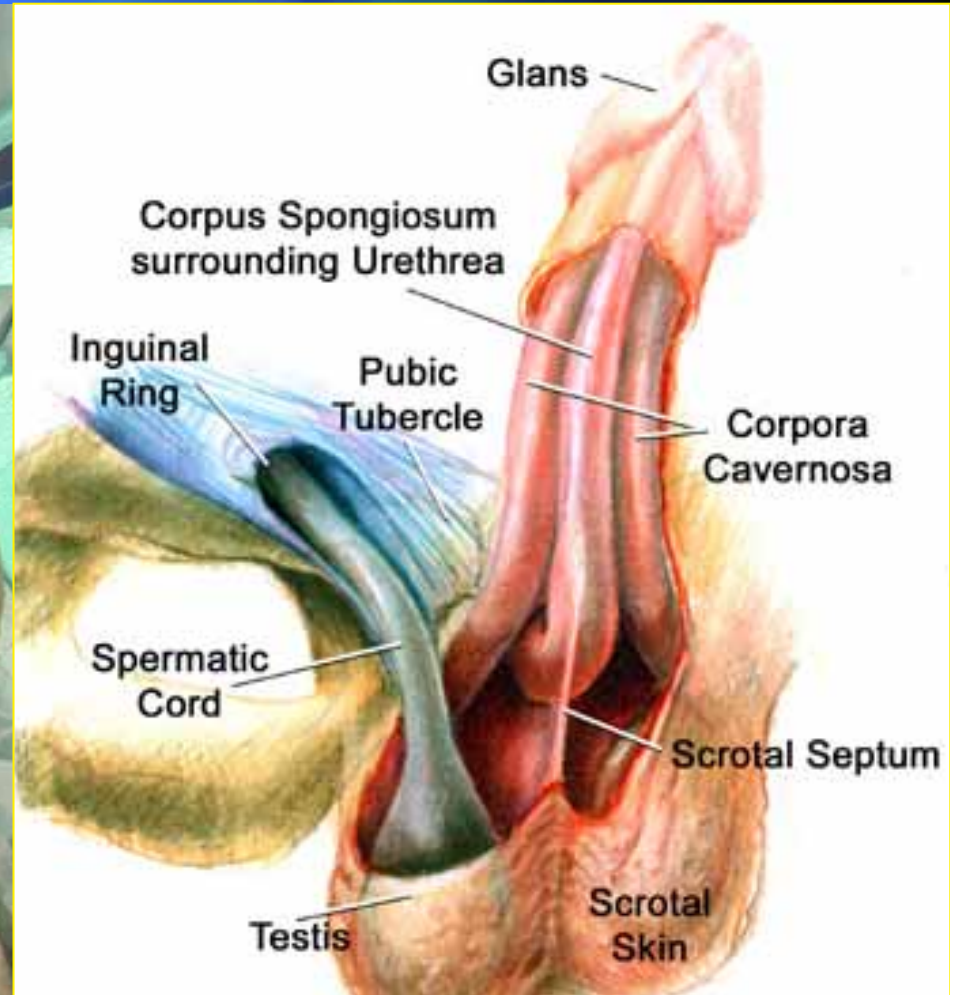


Pass Metz deep to proximal corpora,
Place Infant Deaver in perforation

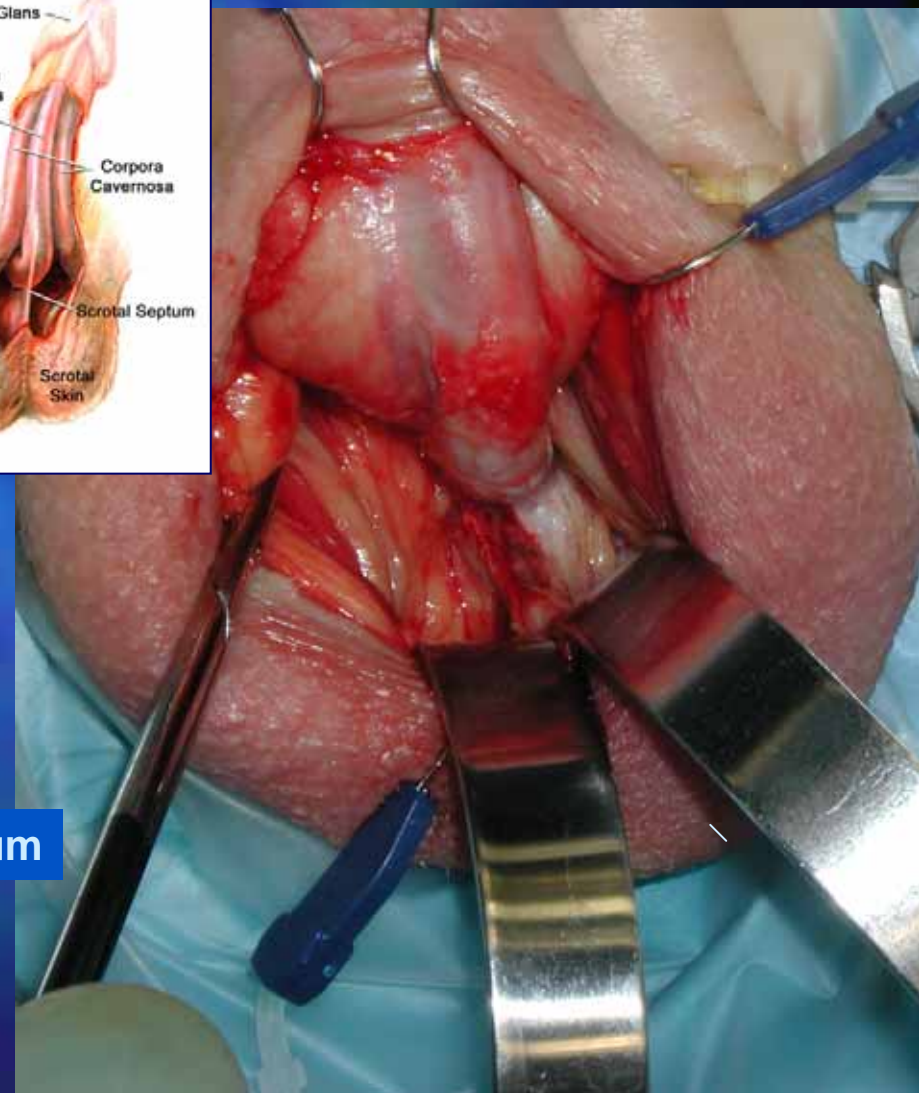
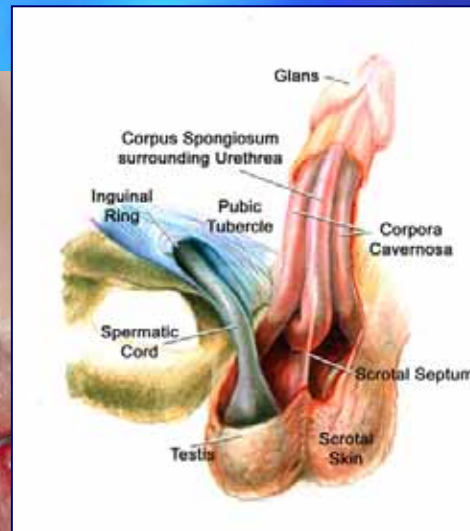
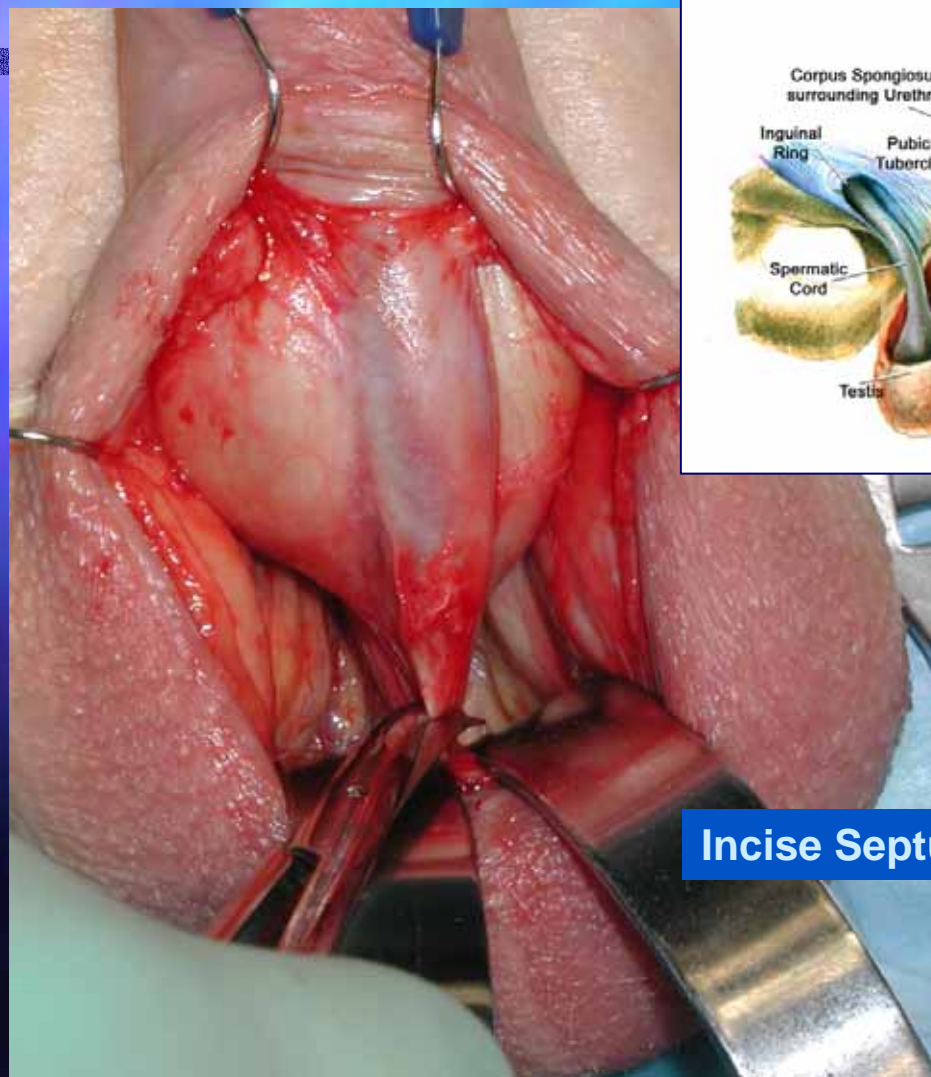
Exposure of Proximal Corpora Define Urethra

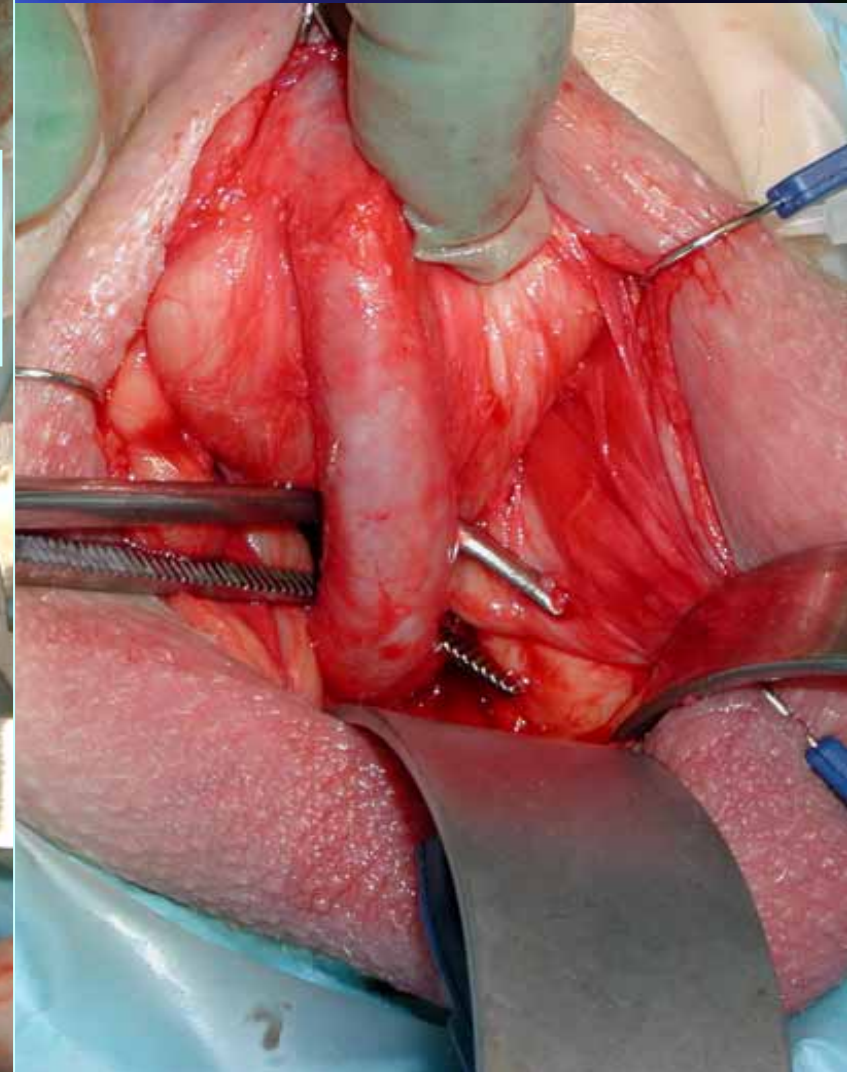
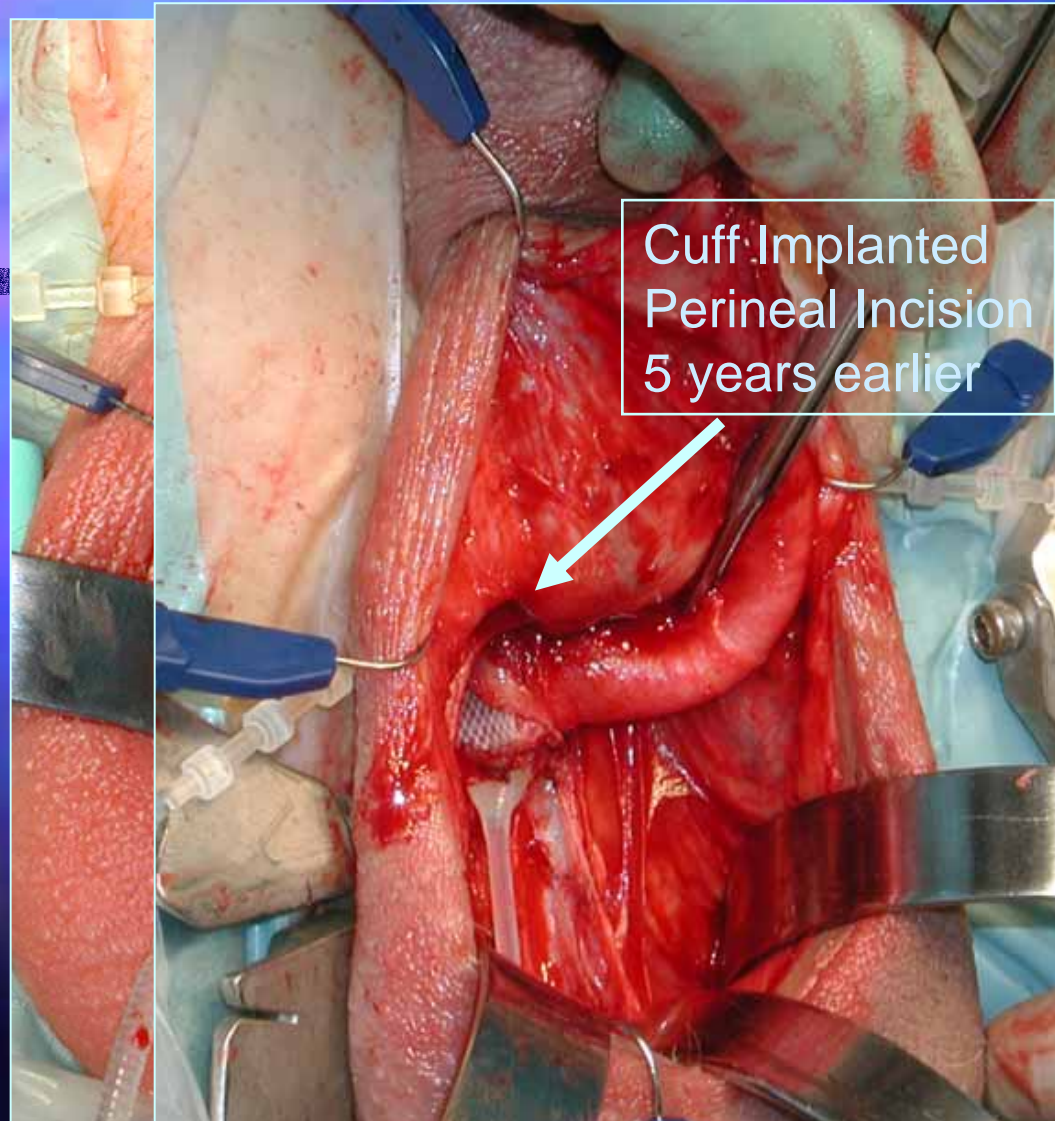


Pull Deavers Caudad
Defining Septum



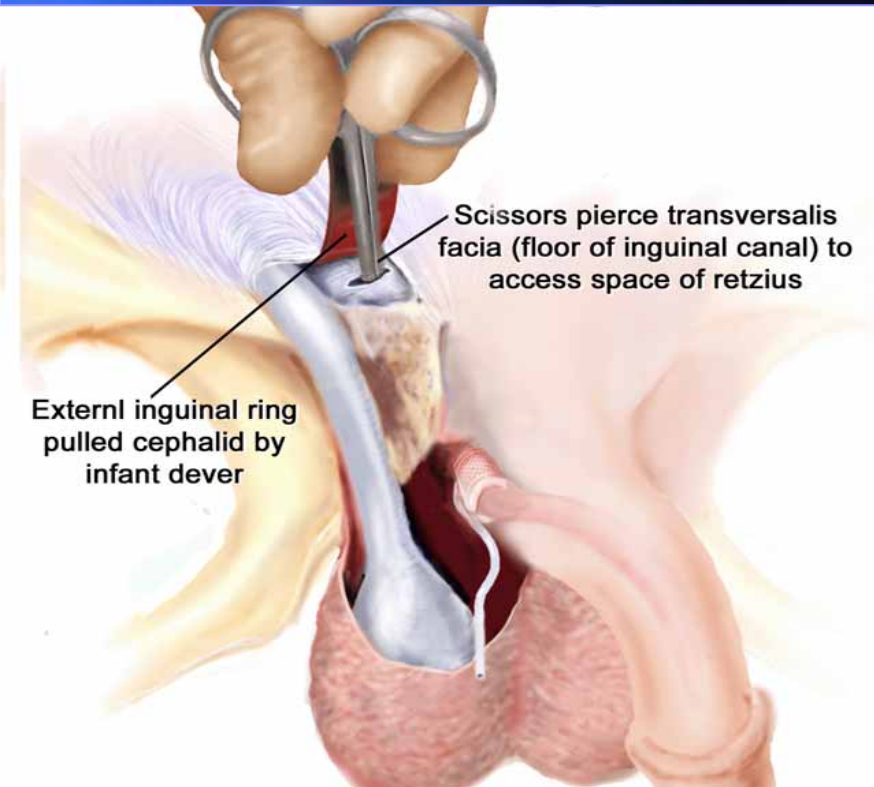
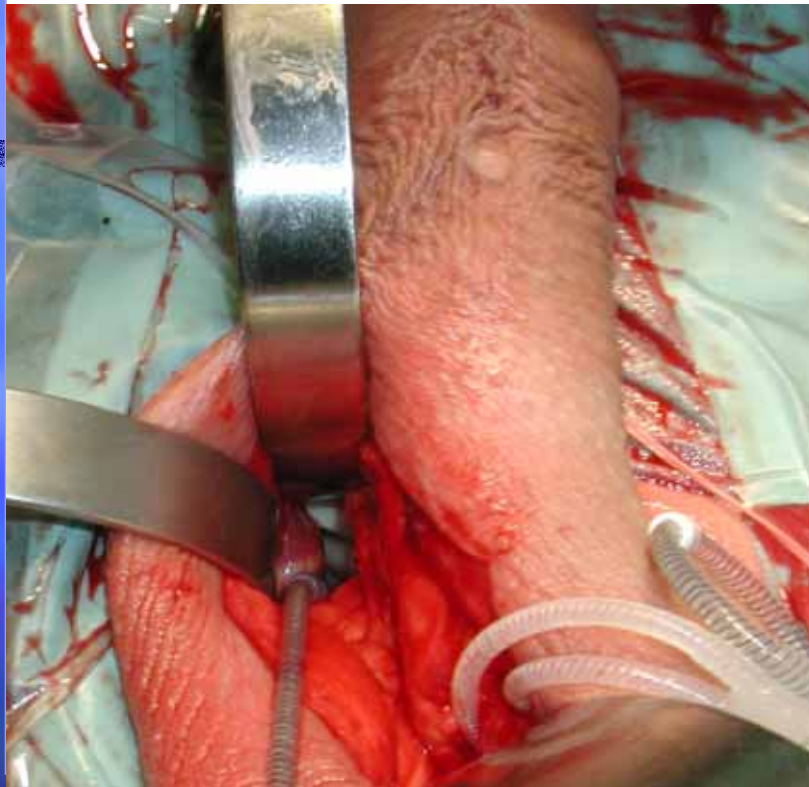
Septum Incision -- Urethral Exposure without Scrotal Dissection





Freely Mobile Urethra Because Supine, Not Lithotomy Position

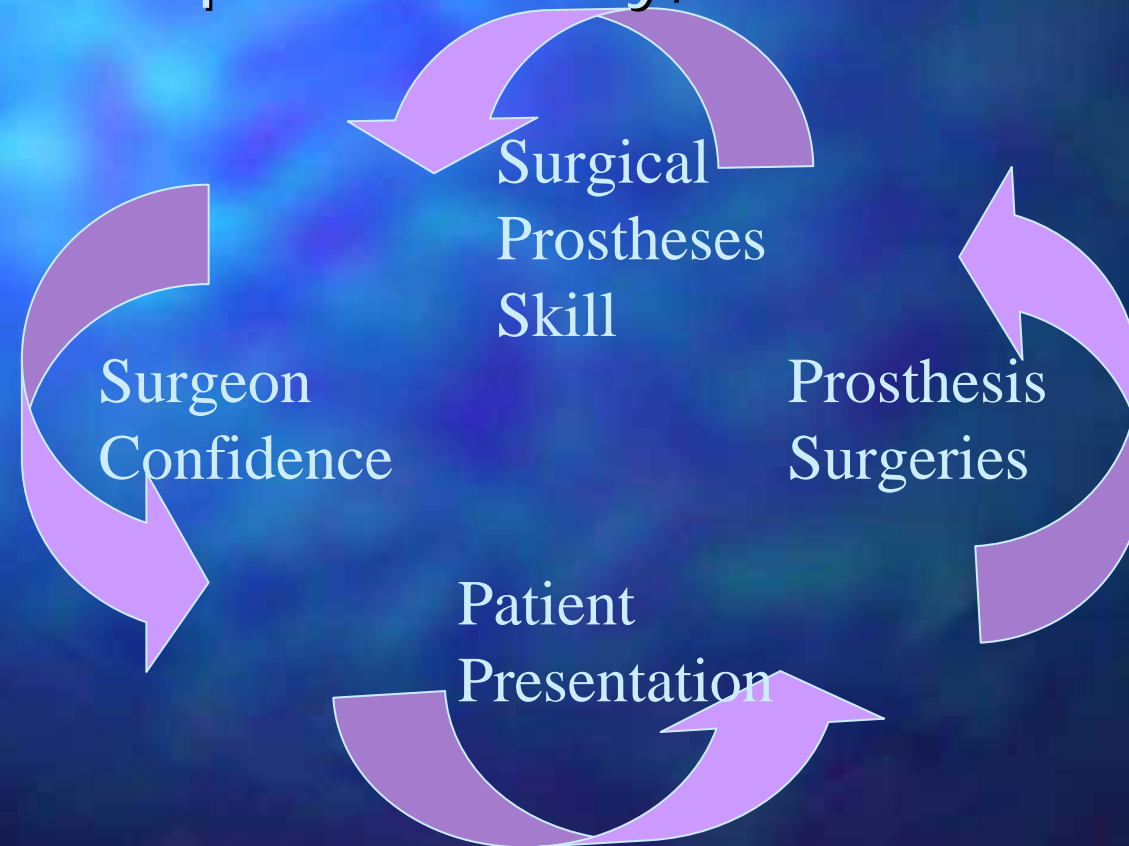
Reservoir Placement Through Scrotal Incision



- q Displace Scrotal Incision Over Inguinal Area
- q Palpate Pubic Tubercle
- q Push Finger into Inguinal Ring &

Impact Of Transverse Scrotal Technique on AUS Sales

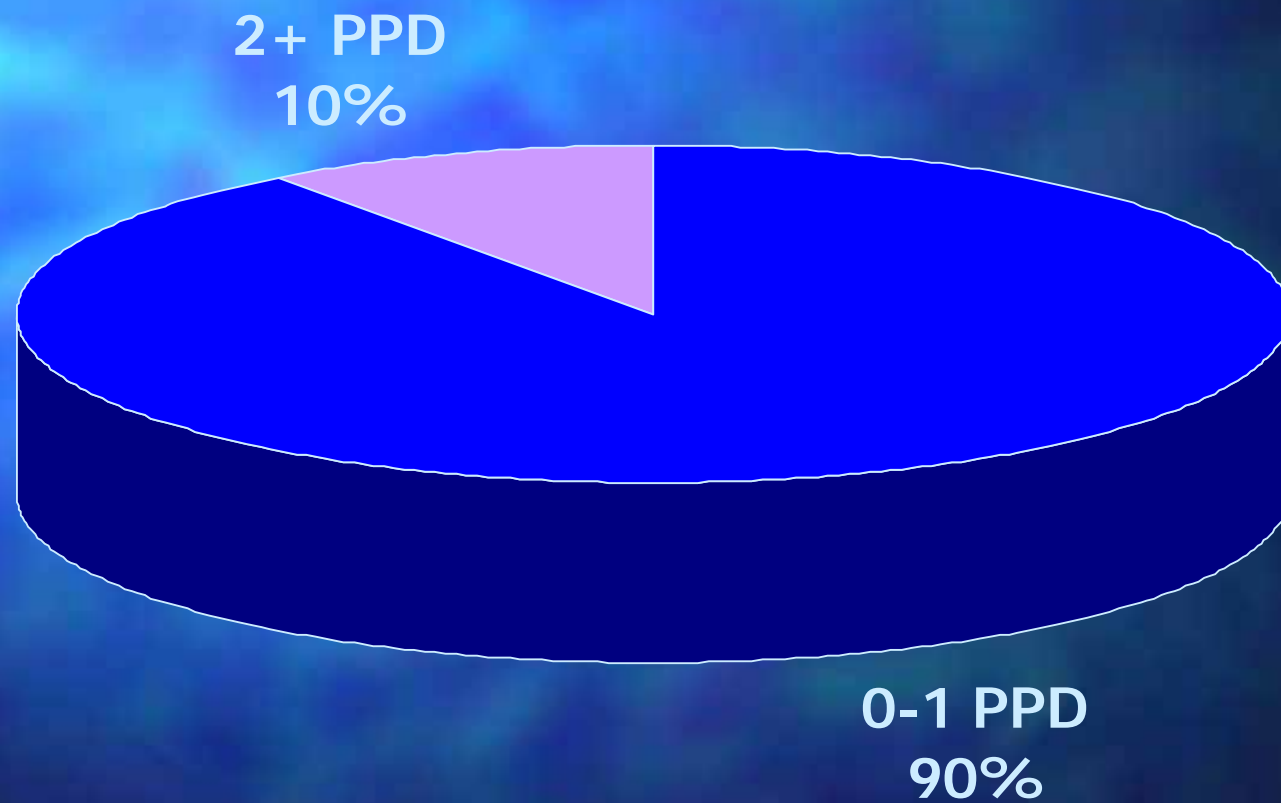
Surgeons Perceive the AUS Transverse Scrotal Technique to be Easy, Fast and Safe



Y-Connector For Double Cuff Procedure



Double Cuff AUS Results

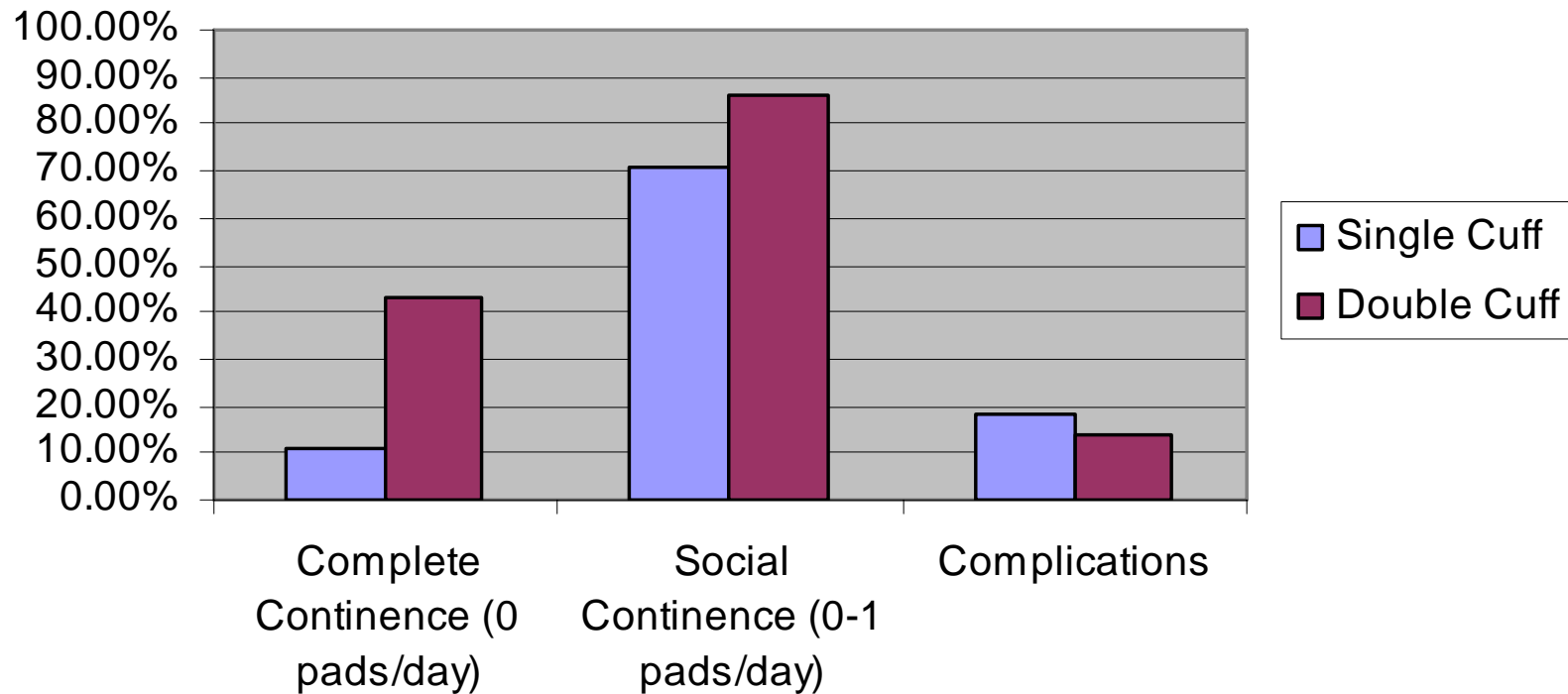


Comparison of Outcomes Following Single or Double Cuff AUS Insertion

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

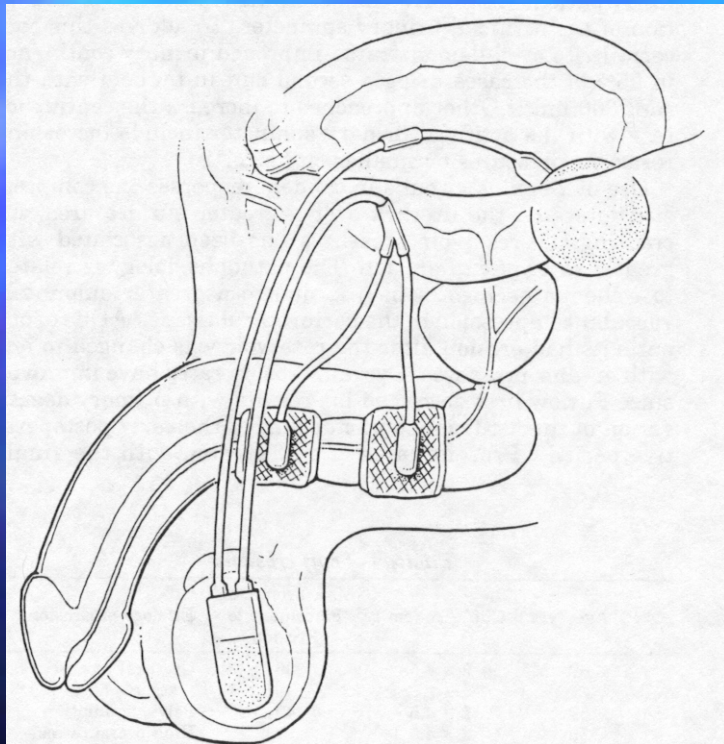
Bales et al, 2003 AUA Abstract

Comparison of Outcomes Following Single or Double Cuff AUS Insertion



Bales et al, 2003 AUA Abstract

AMS Sphincter 800™



Urinary sphincter with 2 cuffs in tandem, 1 reservoir and 1 pump.

Y-Connector For Double Cuff Procedure

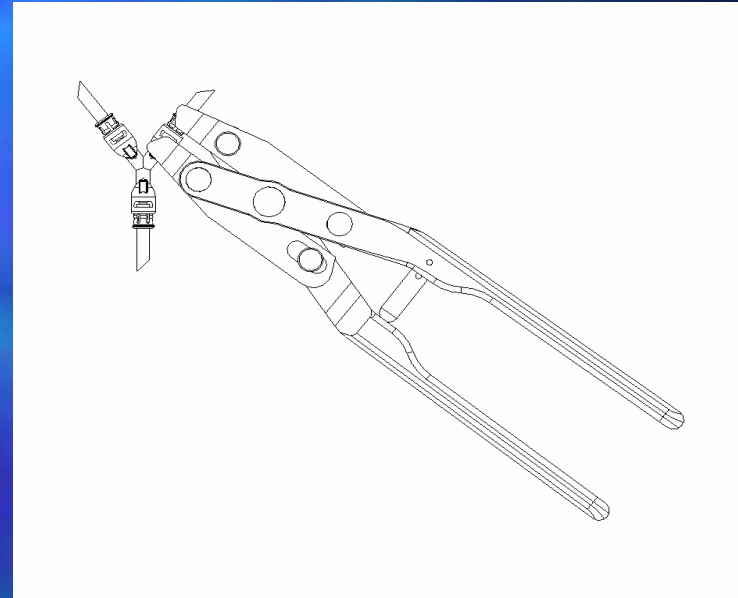
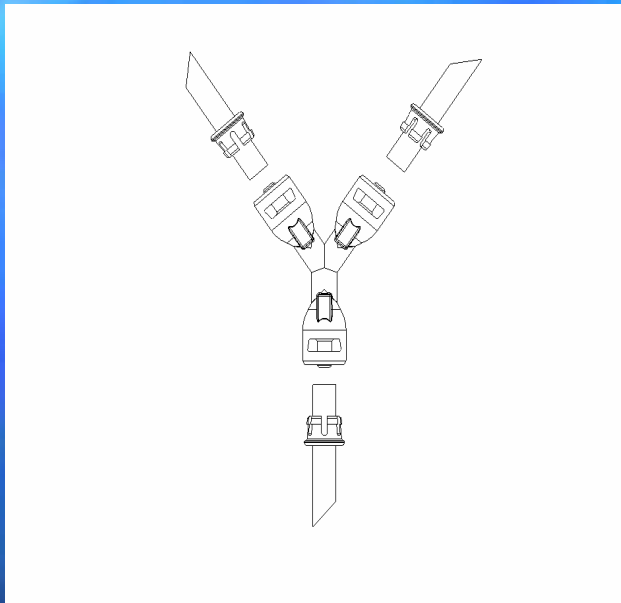


3-Way Connector

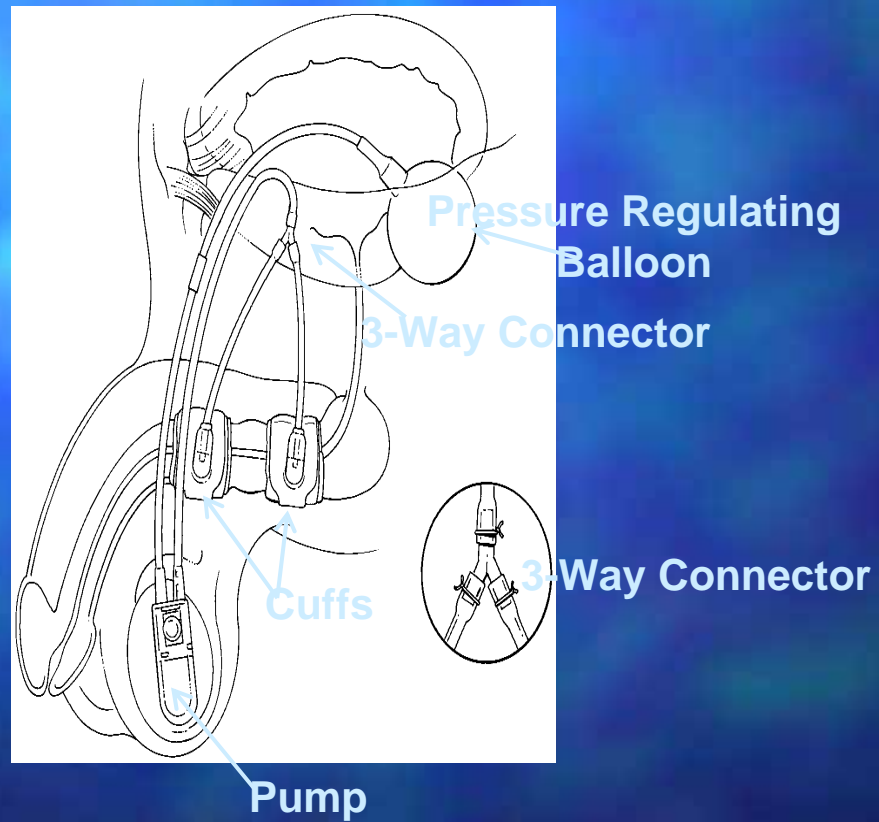
- q Two in AMS 800 AUS Accessory Kit
- q Plastic
- q Bio-compatible
- q MRI compatible



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

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

Adding New Cuff to Existing Cuff

- q Make perineal incision.
- q Implant second cuff approximately 1-2 cm distal to original cuff.

Adding New Cuff to Existing Cuff

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

Adding New Cuff to Existing Cuff

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

Adding New Cuff to Existing Cuff

q 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.

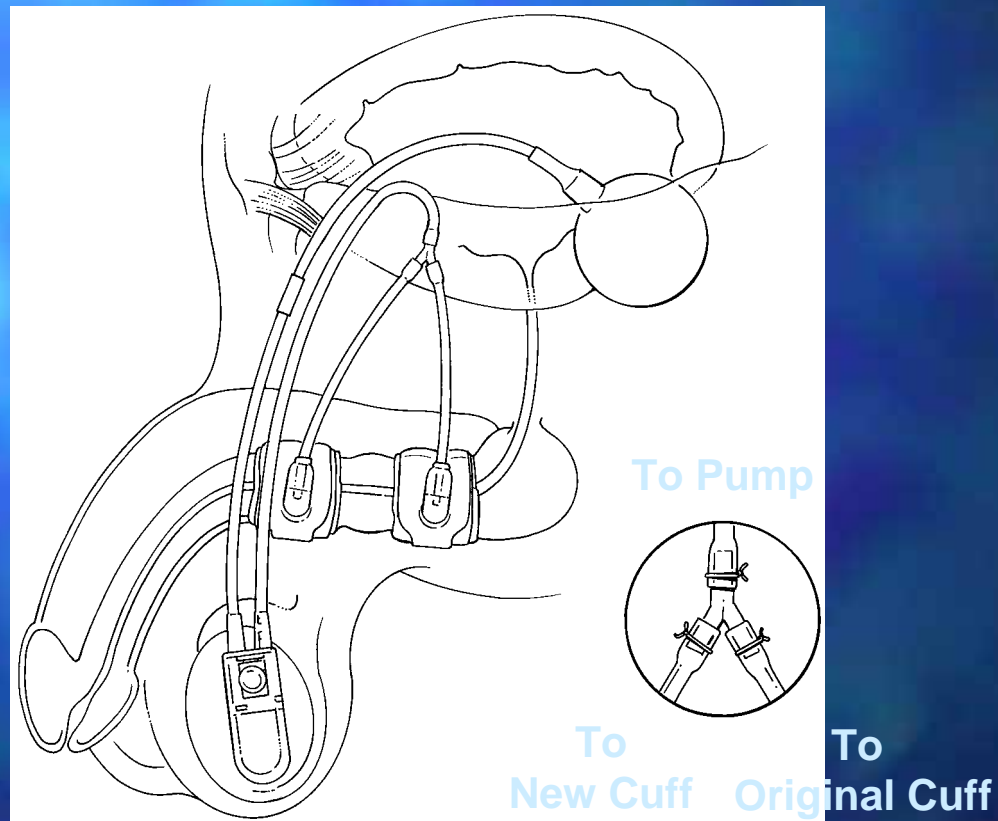
Adding New Cuff to Existing Cuff

- 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

- q Flush original cuff tubing.
- q Attach 3-way connector to tubing, then tie with suture.
- q Flush pump tubing and 3-way connector.
- q Attach 3-way connector to tubing, then tie with suture.

Adding New Cuff to Existing Cuff



Adding New Cuff to Existing Cuff

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



Complications

Intraoperative Complications

Perforations

q Rectal wall perforation

INFECTION!

q Male = Abandon placement, repair rectal wall, consider placing cuff around distal urethra

q Female = Abandon placement, repair rectal wall

Intraoperative Complications

Perforations

q Urethral Perforation

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

INFECTION!

Intraoperative Complications

Perforations

- q Bladder

- q Repair in 2-3 layer closure

- q Re-position PRB on opposite side of perforation and continue with procedure

- q Rarely associated with infection

Intraoperative Complications

Perforations

q Vagina

q 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

q Scrotum or Labium

q Repair and re-position pump on opposite side

Intraoperative Complications

Perforations

- q Bladder Neck

- q Repair with 3-0 or 4-0 absorbable suture

- q Continue cuff placement and deactivate at least 3 months

- q Rarely associated with infection

Post - op Complications

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

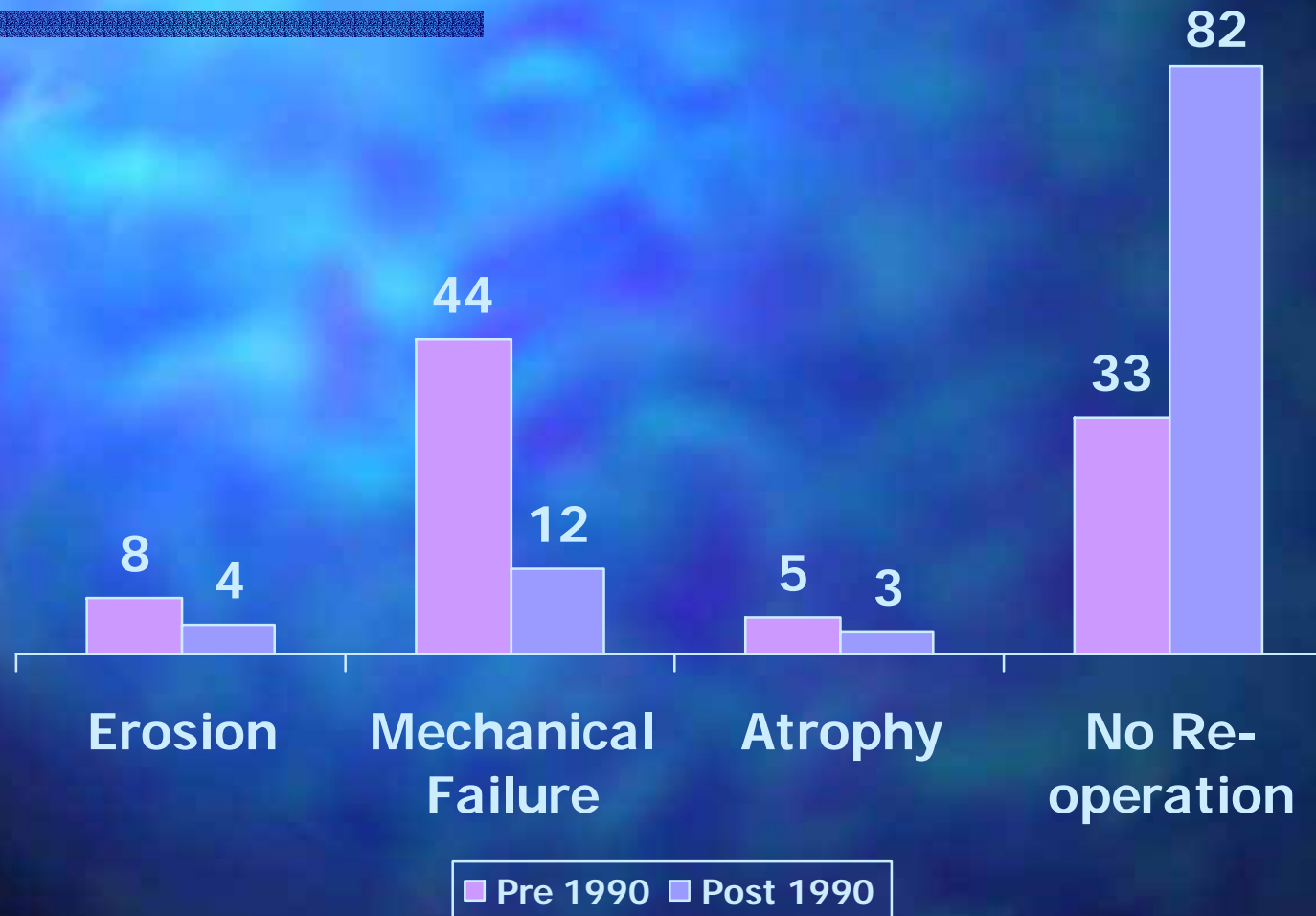
Persistent Incontinence

- q Bladder capacity adequate?
- q Bladder hyperreflexic?
- q Stress Incontinence
- q More pumps to empty cuff/ cuff atrophy
- q Partial vs total incontinence
- q Fluid loss/Cuff coaptation

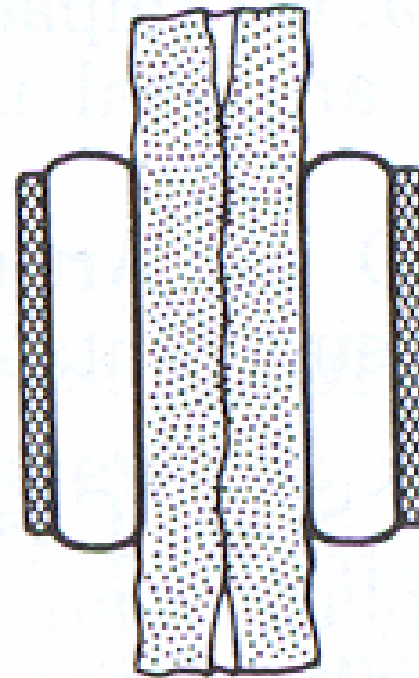
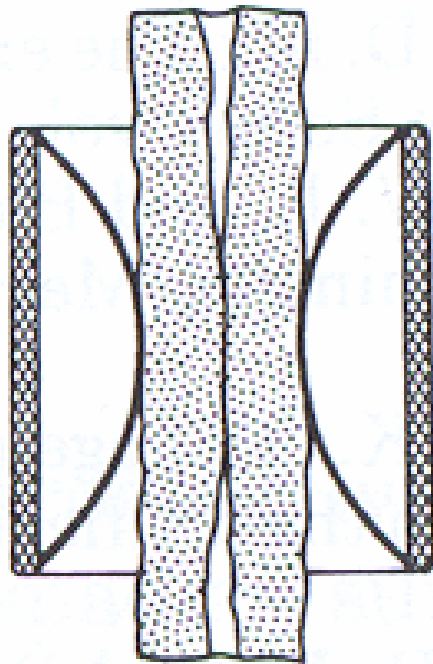
Three Major Changes Circa. 1989

- q Narrow Backed Cuff
- q Kink Resistant Tubing
- q Quick Connect System

Out With The Old, In With The New



Sometimes less is more!



AMS Sphincter 800™ Results

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 it 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

q 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

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

Conclusions

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

Four Important Final Points

- q Always deactivate the system if the patient is going to be catheterized.
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