

## INCONTINENCE DIFFICULTIES TREATABLE BY THE ZSI 375 ARTIFICIAL URINARY SPHINCTER

The ZSI Artificial Urinary Sphincter was designed to treat urinary incontinence caused by damage and/or deficiency of the intrinsic urinary sphincter.

### Main causes:

- Sphincter injured during prostate surgery (radical prostatectomy, prostate adenomectomy, TURP).
- Neurological diseases (spinal-bifida, traumatism...).
- Congenital malformation.

## PRECAUTIONS AND CONTRAINDICATIONS

Before implanting an artificial sphincter, surgeons must respect some precautions and contraindications.

**Caution:** Before sphincter procedure, surgeons and patients must be aware of the risks involved so that the chance of any kind of failure can be decreased. In case of contraindication, implantation of the artificial urinary sphincter is forbidden. The risk of failure is too high.

### PRECAUTIONS

Patient evaluation must be performed by practitioner before procedure.

- Patients must have good mental acuity, motivation, manual strength and sufficient dexterity to use the artificial sphincter correctly.
- A past history of perineal trauma (accident, infection, surgery or radiotherapy) 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 an artificial sphincter implantation.
- Patients suffering from urge incontinence, overflow incontinence, instability of the detrusor urinal muscle and vesical hyper-reflexia must be treated prior to implantation of the artificial sphincter.
- An infection of the genital and perineal area must be treated before a sphincter procedure. It increases the risk of infection.
- Traumatic paraplegia and Spina-bifida are the main issues with patients in wheelchairs. For patients who spend their life sitting because of physical disabilities, cuff implantation around the bulbar urethra increases the risk of perineal pressure and urethral erosion.
- Self-catheterization might increase urethral erosion rate with a cuff implanted around the urethra.
- The decision to implant an artificial sphincter must be thought through thoroughly by patients with known sensitivity to silicone.
- Patients must be well informed about the artificial sphincter, particularly regarding the potential risk of failure and the fact that there is not necessarily complete continence after implantation due to genetic predisposition.

### CONTRAINDICATIONS

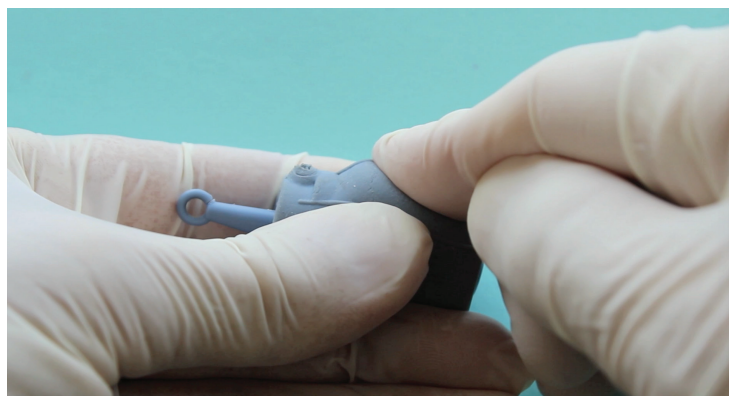
The artificial urinary sphincter is contraindicated when:

- The practitioner so judges it, for example, in the case of a patients past medical history.
- When there is a surgical, anaesthetic and/or medical contraindication.
- In cases of instability of the detrusor urinal muscle or untreated hyper-reflexia.
- Low compliance of untreated bladder.
- In case of irremediable obstruction of the lower urinary tract that is associated with incontinence.

A decision to implant the artificial sphincter is confirmed after pre-clinical exams are performed, such as:

- Urodynamic exam
- Retrograde cystography or cystoscopy
- Urine analysis and culture

It is important to be honest and truthful with patients about the artificial urinary sphincter, the procedure and patient requirements so that they are in agreement.



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