

CAUSES OF INCONTINENCE

- Injury to sphincter after prostate operation (radical prostatectomy, prostatic adenomectomy, TURP/Trans-Urethral Resection of Prostate)
- Defective sphincter due to a neurological disease (spinal-bifida, traumatism)
- Defective sphincter due to a congenital malformation.

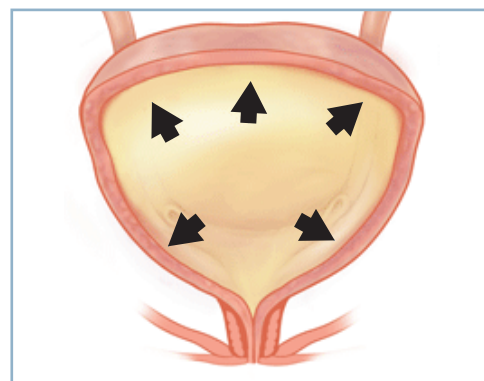
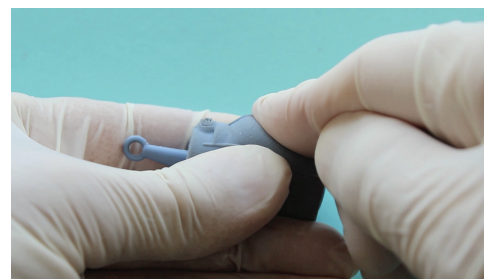
PATIENT SELECTION PRECAUTIONS

Before implanting an artificial sphincter, surgeons and patients must be aware and understand the hazards involved with the procedure so that sound decisions can be made and the risk of failure minimized. Surgeons may implant an artificial urinary sphincter in case of severe incontinence due to a defective intrinsic sphincter only after certain precaution and contraindication have been considered.

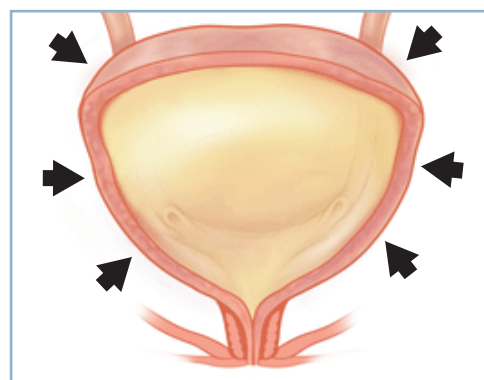
- Patient must have good mental acuity, motivation, physical strength and sufficient dexterity to use the artificial sphincter correctly.

NOTE: Use given rubber mould of device to check if patient is capable of correctly squeezing the pump button.

- Surgeons must inquire into patients medical history. Has patient had a perineal trauma like accident (risk of injured urethra), infection/surgery and/or radiotherapy (risk of thin or blocked urethra).
- A Progressive Degenerative Disease may limit the utility and/or efficacy of the artificial sphincter because the patient will not be able to use it.
- A small bladder may require treatment prior to an artificial sphincter implantation. Due to the lack of urinal capacity of the bladder, the patient will need to urinate very frequently and might also experience pain as the bladder will expand once more in holding urine, something the bladder might have accustomed out off.
- Patients suffering from urge incontinence, overflow incontinence and/or vesical hyper-reflexia must have complications treated prior to the implantation of the artificial sphincter.
- Urge incontinence is the inability to deal and/or control the need to urinate.
- Weakness of the detrusor and hyper-reflexia means that the bladder contracts randomly without patient's control, which can lead to incontinence.
- An infection of the genital and/or perineal area must be treated before implantation. It increases the risk of infection during operation.
- Patients must be checked for known allergic reactions and/or sensitivities to silicone as the artificial sphincter is made from silicone.



Urine expands the bladder, which can cause severe discomfort for a patient whose bladder muscles have become accustomed to flaccidity.



Random contractions of the bladder's muscles can cause irregular and unexpected incontinency.

Patients should be well informed about the artificial sphincter, such as the potential risk of device failure and that there may not be total continence after implantation due to the patients genetic predisposition.

CONTRAINDICATION

In case of a contraindication, it is strongly advised against implanting an artificial sphincter. The risk of failure would be too high.

Contraindication Present When

- The practitioner so judges it, as in the case of an ineligible patient
- When there is a surgical, anaesthetic and/or medical contraindication.
- In cases of weak detrusor urinary muscle due to an untreated hyper-reflexia (random contraction of the bladder leading to high pressure in the bladder and leakage).
- In case of an irremediable or untreatable obstruction of the lower urinary tract that is associated with incontinence

The decision to implant an artificial urinary sphincter can only be confirmed after pre-clinical urodynamic exams have been performed to ensure that no contraindications are present in a patient's case.

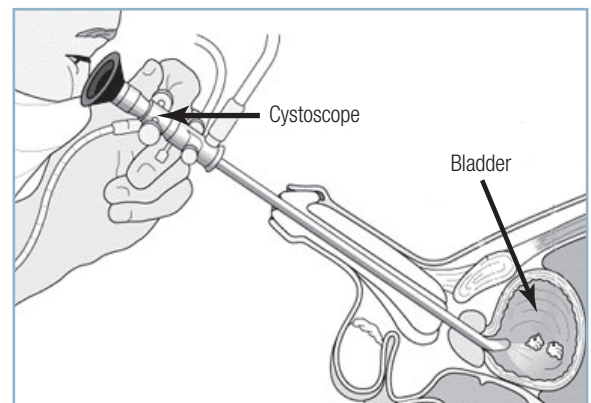
URODYNAMIC EXAMS

Urodynamic exams are performed with a catheter equipped with a pressure sensor system. Surgeons place the catheter in the lower urinary tract through the urethra. Through the catheter the surgeon can fill the bladder and perform the following three exams.

- A Bladder Pressure check is performed using a Cystometer. Bladder pressure should not be too high and patient should not suffer from random bladder contractions such as hyperactivity and/or hyper-reflexy.
- A Urethral Pressure Profile is performed to check urethral pressure and that patient's sphincter is in fact defective.
- A Flow Rate Exam is performed to check urine pressure as patient voids. If the pressure is too low, there might be an obstruction in the urethra such as an urethral stricture/stenosis

RETROGRADE CYSTOGRAPHY OR CYSTOSCOPY

This exam is performed to check that the urethra has not suffered any shrinkage. Before implanting an artificial sphincter, the surgeon must be sure that the urethra is normal and permeable. No stricture or stenosis should be present. In case of obstruction, it must be treated before sphincter procedure.



URINE ANALYSIS AND CULTURE

This exam is performed to check that there is no urinary infection. Urinary infections can lead to further complications after implantation and surgeons are forbidden from implanting a device with an infection in the urinary tract. The risk of infection of the urinary site is too high.

It is important to give truthful information and be honest about the artificial sphincter with the patient so that they may make an informed decision and feel content with this decision.