XZSI PATIENT SELECTION MANUAL FOR UROLOGISTS Precautions and Contraindication to Consider for Patient Eligibility

There are numerous causes of incontinence. It may be a consequence of prostate surgery such as Radical Prostatectomy, Prostate Adenomectomy, Trans-Urethral Resection of the Prostate, or from a neurological difficulty such as Spinal-Bifida or Traumatism, or after a patient has suffered Congenital Malformation. Whatever the causes may be, a positive indication is one where the patient's incontinence has to be helped by an artificial sphincter.

PRECAUTIONS BEFORE IMPLANTATION

All surgeons must be aware of the precautions involved with each case as they can impact the risk of failure of the procedure if not dealt with before hand. A pre-operative evaluation must be done before the procedure to check patient eligibility for the artificial sphincter, such as:

- Patients must have good mental acuity, motivation, manual strength and sufficient dexterity to use the artificial sphincter correctly.
- A history check should be performed to check for perineal trauma (accident, infection, surgery or radiotherapy) as such a history can hinder or even prevent implantation of the artificial sphincter.
- Progressive degenerative diseases may limit the utility and/or efficacy of the artificial sphincter.
- A small bladder may require treatment prior to implantation of the artificial sphincter.
- Patients suffering from urge incontinence, overflow incontinence, instability of the detrusor urinal muscle and/or vesical hyper-reflexia must be treated prior to the implantation of the artificial sphincter.
- An infection in or around the genital and perineal area must be treated before a sphincter procedure.
- The decision to implant an artificial sphincter must be thought through carefully for patients with known sensitivity to silicone
- Patients should be well informed about the artificial sphincter, such as the very low risk of device failure and that there may not be total continence after implantation due to the patients genetic predisposition.

CONTRAINDICATIONS

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

- The practitioner so judges it, as in the case of and ineligible patient
- When there is a surgical, anaesthetic and/or medical contraindication.
- In cases of weak detrusor urinal 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 a 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.