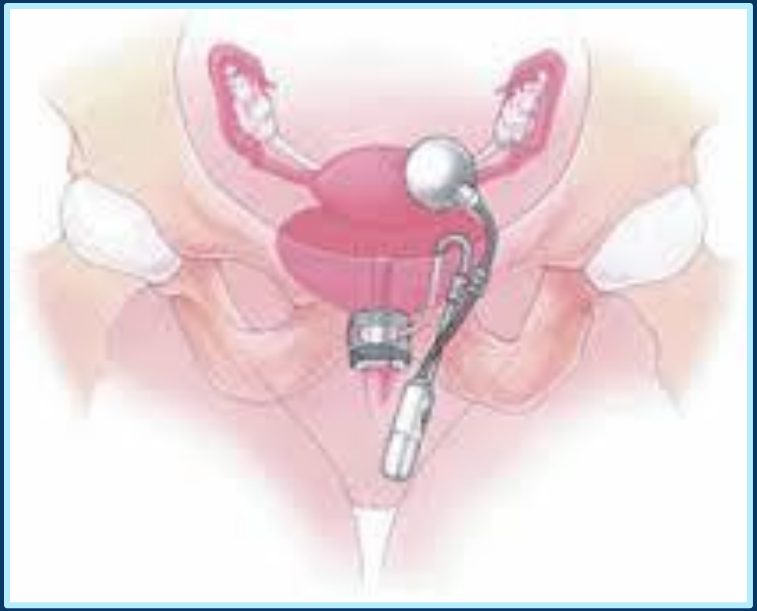
ARTIFICIAL URINARY SPHINCTER IN FEMALE SUI



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General Secretary Elect of International Continence Society

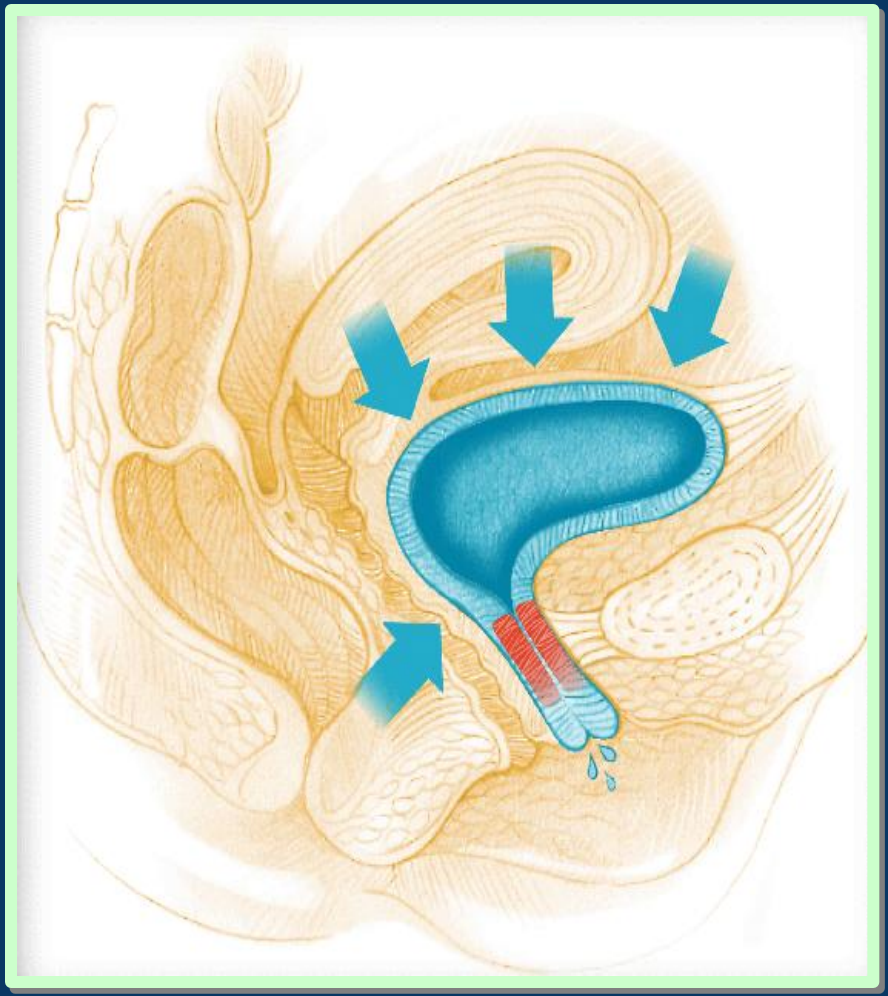
President of Pan Arab Continence Society

Pathophysiology of Stress Urinary Incontinence

- *2 Main Components:*
  - **Intrinsic Sphincteric deficiency**
  - **Urethral Hypermobility**

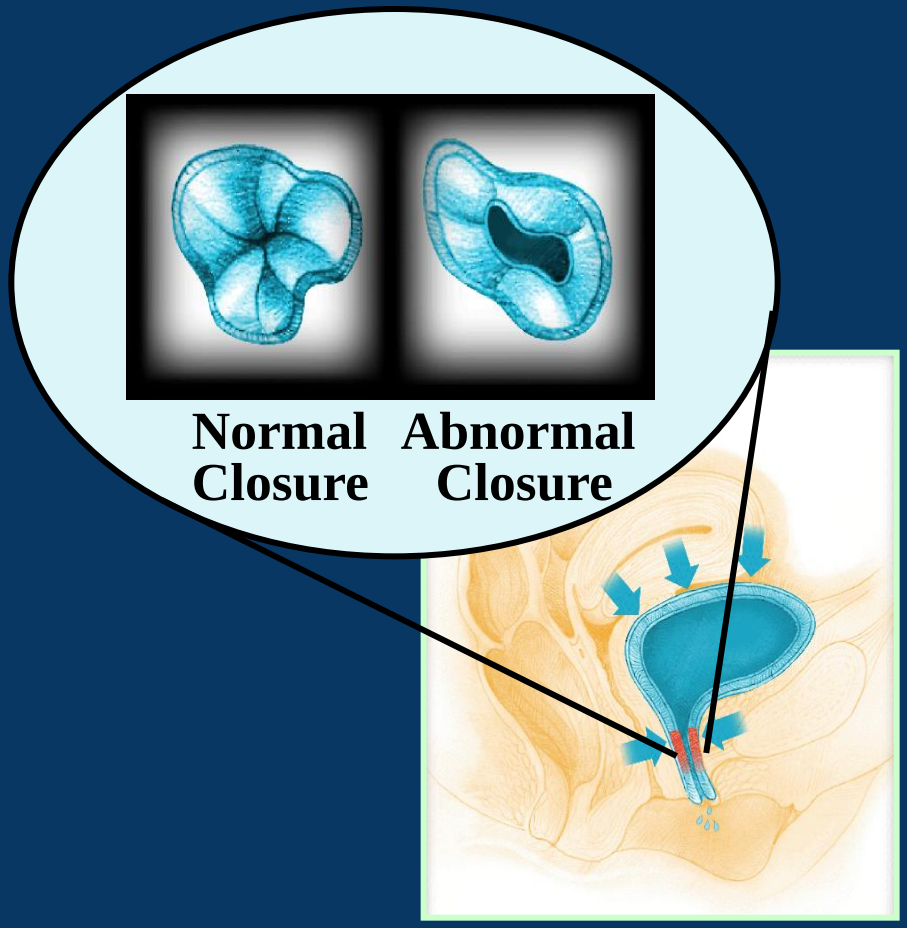
Pathophysiology of Stress Urinary Incontinence

- *Urethral Hypermobility*
  - Displacement of urethra during sudden increase in abdominal pressure decreases pressure transmission



Pathophysiology of Stress Urinary Incontinence

- *Intrinsic Sphincter Deficiency (ISD)*
  - **Urethra is unable to generate enough outlet resistance to keep the urethra closed at rest or with minimal physical activity**



Definitions

_Maximum urethral pressure (MUP)

maximum pressure of the measured profile

_Maximum urethral closure pressure (MUCP)

difference between the MUP and the vesical pressure

_Functional urethral length

length of the urethra along which the urethral pressure exceeds the vesical pressure

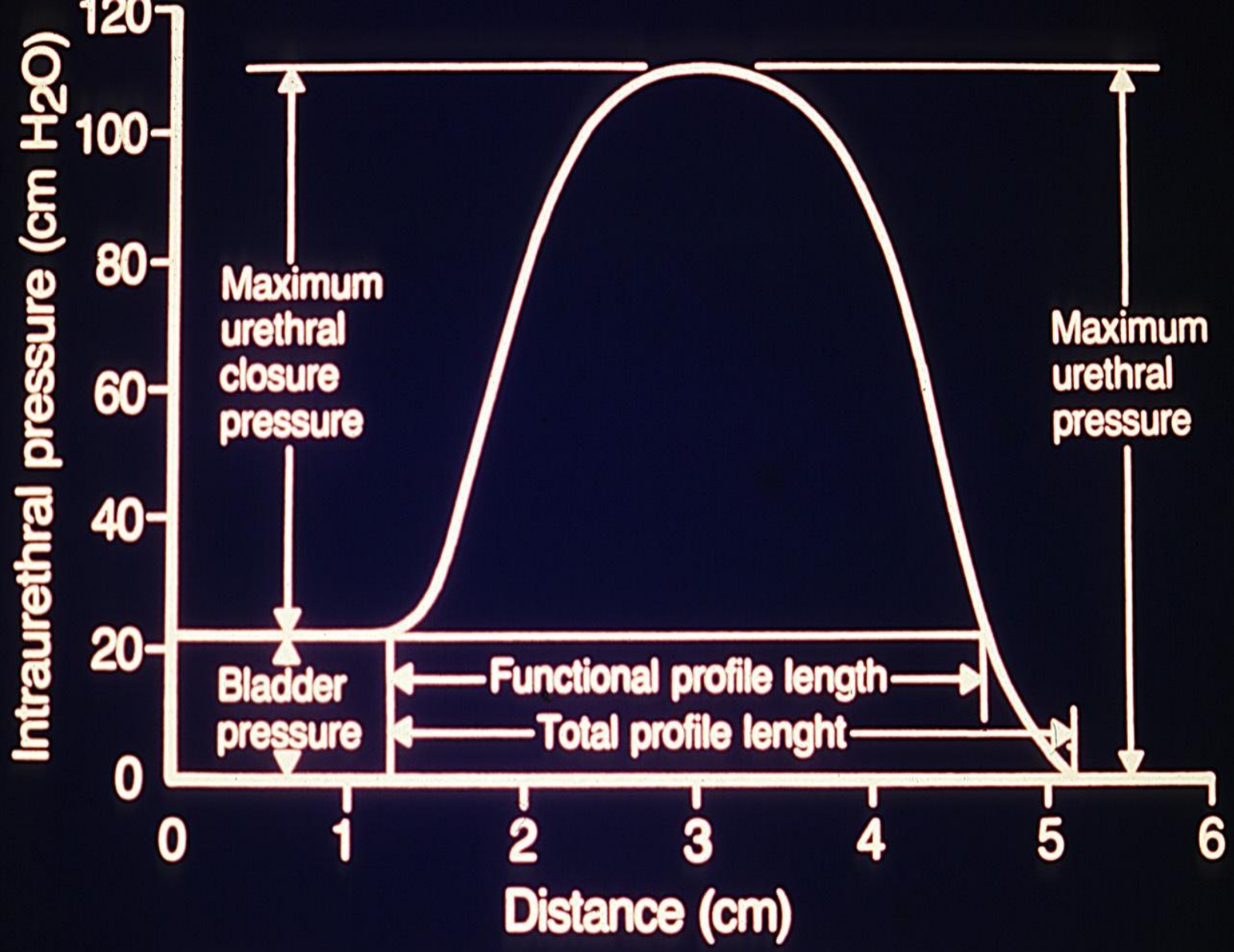
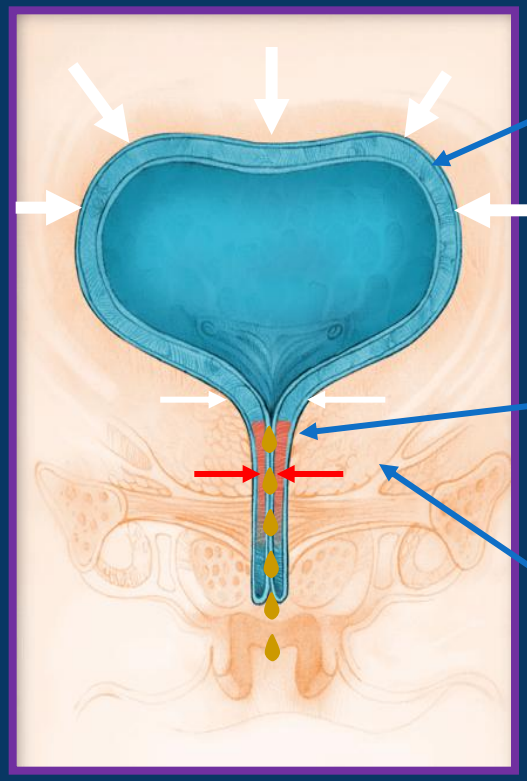


Diagram of a female urethral pressure profile (static) with I.C.S. recommended nomenclature.

SUI Occurs When;
Bladder Pressure > Urethral Pressure

- Any factor that pushes the equation towards a positive urethral pressure gradient has the potential to be effective



Artificial Urinary Sphincter in Women

_In women, AUS is usually considered as the last resort to restore continence after failure of other anti-incontinence procedures.

_The procedure requires appropriate patient selection, with proper counseling, and operative insertion by a surgeon well versed by the anatomy of the pelvis and with good knowledge with the reconstructive techniques.

(Rao and Grange, 2010)

ICI 2009 - 4th International Consultation on Incontinence

Initial Management of Urinary Incontinence in Women

HISTORY

Incontinence on physical activity

Incontinence with mixed symptoms

Incontinence / frequency with urgency

Complicated incontinence
- Recurrent incontinence
- Incontinence associated with:
  - Pain
  - Hematuria
  - Recurrent infection
  - Significant voiding symptoms
  - Pelvic irradiation
  - Radical pelvic surgery
  - Suspected fistula

CLINICAL ASSESSMENT

- General assessment (see relevant chapter)
- Urinary symptom assessment (including frequency-volume chart and questionnaire)
- Assess quality of life and desire for treatment
- Physical examination: abdominal, pelvic and perineal
- Cough test to demonstrate stress incontinence if appropriate
- Urinalysis ± urine culture -> if infected, treat and reassess *If appropriate*
- Assess oestrogen status and treat as appropriate
- Assess voluntary pelvic floor muscle contraction
- Assess post-void residual urine

PRESUMED DIAGNOSIS

STRESS INCONTINENCE presumed due to sphincteric incompetence

MIXED INCONTINENCE (treat most bothersome symptom first)

OAB -with or without URGENCY INCONTINENCE presumed due to detrusor overactivity

- If other abnormality found e.g.
- Significant post void residual
- Significant pelvic organ prolapse
- Pelvic mass

MANAGEMENT

- Life style interventions.
- Pelvic floor muscle training for SUI or OAB
- Bladder retraining for OAB
- Duloxetine* (SUI) or antimuscarinic (OAB ± urgency incontinence)

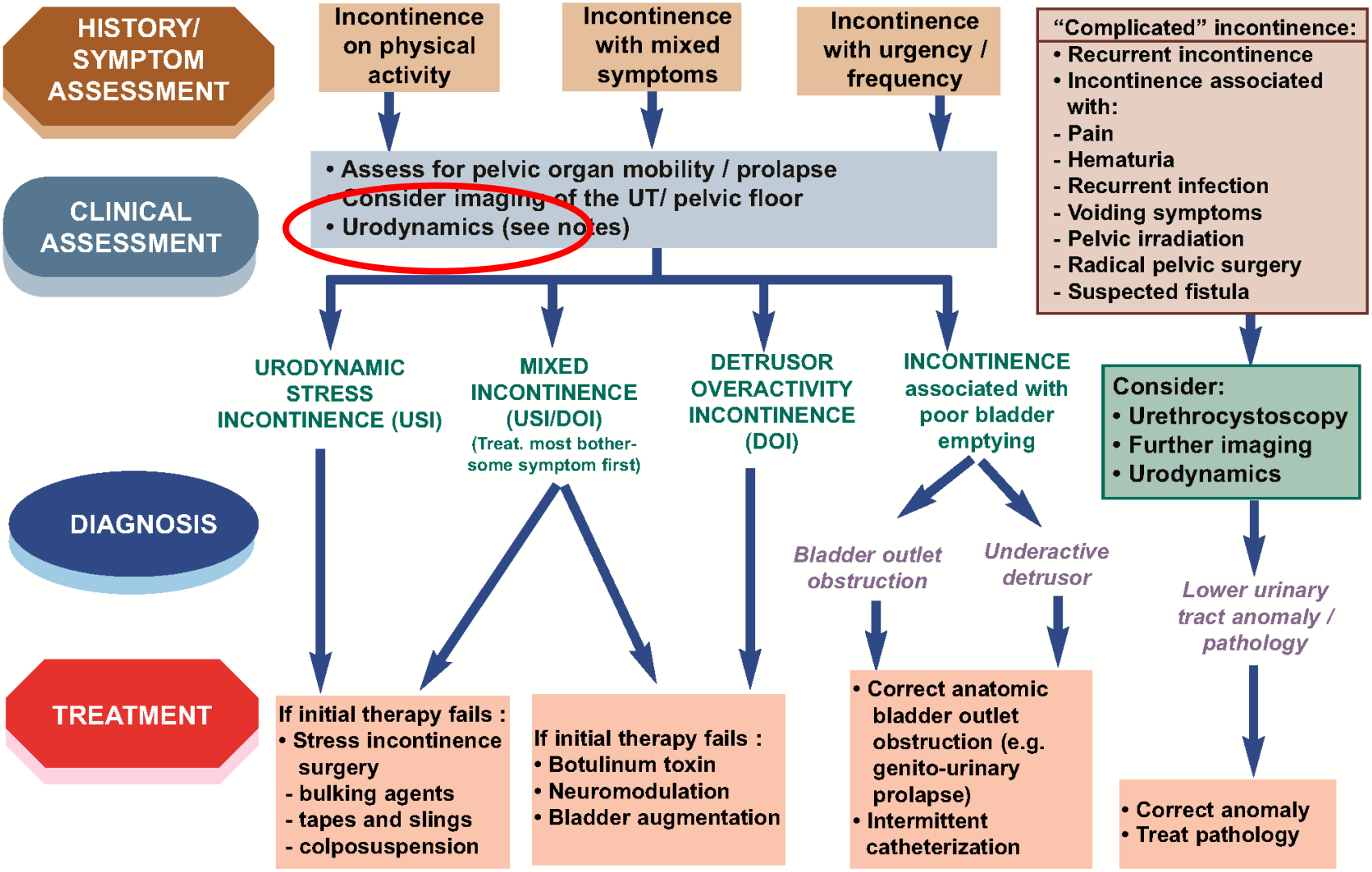
- Other adjuncts, such as electrical stimulation
- Vaginal devices, urethral inserts

Failure

SPECIALIZED MANAGEMENT

* Subject to local regulatory approval (see black box worning).

Specialized Management of Urinary Incontinence in Women



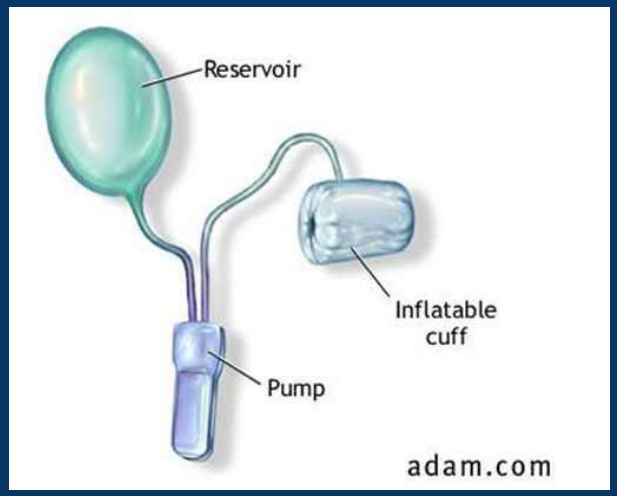
NICE Guidelines, 2006

In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed.

Life-long follow-up is recommended.

AUS … ?!

- An artificial urinary sphincter (AUS) mimics the biological urinary sphincter by providing a competent bladder outlet during urinary storage and an open unobstructed outlet to permit voluntary voiding.

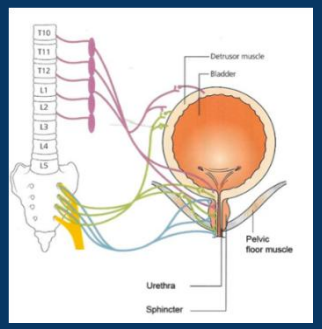


Indications

Indications in women of all ages include the following:

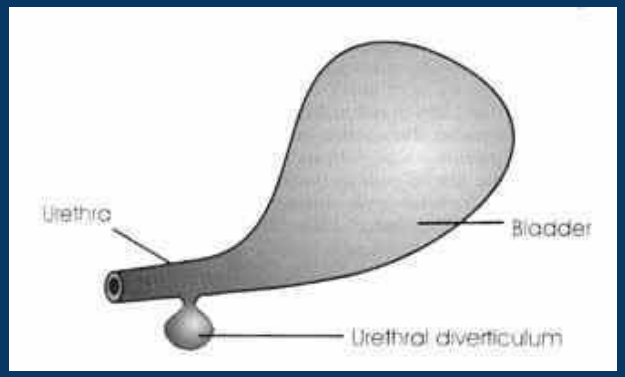
1- Intrinsic sphincteric dysfunction following pelvic fracture, spinal cord injury, urethral reconstruction, or multiple previous failed anti-incontinence procedures.

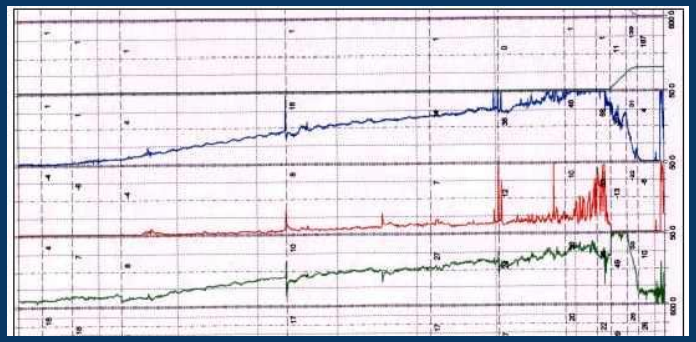
2- Neurogenic bladder with associated sphincter or bladder neck incompetence.



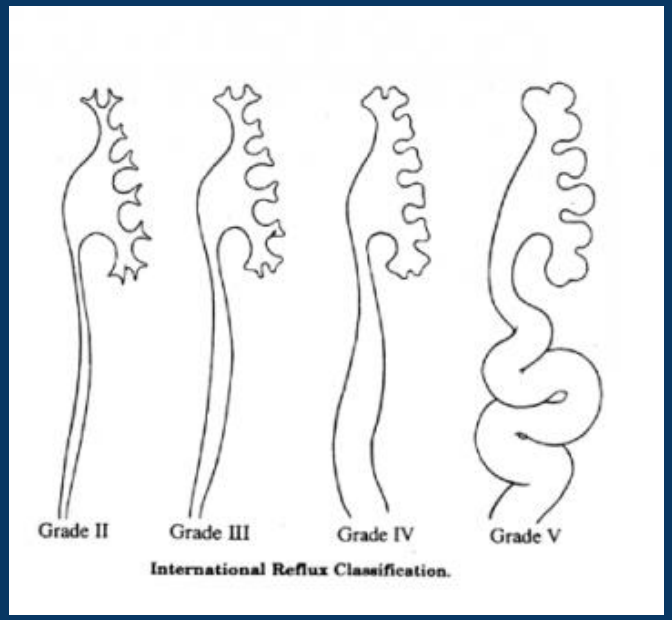
Contraindications

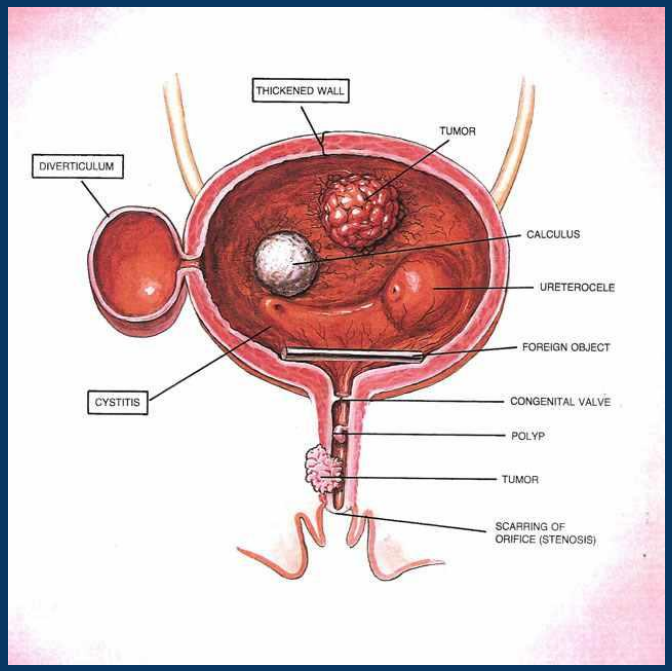
- UTI.
- Recurrent urethral strictures or diverticula.
- Small bladder capacity or poor compliance.





- Grade 2 or higher vesicoureteral reflux should be corrected before artificial urinary sphincter placement.
- Recurrent disease (eg, stone disease, bladder or ureteral tumors) that requires retrograde endoscopic instrumentation is a relative contraindication.





- Bladder neck contractures should be treated first, and cystoscopy or retrograde urethrography should be performed <u>at least 3</u> months afterward to ensure continued patency of the bladder neck before proceeding with artificial urinary sphincter placement.

The AMS 800 device

- The AMS 800 artificial urinary sphincter is the most commonly used device and is the criterion standard for the treatment of incontinence caused by ISD.
- It is composed of:
  - inflatable cuff
  - pressure-regulating balloon
  - control pump.
- The balloon has a dual function as a pressure regulator and a fluid reservoir.

(Webster et al, 1992)

The Inflatable Cuff

_The cuff surrounds the bladder neck/urethra circumferentially.

_In women and children the cuff is placed around the bladder neck.

_In men the cuff is placed around the bulbar urethra.

The Pressure Regulating Balloon Reservoir

_Different pressure preset balloons reservoir are available.

_The balloon with the lowest pressure required to occlude the bladder neck is selected.

Control Pump

_The control pump is placed below the labia majora in women.

_The pump has a unidirectional valave, refill – delay resistor and deactivation button.

Connecting Tubing

- The AMS 800 comes with two sets of color – coded tubing.
- The clear tubing connects to the pump from the cuff.
- The dark tubing connects the pump to the balloon reservoir.

Isotonic saline

Mechanics of the AMS 800

_The AMS 800 artificial urinary sphincter works on the basis of hydraulic mechanics.

_When the sphincter is first activated (unlocked), the fluid from the reservoir travels down the pressure gradient to the cuff.

_The cuff gradually inflates to effectively close the urethra. The inflated cuff causes urine to be stored in the bladder and prevents urine loss.

_The device works in a semiautomatic fashion, with the cuff remaining closed at all times except when the patient opens the cuff for voiding.

Mechanics of the AMS 800

_To void, the patient must open the artificial sphincter.

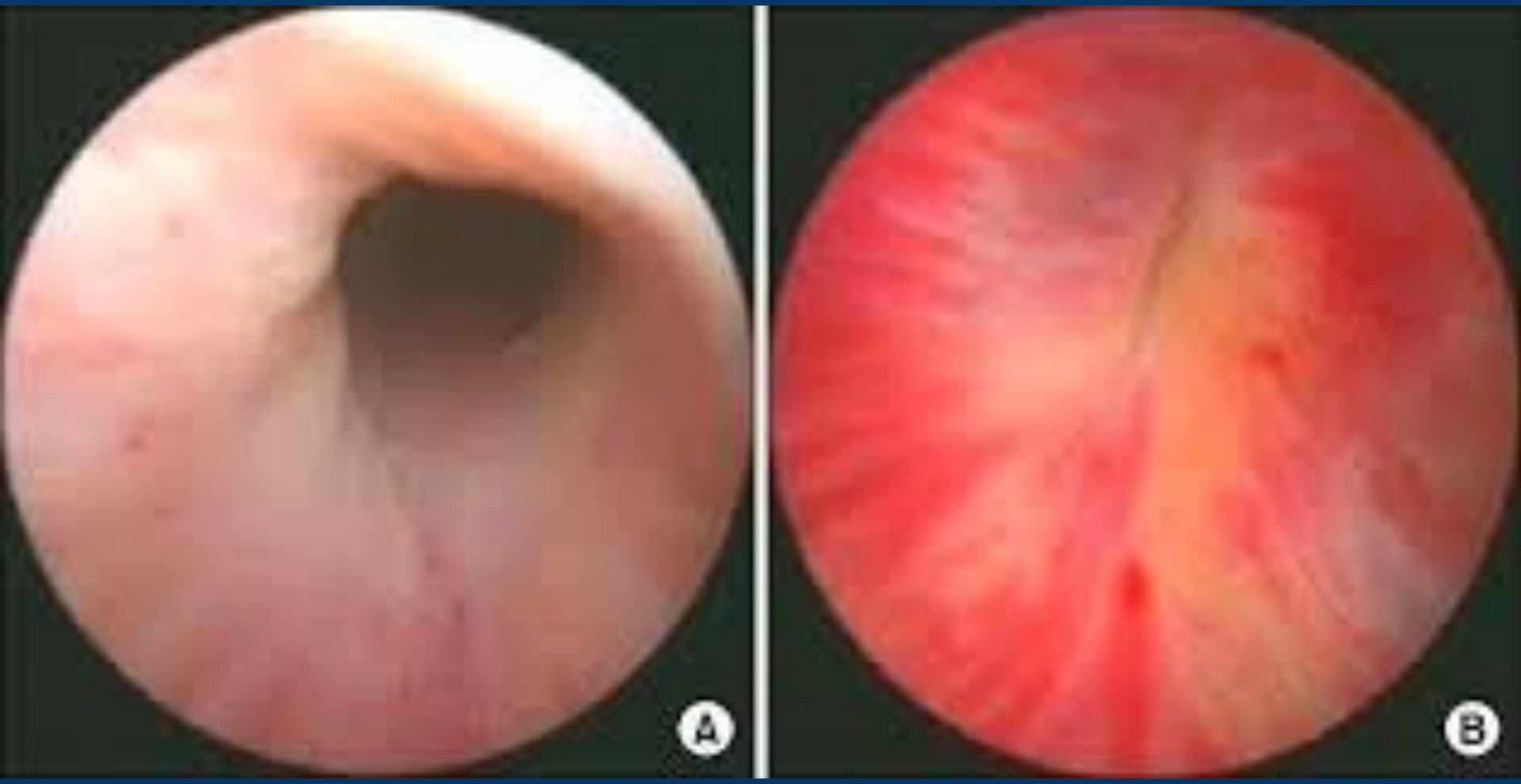
_When the control pump is squeezed, the fluid in the control pump is sent up to the balloon reservoir.

_The control pump then automatically reexpands pulling the fluid out from the cuff, which causes the sphincter cuff to deflate.

_At this point, the urine flows freely from the bladder.

_After 3-5 minutes, the fluid from the balloon reservoir automatically flows through a delayed-fill resistor within the pump and down back to the cuff.

_When the cuff reinflates, the urethra becomes effectively closed and the patient becomes dry.


A
B

Mechanics of the AMS 800

_The locking mechanism (button on the side of the control pump) allows the physician to lock the cuff in an open or closed position.

_Typically, the AMS 800 device is left locked (deactivated) in an open position at the time of surgical implantation to allow for adequate tissue healing and is unlocked in the physician's office 6-8 weeks after operation.

_Patients should be instructed on the locking mechanism to understand and be able to respond to these problems.

Limitations of the AMS 800

- Mechanical malfunctions (ie, cuff leak, defective pump).
- Surgical problems (ie, pump migration, cuff migration, improper cuff size) require reoperation and sphincter revision.
- Urinary incontinence may arise from improper usage, fluid leakage, pressure atrophy, or cuff erosion.

- Urinary retention may occur as a result of particle obstruction or a tube kink in the system.

- Silicone composition: silicone deteriorates and loses tensile strength over time. Because the cuff is permeable, fluid escapes over time, with a resultant decrease in closing cuff pressure.

- Control pump: some patients may have difficulty manipulating the pump. **Labial hematomas** may displace the pump into an unfamiliar location. The pump may rotate upon itself and become kinked. Migration of the pump into the inguinal region may cause failure to deflate the cuff.

- Locking mechanism: The locking mechanism lacks a tactile feedback mechanism, making it difficult to tell if locking has occurred.

Follow-up

- The patient is instructed not to manipulate the sphincter for 6 weeks. The first postoperative clinic visit is in 1-2 weeks.
- At 6-week follow-up, the sphincter is activated by applying a firm, forceful squeeze to the control pump.

- Some surgeons advocate nighttime deactivation of the sphincter. These patients may therefore reduce the risk of or delay the onset of urethral atrophy and recurrent incontinence.

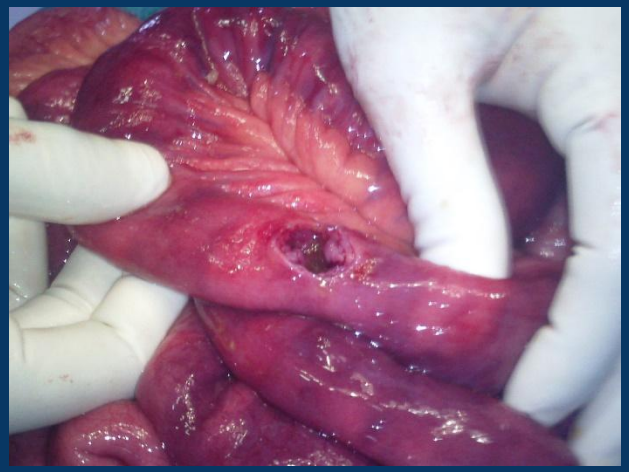
- Other surgeons believe this approach to be ineffective and to impose unnecessary nighttime incontinence on the patient.

(Light et al, 2005)

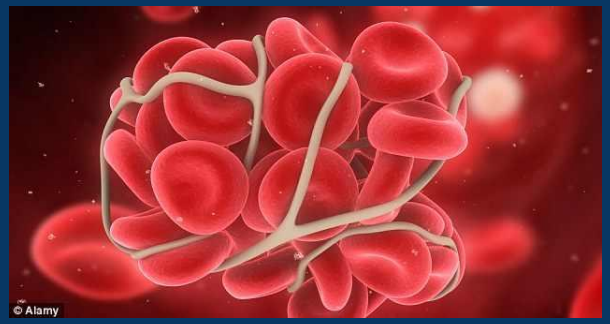
Complications

Intraoperative complications:

- In patients with prior pelvic surgery, scars and adhesions increase the risk of bladder perforation. The intraoperative use of a catheter keeps the bladder decompressed and greatly reduces the risk of bladder injury.
- Iatrogenic peritoneotomy and bowel injury have been reported. If bowel injury occurs, the implantation must be abandoned. *(Appell, 1988)*



- A few air bubbles entering the system are harmless because they are absorbed; however, aggregation of air bubbles into an air lock can obstruct the pump.
- Blood clots can also obstruct the connecting tube or the valves in the pump.



- Care is therefore taken to prevent entry of particulate matter into the system by flushing the air bubble or blood clot out of tubing during surgery.

- A correct plane between the bladder neck and the vagina must be identified to avoid injury to the urethra, vagina, and rectum.

- Vaginal injuries are **closed primarily**.

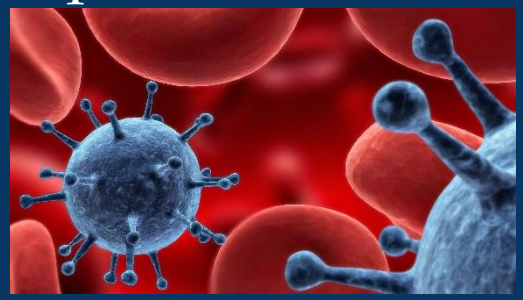
- If a rectal injury occurs, the **procedure must be abandoned**.

- **Postoperative complications:** The reported reoperation rate for the artificial urinary sphincter is **17-35%.**

- **Mechanical**(50% of complicated cases)
- Mechanical failure of the artificial urinary sphincter is most commonly caused by loss of fluid from the system. It can also occur because of obstruction of flow due to debris, airlock, blood, or crystallized material.
- The overall life expectancy of the artificial urinary sphincter is 10 years, with a 5-year device survival rate of 75%.

(Thomas et al, 2002)

- **Non mechanical**(50% of complicated cases)
- Infection
  - The overall risk of infection is reported to be **2-3%** for initial artificial urinary sphincter placement.

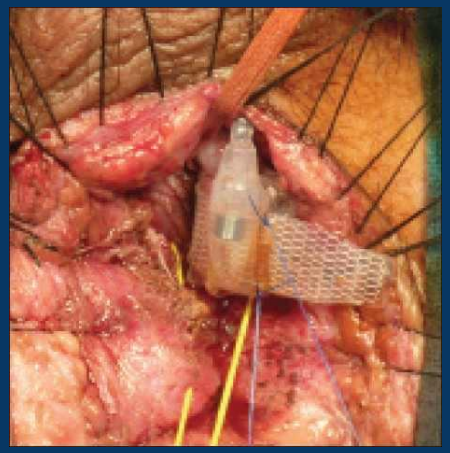


- Tissue atrophy
  - A common cause of recurrent stress incontinence is loss of cuff compression due to tissue atrophy.
  - It is the most common cause of nonmechanical failure and has been reported to be the most common cause of surgical revision.
  - Tissue atrophy results from local tissue ischemia around the cuff.

- **Overactive Bladder Syndrome:**

De novo symptoms of OAB, such as urgency, frequency, nocturia, and urgency incontinence, may develop in **up to 23%** of patients. Those with preoperative OAB will have persistent symptoms in **71% of cases.**

- **Cuff Erosion**
  - Cuff erosion most commonly occurs within **3-4 months after surgery.** The incidence of cuff erosion has been reported to be **1-3%,** which has decreased since the introduction of delayed postoperative activation.
  - Risk factors for cuff erosion include pelvic radiation, excessive cuff pressure, undersized cuff, and retrograde instrumentation without deactivating the device.
  - Patients who have undergone radiation have a reported erosion rate of 10-20%.

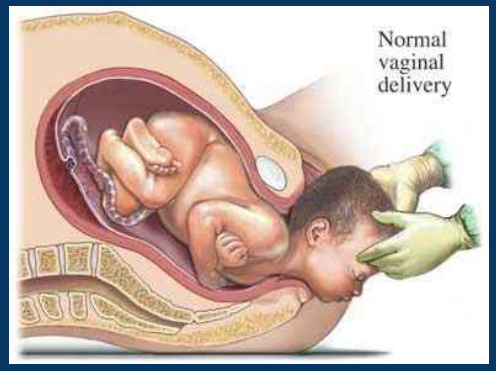


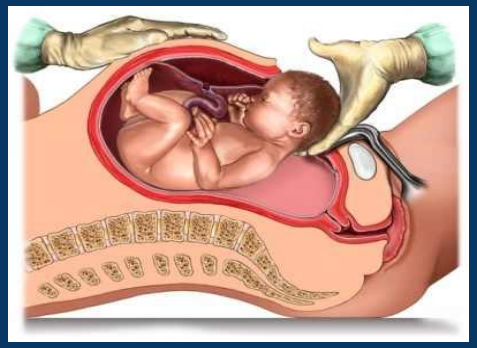
- Efforts to minimize the incidence of cuff erosion include delayed activation, nocturnal deactivation, and use of a low-pressure reservoir. Using a balloon with a pressure of less than 71-80 cm water decreases the risk.

- Early signs of erosion include gross hematuria, burning perineal pain, perineal swelling, swelling at the cuff site, or even urine leakage from the surgical wound. Erosion may also present simply as recurrent incontinence. Erosion is easily confirmed by urethroscopy.

- If the erosion is **clean** and uncomplicated, only the cuff may be removed.
- If purulent drainage is obvious, removal of all sphincter units is mandatory.

- Women of childbearing age should be warned of the danger of cuff erosion during vaginal delivery.
- **Elective Cesarean delivery** is advocated by some.
- Deactivation of the artificial urinary sphincter in the final trimester is recommended to minimize the risk of cuff erosion in this situation, and deactivation during labor is imperative.





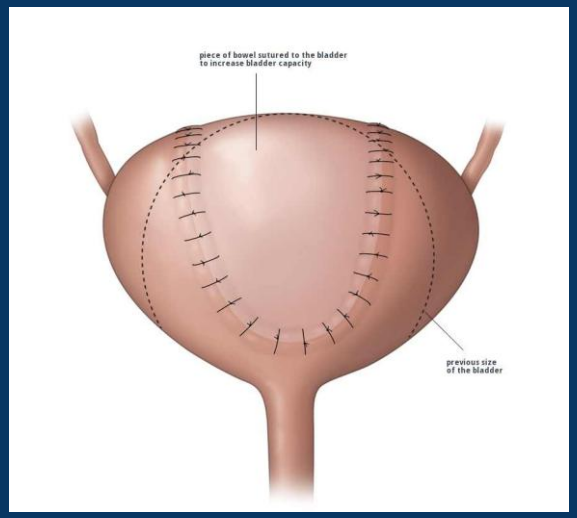
Outcome and Prognosis

- **American Medical Systems** (AMS, the manufacturer of the artificial urinary sphincter) reports that social continence (1 pad or fewer a day) at 3-year follow-up is achieved in 75-95% of patients.

- The largest study of artificial urinary sphincter in the literature reports that 90% of patients have a functional artificial urinary sphincter in place at a mean follow-up of 5 years, with a **28% revision rate**.

(Thomas et al, 2002)

- Multiple series have supported the safety of concomitant augmentation cystoplasty with AUS implantation in patients with intrinsic sphincteric dysfunction and small-capacity or poorly compliant bladders.

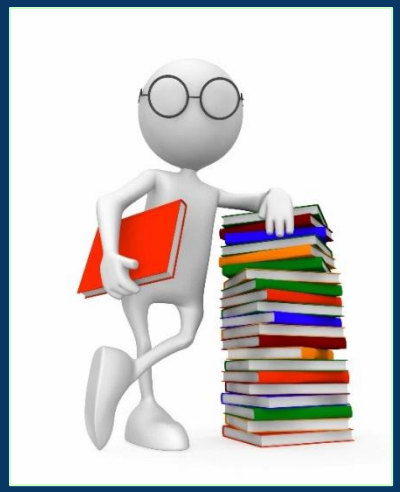


- However, most of these patients still require <u>long-term clean intermittent catheterization</u>.

- In patients with neuropathic bladder dysfunction, **close urodynamic follow-up** is advised after artificial urinary sphincter placement, as urodynamic parameters can change profoundly over time.

- The patient satisfaction rate is reported to be **85-95%** and depends more on the degree of improvement than on the achievement of total continence.

- Success is likely in large part influenced by **proper patient selection** and **careful patient education** regarding expectations and the possible, even eventual, need for operative revisions. *(Chartier-Kastler et al, 2011)*



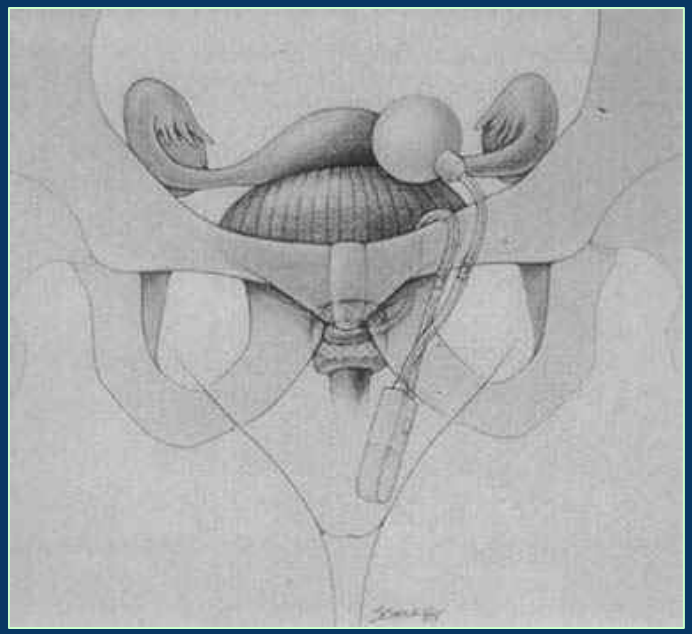
What are the surgical techniques used for AUS implantation??

I. Open surgery technique

A. The *Abdominal Approach:*

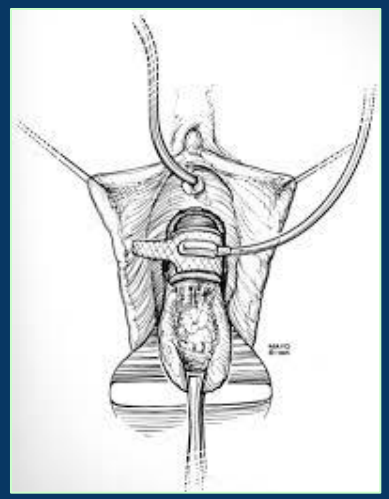
- Mainly used when the intended site for implantation of the AUS is at the bladder neck, especially in females.
- It is done via the **suprapubic approach.**

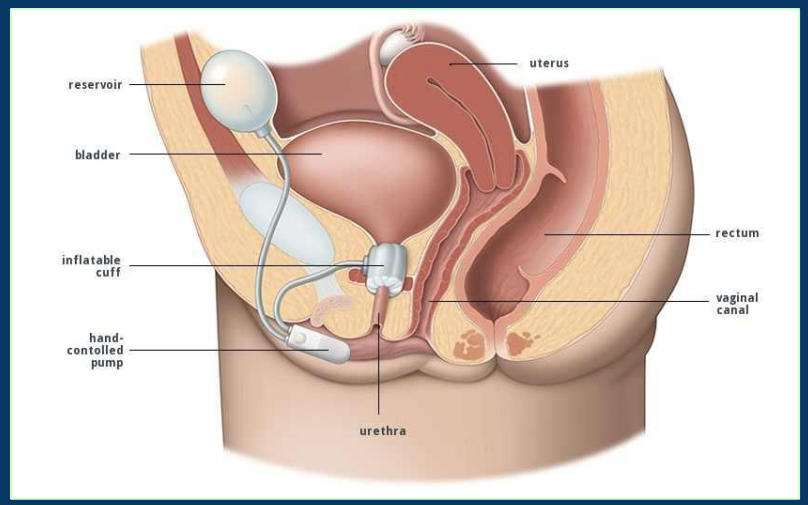
(Light, 2005)



B) The *Combined Abdominal and Transvaginal Approach:*

- This approach mirrors the combined perineal and abdominal approach for males whereby the transvaginal incision is for the insertion of the cuff while the abdominal incision is for the placement of the balloon reservoir.
- 100% success rate was reported with this approach.
- The transvaginal route is associated with a relatively **high morbidity** and **infection rate**. *(Appell, 1988)*





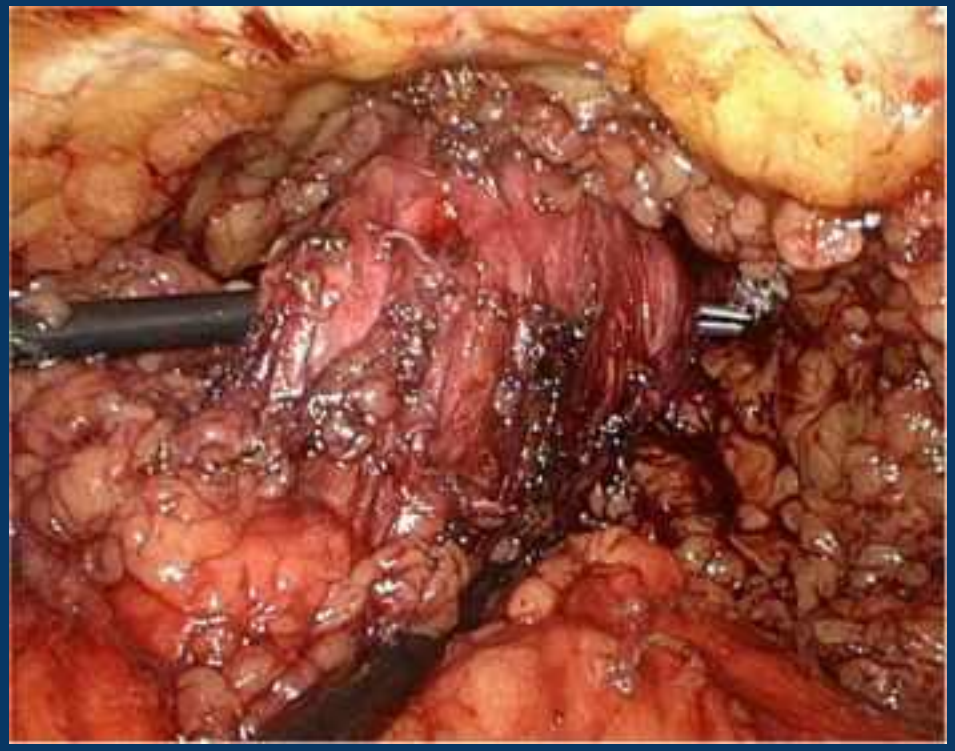
II. Laparoscoic technique

- It is **a safe, effective and considerably a minimally invasive procedure** for implantation of the AUS trans-abdominally.

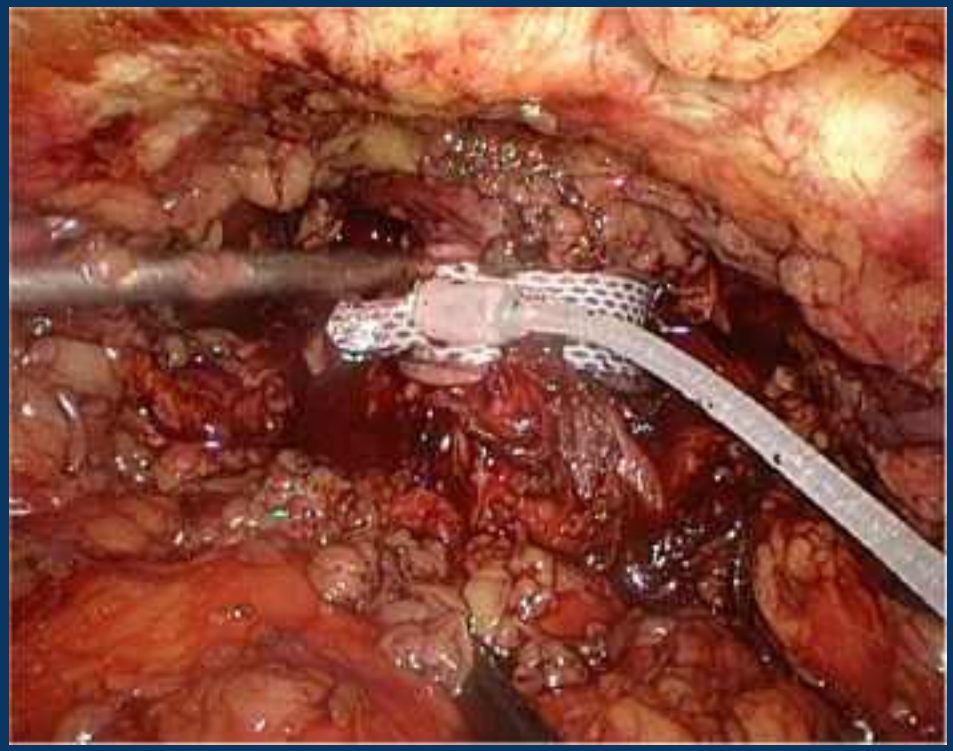
- It is mainly done for female urinary incontinence. Unlike the open approach, it has the advantage of approaching the site of interest via a virgin area. However, it has a steeper learning curve and requires expertise in laparoscopic skills. *(Sharma et al, 2009)*

1- Port placement

2- Start of the dissection of the vesicovaginal pouch



3- A view of the ‘tunnel



4- A laparoscopic view of the urethra with the AUS in place

III. Robotic assisted laparoscopic technique

- **Surgical technique:**
- Procedures were performed with the assistance of a **da Vinci robot**.
- The periurethral space was dissected after transperitoneal access to the Retzius space. An 11-mm port placed in the **right iliac fossa allowed introduction of the AUS device.**
- The cuff and balloon tubes were externalised via a 5-mm suprapubic incision. The peritoneum was finally sutured.

Thank You