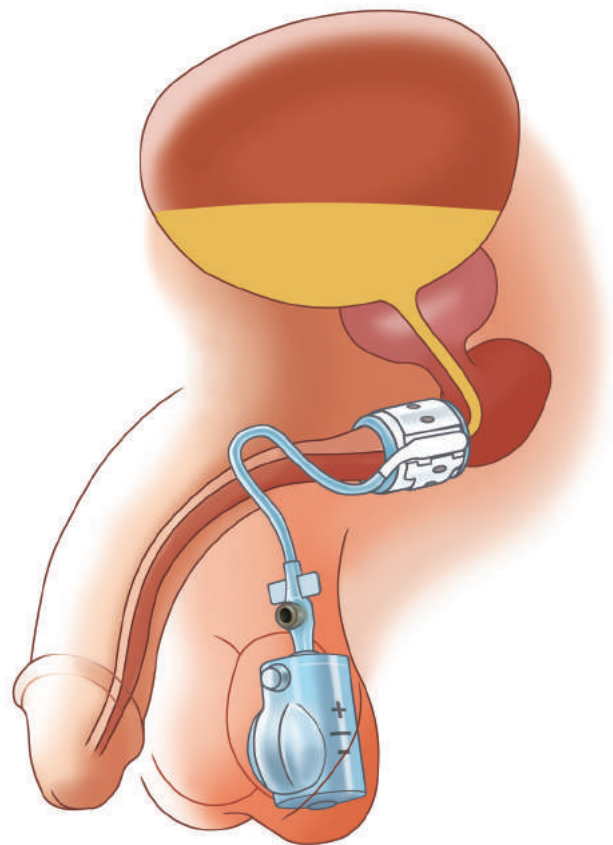


ARTIFICIAL URINARY SPHINCTER ZSI 375

12
YEARS
ANNIVERSARY
2007-2019



A technological breakthrough for male incontinence

SECOND EDITION
NOVEMBER 2019

ZSI 375 MANUAL

Easy to implant

Easy to use

‘Let every man judge according to his own standards,
by what he has himself read, not by what others tell him.’
Albert Einstein (1949) *The World As I See It*

ZSI 375 MANUAL ORIGINS AND GRATITUDE TO EARLY IMPLANTERS

HISTORY OF THE ZSI 375 MANUAL

This manual is a summary of the knowledge acquired to date on the Artificial Urinary Sphincter ZSI 375. It gathers in a single volume, the pedagogical sheets that have been developed and continuously improved for 12 years; it offers readers a better understanding of the functioning of the ZSI 375 Artificial Urinary Sphincter to optimise its use. We hope that this manual will provide you with additional information on the videos available on our website www.zsimplants.ch and complement our local technical team's support. If you have any questions, do not hesitate to contact ZSI directly at contact@zsimplants.ch or your local ZSI team.

Raphaël Gomez Llorens
Global Marketing Manager
Head of Training



ACKNOWLEDGEMENTS TO EARLY IMPLANTERS

From 2009 to 2019, over 4500 Artificial Urinary Sphincters (AUS) ZSI 375 were implanted in different versions. This success would not have been possible without the trust and motivation from visionary surgeons and distributors from Argentina, Austria, Colombia, Costa Rica, Germany, Italy, Poland, Portugal, Spain and Turkey.

From as early as between 2009 and 2011, they promoted the technology and quality of ZSI products around the world.

We especially thank the technical teams and German surgeons, who provided us with the support to offer today an exceptional Artificial Urinary Sphincter and a product line that is revolutionising the world of implants in Urology.

Dr Christophe Llorens
Head of Research and Development
Urology Surgeon



MADE IN SWITZERLAND
In the heart of Europe
ZSI, Zephyr Surgical Implants
Route des jeunes 4bis,
Les acacias-Geneva
CH-1227, Switzerland



2007 Prototype

2009 First generation of implant



- 2 components - preconnected/adjustable
- Adjustable Cuff to fit all patients' urethra
- Cuff designed in a curved form
- Cuff size from 3.75 to 5.5 cm circumference
- Minimally invasive
- Radio opaque mechanism

2011 Second generation of implant



Improvements from First generation - Components reinforced

- 2 components - preconnected/adjustable
- Adjustable Cuff to fit all patients' urethra
- Cuff designed in a curved form
- Cuff size from 3.75 to 5.5 cm circumference
- Minimally invasive
- Radio opaque mechanism

ADDITIONAL FEATURES

- **Bigger Activation-Deactivation Buttons**
- **Addition of Wings to avoid rotation**

2015 Third generation of implant



Prefilled and ready to use

- 2 components - preconnected/adjustable
- Adjustable Cuff to fit all patients' urethra
- Cuff designed in a curved form
- Cuff size from 3.75 to 5.5 cm circumference
- Minimally invasive
- Radio opaque mechanism
- Bigger Activation-Deactivation Buttons
- Addition of Wings to avoid rotation



ADDITIONAL FEATURE

- **Prefilled**

2017 Fourth generation of implant



Prefilled and ready to use

- 2 components - preconnected/adjustable
- Adjustable Cuff to fit all patients' urethra
- Cuff designed in a curved form
- Minimally invasive
- Radio opaque mechanism
- Bigger Activation-Deactivation Buttons
- Addition of Wings to avoid rotation
- Prefilled



ADDITIONAL FEATURES

- **Cuff size from 4 to 6 cm circumference**
- **Fast closure of the Cuff with buttons**
- **Temporary Extension Tab for easy Cuff implantation**
- **All adjustments from scrotum, thanks to new Septum position**
- **Pressure adjustment controlled with a Pressure Sensor (option)**

*Preconnected and Prefilled at manufacture and all functions fully tested for 48hr before delivery.

SUMMARY

ZSI 375 PRESENTATION AND FUNCTIONING	7
1. ZSI 375 PRESENTATION.....	8
A - ARTIFICIAL URINARY SPHINCTER ZSI 375.....	8
B - ZSI 375 DELIVERED PACK CONTENTS.....	8
2. HOW TO URINATE - EASY PATIENT USE	9

PATIENT SELECTION FOR ZSI 375 IMPLANTATION.....	11
1. PRECAUTIONS AND CONTRAINDICATIONS TO CONSIDER FOR PATIENT ELIGIBILITY	12
A - PRECAUTIONS BEFORE IMPLANTATION.....	12
B - CONTRAINDICATIONS.....	12
2. PRECAUTIONS AND CONTRAINDICATIONS TO CONSIDER FOR PATIENT WITH NEUROLOGICAL ISSUES	13
A - INCONTINENCE DIFFICULTIES TREATABLE BY ZSI 375 ARTIFICIAL URINARY SPHINCTER.....	13
B - PRECAUTIONS AND CONTRAINDICATIONS.....	13
3. PATIENT MENTAL ACUITY AND MANUAL DEXTERITY	14
4. MANAGEMENT OF PATIENT EXPECTATION.....	15

PATIENT AND SURGICAL THEATRE PREPARATION BEFORE ZSI 375 IMPLANTATION	17
1. GUIDELINES ON PRECAUTIONS FOR THEATRE NURSE.....	18
A - PATIENT PREPARATION FOR PROCEDURE	18
B - THEATRE PREPARATION	18
C - INSTRUMENTS AND MATERIAL PREPARATION	18
2. FIGHT AGAINST INFECTION.....	19
A - GENERAL INFORMATION	19
B - PREPARATION OF THE PATIENT	19
C - PREPARATION OF THE SURGEON.....	19
D - IRRIGATION OF THE IMPLANTATION SITE.....	19
E - PREPARATION OF THE DEVICE	19
F - PRECAUTION WITH THE PUMP	19
G - LAST PRECAUTIONS	19
H - ANTIBIOPROPHYLAXIS	20
3. SAFETY FIRST: THE OFFICIAL ZSI 375 IMPLANTATION PROTOCOL	21

SURGICAL PROCEDURE	23
1. DISSECTION	24
2. ZSI 375 PREPARATION BEFORE IMPLANTATION	25
A - REMOVING THE ZSI 375 FROM ITS PACKAGING LIQUID.....	25
B - TEST THE SPRING	25
C - PREPARATION OF THE CUFF FOR IMPLANTATION / DEACTIVATION WITH CUFF EMPTY.....	26
3. IMPLANTATION	27
A - IMPLANTATION OF THE CUFF/LOCKING THE CUFF	27
B - CONTROL OF THE CUFF ISSUED PRESSURE	27
C - DEACTIVATION BEFORE IMPLANTATION OF THE PUMP.....	27
D - IMPLANTATION OF THE PUMP AND WINGS SUTURING	28
4. TIPS AND TRICKS.....	29
A - CONTROL OF THE CUFF ISSUED PRESSURE (From image 43).....	29
B - IMPLANTATION OF THE PUMP UNIT, TROUBLESHOOTING (from image 57).....	29

C - ACCESS TO THE PUMP UNIT POST IMPLANTATION (IF REQUIRED)	30
D - FOLLOW THE OFFICIAL IMPLANTATION PROTOCOL TO AVOID EXCESSIVE BENDING (ELBOW) OF THE ARMED TUBING	30
E - TRANSCORPORAL TECHNIQUE FOR A WEAK URETHRA	30
5. OPERATING ROOM CHECKLIST	31
6. GUARANTEE	32
ACTIVATION OF THE ZSI 375	35
1. ACTIVATION DAY GUIDELINES, PATIENT CARE	36
A - CREATE A SECURE ENVIRONMENT	36
B - PREPARE YOUR ACTIVATION KIT	36
C - ACTIVATION - BEST POSITION FOR FINGERS	37
D - ACTIVATION - SUPPORT OF SPATULA AND LOCAL ANAESTHETIC GEL IF NEEDED	37
2. 8 WEEKS AFTER IMPLANTATION, DEVICE CAN BE ACTIVATED	39
A - BEFORE ACTIVATION	39
B - DURING ACTIVATION	39
C - AFTER ACTIVATION	39
X-RAY / FLUOROSCOPY / MRI / AIRPORT SCANNERS	41
1. ZSI 375: HOW TO PERFORM AN X-RAY	42
2. ZSI 375: HOW TO IDENTIFY IT IN AN X-RAY (OR FLUOROSCOPY)	44
A - WHAT IS THE RADIO OPAQUE CYLINDER WE SEE IN THE X-RAY (OR FLUOROSCOPY)?	44
B - ZSI 375 WITH CORRECT CUFF PRESSURE	45
C - ZSI 375 LACKS PRESSURE	45
D - SPRING COMPLETELY DECOMPRESSED	45
E - DEVICE DEACTIVATED WITH CUFF IN OPEN POSITION	45
F - SAFE FOR AIRPORT SCANNER AND MRI	45
DEALING WITH ZSI 375 DOUBTS OF FUNCTIONING AND POST SURGERY MANAGEMENT	47
1. OVERVIEW OF INVESTIGATION PROCESS	48
A - IF THERE IS DOUBT - ALWAYS PERFORM AN X-RAY	48
B - PSYCHOLOGICAL CONSIDERATIONS	48
C - GENERAL PROTOCOL FOR DEALING WITH DOUBT OF FUNCTIONING	49
D - URINARY CONTINENCE STATUS	49
2. MANAGEMENT WHEN IN DOUBT OF FUNCTIONING AFTER ACTIVATION	50
A - EQUIPMENT FOR INVESTIGATION	50
B - PIERCING SEPTUMS PROTOCOL AND INJECTION TIMELINE	50
B1 INSTRUCTIONS TO PIERCE THE HYDRAULIC CIRCUIT SEPTUM THROUGH THE SCROTUM TO PLACE THE TOP OF THE SPRING LEVEL WITH THE MID-LINE:	50
B2 INSTRUCTIONS TO PIERCE THE COMPENSATION POUCH SEPTUM TO INCREASE OR DECREASE THE PRESSURE:	50
C - DOUBTS WHETHER THE ZSI 375 IS OPERATING PROPERLY: INVESTIGATION	51
C1 INCONTINENCE AFTER ACTIVATION OR AFTER A PERIOD OF CONTINENCE	51
C.1.1. SOCIAL CONTINENCE AFTER ACTIVATION OR AFTER A PERIOD OF CONTINENCE	51
C.1.2. LIGHT, MODERATE, SEVERE INCONTINENCE AFTER ACTIVATION OR AFTER A PERIOD OF CONTINENCE	51
C.1.2.1. X-RAY: THE SPRING OF THE ZSI 375 IS COMPRESSED	52
C.1.2.2. X-RAY: THE TOP OF THE SPRING IS AT THE TOP OF THE CYLINDER OR AT THE MID-LINE	52
C.1.2.3. X-RAY: THE TOP OF THE SPRING IS ABOVE THE TOP OF THE CYLINDER OR ABOVE MID-LINE	53
C.1.2.4. X-RAY: THE SPRING SEEMS TO BE FULLY DECOMPRESSED	54

C2 URINARY RETENTION AFTER IMPLANTATION OF THE ZSI 375	55
C.2.1. X-RAY: THE SPRING IS COMPRESSED BELOW THE TOP OF THE CYLINDER BEFORE ACTIVATION - WHILE PATIENT IS IN RETENTION	55
C.2.2. X-RAY: THE TOP OF THE SPRING IS LEVEL OR ABOVE THE TOP OF THE CYLINDER BEFORE ACTIVATION - WHILE PATIENT IS IN RETENTION	55
C.2.3. X-RAY: THE SPRING IS LEVEL WITH OR ABOVE THE TOP OF THE CYLINDER AFTER ACTIVATION - WHILE PATIENT IS IN RETENTION	56
C.2.3.1. SEVERE URETHRAL EROSION	56
C3 INFECTION AND EROSION	56
3. ZSI 375 REMOVAL	57

PRESSURE ADJUSTMENT WITH PRESSURE SENSOR (OPTION)	59
1. PRESSURE ADJUSTMENT FROM COMPENSATION POUCH VOLUME	60
A. PRESSURE SENSOR PREPARATION FOR PRESSURE ADJUSTMENT FROM COMPENSATION POUCH.....	60
B. ISSUED PRESSURE ADJUSTMENT FROM COMPENSATION POUCH DURING PROCEDURE	60
C. ISSUED PRESSURE ADJUSTMENT FROM COMPENSATION POUCH DURING ZSI 375 LIFETIME	61
D. ISSUED PRESSURE ADJUSTMENT MECHANISM	62

ARTIFICIAL URINARY SPHINCTERS TYPES	65
1. ZSI 375 CUFF DESIGN	66
A - CUFF VISUAL COMPARISON	66
B - FLAT CUFF CLOSED, NOT ZSI 375 CUFF DESIGN	66
C - CIRCULAR CUFF CLOSED, ZSI 375 CUFF DESIGN	66
2. PRESSURE COMPARISON BETWEEN TWO TYPES OF ARTIFICIAL URINARY SPHINCTERS	67
A - PRESSURE REGULATING BALLOON SYSTEM.....	67
B - ZSI 375 SPRING SYSTEM	67

TECHNOLOGY IN DETAILS	69
1. ZSI 375 MECHANISM OVERVIEW	70
2. DEACTIVATION BEFORE IMPLANTATION.....	74
A - DEACTIVATION GENERAL PROTOCOL.....	74
B - DEACTIVATION BEFORE CUFF IMPLANTATION (EXPLAINED WITH PICTURES).....	75
C - DEACTIVATION BEFORE CUFF IMPLANTATION (EXPLAINED WITH DRAWING).....	76
3. DEACTIVATIONS AFTER CUFF IMPLANTATION.....	77
A - ISSUED PRESSURE CONTROL AND DEACTIVATION DURING PROCEDURE	77
B - DEACTIVATION AFTER PROCEDURE.....	78
B1 - AFTER PROCEDURE - DEACTIVATING THE ZSI 375, FOR EXAMPLE TO INSERT A CATHETER	78
B2 - DEACTIVATION USING THE DEACTIVATION BUTTON.....	78
B3 - EMPTYING COMPENSATION POUCH (EMERGENCY).....	79
4. ACTIVATION	80
5. MICTURITION.....	82

AVAILABLE ON ZSI WEBSITE: PUBLICATIONS AND TRAINING VIDEOS.....	85
1. PUBLICATIONS.....	86
2. COMPLEMENTARY VIDEOS	88
0 - FUNCTIONING (HOW TO URINATE).....	88
1 - DEACTIVATIONS	88
2 - ACTIVATION	88
3 - TOP OF THE SPRING ADJUSTMENT AFTER CUFF IMPLANTATION	88

4 - TOP OF THE SPRING ADJUSTMENT POST SURGERY..... 88

5 - SPRING STRENGTH POST SURGERY..... 89

6 - CUFF SIZE 89

7 - EXCESS OF SALINE SOLUTION IN THE HYDRAULIC CIRCUIT 89

8 - EXTRA SALINE SOLUTION IN THE COMPENSATION POUCH..... 89

9 - EMERGENCY DEACTIVATION 89

10 - HYDRAULIC MECHANISM (HOW TO URINATE) 89

Part of this manual is linked with 11 short videos (around 1 minute each) which will help you to quickly understand the features of the ZSI 375.

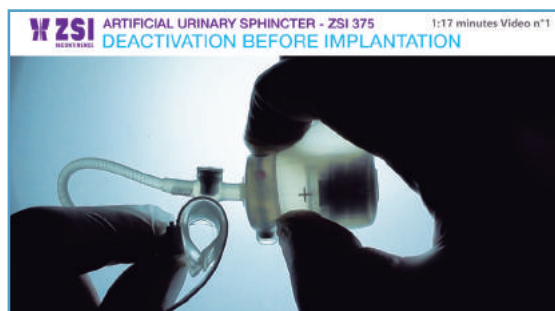
- See page 88-89
- Available at www.zsimplants.ch (fast access to videos)
- Available on WhatsApp - ask your ZSI representative



ESSENTIAL KNOWLEDGE VIDEO

1 - DEACTIVATIONS
1:17 minutes video

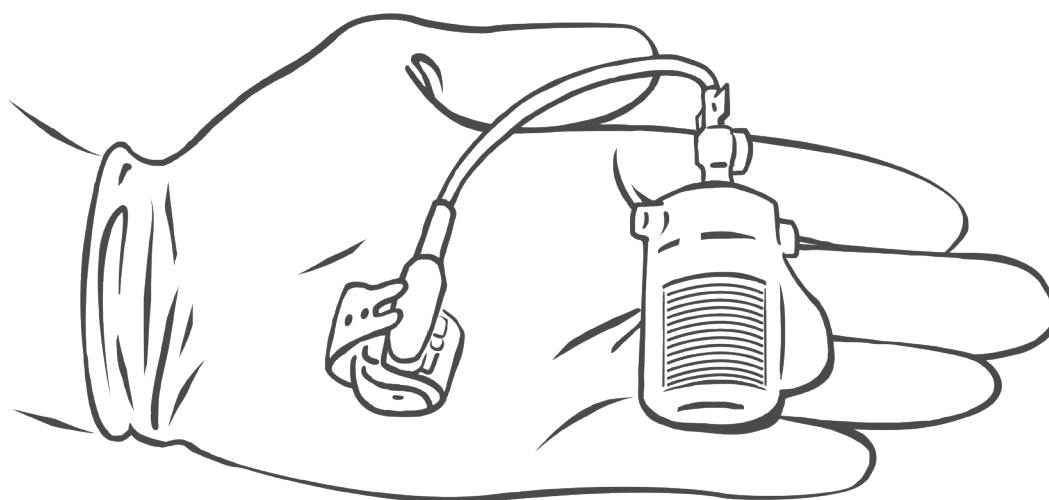
DIRECT ACCESS



I

ZSI 375 PRESENTATION AND FUNCTIONING

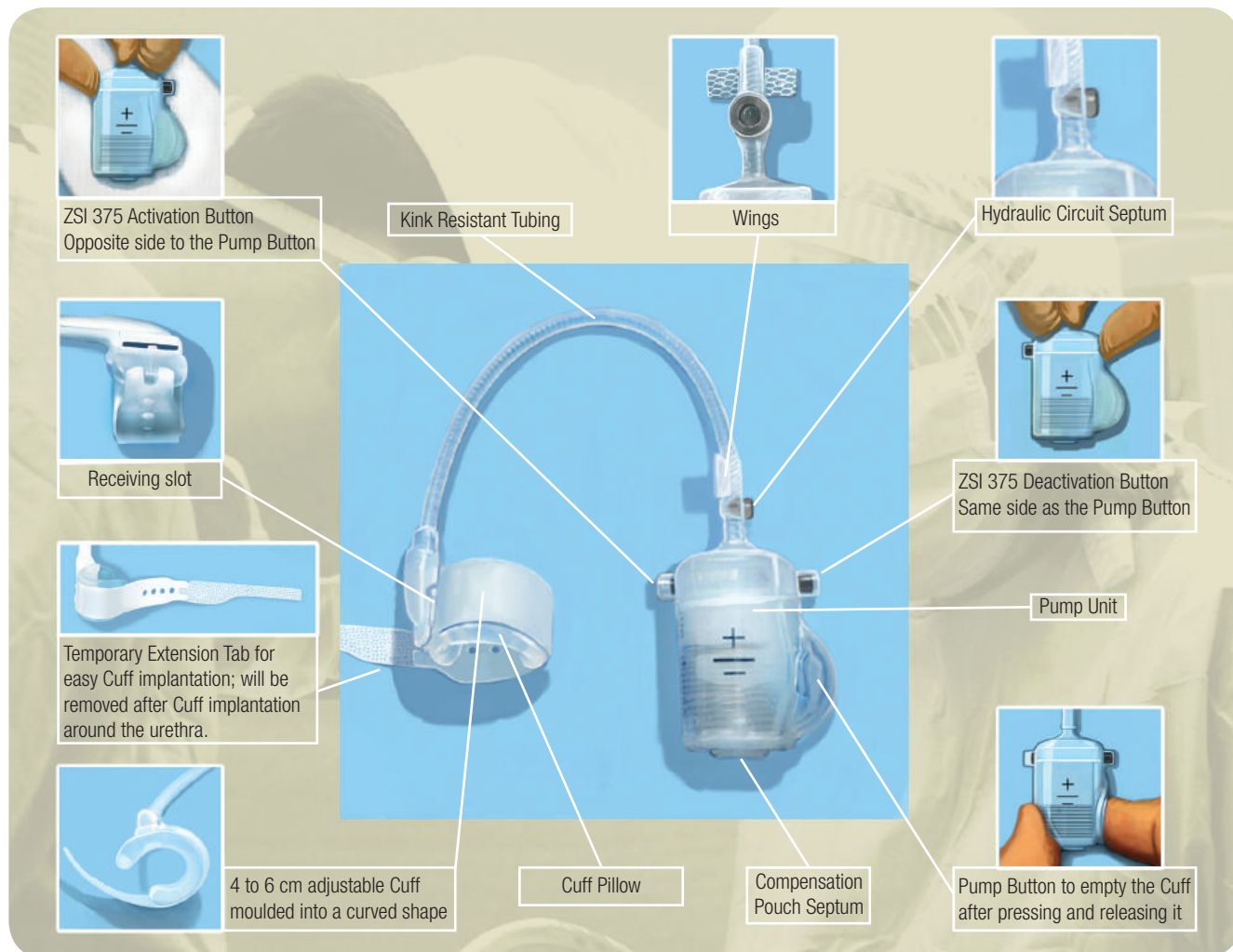
ZSI 375 PRESENTATION AND FUNCTIONING	7
1. ZSI 375 PRESENTATION.....	8
A - ARTIFICIAL URINARY SPHINCTER ZSI 375.....	8
B - ZSI 375 DELIVERED PACK CONTENTS.....	8
2. HOW TO URINATE - EASY PATIENT USE	9



1. ZSI 375 PRESENTATION

A - ARTIFICIAL URINARY SPHINCTER ZSI 375

ZSI 375 is a one-piece assembly medical device that can be implanted in men. It is made of a silicone elastomer and filled with sterile Saline Solution 0.9‰. It is designed to treat moderate to severe urinary incontinence secondary to an intrinsic urinary sphincter deficiency.



B - ZSI 375 DELIVERED PACK CONTENTS

1 - ZSI 375 packed in Saline Solution 0.9‰ delivered sterile



2 - Two Huber needles of 24 Gauge delivered sterile



3 - Patient Implantation Form to activate guarantee

PATIENT INFORMATION FORM	
<p>PURPOSE OF USE: SURVEILLANCE OF THE PATIENT'S CLINICAL STATUS</p>	
<p>1. Patient Information:</p> <p>Name: _____</p> <p>Address: _____</p> <p>City: _____</p> <p>Postal Code: _____</p> <p>Country: _____</p>	<p>2. Date of Implantation:</p> <p>_____</p>
<p>3. Implantation Details:</p> <p>Implanted by: _____</p> <p>Implanted at: _____</p>	<p>4. Signature of the Patient:</p> <p>_____</p>
<p>5. Signature of the Physician:</p> <p>_____</p>	

4 - Traceability Stickers



5 - Instructions



6 - Patient Implantation ID



2. HOW TO URINATE - EASY PATIENT USE

Page 88, 89 - Video 0 - Video 10



Representative view of the urethra state at different stages of opening. The aim throughout this manual is to explain the relationship between the urethra state and the position of the Spring (whether the Pump Button is released or not).

1

With one hand hold the Pump Unit in the scrotum with the Pump Button forward.

2

With the index finger of the other hand Press and...

3

...Release the Pump Button once. The Cuff deflates, decompressing the urethra.

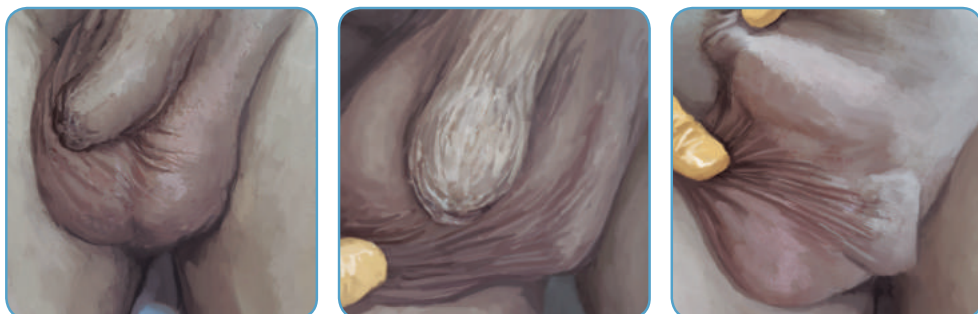
4

The Cuff needs 2-3 minutes to automatically re-inflate and compress the urethra once again.

Question: if the patient did not have time to complete voiding after 2 minutes?
 Answer: press the Pump Button again.

Neither the device nor the Cuff will interfere with your sexual libido and/or your erection. If ejaculation is still possible, it will also be unaffected if the flow of ejaculate has sufficient strength.

While the Pump Unit has been anatomically designed to be discreet and concealed from view, it can be easily found and manipulated in the scrotum.



Patient satisfaction depends on two factors besides appropriate medical selection:

- They have good mental acuity to understand the concept of an AUS.
- Their expectations are realistic and well managed.

II

PATIENT SELECTION FOR ZSI 375 IMPLANTATION

PATIENT SELECTION FOR ZSI 375 IMPLANTATION.....	11
1. PRECAUTIONS AND CONTRAINDICATIONS TO CONSIDER FOR PATIENT ELIGIBILITY	12
A - PRECAUTIONS BEFORE IMPLANTATION.....	12
B - CONTRAINDICATIONS.....	12
2. PRECAUTIONS AND CONTRAINDICATIONS TO CONSIDER FOR PATIENT WITH NEUROLOGICAL ISSUES	13
A - INCONTINENCE DIFFICULTIES TREATABLE BY ZSI 375 ARTIFICIAL URINARY SPHINCTER.....	13
B - PRECAUTIONS AND CONTRAINDICATIONS.....	13
3. PATIENT MENTAL ACUITY AND MANUAL DEXTERITY	14
4. MANAGEMENT OF PATIENT EXPECTATION.....	15



1. PRECAUTIONS AND CONTRAINDICATIONS TO CONSIDER FOR PATIENT ELIGIBILITY

There are many 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 spina 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 needs to be helped by an Artificial Urinary Sphincter (AUS).

A - PRECAUTIONS BEFORE IMPLANTATION

All surgeons must be aware of the precautions required for each case, as they can increase the risk of failure of the procedure if not dealt with beforehand. A pre-operative evaluation must be done before the procedure, to check patient eligibility for the Artificial Urinary Sphincter. Surgeon should consider:

- The patient's mental acuity, motivation, manual strength and sufficient dexterity to use the Artificial Urinary Sphincter correctly.
- A history check should be performed to check for perineal trauma (accident, infection, surgery or radiotherapy) since this can hinder or even prevent implantation of the Artificial Urinary Sphincter.
- Progressive degenerative diseases may limit the utility of the Artificial Urinary Sphincter.
- A small bladder may require treatment prior to implantation of the Artificial Urinary Sphincter.
- Patients suffering from urge incontinence, overflow incontinence, instability of the detrusor muscle and/or vesical hyperreflexia must be treated prior to implantation of the Artificial Urinary Sphincter.
- Any infection in or around the genital and perineal area must be treated before a Artificial Urinary Sphincter procedure.
- The decision to implant an Artificial Urinary Sphincter must be considered carefully for patients with a known sensitivity to silicone.
- Patients should be well informed about the Artificial Urinary Sphincter, for example there may not be total continence after implantation due to their patient's genetic predisposition.

B - CONTRAINDICATIONS

Due to the high risk of failure, it is strongly advised that an Artificial Urinary Sphincter is not implanted in cases of contraindications. Contraindications are present when:

- The practitioner judges a patient ineligible.
- There is a surgical, anaesthetic and/or medical contraindication.
- In cases of hyperactive detrusor muscle, due to an untreated hyperreflexia (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.

Urodynamic exams

Urodynamic exams are performed with a catheter equipped with a Pressure Sensor system. The surgeon places 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 the patient should not suffer from random bladder contractions such as hyperactivity and/or hyperreflexia.
- A urethral pressure profile is performed to check urethral pressure and that the patient's sphincter is, in fact, defective.
- A flow rate exam is performed to check urine pressure as the 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 Urinary 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 the Artificial Urinary Sphincter implantation.

Urinalysis and culture

This exam is performed to check that there is no urinary infection which can lead to further complications after implantation. Due to the high risk of infection of the urinary site, the surgeon must not implant a device with an infection of the urinary tract.

2. PRECAUTIONS AND CONTRAINDICATIONS TO CONSIDER FOR PATIENT WITH NEUROLOGICAL ISSUES

A - INCONTINENCE DIFFICULTIES TREATABLE BY ZSI 375 ARTIFICIAL URINARY SPHINCTER

The ZSI 375 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 (spina-bifida, traumatism, etc...).
- Congenital malformation.

B - PRECAUTIONS AND CONTRAINDICATIONS

Before implanting an Artificial Urinary Sphincter, surgeons must consider some precautions and contraindications.

Caution: Before any Artificial Urinary Sphincter procedure, surgeons and patients must be fully aware of the risks involved. In case of contraindication, implantation of the Artificial Urinary Sphincter should not be attempted because of the high risk of failure.

PRECAUTIONS

Patient evaluation must be performed by the practitioner before procedure.

- Patients must have good mental acuity, motivation, manual strength and sufficient dexterity to use the Artificial Urinary Sphincter correctly.
- A past medical history of perineal trauma (accident, infection, surgery or radiotherapy) can hinder or even prevent implantation of the Artificial Urinary Sphincter.
- Progressive degenerative diseases may limit the utility and/or efficacy of the Artificial Urinary Sphincter.
- A small bladder may require treatment prior to an Artificial Urinary Sphincter implantation.
- Patients suffering from urge incontinence, overflow incontinence, instability of the detrusor urinal muscle and vesical hyperreflexia must be treated prior to implantation of the Artificial Urinary Sphincter.
- An infection of the genital and perineal area must be treated before an Artificial Urinary Sphincter procedure as it increases the risk of infection.
- Traumatic paraplegia and spina bifida are the main issues with patients in wheelchairs. For patients who are confined to sitting due to physical disabilities, Cuff implantation around the bulbar urethra increases the risk of perineal pressure and urethral erosion.
- Self-catheterisation might increase the urethral erosion rate with a Cuff implanted around the urethra.
- The decision to implant an Artificial Urinary Sphincter must be considered by patients with known sensitivity to silicone.
- Patients must be well informed about the Artificial Urinary 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 patient's medical history is unsuitable.
- There is a surgical, anaesthetic and/or medical contraindication.
- There is instability of the detrusor urinal muscle or an untreated hyperreflexia.
- There is low compliance of untreated bladder.
- There is a case of irremediable obstruction of the lower urinary tract, that is associated with incontinence.

A decision to implant the Artificial Urinary Sphincter is confirmed after pre-clinical exams are performed, such as:

- Urodynamic exams.
- Retrograde cystography or cystoscopy.
- Urinalysis and culture.

3. PATIENT MENTAL ACUITY AND MANUAL DEXTERITY

Patients must have good mental acuity, motivation, manual strength and sufficient dexterity to use the Artificial Urinary Sphincter correctly. If these conditions are not respected, even after a successful Activation, the patient's perception of the result can be incorrect. The partner of the patient should also be offered guidance on how best to provide support.

Test the patient's dexterity in pressing the blue rubber mould of the Pump Button or if they have any difficulty using the device.



Test the patient's dexterity by also placing the blue rubber mould of the Pump Button in their trouser pocket and pressing it to assess if they have any difficulty using the device.



NOTE: Use given rubber sample of ZSI 375 to check if patient is capable of correctly pressing the Pump Button.

4. MANAGEMENT OF PATIENT EXPECTATION

ZSI recommend that discussion is held with the patient and their partner before implantation, about what can be expected from an Artificial Urinary Sphincter (or any kind of device to treat incontinence). This is to ensure their expectations are realistic.

- The aim of an Artificial Urinary Sphincter is to improve the patient's quality of life. However, no implant for the treatment of incontinence can fully restore the level of functionality the patient had before their pathology was diagnosed.
- Incontinence immediately after the ZSI 375 has been initially implanted is normal. The ZSI 375 is in a 'Deactivated' position, with the Cuff open for urethral healing. Continence status must be the same before and after procedure.
- The Artificial Urinary Sphincter ZSI 375 can always be adjusted if needed. It is delivered and implanted with an adjustable standard pressure adapted for 80% of patients. Nevertheless, the more the surgeon increases the issued pressure the more he increases the risk of urethral ischaemia and the risk of erosion. Erosion will lead to the ZSI 375 having to be completely removed. The surgeon will determine if there is a risk for each particular patient to increase the pressure. It is always better to accept Social Continence or improvement as a good result.

FLYER FOR PATIENTS AVAILABLE AT WWW.ZSIMPLANTS.CH

ZSI recommend presenting this flyer to the patient to give them better knowledge about the ZSI 375 and what can be expected from an Artificial Urinary Sphincter.



SELECTED CONTENT FROM PATIENT'S FLYER (Available for download from www.zsimplants.ch)

After Procedure

1. You will continue to be incontinent and use pads for 2 months until the device is Activated by your doctor.
2. It is normal that your scrotum may be swollen and/or sensitive with discomfort for a month or two.
 - If the discomfort persists, contact your doctor
 - If there is severe pain, inflammation and/or leakage from your incisions, it is important to contact your doctor promptly. You might have an infection.
3. The device is implanted well under the skin and none of its components will ever be visible.
4. The device is Activated two months after the operation, at which time you will visit your doctor and he will firmly press the Activation Button located just above the Pump Button.
 - The goal is to be drier than before the implantation.
 - Some patients have either no need for the use of pads or a substantial reduction in the number used per day.
 - After the Activation most patients have social continence.
5. It is perfectly normal to experience minor leakages when straining your body through minor or major physical activity such as playing sports, working out, certain postures and coughing. This is normal. The Cuff has a constant pressure on the urethra that cannot adapt to sudden muscular strains, as in the case of coughing.
6. It is strongly recommended that you do not ride bicycles, motorbikes and/or horses (only if a special saddle or seat is provided). Such activities create an external pressure on the cuff and urethra and can cause temporary and/or lasting injury to both.
7. Take care when sitting. Any surface is ok as long as the sitting position does not add excessive pressure on the cuff, as pressure on it can aspirate it and cause a small amount of leakage when you stand up. When the pressure is removed, the cuff will inflate again as per normal. Just remember that no sitting position should be putting pressure around the area of your perineum.
8. Neither the device nor the Cuff will interfere with your sexual libido and/or your erection. If ejaculation is still possible, it will also be unaffected if the flow of ejaculate has sufficient strength.
9. The device has been designed to be discrete and undetectable to MRI and Airport scanners.
10. While the device has a minimum life of 30,000 cycles (or on average, 7 to 10 years), it can work perfectly for much longer.
11. If you notice an increase in leakage, it might mean that the device pressure has decreased slightly; it could also simply mean that some fine tuning is required to more closely match the individual's urethra. This is perfectly normal and you should contact your doctor who will be able to make the necessary adjustments.

IMPORTANT: The more the surgeon increases the issued pressure the more he increases the risk of urethral ischaemia and the risk of erosion leading to total removal of the ZSI 375. The surgeon will determine if there is a risk for each particular patient to increase the pressure. It is always better to accept Social Continence or improvement as a good result.
12. If, for whatever reason, you need to introduce a catheter into your urethra, the Cuff must be emptied and the device Deactivated. If not, there is a risk of injuring the urethra and/or Cuff. The injury is almost certain if the device is not Deactivated.

Ask to be given the ZSI 'Pocket Card' which you should carry any with you to present to doctors if performed procedure should be performed on your pelvic area.



III

PATIENT AND SURGICAL THEATRE PREPARATION BEFORE ZSI 375 IMPLANTATION

PATIENT AND SURGICAL THEATRE PREPARATION BEFORE ZSI 375 IMPLANTATION 17

1. GUIDELINES ON PRECAUTIONS FOR THEATRE NURSE..... 18

 A - PATIENT PREPARATION FOR PROCEDURE 18

 B - THEATRE PREPARATION 18

 C - INSTRUMENTS AND MATERIAL PREPARATION 18

2. FIGHT AGAINST INFECTION..... 19

 A - GENERAL INFORMATION 19

 B - PREPARATION OF THE PATIENT 19

 C - PREPARATION OF THE SURGEON 19

 D - IRRIGATION OF THE IMPLANTATION SITE 19

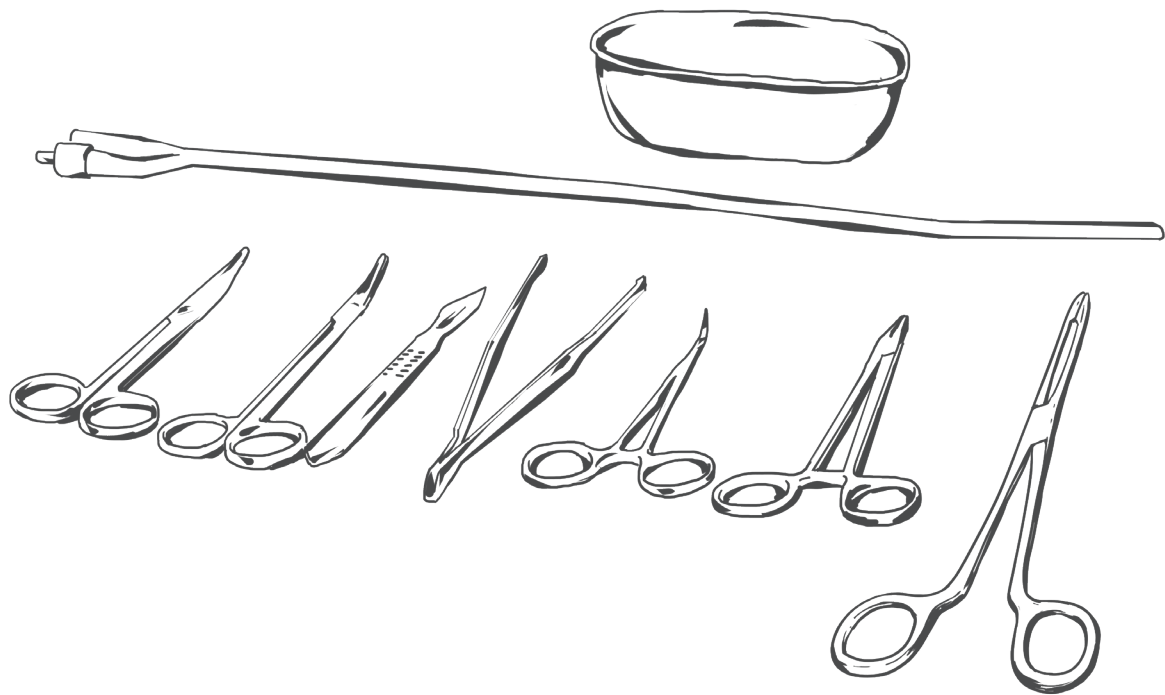
 E - PREPARATION OF THE DEVICE 19

 F - PRECAUTION WITH THE PUMP 19

 G - LAST PRECAUTIONS 19

 H - ANTIBIOPROPHYLAXIS 20

3. SAFETY FIRST: THE OFFICIAL ZSI 375 IMPLANTATION PROTOCOL..... 21



1. GUIDELINES ON PRECAUTIONS FOR THEATRE NURSE

A - PATIENT PREPARATION FOR PROCEDURE

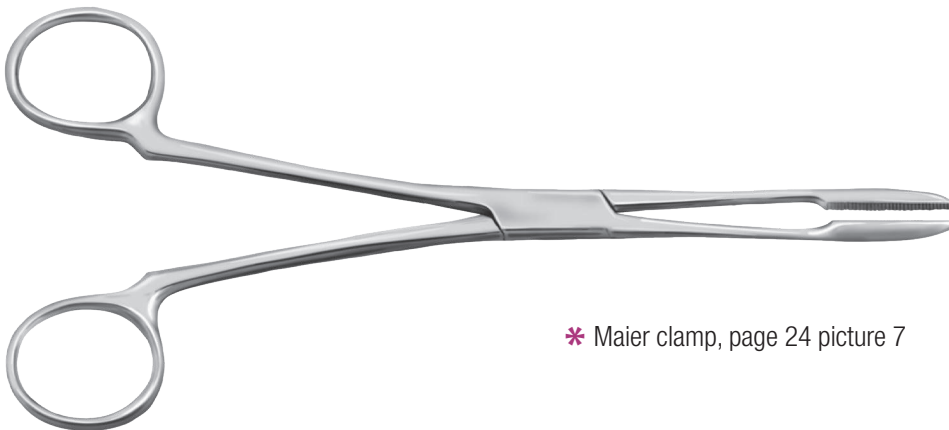
- The patient should be showered with shampoo and antibacterial soap, such as Betadine, both the night and morning before the operation.
- The genitals should be shaved in the holding area or the theatre to minimize bacterial colonization.
- The most common contaminant is staph. epidermidis.
- The patient should be placed in the lithotomy position after the administration of general or spinal anaesthesia.
- Wash the patient's genitals twice with antibacterial soap and antiseptic for 5 minutes.
- With all drapes placed, perform a third scrub.
- Prepare the antibiotic(s) for antibioprohylaxis injection. Use antibiotics adapted to the bacteria of your region prior to the incision.
For example:
 - Inject 2 g of Cefoxitin, using a slow intravenous injection. For a procedure of more than 4 hours, inject 1 g more of Cefoxitin.
 - Antibiotics may be continued 48 hours postoperatively.
- In case the patient is allergic to Cefoxitin, use:
 - 5 mg/Kg of Gentamycin + 1 g of Metronidazole injected in one injection.

B - THEATRE PREPARATION

- The implantation of the device must be the first procedure of the morning to reduce chances of bacterial infection.
- Reduce traffic in the theatre. Doors must be closed to avoid unnecessary air movement. Many bacteria are airborne.
- Minimize procedure time and time the device is exposed to open air. The longer the procedure, the higher the risk of infection.

C - INSTRUMENTS AND MATERIAL PREPARATION

- Use a sterile gel + a sterile 16 Fr/Ch Foley catheter to calibrate the urethra during the procedure, and to drain the bladder.
- Use a sterile gel + a sterile 12 Fr/Ch Foley catheter to drain the bladder after the procedure. The catheter will stay in place overnight after the procedure (24 hours maximum).
- Prepare two bowls. One to receive the ZSI 375 package contents. A second bowl will be filled with 600 mg Rifampin and 640 mg (8 ampules = 640mg) Gentamicin in 600 ml of sterile Saline Solution 0.9‰. This will be used to soak the device and to wash the incision area.
- Instruments: One bipolar cautery, one set of Metzembraum scissors, two bipolar forceps, two surgical retractors (Langenbeck), two mosquito clamps, sterile gauzes and Maier clamp. *
- Sutures: Non-absorbable, monofilament 4-0. This will be used to suture the Cuff and the Wings, which hold the device in place, preventing it from rotating within the scrotum. Absorbable 3-0 for internal tissue closure. Skin closure depends on preferences of the surgeon.
- All surgeons must use a full gown, hood (no cap) and double gloved.
- All surgeons must replace their gloves after draping and before handling the device.



* Maier clamp, page 24 picture 7

2. FIGHT AGAINST INFECTION

A - GENERAL INFORMATION

- The implantation of the device should be the first procedure of the morning, to reduce the risk of bacteria in the operating room.
- Reduce traffic in the operating room. Doors must be closed to avoid air movement, as many bacteria are airborne.
- Reduce procedure time and minimize time the device is exposed to open air. The longer the procedure, the higher the risk of infection.
- Minimize prosthesis skin contact, due to the abundance of bacteria on skin.
- Reduce bleeding. Blood clots are a breeding ground for bacteria.
- An antibiophylaxis is necessary. Use antibiotics adapted to the bacteria of your region prior to the incision.

B - PREPARATION OF THE PATIENT

- Shave the genitals in the holding area or the operating room to minimize bacterial colonization of the skin. The most common contaminant is staph. epidermidis.
- Wash the genitals with antibacterial soap and antiseptic solution for 5 minutes. When all drapes are placed, wash for a second time. Use new, clean scrubs for every case.
- Insert a sterile 16 Fr/Ch Foley catheter in order to drain the bladder.
- Incise draping during surgical procedures is recommended. It provides a effective barrier to bacteria on the skin.



C - PREPARATION OF THE SURGEON

- All surgeons must wear a gown, hood (no cap) and double gloved.
- All surgeons should replace their gloves after draping the area, before skin incision and before touching the device.

D - IRRIGATION OF THE IMPLANTATION SITE

- Before implanting the device, irrigate the scrotal pouch and the perineal incision with local antibiotics.
- Prepare a 600 ml of sterile Saline Solution 0.9‰ with Rifampicin 600 mg then add Gentamicin 80 mg/2 ml (8 ampules = 640mg total).
- Then on the implant trolley prepare a bowl and pour in 100 ml of the prepared antibiotic solution for local irrigation. Then the 500 ml is used for washing the dissection area.

E - PREPARATION OF THE DEVICE

- Change gloves before handling the device.
- Minimize time the device is exposed to open air as many bacteria are airborne.
- Clean the device of its packaging liquid and dip it in the bowl filled with 100 ml prepared of Saline Solution and antibiotic solution.
- Place the device in clean gauze for the transit from the bowl to the implantation site.

F - PRECAUTION WITH THE PUMP

- During the preparation and implantation procedure, the Pump should be wrapped in a clean gauze; it must not touch the skin.

G - LAST PRECAUTIONS

- Final antibiotic solution is done with device installed.
- Remove/wash away the blood clots on the device. Blood clots are an ideal source for the proliferation of bacteria.
- Sew multiple layers over the device in order to have the maximum amount of tissue between the device and the skin, so even if the tissues separates, the device cannot be exposed.

H - ANTIBIOPROPHYLAXIS

Antibiotics must be adapted to the bacteria you encounter in your region. The injection is prior to the incision.

Example:

- Inject 2 g of Cefoxitin, using a slow intravenous injection. For a procedure of more than 4 hrs, inject 1 g more of Cefoxitin.
- Antibiotics may be continued 48 hours postoperatively.

In case of an allergy, instead of Cefoxitin, you could use:

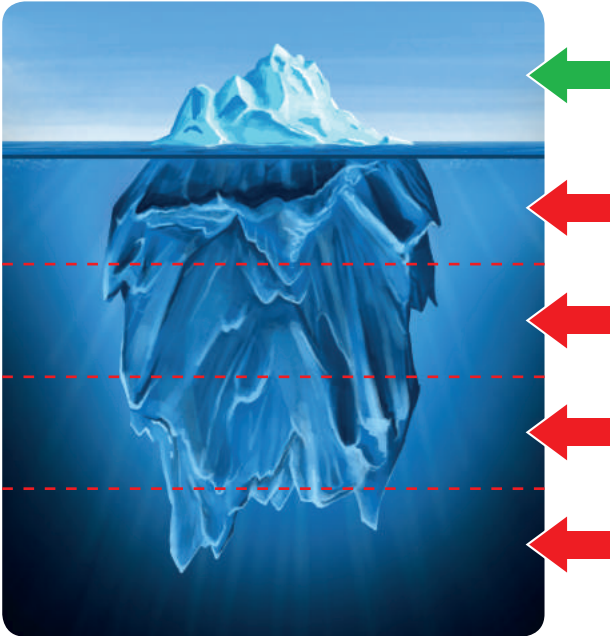
- 5 mg / kg Gentamycin + 1 g of Metronidazole injected as one intravenous injection.

Local antibiotic solution:

- 600 mg Rifampin and 640 mg Gentamicin in 600 ml of sterile Saline Solution 0.9%.

3. SAFETY FIRST: THE OFFICIAL ZSI 375 IMPLANTATION PROTOCOL

After 10 years of experience with implantation of the ZSI 375, there are a few surgeons who have gradually refined the official ZSI protocol with their own implantation technique, and have been able to maintain the same high rate of success. Should a surgeon wish to make any changes in the ZSI 375 implantation protocol, they should not do so until they become expert with the ZSI 375's technology, official ZSI 375 implantation protocol and patient follow up.



Strictly following the official ZSI 375 implantation protocol ensures that you are operating within the safest parameters and minimising risk.

If a decision is made to deviate from the official implantation protocol, the risk(s) of unexpected and unintended consequences increases substantially.

Surgeons with extensive experience of implanting the ZSI 375 are likely to be the only persons who may have any success in modifying the official implantation protocol because they have developed a deep understanding of ZSI 375 technology, and carefully consider the wider consequences of their modifications.

On the following pages is the ZSI recommended safety protocol which has been continuously improved over 10 years. Strictly following this implementation protocol gives the surgeon the highest chances for success. Not following established protocol may increase the risk of failure of the implantation either during or after surgery. Not following the established protocol also means that the ZSI team will be unable to provide the proper support required during and post implantation. Not following the established protocol may invalidate any ZSI warranties in place.

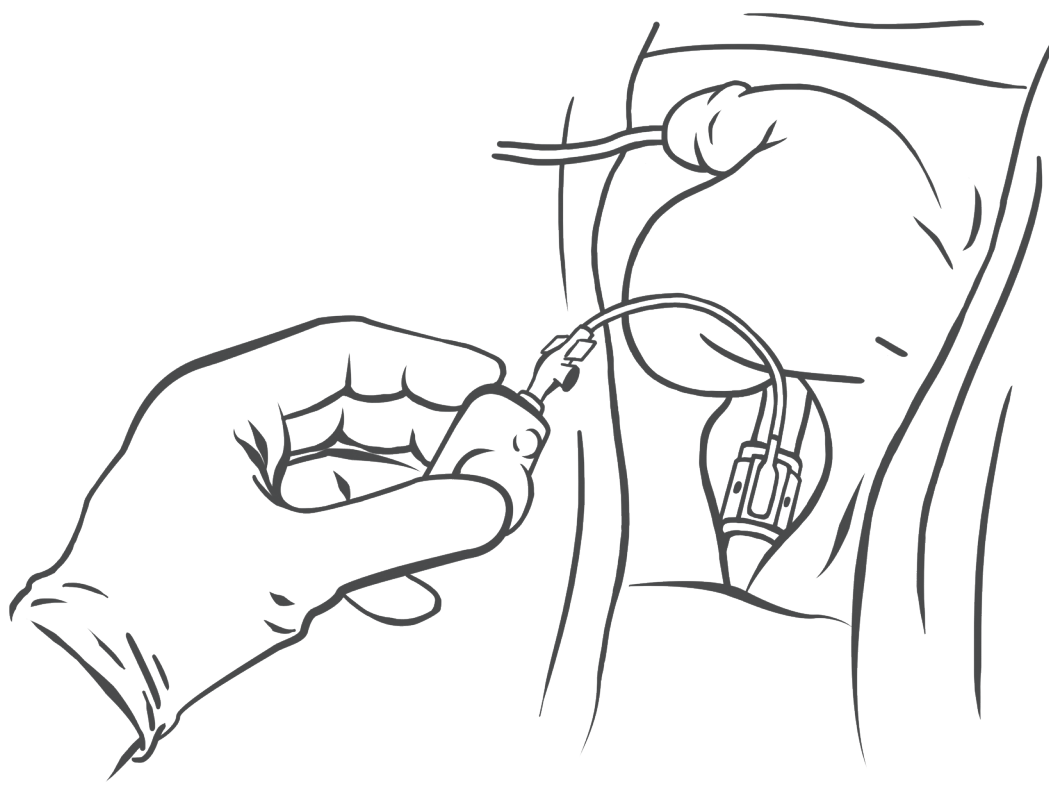
The two incisions implantation protocol is recommended by ZSI because:

- It reduces the risk of connection rupture with an ergonomic angle (no excessive tube bending).
- It reduces the risk of restricting the flow of fluid with an ergonomic angle (no excessive tube bending).
- It provides easy access to the subdartos pouch (easy access to the Activation Button; lower risk of extrusion of the Pump Unit or tubing).
- It allows the possibility to suture the Wings (no migration or rotation of the implant).
- It provides easy access to the Hydraulic Circuit Port.

IV

SURGICAL PROCEDURE

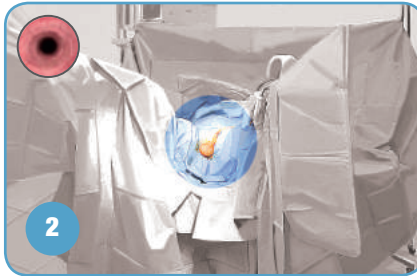
SURGICAL PROCEDURE	23
1. DISSECTION	24
2. ZSI 375 PREPARATION BEFORE IMPLANTATION	25
A - REMOVING THE ZSI 375 FROM ITS PACKAGING LIQUID.....	25
B - TEST THE SPRING	25
C - PREPARATION OF THE CUFF FOR IMPLANTATION / DEACTIVATION WITH CUFF EMPTY.....	26
3. IMPLANTATION	27
A - IMPLANTATION OF THE CUFF/LOCKING THE CUFF	27
B - CONTROL OF THE CUFF ISSUED PRESSURE	27
C - DEACTIVATION BEFORE IMPLANTATION OF THE PUMP	27
D - IMPLANTATION OF THE PUMP AND WINGS SUTURING	28
4. TIPS AND TRICKS	29
A - CONTROL OF THE CUFF ISSUED PRESSURE (From image 43).....	29
B - IMPLANTATION OF THE PUMP UNIT, TROUBLESHOOTING (from image 57).....	29
C - ACCESS TO THE PUMP UNIT POST IMPLANTATION (IF REQUIRED)	30
D - FOLLOW THE OFFICIAL IMPLANTATION PROTOCOL TO AVOID EXCESSIVE BENDING (ELBOW) OF THE ARMED TUBING	30
E - TRANSCORPORAL TECHNIQUE FOR A WEAK URETHRA.....	30
5. OPERATING ROOM CHECKLIST	31
6. GUARANTEE	32



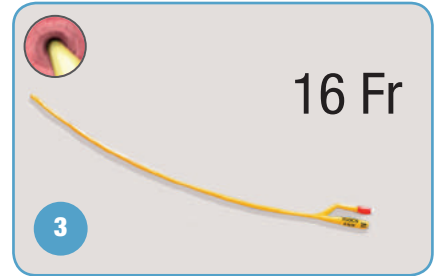
1. DISSECTION



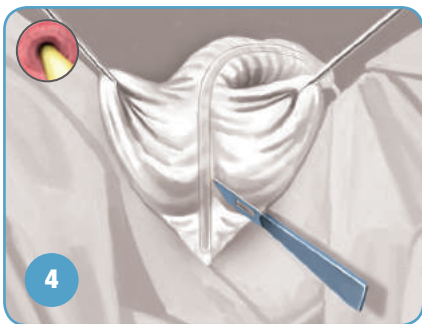
1 Instruments. Use a long Maier Clamp to make the scrotal pouch for the Pump.



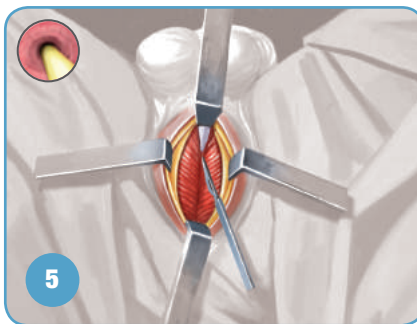
2 Place the patient in the lithotomy position. All surgeons should use new, clean scrubs for every operation. Use a certified operating room. Try to minimize traffic.



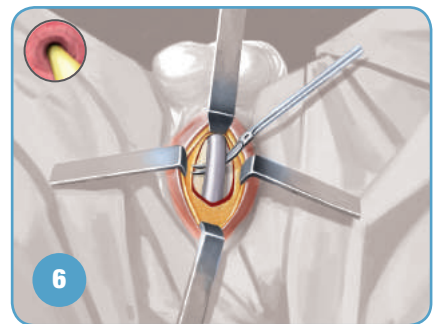
3 Install a size 16 Fr/Ch Foley catheter (no smaller) to calibrate the urethra.



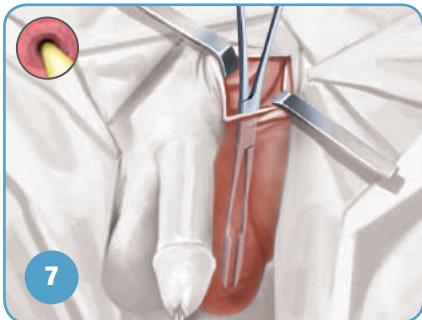
4 Perform a perineal incision. The Foley catheter helps to identify the urethra during dissection.



5 Dissect the fat and the bulbospongiosus muscle covering the urethra.



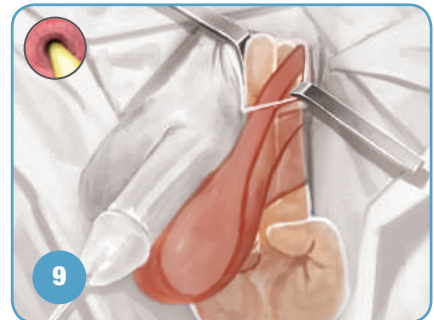
6 Dissect two centimetres of the urethra that is surrounded by the corpus spongiosum.



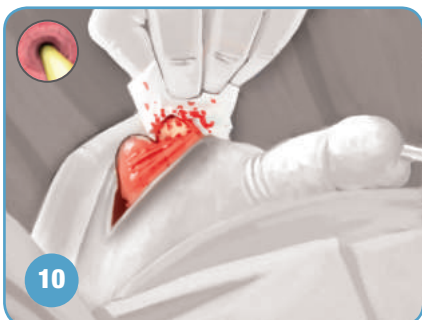
7 Perform an inguinal incision. It is easier to find the subdartos space from an inguinal incision rather than a scrotal incision. It is easier to create a deep, large pouch with a Maier clamp.



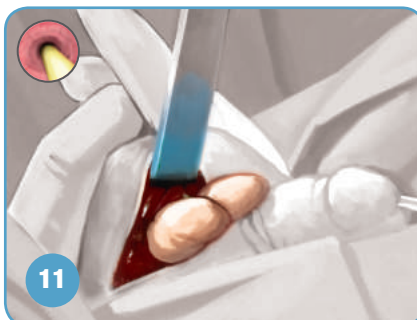
8 Prepare a subdartos pouch for the Pump Unit with the scissors and the maier clamp. The subdartos is between 2 layers: the dartos and the cremaster muscles (same as for orchidopexy).



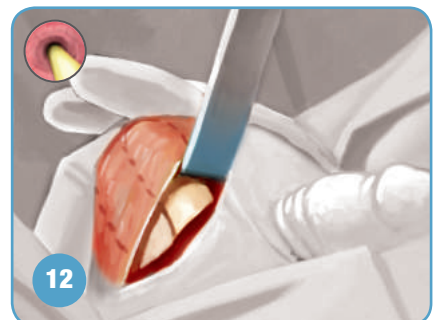
9 Open the passage between the perineal incision and the inguinal incision with the index and the middle fingers. Stay parallel to the urethra. The passage is behind the spermatic cord.



10 Help the fingers go through the tissue with a gauze pad.



11 Check the passage. The subdartos pouch, which receives the Pump Unit, is between 2 layers: the dartos and the cremaster muscles. Enlarge the passage with 2 fingers so that the Pump Unit may enter easily.



2. ZSI 375 PREPARATION BEFORE IMPLANTATION

A - REMOVING THE ZSI 375 FROM ITS PACKAGING LIQUID



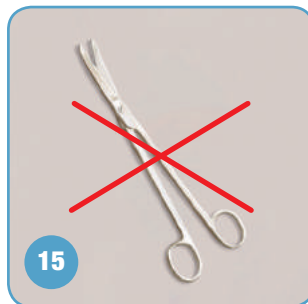
13

Change gloves for preparation. Change gloves if any contact is made with the skin.



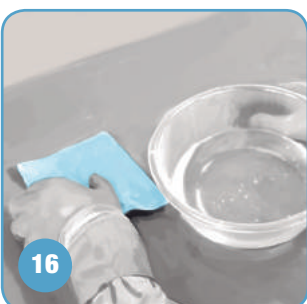
14

There should be minimal contact with the device and only the surgeon should handle it.



15

Never use scissors to open the bag, it can damage the ZSI 375.



16



17



18



19

Open the bag and remove the device carefully into the first bowl full of Sterile Saline Solution 0.9%. The ZSI 375 arrives Pre-filled and Activated. Prepare a second bowl filled with Sterile Saline Solution 0.9%, and antibiotics to clean the device of its packaging liquid.



20

Place the ZSI 375 into the bowl. Minimize the time the device is exposed to open air.

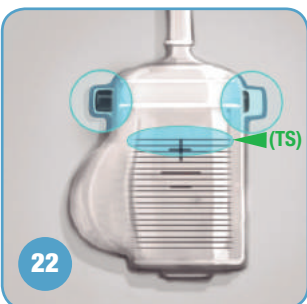


21

Prepare a Huber needle and a syringe filled with Sterile Saline Solution 0.9%.

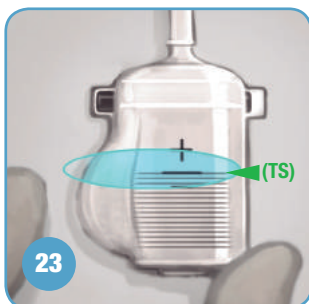
Temporary Extension Tab will facilitate the passage of the Tab into the slot. It will be removed after Cuff implantation around the urethra.

B - TEST THE SPRING



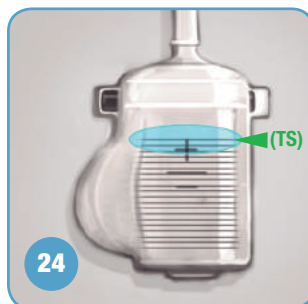
22

The device is ready for test.



23

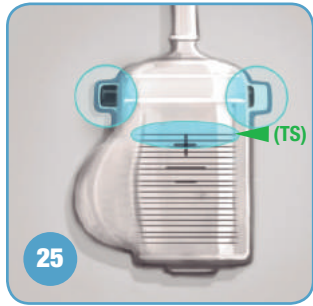
Test the device by pressing and releasing the Pump Button 1 time.



24

Wait for the Top of the Spring (TS) to return above the Plus '+' sign.

C - PREPARATION OF THE CUFF FOR IMPLANTATION / DEACTIVATION WITH CUFF EMPTY

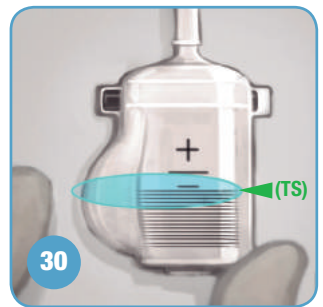
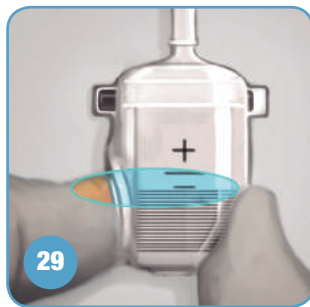


Spring released (ZSI 375 Activated).



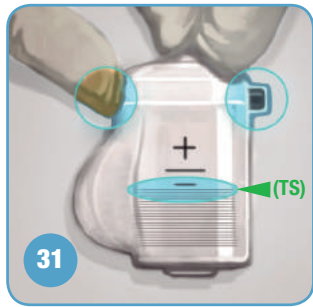
Cuff full (ZSI 375 Activated).

OBJECTIVE:
TO DEFLATE THE CUFF AND
DEACTIVATE THE ZSI 375
TO KEEP THE CUFF FLAT



In order to deflate the Cuff completely, aspirate the Saline Solution from the Cuff to the Tank of the Pump Unit by pressing and releasing the Pump Button. Once the Spring is fully compressed, you will not be able to press the Pump Button any further.

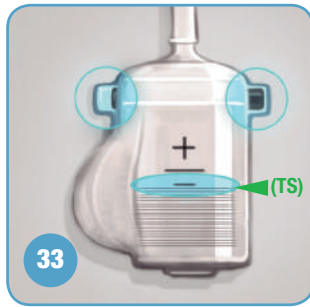
Press and release 3 or 4 times until the Top of the Spring (TS) is below the Minus '-' sign.



When the Top of the Spring (TS) is below the Minus '-' sign, press the Deactivation Button **firmly**.



Cuff must be deflated.



The Top of the Spring (TS) is below the Minus '-' sign. The Cuff is flat. Wait **20 seconds** to check that the ZSI 375 keeps Deactivated.

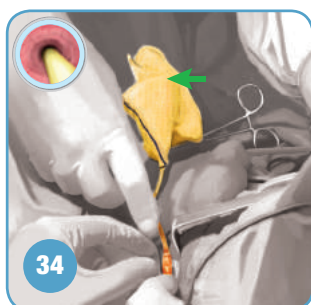
ZSI 375
READY TO BE
IMPLANTED

(DEVICE DEACTIVATED)

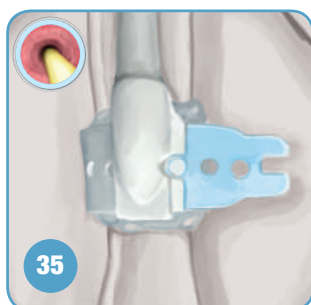
(DEVICE PROPERLY DEACTIVATED)

3. IMPLANTATION

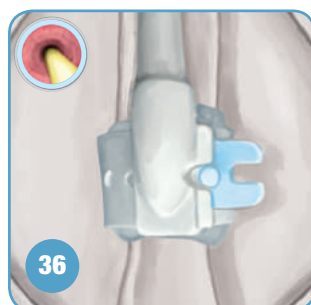
A - IMPLANTATION OF THE CUFF/LOCKING THE CUFF



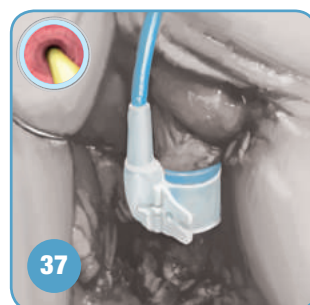
34
Install the deflated Cuff and protect the Pump with a gauze pad. The device should never come in contact with the skin. Remove the Temporary Extension Tab after implantation.



35
New Cuff Tab has simpler and faster button to lock. Fit the Cuff around the urethra. The 16 Fr/Ch Foley Catheter calibrates the urethra and prevents it from being tightened excessively.

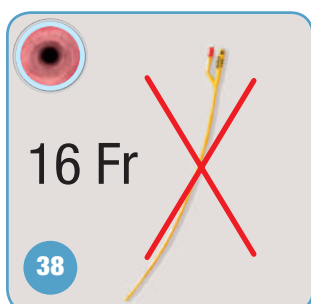


36
You can also keep the Cuff more loose around the urethra, but you will probably have to adjust the volume of Saline Solution in the Hydraulic Circuit; this will move the Spring to the Mid-line.

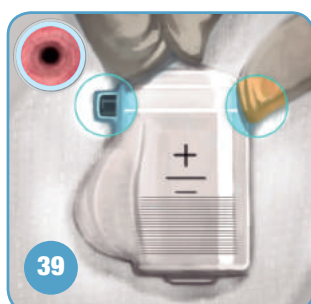


37
Tighten the Cuff with the 16 Fr/Ch Foley catheter to calibrate the urethra. When the Cuff is closed, it must be able to be rotated towards both the right side and the left side of the urethra.

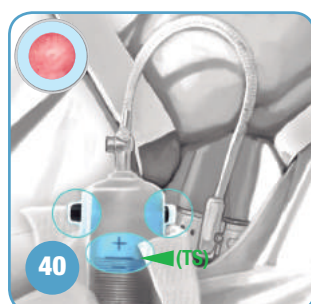
B - CONTROL OF THE CUFF ISSUED PRESSURE



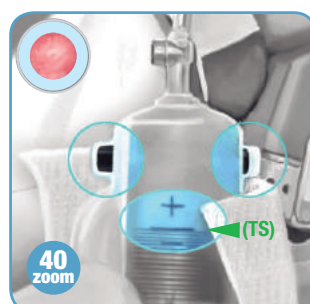
38
Remove the size 16 Fr/Ch Foley catheter.



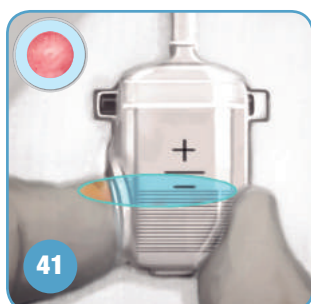
39
Press the Activation Button to Activate the device to check that the correct pressure is delivered.



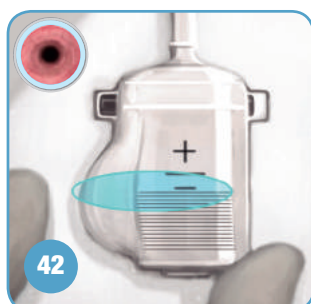
40
After pressing the Activation Button, the Top of the Spring (TS) will automatically rise. **Wait for at least two minutes**



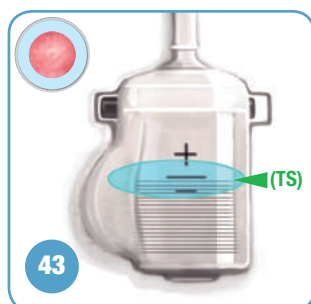
40 zoom
With the urethra in the Cuff, the Top of the Spring (TS) should stop just below or level with the Mid-line.



41
PRESS
TEST: CHECK THE DELIVERED PRESSURE AGAIN



42
RELEASE

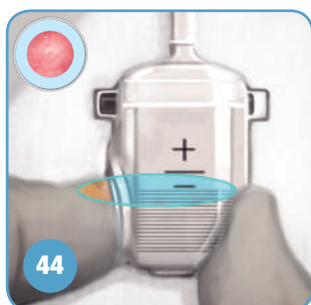


43
The Top of the Spring (TS) will come back just below or level with the Mid-line to achieve standard issued pressure within two minutes.

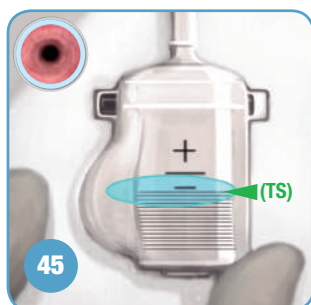
PICTURE 43 SHOWS THE CORRECT POSITION OF THE SPRING. THE TOP OF THE SPRING (TS) IS JUST BELOW THE MID-LINE. THE ZSI 375 DELIVERS THE STANDARD PRESSURE.

IF THE TOP OF THE SPRING (TS) IS NOT JUST BELOW OR LEVEL WITH THE MID-LINE, SEE TIPS AND TRICKS PAGE 29. PICTURE A43 & D43.

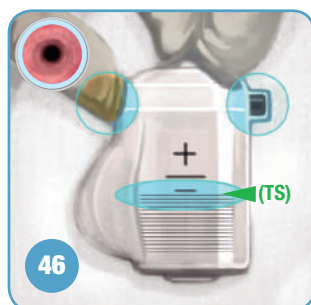
C - DEACTIVATION BEFORE IMPLANTATION OF THE PUMP



44
Press and release once or twice, until the Spring is fully compressed and the Cuff is deflated. We deflate the Cuff and Deactivate the ZSI 375 so that the Cuff is not compressing the urethra during healing.

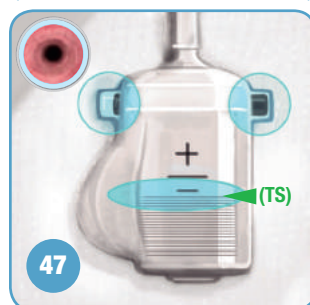


45



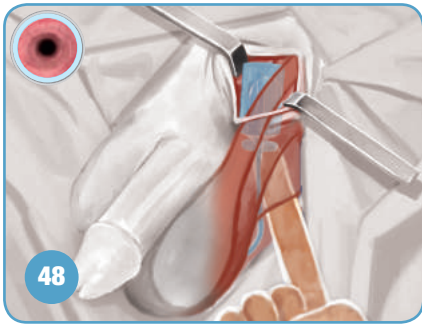
46
Firmly press the Deactivation Button. ZSI 375 is Deactivated.

(DEVICE PROPERLY DEACTIVATED)

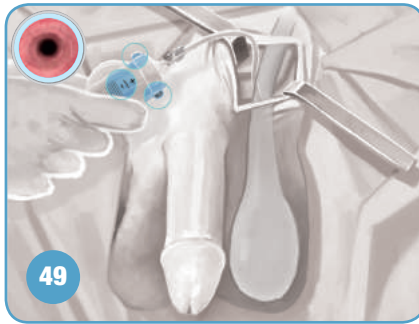


47
The Top of the Spring (TS) is below the Minus '-' sign. Wait for **20 seconds** to be sure the ZSI 375 keeps Deactivated.

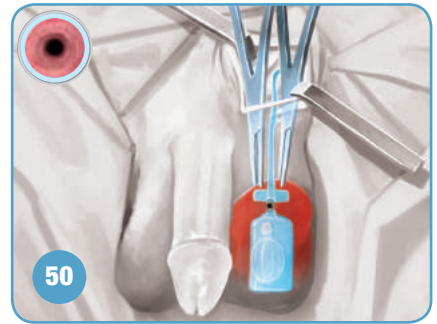
D - IMPLANTATION OF THE PUMP AND WINGS SUTURING



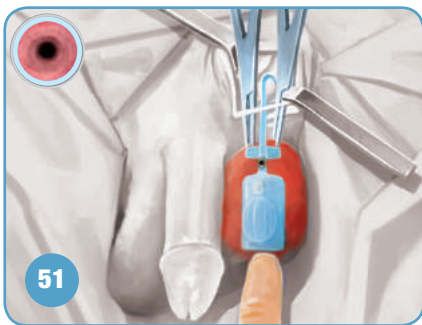
48 Pump Unit passage from the perineal incision to the inguinal incision.



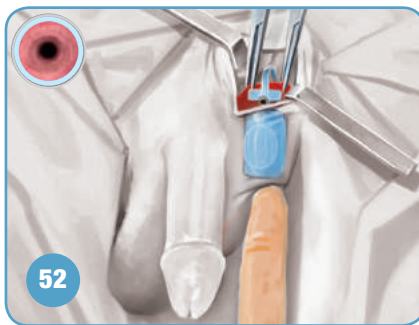
49 After this passage, check that device is still Deactivated, and that the Spring is below the Minus '-' sign.



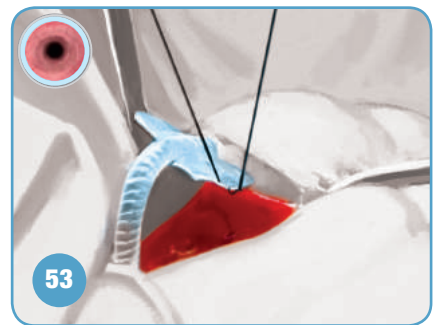
50 Insert the Pump Unit into subdartos pouch.



51 With the index finger push the Pump Unit upwards to expose the deep internal scrotal tissue.

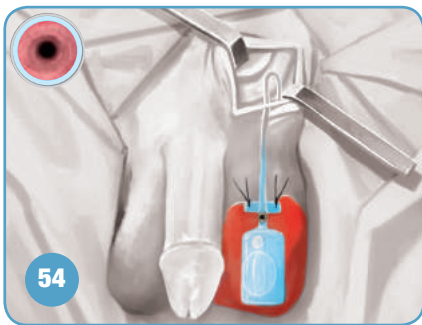


52 With two mosquito clamps, pick and pull out the deep internal scrotal tissue.

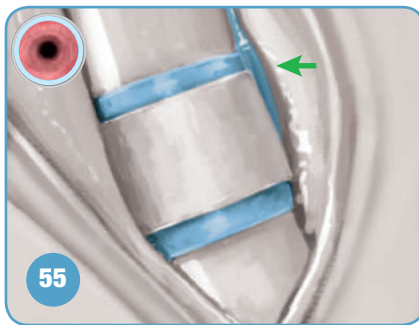


53 Use non-absorbable monofilament 4-0 sutures to fix the Wings into the deep internal tissue of the scrotal pouch.

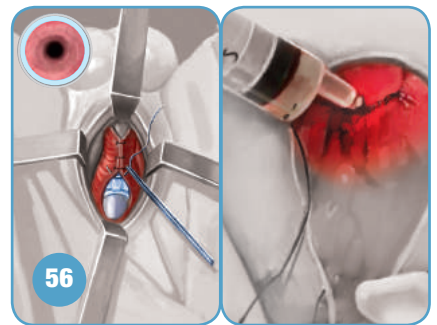
Suture the Wings to the deep internal tissue, so that the Pump Unit is not placed too high in the scrotum pouch. Insertion follows the same technique as implanting a testicular prosthesis.



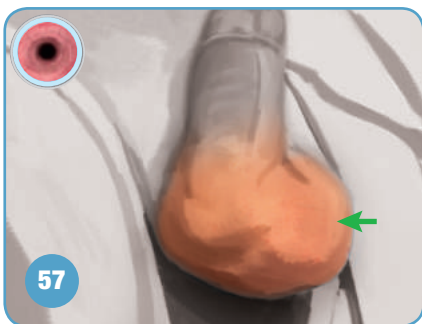
54 Drop the Pump Unit deep in the scrotum.



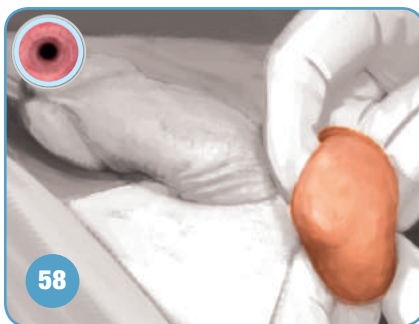
55 Turn the Cuff to the side. Check that the Cuff pillow is properly installed.



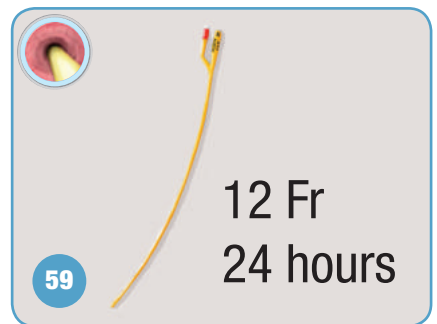
56 Suture two or three different layers. Intravenous antibiotics and local antibiotics are usually applied during the procedure.



57 This is the view of the Pump after it has been properly installed deep in the subdartos pouch.



58 Because of the size and placement of the Pump Unit, the patient will easily find the Pump Unit.

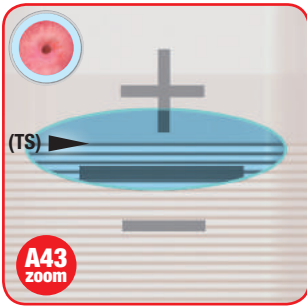


59 Install a size 12 Fr/Ch Foley catheter for 24 hours (Caution: installation of a catheter for longer than 24 hours will lead to urethral erosion).

4. TIPS AND TRICKS

Page 88, 89 - Video 3 - Video 7

A - CONTROL OF THE CUFF ISSUED PRESSURE (From image 43)



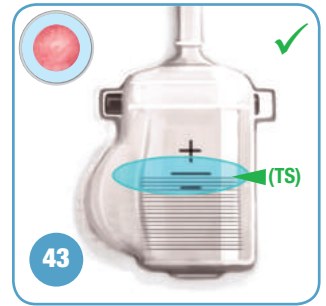
The Top of the Spring (TS) is above the Mid-line.



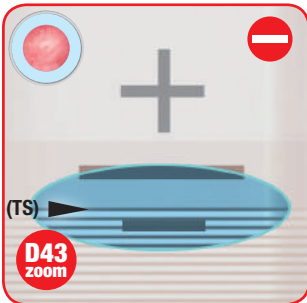
Gently inject 0.1 ml of Sterile Saline Solution 0.9‰ into the Hydraulic Circuit and wait 20 seconds for the Top of the Spring (TS) to move down just below the Mid-line.



If necessary, repeat the injection of 0.1 ml of Saline Solution. Then wait 20 seconds. Repeat the procedure until the Top of the Spring (TS) is stabilised just below the Mid-line.



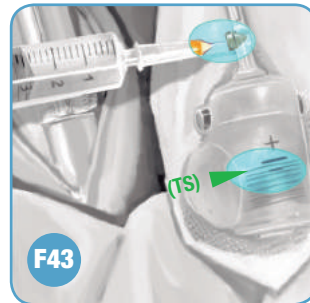
The Top of the Spring (TS) is just below the Mid-line. The standard pressure is delivered into the Cuff.



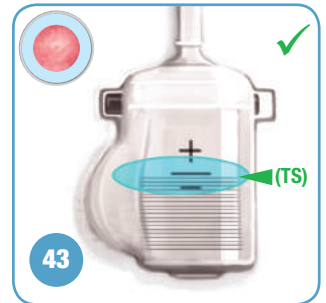
If the Top of the Spring (TS) is too far below the Mid-line, there is too much Saline Solution in the Hydraulic Circuit and it will be impossible to deflate the Cuff.



Gently remove 0.1 ml of Saline Solution for the Top of the Spring (TS) to move up to just below the Mid-line. Wait for 20 seconds to check that the Spring is well stabilised.

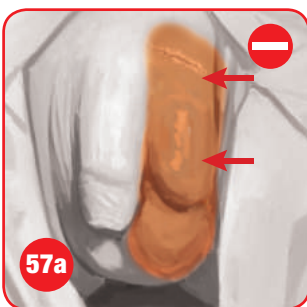


If necessary, repeat the removal of 0.1 ml of Saline Solution. Then wait 20 seconds. Repeat the procedure until the Top of the Spring (TS) is stabilised just below the Mid-line.



The Top of the Spring (TS) is just below the Mid-line. The standard pressure is delivered into the Cuff.

B - IMPLANTATION OF THE PUMP UNIT, TROUBLESHOOTING (from image 57)



Pump Unit not in a good position

Reason 1 The Wings of the device have been sutured with the internal tissue close to the inguinal incision. There is a high risk of erosion from the Wings at the level of the suture and it is not an aesthetic position. Insertion follows the same technique as implanting a testicular prosthesis. The Pump Unit should have been implanted deeper into the scrotum.

Reason 2 Wings not fixed by suture, the device has migrated. Possible difficulty to reach Activation or Deactivation Button. Armed tubing may be subject to excessive bending, resulting in risk of rupture.



Pump not situated in an optimal layer.

The Pump Unit should be placed between the dartos and cremaster muscles.

If the Pump Unit is implanted in a level that is too internal, it will be difficult to find the Activation Button.

If the Pump Unit is implanted in a level that is too external, there is a risk of extrusion of the Pump Unit or the tubes. A new subdartos pouch will need to be formed to enable the Pump Unit to be implanted in an optimal layer.

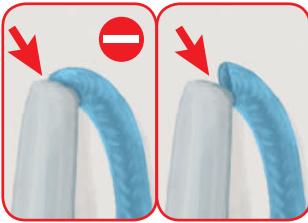
C - ACCESS TO THE PUMP UNIT POST IMPLANTATION (IF REQUIRED)



EXAMPLE : Relocation or visual checking

1. To access the Pump Unit: Perform an inguinal incision pushing up the Pump Unit through the incision. Remove the tissue around the Pump using a monopolar cautery/bistouri at the end of the procedure; create a new subdartos pouch or re-insert back into the pouch.
2. Use a monopolar cautery with a flat spatula - Never use a scalpel. With monopolar cautery, do not be afraid of damaging the silicone: it can withstand up to 200°C before melting.

D - FOLLOW THE OFFICIAL IMPLANTATION PROTOCOL TO AVOID EXCESSIVE BENDING (ELBOW) OF THE ARMED TUBING



WARNING: Using a single incision (instead of two incisions as recommended by ZSI) for implantation, increases the risk of a kink and/or an elbow in the armed tubing which could lead to its rupture or early breakage.

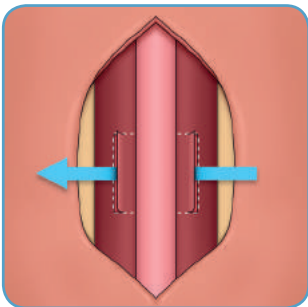
E - TRANSCORPORAL TECHNIQUE FOR A WEAK URETHRA

The erosion rate can increase significantly with a weak urethra that is pressed by the Cuff of the AUS. A transcorporal passage is strongly recommended to reduce the risk of urethral erosion.

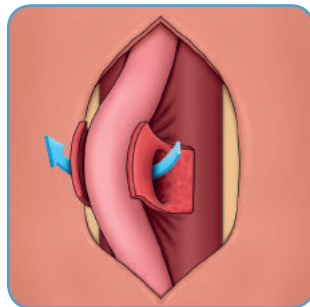
Example causes of a weak urethra include prostate radiotherapy, urethroplasty, previous urethral erosion (AUS).

Two techniques are presented here:

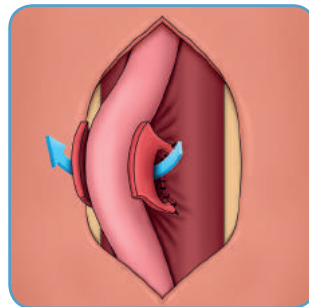
FIRST TECHNIQUE



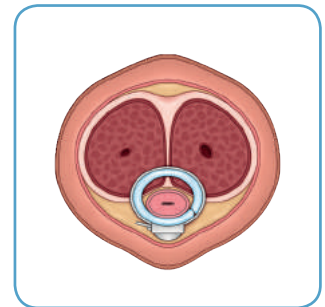
Perform an incision of corpus cavernosa, on each side of the urethra.



Pull the segment of corpus cavernosa.

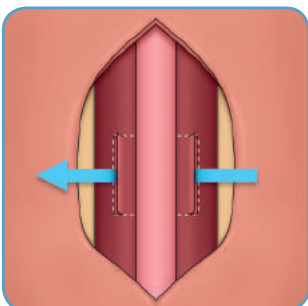


Suture the edges of the open corpus cavernosa.

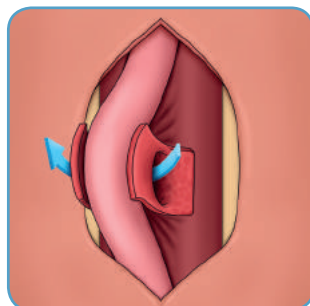


Close the cuff around the urethra + the section of corpus cavernosa.

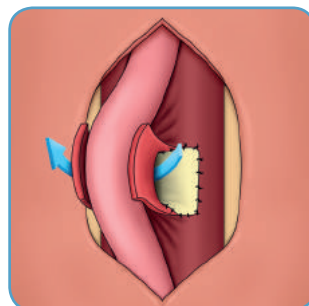
SECOND TECHNIQUE



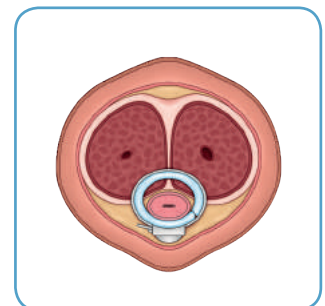
Perform an incision of corpus cavernosa, on each side of the urethra.



Pull the segment of corpus cavernosa.



Cover the open corpus cavernosa suturing a patch of Surgisis®.



Close the cuff around the urethra + the section of corpus cavernosa.

5. OPERATING ROOM CHECKLIST

17 chronological steps that should be followed and performed when implanting the ZSI 375.

- 1. INSERT 16 Fr/Ch FOLEY CATHETER
- 2. PERFORM DISSECTION
- 3. OPEN THE BAG AND REMOVE THE ZSI 375 CAREFULLY
- 4. TEST THE SPRING (PRESS AND RELEASE THE PUMP BUTTON)
- 5. DEACTIVATE THE DEVICE
- 6. IMPLANT THE CUFF AROUND THE URETHRA
- 7. LOCK THE CUFF
- 8. REMOVE 16 Fr/Ch FOLEY CATHETER
- 9. ACTIVATE THE DEVICE
- 10. CHECK SPRING POSITION. ADJUST SALINE VOLUME AS NEEDED
- 11. DEFLATE THE CUFF AND DEACTIVATE THE DEVICE
- 12. IMPLANT THE PUMP UNIT
- 13. INSERT A 12 Fr/Ch FOLEY CATHETER FOR 24 HOURS
- 14. SUTURE
- 15. ATTACH TRACEABILITY STICKERS ON PATIENT IMPLANTATION FORM, INCLUDED IN THE BOX..
- 16. FILL-IN & GIVE THE PATIENT HIS IMPLANTATION CARD INCLUDED IN THE BOX
- 17. SEND BACK TO ZSI THE COMPLETED PATIENT FORM WITH TRACEABILITY STICKERS

6. GUARANTEE

Included in each ZSI 375 kit are:

- 4 sets of Patient Implantation Forms to activate the guarantee.
- 10 sets of Traceability Stickers
- 1 Patient Implantation ID CARD

Fully complete one Patient Implantation Form and send it back to ZSI in order to activate the mechanical failure guarantee.

Remember to attach the Traceability Sticker of the ZSI 375 you have implanted.

Do not forget to attach the patient traceability sticker given by the hospital/clinic. Subject to local regulation you can erase confidential patient information.

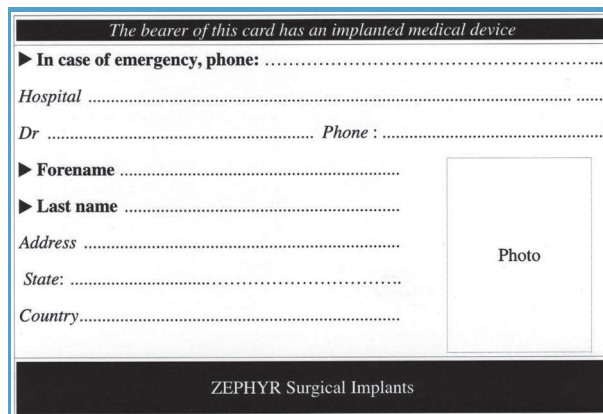
The other Stickers and Patient Implantation Forms are for the distributor and the hospital/clinic.

Minimum information required:

- Hospital name, city, country. *
- Name of the surgeon. *
- Date of implantation. *
- Patient's name and telephone number (subject to local regulations). *
- ZSI 375 Traceability Stickers. *
- Name of ZSI or distributor representative present in the OR to support the surgeon. *

Scan and Email the Patient Implantation Form to: quality@zsimplants.ch

Give the patient his implantation card



The bearer of this card has an implanted medical device

► In case of emergency, phone:

Hospital

Dr Phone :

► Forename

► Last name

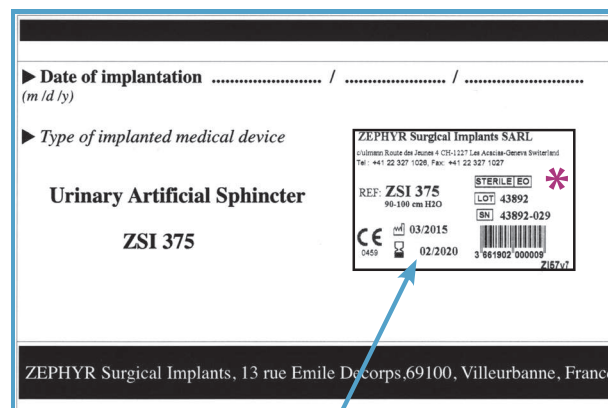
Address

State:

Country.....

Photo

ZEPHYR Surgical Implants



► Date of implantation / /
(m / d / y)

► Type of implanted medical device

Urinary Artificial Sphincter

ZSI 375

ZEPHYR Surgical Implants SARL
Châlonnais Route des Jumeaux 4 CH-1121 Les Allières-Oleron Switzerland
Tel: +41 22 327 1026 Fax: +41 22 327 1027

REF: **ZSI 375**
90-1100 cm 3120

STERILE EO *
LOT 43892
SN 43892-029

CE 03/2015
02/2020




3 561902 000009 Z157v7

ZEPHYR Surgical Implants, 13 rue Emile De corps, 69100, Villeurbanne, France

Place the ZSI 375 Traceability Sticker here

Place the patient Traceability Sticker
(given by the hospital/clinic)

Patient Implantation Form

PATIENT INFORMATION FORM FICHE D'INFORMATION PATIENT / PATIENTEN INFORMATIONSBLATT/ MODULO DI INFORMAZIONI SUL PAZIENTE / FORMULARIO DE INFORMACION DEL PACIENTE		
FOR HOSPITAL USE - IMPRINT PATIENT I.D. CARD ABOVE RESERVE A L'USAGE DE L'HOPITAL - INSCRIRE NUMERO D'IDENTIFICATION DU PATIENT CI-DESSUS VOM KRANKENHAUS AUSZUFÜLLEN - AUSWEIS-INFORMATIONEN DES PATIENTEN RISERVATO ALL'OSPEDALE - STAMPARE IL NUMERO DELLA CARTA D'IDENTITA DEL PAZIENTE NELLO SPAZIO SOVRASTANTEPARA USO ESCLUSIVO DEL HOSPITAL - IMPRIMIR ARRIBA LA TARJETA DE IDENTIFICACION DEL PACIENTE		HOSPITAL/ Hôpital, Krankenhaus/ Ospedale/ Hospital *
		ADDRESS /Adresse/ Indirizzo/ Dirección *
Component implanted 		IMPLANTING SURGEONS Chirurgen / chirurg/chirurgo / cirujano *
		DATE OF SURGERY/Date de l'intervention/ operation-datum/ Data dell'intervento chirurgico/ Fecha de la cirugía. *
ETIOLOGIE DE L'INCONTINENCE/ URSACHE DER INKONTINENZ/ Eziologia dell'incontinenza / ETIOLOGIA DE LA INCONTINENCIA		
<input type="checkbox"/> PROSTATECTOMY /prostectomie/ prostatektomie/ prostatectomia	<input type="checkbox"/> TURP /résection transurétrale/ transurethraler resektion/ resezione transuretrale/ reseccion transuretral	<input type="checkbox"/> NON-NEUROGENIC/ non-neurogene, nicht neurogen/ non neurogena/ no neurogenica
<input type="checkbox"/> NEUROGENIC/ neurogène/neurogen/ neurogena/ neurogenica	<input type="checkbox"/> MYELOMENINGOCELE/ myéloméninogocèle/myelomeninogzele/mielomeninogocelo	<input type="checkbox"/> Pelvic trauma surgery, traumtism/ opération du périnée, trauma/ operation im beckenbereich/ intervento chirurgico o trauma della pelvi/ Cirurgia o traumatismo de la pelvis.
<input type="checkbox"/> URETHRAL SURGERY/ opération de l'urètre, /cirugia uretral/ harnöhrenoperation/intervento all'uretra	<input type="checkbox"/> Spinal Trauma, tumor/surgery/ traumatisme, tumeur/opération de la moëlle épinière/ rückenmarksverletzung/tumor/operation/intervento chirurgico, tumor o trauma del midollo spinale/ cirugía, tumor, traumatismo de la médula spinal.	<input type="checkbox"/> OTHER Autre/ andere ursache/ altro/ Otra
<input type="checkbox"/> RECURRING INCONTINENCE / INCONTINENCE RECURRENTE / WIEDERAUFTRETENDEINKONTINENZ / INCONTINENCIA RICORRENTE / INCONTINENCIA RECURRENTE		
<input type="checkbox"/> EROSION (LOCATION) / ERODION (EMPLACEMENT) / EROSION (STELLE) /EROSIONE (SITO) / EROSION (LOCALIZACION)		
<input type="checkbox"/> FLUID LOSS (LOCATION) / PERTE DE FLUIDE (EMPLACEMENT) / FLUSSIGKEITSVERLUST/ (STELLE) / PERDITA DI FLUIDO (SITO) / PERDIDA DE FLUIDO (LOCALIZACION)		
<input type="checkbox"/> INFECTION (LOCATION) / INFECTION (EMPLACEMENT) / INFEKTION (STELLE)/INFEZIONE (SITO) / INFECCION (LOCALIZACION) PAIN (LOCATION) / DOULEUR (EMPLACEMENT) /SCHMERZ (STELLE) / DOLORE (SITO) / DOLOR (LOCALIZACION)		
<input type="checkbox"/> PATIENT DISSATISFACTION (Please Explain) / PLAINTES DU PATIENT (justifier)/UNZUFRIEDENHEIT DES PATIENTEN (bitte erläutern)/INSODDISFAZIONE DEL PAZIENTE (SPIEGARE)/ DISCONFORMIDAD DEL PACIENTE (Por favor, plicar)		
<input type="checkbox"/> OTHER / Autre(s) / Andere Gründe / Altro / Otra COMMENTS / COMMENTAIRES / COMMENTS/ ANMERKUNGEN / COMENTARIOS :		
 ZSI, Zephyr Surgical Implants sàrl Route des jeunes 4bis, CH-1227, les acacias-Genève, Switzerland Phone: +41 22 342 31 57- Email : contact@zsimplants.ch		

SURGERY

Place the ZSI 375 Traceability Sticker here

We are aiming for:

- Social continence (0 to 1 pads a day).
- Improvement: 50% less than the baseline before implantation is acceptable.

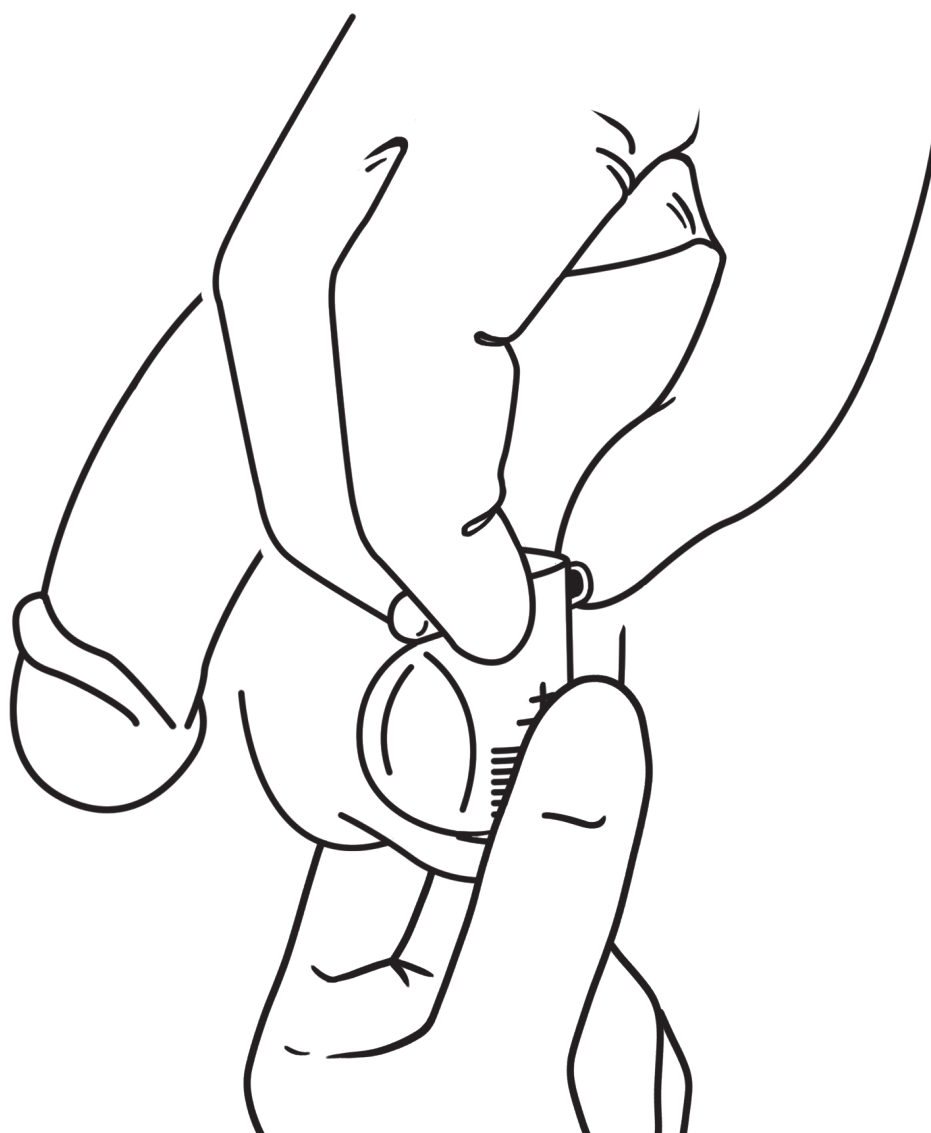
Total continence or better improvement can always be reached by gradually increasing pressure
However, the greater the pressure, the greater the risk of urethral erosion.

It is always a compromise which the urologist must determine: the level of continence desired, the patient's satisfaction and the risk of urethral erosion.

V

ACTIVATION OF THE ZSI 375

ACTIVATION OF THE ZSI 375	35
1. ACTIVATION DAY GUIDELINES, PATIENT CARE	36
A - CREATE A SECURE ENVIRONMENT	36
B - PREPARE YOUR ACTIVATION KIT	36
C - ACTIVATION - BEST POSITION FOR FINGERS	37
D - ACTIVATION - SUPPORT OF SPATULA AND LOCAL ANAESTHETIC GEL IF NEEDED	37
2. 8 WEEKS AFTER IMPLANTATION, DEVICE CAN BE ACTIVATED	39
A - BEFORE ACTIVATION	39
B - DURING ACTIVATION	39
C - AFTER ACTIVATION	39



1. ACTIVATION DAY GUIDELINES, PATIENT CARE

Page 88 - Video 0 - Video 2

A - CREATE A SECURE ENVIRONMENT

The patient has had the necessary 6 to 8 weeks for his incisions and urethra to heal, and the surgeon has decided that the patient is ready for Artificial Urinary Sphincter Activation.

Generally, one hour should be planned for the procedure. The local ZSI agent can organize and direct the meeting. (subject to local regulation).

If appropriate: The ZSI local agent can perform the Activation with the surgeon. If the surgeon is not able to attend the Activation process, the ZSI local agent will ask to be provided with a patient medical room where the Activation can be performed in private. It is suggested that a family member is present with the patient on the day. The presence and support of the family can help the patient remember all the information and training given.

B - PREPARE YOUR ACTIVATION KIT

THE KIT SHOULD INCLUDE:



Pocket Card



Hand sanitizer



Medical grade examination gloves



Rubber demo mould of the ZSI 375



Patient Manual



Paper towels



Bottle of drinking water



White lab coat



Spatula (metal or wood)

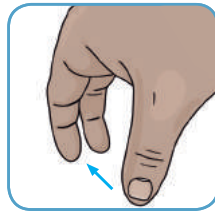


Anaesthesia Gel

It is recommended that a member of the patient's family attends during the activation day to help the patient recall the training when at home. The ZSI 375 Patient Manual will also provide useful information. The ZSI 375 Patient Manual is also useful in this regard.

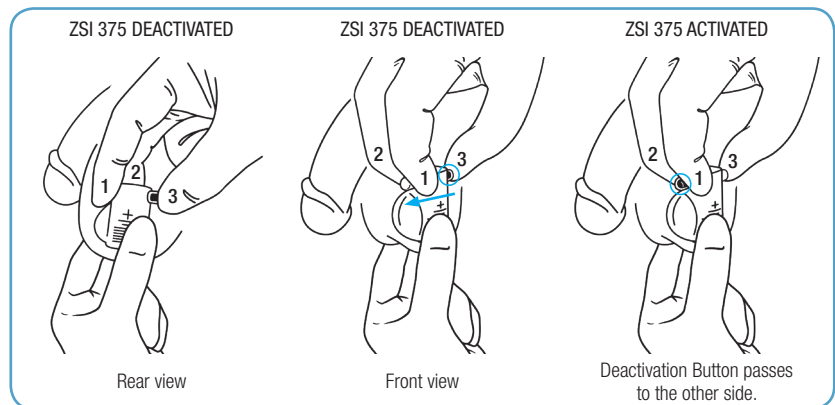
C - ACTIVATION - BEST POSITION FOR FINGERS

Fingers in a pliers position provides stability and effective pinch strength.



With one hand hold the Pump Unit.
With the other hand:

- Place index finger [1] and middle finger [2] either side of the Deactivation Button (Front view).
- Only pinch strength should be required to operate the Activation Button (Rear view) with the thumb [3]. However, if the Pump Button seems slightly resistant to move (due to the nature of the silicone material) simply press it a little more firmly.

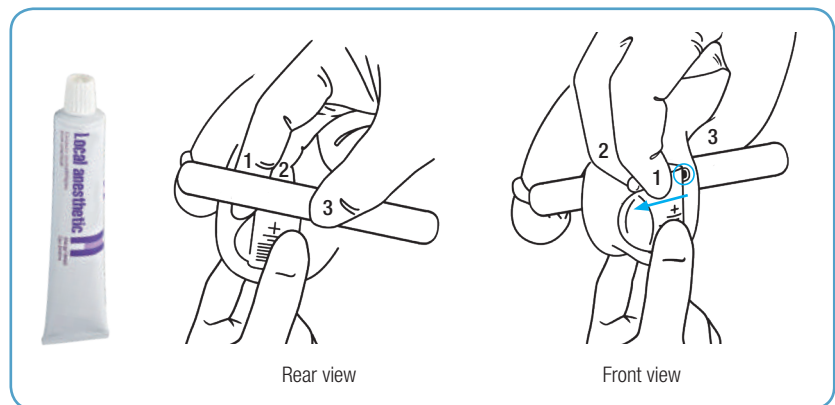


While activating the ZSI 375 you will be touching the scrotal skin, which is very sensitive. Observe the patient and his reaction to touching and possible tenderness. Sometimes he will react as if he is experiencing pain without you even having touched him, for example by tightly closing his eyes or contracting his muscles. Assure the patient that he should only feel minor discomfort; ask him to relax and breathe deeply during the process. The tenderness that the patient thinks he feels or will feel often comes from fear rather than actual physical pain.

D - ACTIVATION - SUPPORT OF SPATULA AND LOCAL ANAESTHETIC GEL IF NEEDED

If you have not been able to Activate the ZSI 375, the following protocol is often successful.

- Apply the local anaesthetic gel. Follow the manufacturer's directions for use.
- Place index finger [1] and middle finger [2] either side of the Deactivation Button (Front view).
- A very firm pinch strength should be required to operate the Activation Button (Rear view) with the thumb and the spatula [3].



If the patient is unable to bear the sensation of pressure on his skin to Activate the ZSI 375, a spatula may be useful to properly press the Activation Button, it is recommended that a non-slippery anaesthetic gel is applied to the patient's scrotum to reduce sensitivity.

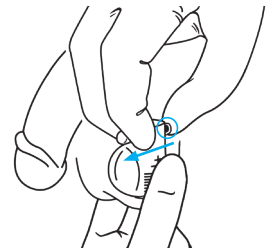
TIP - To check that the ZSI 375 is properly Activated if an X-Ray is not possible:

If the Pump Button does not deflate and the Saline Solution is locked inside, the ZSI 375 is DEACTIVATED.

If the flow of Saline Solution can be heard (and felt by the thumb through the skin) when the Pump Button is pressed, the ZSI 375 is PROPERLY ACTIVATED.

STEP 1: 15 Minutes

- Put on a pair of examination gloves. A white coat should be worn for sanitary and professional reasons.
- Ask the patient to remove his underwear, preferably lying down, to provide clear access to his scrotum.
- Feel for the Pump Button. It should be full of Saline Solution. The Hydraulic Circuit is locked and will not let the device function as it is Deactivated.
- Feel for and locate the Activation Button, which is on the opposite side to the Pump Button. Firmly press it until you feel a 'click' and a sinking of the Button. This 'click' and complete sinking is the passage of the Button through to the other side of the ZSI 375. Because of the nature of the Button, it will require a firm push to depress it. This may cause some discomfort for the patient. Proper Activation of the ZSI 375 at this stage is more important than the temporary discomfort of the patient. Once Activated, the Hydraulic Circuit will allow the Saline Solution to run through the ZSI 375. This can be tested by pressing the Pump Button, as it will empty when you press it and re-fill when you release it.
- If there is doubt that the ZSI 375 has been properly Activated, ask for an X-Ray to check the position of the Top of the Spring.
- If it is not possible for an X-Ray to be taken, Deactivate the ZSI 375 by pressing the Deactivation Button, which sits above the Pump Button, and Activate it again.



Remember the Activation Button is on the opposite side to the Pump Button.

STEP 2: 30 Minutes

The patient has become accustomed to drinking small amounts of fluids, so when he arrives on the day, he may have an empty bladder. This means the ZSI 375 cannot be tested properly. Give the patient a bottle of water and ask him to drink it as quickly as he can. Then ask to see the patient again in 30 minutes for the first test run of the ZSI 375.

STEP 3: 15 Minutes

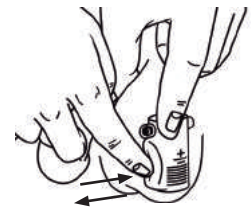
Take the blue Rubber Pump mould and demonstrate to the patient how to properly operate the ZSI 375.

Then ask the patient to demonstrate he understands how to operate the ZSI 375. See page 09.

Accompany him into the bathroom and visually check he can control his micturition.

If the patient still has some drops of urine (perhaps due to a hypertonic bladder), they can be treated with an anticholinergic for one week to relax the detrusor (bladder muscle).

If the patient still has some drops of urine and the surgeon wants to increase the pressure within the ZSI 375, follow protocol C1.1 (page 51).



Give the patient the 'Patient Manual' and explain what information it contains:

- How the ZSI 375 functions
- The expectations and limitations of the device
- What can be expected in the coming days

Give him the 'Pocket Card' and explain its purpose:

- Deactivation without ZSI 375 operating knowledge



Write down the patient's information (if allowed by local data protection regulations):

- Name, phone, email, address.
- We recommend phoning the patient the same evening and then making follow up calls over the next few days to ensure they are making good progress.

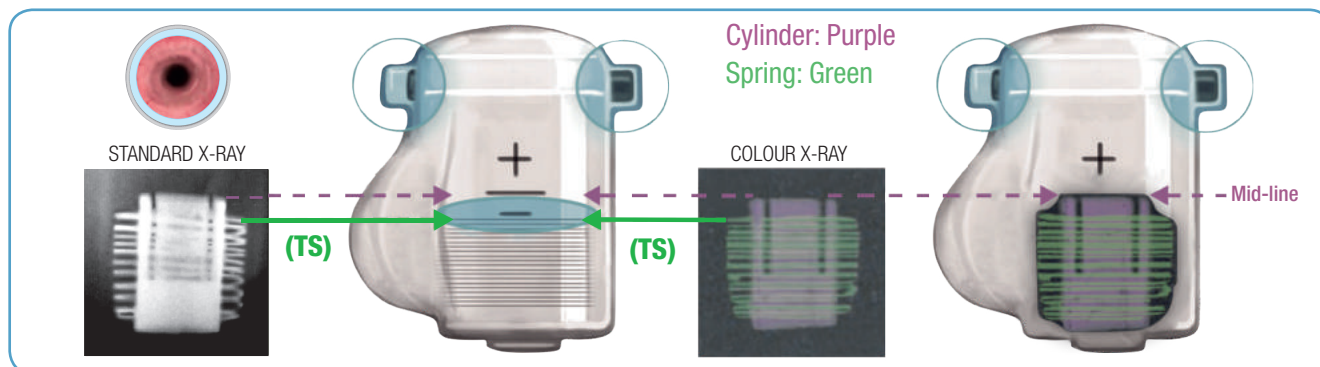
After Activation, if the patient does not present social continence, do not increase the the ZSI 375's pressure the same day. Wait for a minimum of 1 week. Sometimes the situation improves by itself as the urethra gets smoother.

2. 8 WEEKS AFTER IMPLANTATION, DEVICE CAN BE ACTIVATED

Page 88 - Video 2

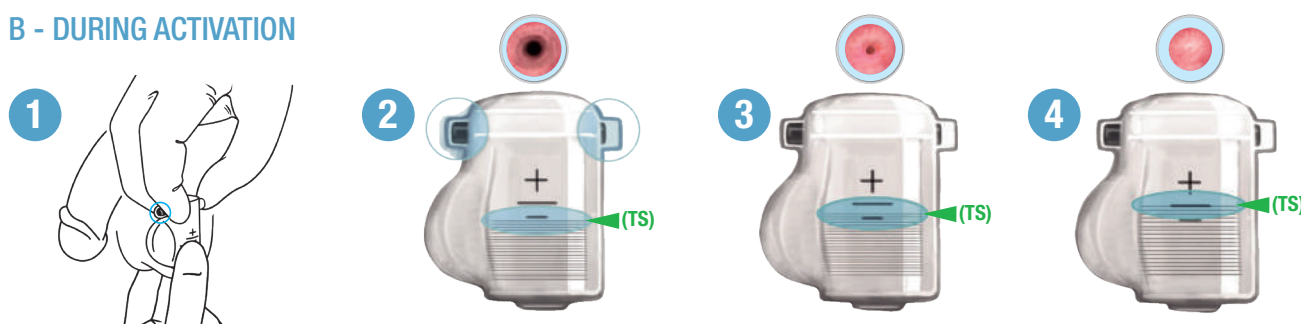
A - BEFORE ACTIVATION

The ZSI 375 is **Deactivated** for 8 weeks after implantation: the Spring is fully compressed, the Cuff is empty, the urethra is open, the patient is incontinent. You can check that the ZSI 375 is Deactivated with scrotal radiography: the Spring is fully compressed, the Top of the Spring (TS) sits below the Top of the Cylinder (under the Minus '-' sign).



The Cylinder's height has been designed to make discernment easier when viewing an X-Ray. The Spring is compressed and remains compressed. The device is properly Deactivated.

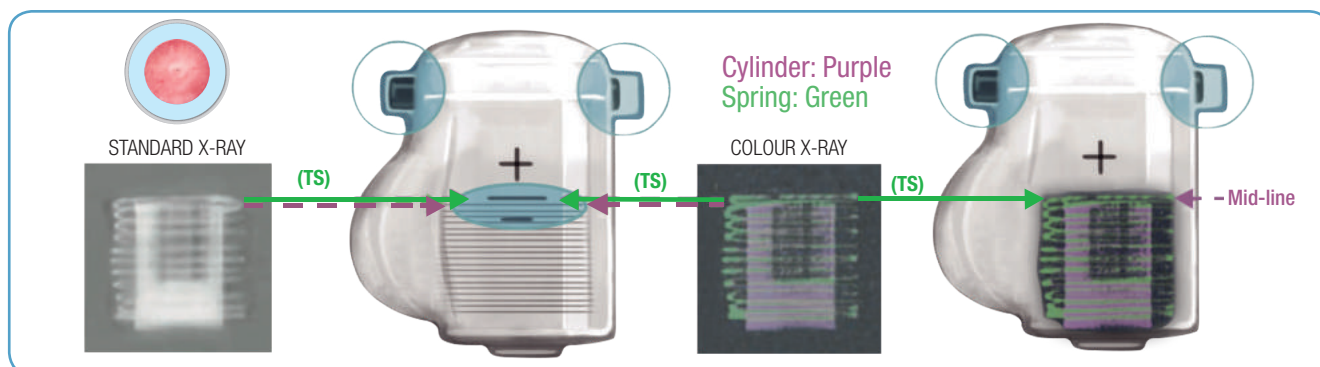
B - DURING ACTIVATION



To **Activate** the ZSI 375 after 2 months of healing, press the Activation Button (opposite side to the Pump Button). The Spring is released and pushes the Saline Solution from the Tank to the Cuff, drop by drop. Wait 120 seconds for the Cuff to compress the urethra. The patient will be continent.

C - AFTER ACTIVATION

The ZSI 375 is **Activated**: the Top of the Spring (TS) is decompressed and at the Mid-line. The Cuff is compressing the urethra: the patient is continent. You can check that the ZSI 375 is Activated with scrotal radiography. The Top of the Spring (TS) is decompressed; it sits in line with the Top of the Cylinder.



The Cylinder height has been designed to make discernment easier when viewing an X-Ray. The Top of the Spring (TS) sits in line with the Top of the Cylinder. It is decompressed and remains decompressed. The device is properly Activated.

To perform an X-Ray properly, the Pump Unit **MUST** be seen in axial plane view.

VI

X-RAY / FLUOROSCOPY / MRI / AIRPORT SCANNERS

X-RAY / FLUOROSCOPY / MRI / AIRPORT SCANNERS	41
1. ZSI 375: HOW TO PERFORM AN X-RAY	42
2. ZSI 375: HOW TO IDENTIFY IT IN AN X-RAY (OR FLUOROSCOPY)	44
A - WHAT IS THE RADIO OPAQUE CYLINDER WE SEE IN THE X-RAY (OR FLUOROSCOPY)?	44
B - ZSI 375 WITH CORRECT CUFF PRESSURE.....	45
C - ZSI 375 LACKS PRESSURE.....	45
D - SPRING COMPLETELY DECOMPRESSED.....	45
E - DEVICE DEACTIVATED WITH CUFF IN OPEN POSITION	45
F - SAFE FOR AIRPORT SCANNER AND MRI	45



1. ZSI 375: HOW TO PERFORM AN X-RAY

DIRECT ACCESS

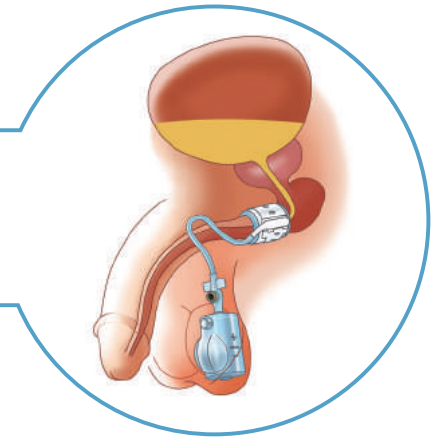


THE DOCUMENT 'HOW TO PERFORM AN X-RAY' CAN BE DOWNLOADED FOR THE RADIOLOGIST ON WWW.ZSIMPLANTS.CH

<https://www.zsimplants.ch/en/products-en/incontinence/zsi-375-en/urologist-downloads>

What is an Artificial Urinary Sphincter?

The Artificial Urinary Sphincter ZSI 375 is a medical device implanted in the scrotum and around the urethra. Its function replicates an organic urinary sphincter.



What must be seen in the X-Ray?

We need only 1 view of the Pump Unit which is implanted in the scrotum.

The Pump Unit must be seen from axial plane view (see next page).

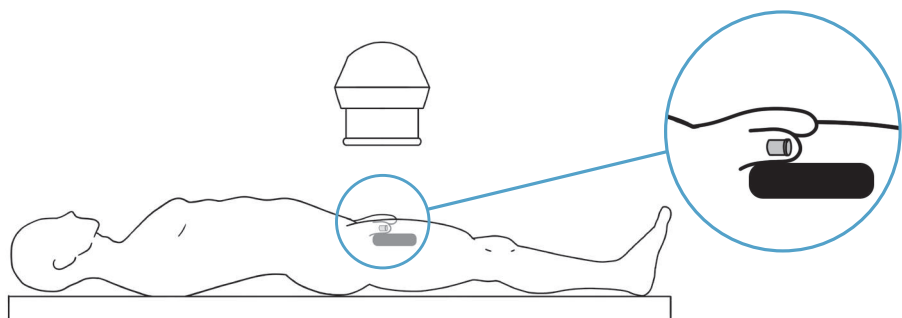
The Pump Button may be seen from a front, back, or side perspective. Any of these 3 options will work.



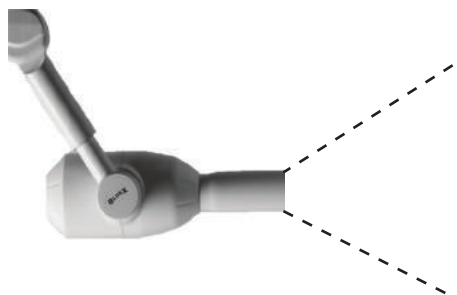
What if the Pump Unit is not seen from axial plane view ?

Check if the Pump Unit is seen axial plane view with the X-Ray Generator. If not, adjust the scrotum like presented in the following drawing.

To secure the Pump Unit in axial plane view you can stabilise the scrotum and Pump Unit (example with gauze pads).



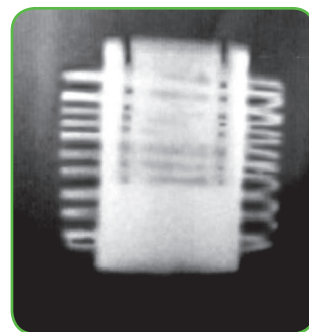
CORRECT - ZSI 375 Standing axial plane view



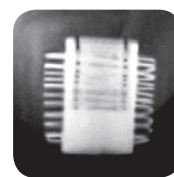
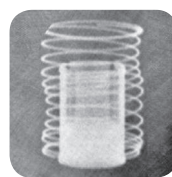
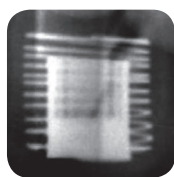
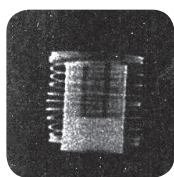
CORRECT



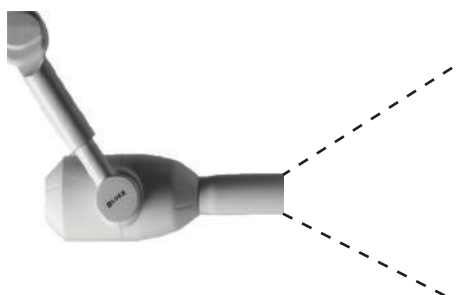
CORRECT



CORRECT



INCORRECT - ZSI 375 is tilted



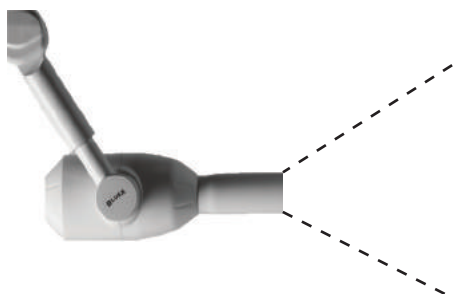
INCORRECT



INCORRECT



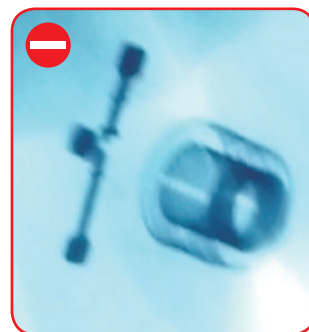
INCORRECT - ZSI 375 is tilted



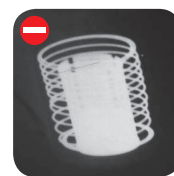
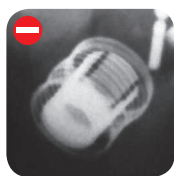
INCORRECT



INCORRECT



INCORRECT



2. ZSI 375: HOW TO IDENTIFY IT IN AN X-RAY (OR FLUOROSCOPY)

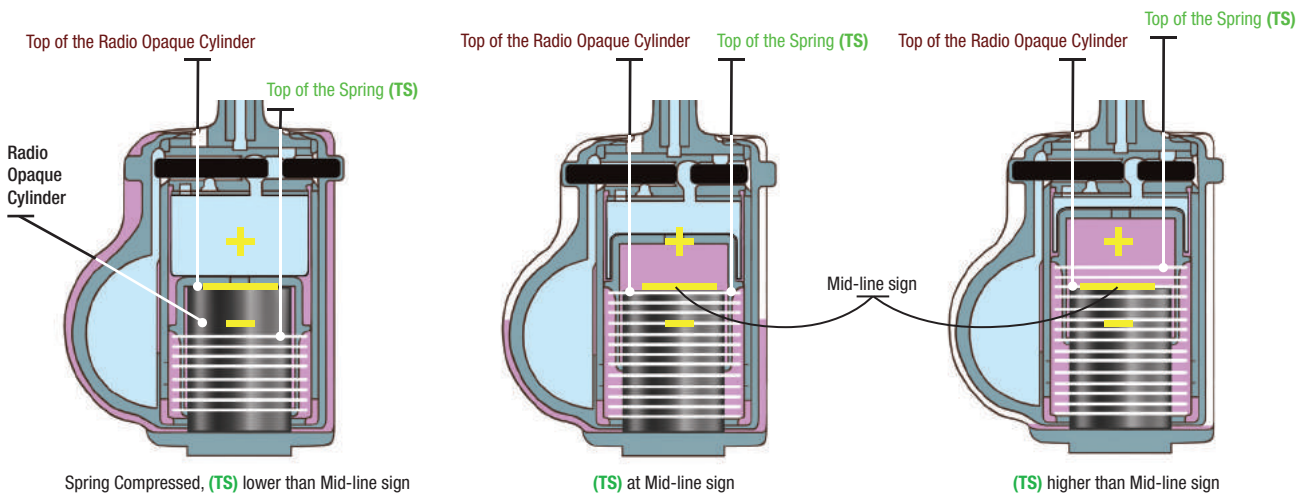
A - WHAT IS THE RADIO OPAQUE CYLINDER WE SEE IN THE X-RAY (OR FLUOROSCOPY)?

The Radio Opaque Cylinder is the stainless steel Cylinder which compresses the silicone of the Compensation Pouch Septum. The ZSI 375 has been dissected at the level of the Compensation Pouch Septum in order to show the Radio Opaque Cylinder. This is usually not visible to the naked eye.

Radio Opaque Cylinder ●

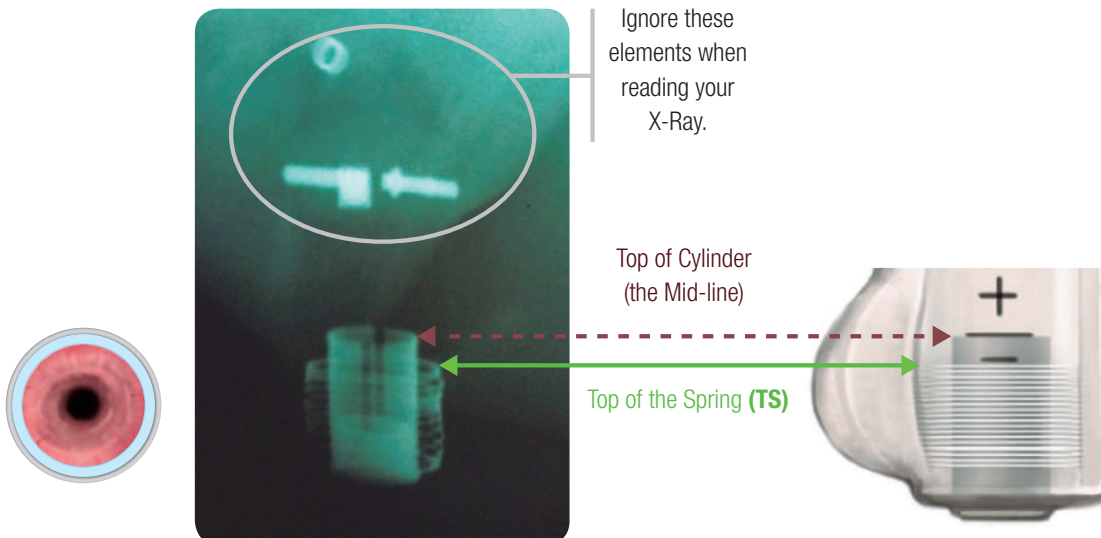


The Top of the Radio Opaque Cylinder is at the same level as the Mid-line sign of the device even if the Spring is moving.



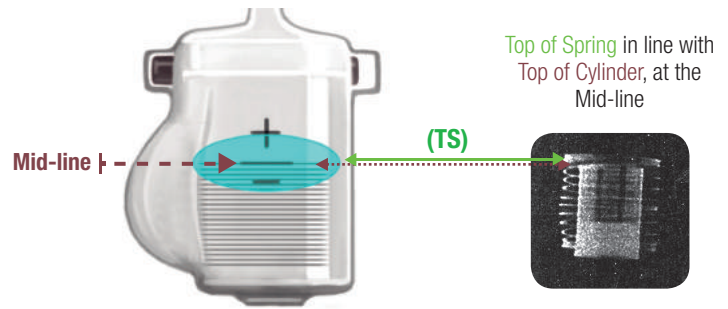
The relation between the Spring and the stainless steel Septum Cylinder gives a clear picture of the state of the Cuff (when Pump Button released).

- If the Top of the Spring (TS) is in line with the Top of the Cylinder, the Cuff has the right amount of pressure.
- The higher the Top of the Spring (TS) is positioned above the Top of the Cylinder, the less pressure in the Cuff.
- The lower the Top of the Spring (TS) is positioned below the Top of the Cylinder, the greater the pressure in the Cuff.



B - ZSI 375 WITH CORRECT CUFF PRESSURE

Top of the Spring sits at the Top of the Cylinder.
Device is Activated and functioning with the correct amount of pressure in the Cuff and around the urethra.

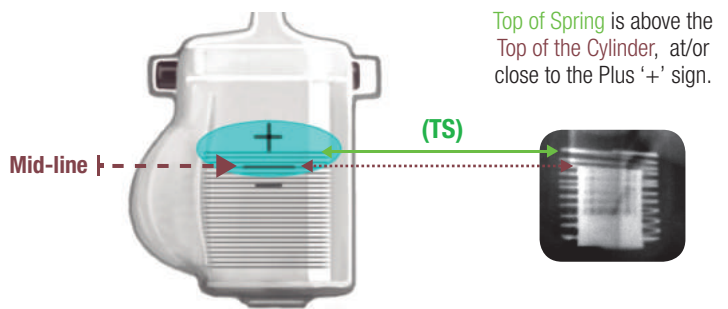


C - ZSI 375 LACKS PRESSURE

The Top of the Spring (TS) sits above the Top of the Cylinder leading to a lack of pressure in the device and in the Cuff.

This could be due to:

1. Urethral atrophy.
2. Air being left in the ZSI 375 Hydraulic Circuit. Over time, air disappears by passing through the silicone. This leaves free space which is filled by the Spring as it rises.

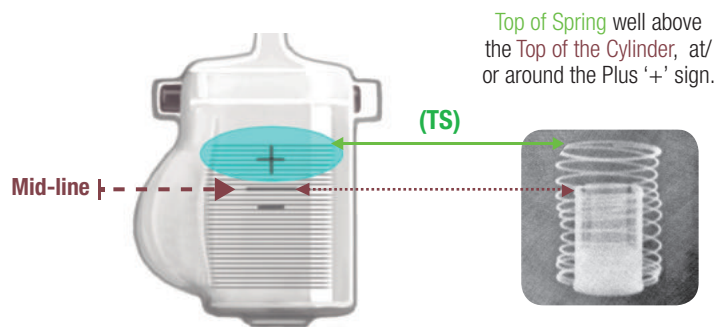
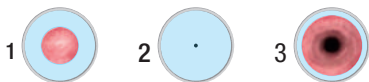


D - SPRING COMPLETELY DECOMPRESSED

This Top of the Spring (TS) position means that something is wrong with the patient and/or the pressure in the ZSI 375. The Spring is fully decompressed and the (TS) position is near or at the Plus '+' sign.

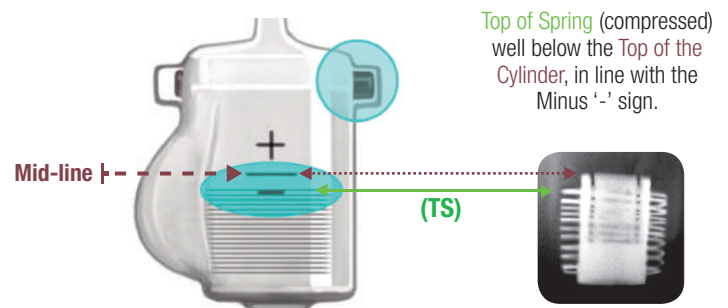
This could be due to:

1. Urethral atrophy.
2. Urethral necrosis.
3. ZSI 375 is leaking Saline Solution.



E - DEVICE DEACTIVATED WITH CUFF IN OPEN POSITION

This means: Cuff is deflated, Deactivation Button is pressed, Saline Solution circulation is blocked. The Top of the Spring (TS) is down at the Minus '-' sign, leaving the Cuff open and the urethra decompressed.



F - SAFE FOR AIRPORT SCANNER AND MRI

1. Patient can travel with the ZSI 375. It is not detected by airport scanners.
2. The ZSI 375 is also safe in MRI (medical scanners).

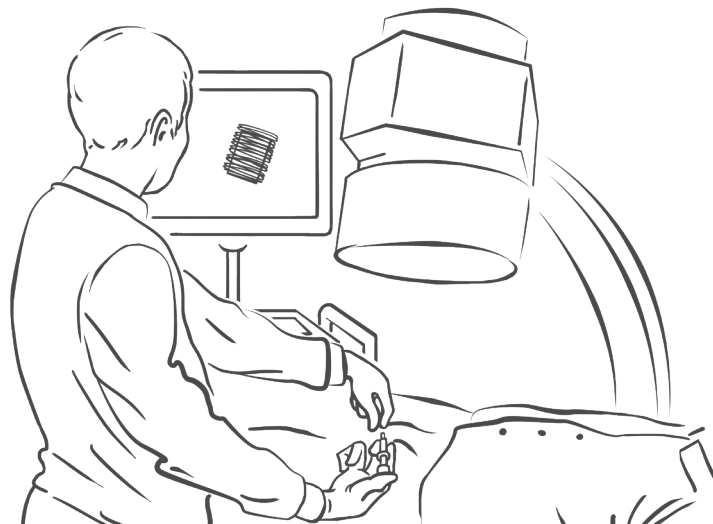


Less than 1% of the ZSI 375 Artificial Urinary Sphincters returned to ZSI for inspection and analysis, are due to confirmed mechanical failure. ZSI 375s are most frequently returned due to accidental punctures, lack of understanding of how the ZSI 375 functions or incorrect adjustments.

VII

DEALING WITH ZSI 375 DOUBTS OF FUNCTIONING AND POST SURGERY MANAGEMENT

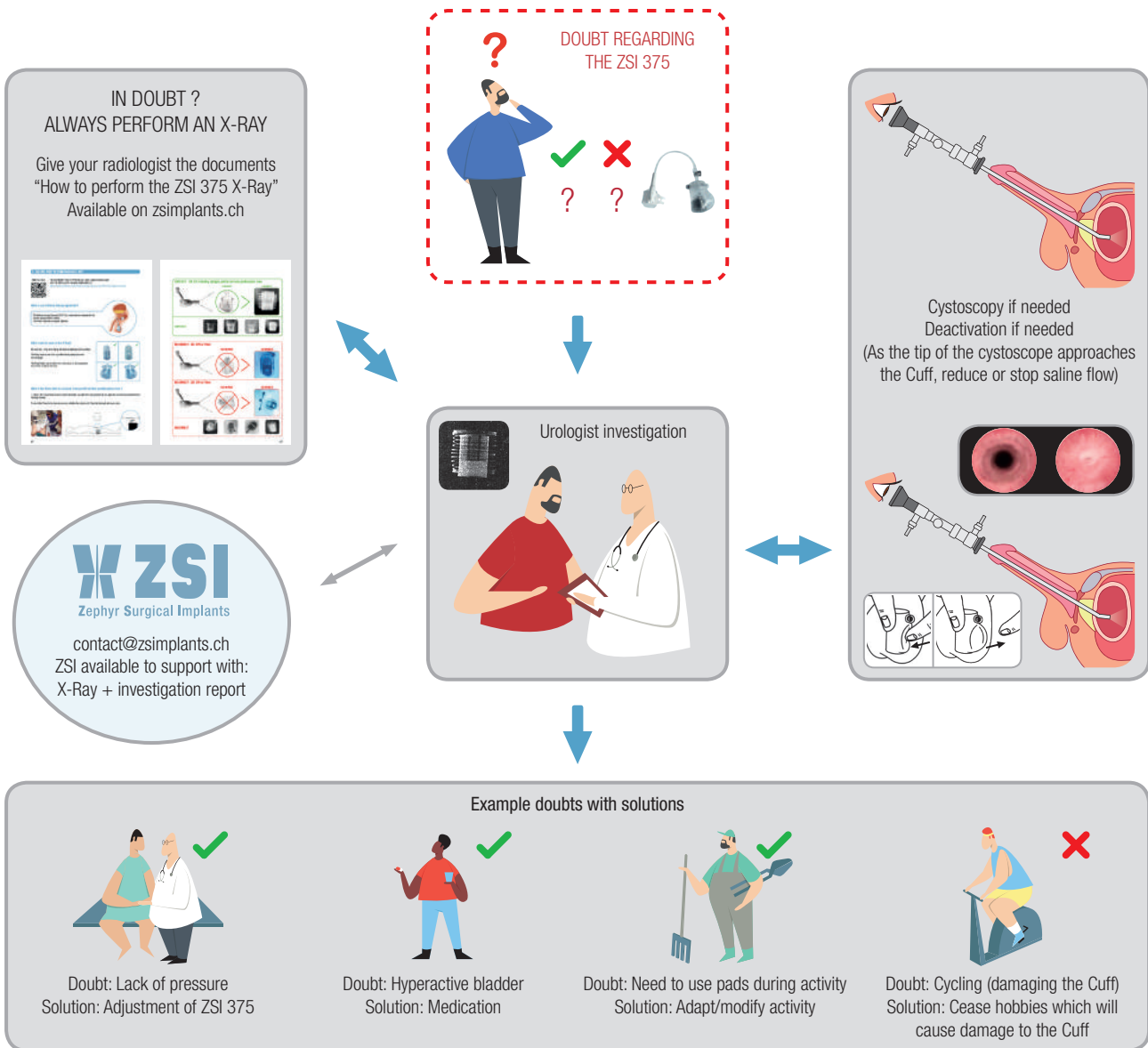
DEALING WITH ZSI 375 DOUBTS OF FUNCTIONING AND POST SURGERY MANAGEMENT	47
1. OVERVIEW OF INVESTIGATION PROCESS.....	48
A - IF THERE IS DOUBT - ALWAYS PERFORM AN X-RAY	48
B - PSYCHOLOGICAL CONSIDERATIONS	48
C - GENERAL PROTOCOL FOR DEALING WITH DOUBT OF FUNCTIONING	49
D - URINARY CONTINENCE STATUS	49
2. MANAGEMENT WHEN IN DOUBT OF FUNCTIONING AFTER ACTIVATION.....	50
A - EQUIPMENT FOR INVESTIGATION.....	50
B - PIERCING SEPTUMS PROTOCOL AND INJECTION TIMELINE.....	50
B1 INSTRUCTIONS TO PIERCE THE HYDRAULIC CIRCUIT SEPTUM THROUGH THE SCROTUM TO PLACE THE TOP OF THE SPRING LEVEL WITH THE MID-LINE:.....	50
B2 INSTRUCTIONS TO PIERCE THE COMPENSATION POUCH SEPTUM TO INCREASE OR DECREASE THE PRESSURE:	50
C - DOUBTS WHETHER THE ZSI 375 IS OPERATING PROPERLY: INVESTIGATION.....	51
C1 INCONTINENCE AFTER ACTIVATION OR AFTER A PERIOD OF CONTINENCE	51
C.1.1. SOCIAL CONTINENCE AFTER ACTIVATION OR AFTER A PERIOD OF CONTINENCE.....	51
C.1.2. LIGHT, MODERATE, SEVERE INCONTINENCE AFTER ACTIVATION OR AFTER A PERIOD OF CONTINENCE	51
C.1.2.1. X-RAY: THE SPRING OF THE ZSI 375 IS COMPRESSED	52
C.1.2.2. X-RAY: THE TOP OF THE SPRING IS AT THE TOP OF THE CYLINDER OR AT THE MID-LINE	52
C.1.2.3. X-RAY: THE TOP OF THE SPRING IS ABOVE THE TOP OF THE CYLINDER OR ABOVE MID-LINE	53
C.1.2.4. X-RAY: THE SPRING SEEMS TO BE FULLY DECOMPRESSED.....	54
C2 URINARY RETENTION AFTER IMPLANTATION OF THE ZSI 375	55
C.2.1. X-RAY: THE SPRING IS COMPRESSED BELOW THE TOP OF THE CYLINDER BEFORE ACTIVATION - WHILE PATIENT IS IN RETENTION	55
C.2.2. X-RAY: THE TOP OF THE SPRING IS LEVEL OR ABOVE THE TOP OF THE CYLINDER BEFORE ACTIVATION - WHILE PATIENT IS IN RETENTION	55
C.2.3. X-RAY: THE SPRING IS LEVEL WITH OR ABOVE THE TOP OF THE CYLINDER AFTER ACTIVATION - WHILE PATIENT IS IN RETENTION	56
C.2.3.1. SEVERE URETHRAL EROSION	56
C3 INFECTION AND EROSION.....	56
3. ZSI 375 REMOVAL	57



1. OVERVIEW OF INVESTIGATION PROCESS

A - IF THERE IS DOUBT - ALWAYS PERFORM AN X-RAY

An X-Ray provides factual evidence; an interview gives important supplementary information to the investigation.



All cases of 'Doubt of functioning' can be managed by:

- Good understanding of how the ZSI 375 functions
- Strictly following the 'OVERVIEW OF INVESTIGATION PROCESS'

B - PSYCHOLOGICAL CONSIDERATIONS

Keep in mind that, for a man to have reached the need for an Artificial Urinary Sphincter, he will have experienced physical, psychological and/or neurological traumas. Such a state can create an emotionally frail patient who might be expecting too much either from the device and/or the surgeon and/or the ZSI local representative. This is especially the case when the patient himself has paid the total cost of the device and implantation. Empathy is important to solve almost all cases which patients bring. Sometimes the difficulties perceived by the patients about the device are not because the device is actually malfunctioning, but because it is perceived as so. Emotions play an important role in how things are perceived, and an emotionally frail patient may be perceiving difficulties in the functioning of the device which are not real. In all cases it is absolutely essential to treat the patient with respect and emotional sensitivity. Usually this is enough to resolve most difficulties. If such cases occur or persist, it is best that you help the patient seek psychological help, such as with a psychologist. His difficulties are not linked to you or the ZSI 375.

C - GENERAL PROTOCOL FOR DEALING WITH DOUBT OF FUNCTIONING

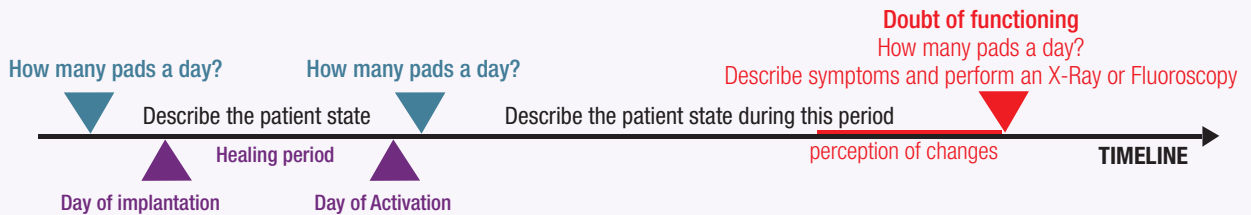
Given the very low probability of mechanical failure of the ZSI 375, when dealing with a doubt of functioning, it should be assumed that the ZSI 375 is functioning properly. If the expected results are not achieved with the ZSI 375, the primary hypothesis should be considered:

What changes has the patient's body and mind undergone for the ZSI 375 to be perceived as not functioning properly?

In case of a patient claim, before considering the claim as a problem or a failure, always ask him the following questions:

1. Ask for a properly performed X-Ray or Fluoroscopy. Provide a relevant video (phone/camera) to help with understanding of the case/situation.
2. When the patient says " it is not functioning " what does this mean for him? " Not functioning " Please describe in detail.
3. Ask for the patient's medical history related to his severe urinary incontinence.
4. Ask for a detailed description of the patient's current physical state.
5. Date of the implantation?
6. Date of the activation?
7. What happened during the activation day? How was the ZSI 375 functioning?
8. If during activation day it was functioning: what was the date when doubt of functioning was first noticed? Please describe.
9. How was the patient's physical state before the symptoms appeared and after?
10. How many pads a day had the patient used before the device was implanted?
11. How many pads a day had the patient used after the device was implanted?
12. How many pads a day had the patient used before the device was activated?
13. How many pads a day had the patient used after the device was activated?

When sharing information regarding the ZSI 375 always specify the relevant Timeline stage.
Before implantation? / During implantation (which step)? / Post implantation?



D - URINARY CONTINENCE STATUS

Continence status helps to evaluate the patient's continence before and after ZSI 375 implantation:

- Total continence: 0 pad per day.
- Social continence: 0 to 1 pad per day.
- Light incontinence: 2 pads per day.
- Moderate incontinence: 3 pads per day.
- Severe incontinence: 4 or more pads per day.

An alternative standard of continence status measurement has been published and offers a very precise analysis of states of patient incontinence.

It is less subjective than referring only to numbers of pads. Each patient does not fulfil pads with the same volume of urine. However, this can be problematic/challenging to apply in practice.

Status	24h Pad Weight Test g/24h or ml/24h	1h Pad Weight Test g/h or ml/h
Mild incontinence	4.4-20g	< 10
Medium incontinence	21-74g	11-50
Severe incontinence	> 75g	> 50

O'Sullivan R, Karantanis E, Stevermuer TL, Allen W, Moore KH: Definition of mild, moderate and severe incontinence on the 24 hours pad test. BJOG 2004; 111: 859-862

2. MANAGEMENT WHEN IN DOUBT OF FUNCTIONING AFTER ACTIVATION

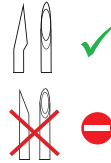
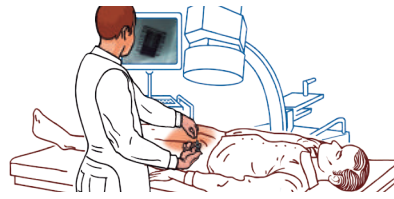
Page 88, 89 - Video 4 - Video 5 - Video 7

A - EQUIPMENT FOR INVESTIGATION

X-Ray is a perfect tool to view the Spring at a fixed moment in time.
FLUOROSCOPY is the perfect tool to check the Spring motion.

Remember: 2 sterile Huber needles are included in the ZSI 375 package.
 Contact ZSI for Huber needle references if needed.

- A Huber needle should be used for all injections concerning the device as it poses no risk to the silicone.
- Standard bevel point needle. Risk damage the silicone Septum. It can create a core/tunnel in the silicone causing leakage.



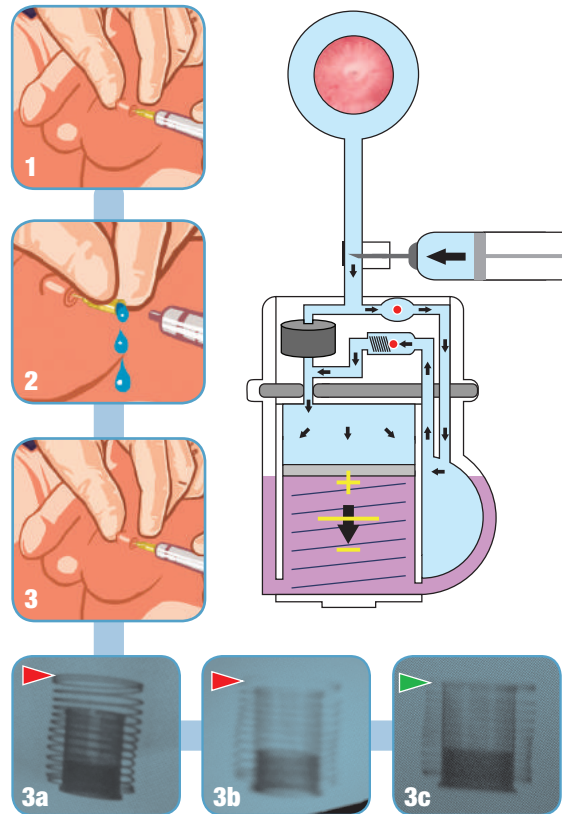
B - PIERCING SEPTUMS PROTOCOL AND INJECTION TIMELINE

■ B1 INSTRUCTIONS TO PIERCE THE HYDRAULIC CIRCUIT SEPTUM THROUGH THE SCROTUM TO PLACE THE TOP OF THE SPRING LEVEL WITH THE MID-LINE:

Blood can block the ZSI 375 Valves. To reduce the risk of blood being injected into the Hydraulic Circuit, follow the injection protocol:

1. Pierce the Hydraulic Circuit Septum with 22-25 Gauge Huber needle connected to a syringe.
2. Remove the syringe and allow a drop of Saline Solution from the Hydraulic Circuit to flush out any blood in the Huber needle.
3. Connect the syringe to the Huber needle.

If you do not have a fluoroscope, inject (or remove) between 0.1 to 1 ml of Saline Solution and check with an X-Ray after each injection.
 Repeat this if necessary.

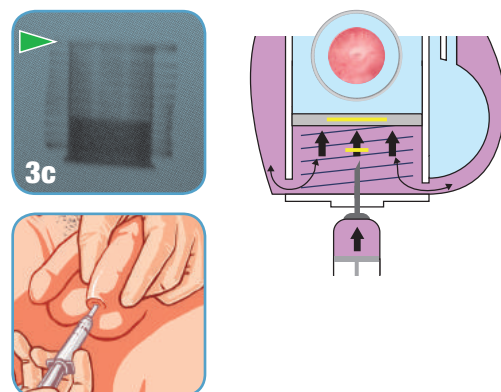


■ B2 INSTRUCTIONS TO PIERCE THE COMPENSATION POUCH SEPTUM TO INCREASE OR DECREASE THE PRESSURE:

1. Use a 22-25 Gauge Huber needle connected to a syringe.
2. Hold the Pump with 2 fingers and pierce exactly in the centre (Septum can be felt by finger).

Nota 1: Spring is not seen moving.

Nota 2: Spring always at Mid-line/Top of Cylinder before starting injecting.



INJECTION IN THE COMPENSATION POUCH: TIMELINE TO INCREASE PRESSURE

Note 1: The fibrosis around the Pump Unit influences the amount of Saline Solution needed to reach the level of continence required.

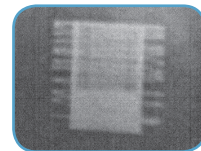
Note 2: Before injecting any Saline Solution, read and understand page 48-49

Note 3: Before injecting, check with the patient how he is using the ZSI 375 and confirm for yourself the level of incontinence.

Adjustment of pressure after activation, if the patient is still incontinent.

Before every injection, perform your usual skin preparation, and confirm for yourself the level of incontinence.

- Inject 1 ml into the Compensation Pouch. Injection of the first 1 ml usually places the Compensation Pouch under pressure.
- Ask the patient to go for about an hour's walk around the hospital. Then check his continence status.
- If the patient is still incontinent, inject 1 more ml and allow him to go home.
- Other visits: if the patient is still incontinent after 2 ml injected in the Compensation Pouch.
- Inject 0.5 ml at each visit until you reach the continence requested. Allow one week between each injection of 0.5 ml.
- Always remember, the greater the pressure, the greater the risk of urethral erosion.



C - DOUBTS WHETHER THE ZSI 375 IS OPERATING PROPERLY: INVESTIGATION

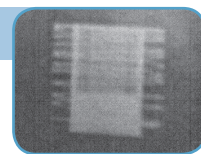
■ C1 INCONTINENCE AFTER ACTIVATION OR AFTER A PERIOD OF CONTINENCE

■ C.1.1. SOCIAL CONTINENCE AFTER ACTIVATION OR AFTER A PERIOD OF CONTINENCE

a) **Situation:** Social Continence: the leakage of a few drops of urine when coughing or performing a physical task is considered a good result. Remember that the pressure of the ZSI 375 Cuff does not increase as the patient performs physical tasks, so this limited leakage is normal.

b) **Action:** If the patient presents with Social Continence and wants Total Continence, the surgeon can increase the ZSI 375 issued pressure by injecting Sterile Saline Solution 0.9‰ into the Compensation Pouch of the ZSI 375 gradually, in 1 ml steps up to 2 ml then 0.5 ml steps. See INJECTION TIMELINE page 51.

IMPORTANT: The more the surgeon increases the issued pressure the more he increases the risk of urethral ischaemia and the risk of erosion leading to total removal of the ZSI 375. The surgeon will determine the level of risk of increasing the pressure for each patient. It is always better to accept Social Continence or improvement as a good result. Verify the pressure using a Pressure Sensor.



Injection into the Compensation Pouch

■ C.1.2. LIGHT, MODERATE, SEVERE INCONTINENCE AFTER ACTIVATION OR AFTER A PERIOD OF CONTINENCE

a) **Situation:**

- Light incontinence: 2 pads per day.
- Improvement: 2 pads per days or 50% less than the base line before ZSI 375 implantation.
- Moderate incontinence: 3 pads per day.
- Severe incontinence: 4 or more pads per day.

b) **Action:** The ZSI 375 status must be checked: the patient should meet his surgeon for a clinical examination of his perineal and genital area and urine. The surgeon will look for signs of infection and/or erosion. In case of infection: infection must be treated. Sometimes the ZSI 375 must be removed.

In case of erosion: infection must be treated. If the erosion is confirmed: ZSI 375 must be removed.

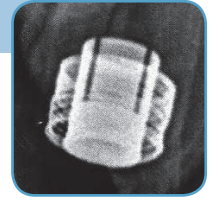
Two main exams will be performed:

An X-Ray to check the position of the Spring of the ZSI 375.

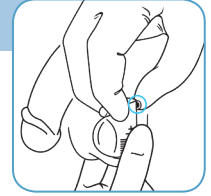
A Cystoscopy to check the urethra of the patient.

C.1.2.1. X-RAY: THE SPRING OF THE ZSI 375 IS COMPRESSED

a) **Situation:** The Top of the Spring is below the Top of the Cylinder (under the Mid-line). The ZSI 375 is still Deactivated, with Tank full of Saline Solution, Cuff empty and urethra open.



b) **Action:** Press again the Activation Button to Activate properly the Deactivated ZSI 375. After Activation, the Top of the Spring should rise to the Top of the Cylinder/Mid-line, filling the Cuff drop by drop and closing the urethra.

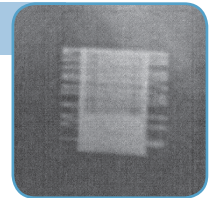


Activation

C.1.2.2. X-RAY: THE TOP OF THE SPRING IS AT THE TOP OF THE CYLINDER OR AT THE MID-LINE

a) **Situation:** The Top of the Spring is at the Top of the Cylinder.

The ZSI 375 is Activated and the issued pressure in the Cuff is 90 cmH₂O +/- 5 cmH₂O. This standard pressure in the Cuff is too weak for this particular patient. The surgeon can increase the issued pressure in the Cuff to improve the patient continence status.



b) **Action:** The surgeon can increase the ZSI 375 issued pressure by injecting Sterile Saline Solution 0.9% in the Compensation Pouch through the scrotum gradually, in 1 ml steps up to 2 ml then 0.5 ml steps. See INJECTION TIMELINE page 51.

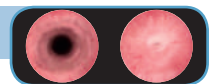
IMPORTANT: The more Saline Solution injected into the Compensation Pouch, the greater the issued pressure in the Cuff. It increases the risk of urethral ischaemia and the risk of erosion, leading to a total removal of the ZSI 375. The surgeon will determine the level of risk of increasing the pressure for each patient. The visual position of the Spring does not change, it gains extra force. The injection of Saline Solution in the Compensation Pouch increases the issued pressure and must be done with care. Verify the issued pressure using a Pressure Sensor.



Injection into the Compensation Pouch

If the injection of Saline Solution in the Compensation Pouch does not improve continence status, the surgeon must do a cystoscopy to explore the urethra and search for urethral erosion. In case of urethral erosion, the ZSI 375 must be removed.

Note: As the tip of the cystoscope approaches the Cuff, reduce or stop saline flow. Continuing with saline flow from the cystoscope can force open the Cuff, giving the impression the Cuff is operating incorrectly by appearing to be open.

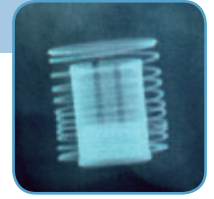


Perform a cystoscopy

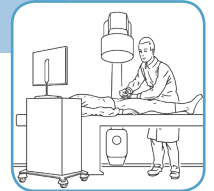
If Saline Solution has been added in the Compensation Pouch, always make a note of the volume injected to be able to remove the same volume to return to the initial Spring standard pressure if needed.

C.1.2.3. X-RAY: THE TOP OF THE SPRING IS ABOVE THE TOP OF THE CYLINDER OR ABOVE MID-LINE

a) **Situation:** The Top of the Spring is above the Top of the Cylinder reaching the Plus '+' sign. The issued pressure is too weak for the Cuff to close properly around the urethra leading to leakage.

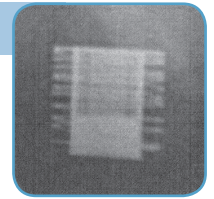


b) **Action:** The surgeon has to inject Sterile Saline Solution 0.9‰ into the Hydraulic Circuit through the Hydraulic Circuit Septum to place the Top of the Spring at the Top of the Cylinder, at Mid-line level. When the Top of the Spring is at the Top of the Cylinder or at Mid-line, the issued pressure is 90 cmH₂O +/- 5 cmH₂O. The Saline Solution will be injected into the Hydraulic Circuit in steps of 0.1 ml looking at the Top of the Spring going back to the Top of the Cylinder through Fluoroscopy. The continence status should improve.

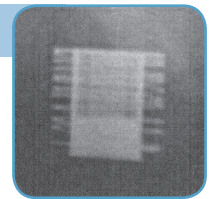


Injection into the Hydraulic Circuit

c) **Result:** The Top of the Spring is at the Top of the Cylinder (means at Mid-line) the continence status should improve as the Cuff pressure is 90 cmH₂O +/- 5 cmH₂O.



d) **Situation:** If the continence status does not improve after placing the Top of the Spring at the Top of the Cylinder or at the Mid-line (the issued pressure in the Cuff is 90 cmH₂O +/- 5 cmH₂O), then this issued pressure of 90 cmH₂O +/- 5 cmH₂O is too weak for this particular patient.



e) **Action:** The surgeon can increase the ZSI 375 issued pressure injecting Sterile Saline Solution 0.9‰ in the Compensation Pouch gradually, in 1 ml steps up to 2 ml then 0.5 ml steps. See INJECTION TIMELINE page 51. Verify the issued pressure using a Pressure Sensor.

IMPORTANT: The more the surgeon increases the issued pressure the more he increases the risk of urethral ischaemia and the risk of erosion, leading to a total removal of the ZSI 375. This increasing of the issued pressure must be done with care. The surgeon will determine the level of risk of increasing the pressure for each patient. Verify the issued pressure using a Pressure Sensor.

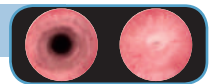


Injection into the Compensation Pouch

f) **Situation:** If the increasing of the issued pressure does not improve the continence status: the patient still presents with moderate incontinence or severe incontinence.

g) **Action:** The surgeon must do a Cystoscopy to explore the urethra looking for urethral erosion. In case of urethral erosion, the ZSI 375 must be removed.

Note: As the tip of the cystoscope approaches the Cuff, reduce or stop saline flow. Continuing with saline flow from the cystoscope can force open the Cuff, giving the impression the Cuff is operating incorrectly by appearing to be open.



Perform a cystoscopy

In case of urethral atrophy, increase pressure only once. Increasing the pressure twice could lead to urethral erosion. It is better to change the position of the Cuff to a non-atrophic segment of the urethra.

C.1.2.4. X-RAY: THE SPRING SEEMS TO BE FULLY DECOMPRESSED

a) **Situation:** This position of the Top of the Spring means that something is wrong with the patient's urethra and/or the pressure in the device. The Spring is fully decompressed and the Top of the Spring position is above the Plus '+' sign.

This could be due to:

- Severe Urethral atrophy.
- Urethral necrosis.
- The ZSI 375 is leaking Saline Solution from the Hydraulic Circuit.

■ Case 1: Severe urethral atrophy

The patient might report that he gradually returned to incontinence over a period of days. Using endoscopy, check the state of the urethra.

b) **Action:** Surgeon can inject Sterile Saline Solution 0.9‰ in the Hydraulic Circuit through the Hydraulic Circuit Septum to place the Top of the Spring at the Top of Cylinder or Mid-line to get back to standard pressure and to improve continence.

Remark: the ZSI 375 is functioning perfectly, it just needs to be adjusted to the patient's new urethral state.

■ Case 2: Urethral erosion

The patient might report that he gradually returned to incontinence over a period of days.

b) **Action:** Check with endoscopy the state of the urethra.

In case of urethral erosion, the ZSI 375 must be removed.

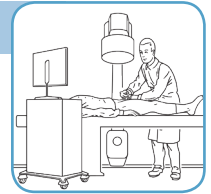
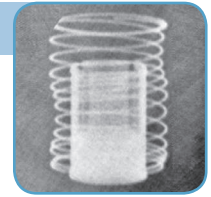
Remark: In case of erosion, the device is still considered as functioning perfectly, the urethra has changed state.

■ Case 3: Device leakage

The patient might report that he suffers incontinence again.

d) **Action:** Each ZSI 375 unit has undergone very strict and extensive quality control during production.

The unit is checked again by the surgeon before implantation. A liquid leakage is highly unlikely to happen unless there was a problem at the time of implantation. In any case, the ZSI 375 must be removed and replaced by a new one. The ZSI 375 in question must be sent to be investigated/tested by ZSI for the problem to be considered and the cause determined.



Injection into the Hydraulic Circuit

In case of urethral atrophy, increase pressure only once.
Increasing the pressure twice could lead to urethral erosion.
It is better to change the position of the Cuff to a non-atrophic segment of the urethra.

■ C2 URINARY RETENTION AFTER IMPLANTATION OF THE ZSI 375

The patient state after initial implantation of the Artificial Urinary Sphincter ZSI 375 should be incontinence. Incontinence must be the same before and after procedure because the ZSI 375 is in the Deactivated position with Cuff open for urethral healing.

Retention after the removal of the catheter could be due to:

- Poor or no Deactivation of the ZSI 375.
- Accidental Activation of the ZSI 375.
- Cuff too tight around the urethra.

- » If the retention is painful, a suprapubic catheter must be inserted.
- » If the retention is not painful, an X-Ray must be performed to check the Spring position.

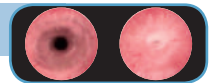
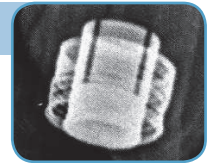
■ C.2.1. X-RAY: THE SPRING IS COMPRESSED BELOW THE TOP OF THE CYLINDER BEFORE ACTIVATION - WHILE PATIENT IS IN RETENTION

a) **Situation:** The ZSI 375 is Deactivated properly, the Cuff might be too tight around the urethra and/or the inflammation of the urethra is too severe to let the urine pass through.

b) **Action:** The surgeon would reinsert a 12 Fr/Ch Foley catheter for 48 hours waiting for a decrease of the urethral inflammation.

c) **Action:** After the 12 Fr/Ch Foley catheter has been removed, in case of persistent retention, a Cystoscopy must be performed.

If there is no urethral erosion and the opening of the urethra is too narrow, a perineal incision must be performed again. The Cuff will have to be loosened to allow a urethral passage for urine. The ZSI 375 must be Activated and the Spring position at Mid-line must be checked again after performing a new X-Ray. The Cuff must be deflated and the ZSI 375 must be Deactivated before perineal closure.



Perform a cystoscopy

■ C.2.2. X-RAY: THE TOP OF THE SPRING IS LEVEL OR ABOVE THE TOP OF THE CYLINDER BEFORE ACTIVATION - WHILE PATIENT IS IN RETENTION

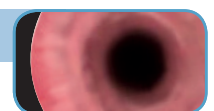
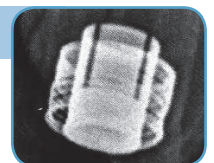
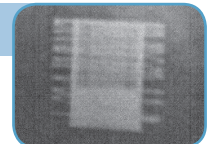
a) **Situation:** The ZSI 375 is Activated or has not been properly Deactivated. The Cuff was not flat during the Deactivation procedure.

CAUTION: Always use a suprapubic catheter, never a urethral catheter.

b) **Action:** The surgeon must Reactivate the ZSI 375 by pressing the Activation Button and repeat the Deactivation procedure. He will deflate the Cuff by pressing and releasing the Pump Button two or three times. Then he will press the Deactivation Button to Deactivate the Artificial Urinary Sphincter to keep the Cuff flat and open during the urethral healing period. The patient must remain incontinent. Performing a new X-Ray, the Spring must be compressed, and the Top of the Spring must stay below the Top of the Cylinder.

c) **Action:** Performing a cystoscopy, the urethra must be open, and the patient should be incontinent. The ZSI 375 will be Activated in 6 to 8 weeks.

Note: As the tip of the cystoscope approaches the Cuff, reduce or stop saline flow. Continuing with saline flow from the cystoscope can force open the Cuff, giving the impression the Cuff is operating incorrectly by appearing to be open.



Perform a cystoscopy

If the patient is still in retention after the ZSI 375 has been properly Deactivated, it is highly unlikely that the ZSI 375 is the cause of the retention. Other possible causes should be examined.

C.2.3. X-RAY: THE SPRING IS LEVEL WITH OR ABOVE THE TOP OF THE CYLINDER AFTER ACTIVATION - WHILE PATIENT IS IN RETENTION

CAUTION: Always use a suprapubic catheter, never a urethral catheter.

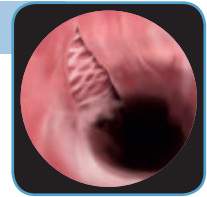
In case of retention after Activation or after a period of continence. For investigation:

1. An X-Ray must be performed to check the Spring position. The Top of the Spring will be shown to be at the Top or above the Top of the Cylinder.
2. A Fluoroscopy shows that the Spring is moving as expected. This means the ZSI 375 is Activated properly and functioning correctly. The problem is not due to the ZSI 375, search for other origin of the problem.

C.2.3.1. SEVERE URETHRAL EROSION

a) **Situation:** With Fluoroscopy, check that the Spring is seen to be moving up with a normal speed when pressing and releasing the Pump Button.

b) **Action:** The cuff can cause severe erosion of the urethra; eventually this leads to the cuff penetrating the wall of the urethra.



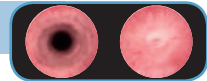
Cystoscopy/Erosion

C3 INFECTION AND EROSION

a) **Situation:** The patient must contact the surgeon if he experiences pain, scrotal inflammation, perineal inflammation, difficulties voiding and any abnormal symptoms.

b) **Action:** The surgeon should perform an X-Ray checking Spring position and a cystoscopy checking the urethra.

Note: As the tip of the cystoscope approaches the Cuff, reduce or stop saline flow. Continuing with saline flow from the cystoscope can force open the Cuff, giving the impression the Cuff is operating incorrectly by appearing to be open.



If the ZSI 375 is perceived by either the surgeon or the patient as no longer functioning correctly after the appropriate functioning period, it is important to assess what has changed in the patient's body, to better understand their perception of the 'doubt of functioning'.

If the ZSI 375 has already been working correctly, it should continue to do so for its entire estimated lifetime. The design and technology of the ZSI 375 is proven and operates with a very low risk of mechanical failure.

3. ZSI 375 REMOVAL

A - STEPS FOR ZSI 375 REMOVAL

Causes of prefilled ZSI 375 removal after learning curve:

- Erosion
- Infection
- Mechanical failure

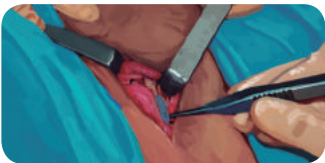
For ZSI inspection and analysis, it is important the Cuff and the Pump Unit are not damaged during removal. Only the anti-kink tubing can be cut.

1. Prepare a Foley catheter 12 Fr/Ch or 14 Fr/Ch, a scalpel, monopolar cautery/bistouri, scissors, mosquito forceps and Langenbeck retractor. With a monopolar cautery, do not be afraid of damaging the silicone: it withstands up to 200°C before melting.

2. Patient is in the lithotomy position and under general or spinal anesthesia. Prepare and drape for a perineal incision and pinpoint the position of the Cuff through the perineal skin. Press the Pump Button to deflate the Cuff and insert a 12 Fr/Ch or 14 Fr/Ch Foley catheter for guidance. No need to Deactivate the ZSI 375.



3. Perform a perineal incision with a monopolar cautery. Then use the monopolar cautery only to dissect the tissue covering the Cuff. Do not be afraid of damaging the silicone. The monopolar cautery must always be in contact with the silicone of the Cuff. Take care not to damage the urethra. Open the Cuff and use scissors to cut the anti-kink tubing 2 or 3 cm above the Cuff. If the Cuff closure was secured with two sutures, cut the sutures: take care not to damage the Cuff.



4. Push the scrotal Pump through the perineal incision.



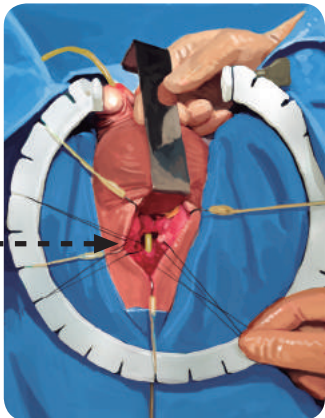
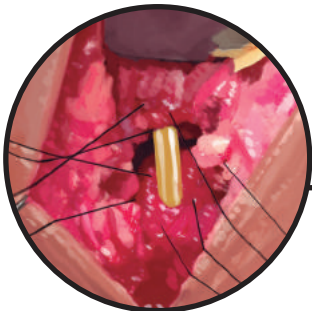
5. Open the internal scrotal tissue with the bipolar cautery only. Stay in contact with the silicone of the Pump Unit. Take care not to damage the Compensation Pouch of the Pump Unit. Remove the Pump Unit.



B - HOW TO TREAT URETHRAL EROSION

Remove the 12 Fr/Ch or 14 Fr/Ch Foley catheter and insert a 18 Fr/Ch Foley catheter. Close the urethral erosion and close with two layers of tissue over a drain. The drain must be in contact with the urethra. Usually the catheter must remain in situ for one month for the urethra to heal. Prescribe antibiotics. A cystoscopy must be performed before implanting a new ZSI 375. A new ZSI 375 insertion can be proposed 6 to 12 months after previous ZSI 375 removal.

Note: It is best not to implant the Cuff at the spot where the urethra was formerly eroded.



Never insert any urethral catheter while any Artificial Urinary Sphincter is Activated. It will lead to urethral erosion/necrosis.

In the 40 year history of Artificial Urinary Sphincters, few studies investigated Cuff issued pressure in vivo. Main data were provided by manufacturers based on their laboratory testing and considered definitive without further investigations.

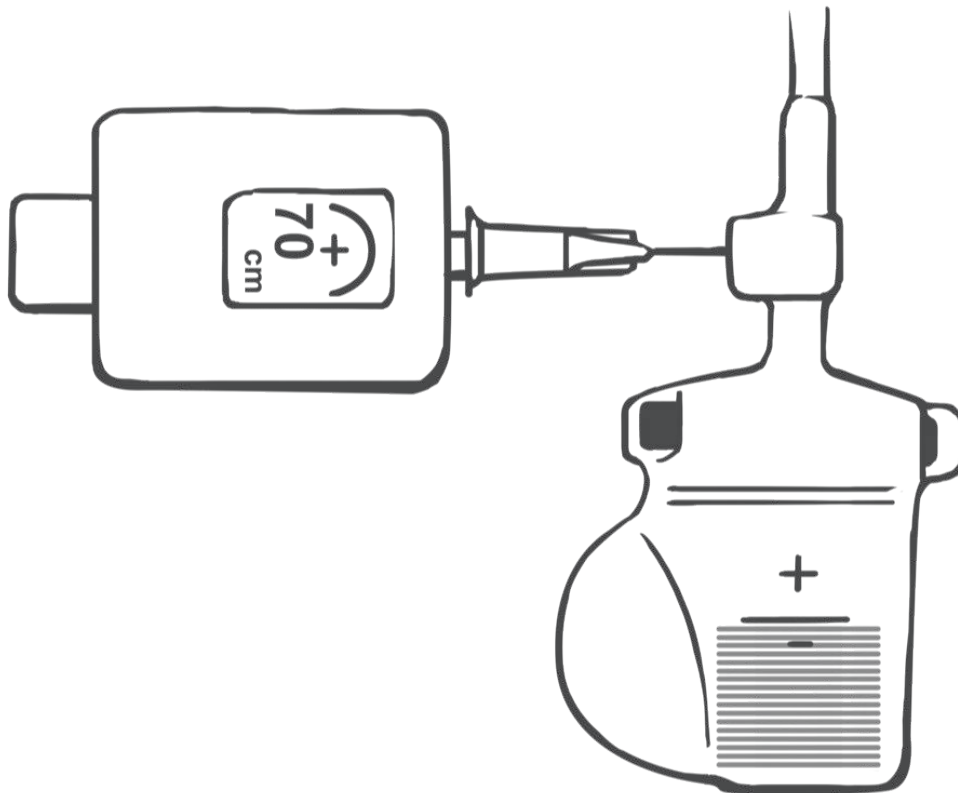
The ZSI 375 option of using a Pressure Sensor is opening a new field of investigation for all Urologists involved in incontinence research and Artificial Urinary Sphincters.

Since 2009, the ZSI 375 AUS has been supplied with a standard issued pressure suitable for most patients: 90 cmH₂O +/- 5 cmH₂O with the possibility to increase or decrease the pressure by injecting or removing Sterile Saline Solution 0.9‰ into the Compensation Pouch.

VIII

PRESSURE ADJUSTMENT WITH PRESSURE SENSOR (OPTION)

PRESSURE ADJUSTMENT WITH PRESSURE SENSOR (OPTION)	59
1. PRESSURE ADJUSTMENT FROM COMPENSATION POUCH VOLUME	60
A. PRESSURE SENSOR PREPARATION FOR PRESSURE ADJUSTMENT FROM COMPENSATION POUCH.....	60
B. ISSUED PRESSURE ADJUSTMENT FROM COMPENSATION POUCH DURING PROCEDURE.....	60
C. ISSUED PRESSURE ADJUSTMENT FROM COMPENSATION POUCH DURING ZSI 375 LIFETIME	61
D. ISSUED PRESSURE ADJUSTMENT MECHANISM	62



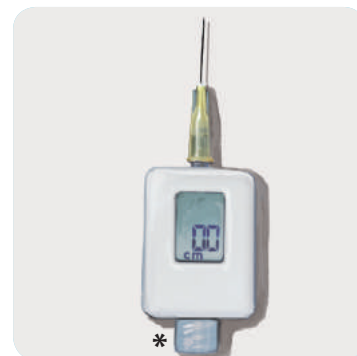
1. PRESSURE ADJUSTMENT FROM COMPENSATION POUCH VOLUME

Issued pressure can be changed by injecting or removing Sterile Saline Solution 0.9% into/from the Compensation Pouch when the Spring is level with the Mid-line (90 cmH₂O, +/- 5 cmH₂O standard pressure).

- Removing Saline Solution from the Compensation Pouch, the pressure can be decreased from 90 cmH₂O +/- 5 cmH₂O (standard pressure) to 00 cmH₂O (Deactivation).
- Injecting Sterile Saline Solution 0.9% in the Compensation Pouch, the issued pressure can be increased from 90 cmH₂O +/- 5 cmH₂O (standard pressure) to more than 120 cmH₂O. The increasing of pressure must be done with care as it increases the risk of urethral erosion. The lower the pressure the better, but if the pressure is too low, this leads to incontinence.

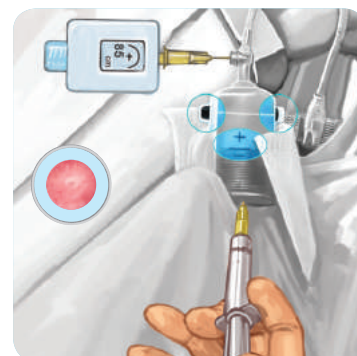
A. PRESSURE SENSOR PREPARATION FOR PRESSURE ADJUSTMENT FROM COMPENSATION POUCH

1. Connect a 24G Huber needle to the Pressure Sensor on one side.
2. Connect a syringe filled with Sterile Saline Solution 0.9% on the other side.
3. Remove the air by injecting Sterile Saline Solution 0.9% into the Pressure Sensor with the 24 Gauge Huber needle.
4. Switch on the Pressure Sensor and check that the pressure on the screen is 00.00 cmH₂O.
5. Remove the syringe from Pressure Sensor.
6. Reconnect the plug to the Pressure Sensor. *
7. Prepare a second syringe filled with 5 ml of saline solution, and equipped with a 24G Huber needle.



B. ISSUED PRESSURE ADJUSTMENT FROM COMPENSATION POUCH DURING PROCEDURE

1. After the Cuff is closed around the urethra and the catheter has been removed, activate the ZSI 375.
2. Press the Pump Button. Be sure the Spring is pushed properly by the Piston.
3. **Wait for the Spring to return to the Mid-line level.**
4. Pierce the Hydraulic Circuit Septum with the Huber needle connected to the Pressure Sensor and wait for 3-4 minutes before reading the issued Pressure in the Hydraulic Circuit and the Cuff on the screen. *
5. Pierce the Compensation Pouch Septum with the 24G Huber needle connected to the 5 ml syringe filled with Sterile Saline Solution 0.9%.
6. Increase pressure by injecting Sterile Saline Solution 0.9% into the Compensation Pouch.
7. Decrease pressure by removing Saline Solution from the Compensation Pouch.
8. To have an accurate measure of pressure, always Press and Release the Pump Button/Bulb then wait for 3-4 minutes (this includes the 2-3 minutes for the Spring to return to the Mid-line). This is because the needle piercing the Septum is very thin and pressure transmission and balance takes time. *
9. At the end of the procedure, remove the Huber needle from the Compensation Pouch Septum and from the Hydraulic Circuit Septum.



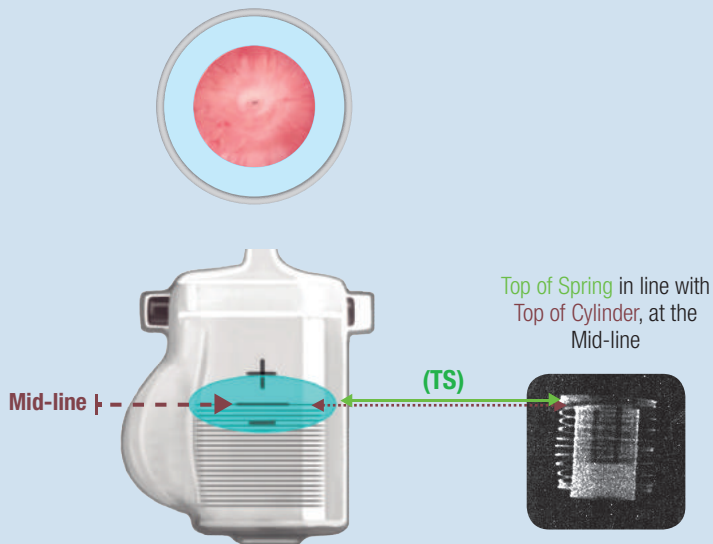
C. ISSUED PRESSURE ADJUSTMENT FROM COMPENSATION POUCH DURING ZSI 375 LIFETIME

1. Perform an X-RAY to confirm the Spring is level with the Mid-line.
2. Prepare the Pressure Sensor as described in Chapter A. Prepare a second 24G Huber needle connected to a 5 ml Syringe filled with Sterile Saline Solution 0.9%.
3. Pierce the Hydraulic Circuit Septum with the Huber needle connected to the Pressure Sensor.
4. Pierce the Compensation Pouch Septum with the second Huber needle connected to the 5 ml syringe filled with Sterile Saline Solution 0.9%.
5. Choose the issued pressure required by injecting or removing Saline Solution from the Compensation Pouch.
6. To have an accurate measure of pressure, always Press and Release the Pump Button/Bulb then wait for 3-4 minutes (this includes the 2-3 minutes for the Spring to return to the Mid-line). This is because the needle piercing the Septum is very thin and pressure transmission and balance takes time. *
7. At the end of the procedure remove the Huber needle from the Compensation Pouch Septum and from the Hydraulic Circuit Septum.



* To have an accurate measure of pressure, always Press and Release the Pump Button/Bulb then wait for 3-4 minutes (this includes the 2-3 minutes for the Spring to return to the Mid-line). This is because the needle piercing the Septum is very thin and pressure transmission and balance takes time.

BEFORE ANY PRESSURE ADJUSTMENT SPRING MUST BE LEVEL WITH MID-LINE OR AT THE TOP OF CYLINDER WITH X-RAY

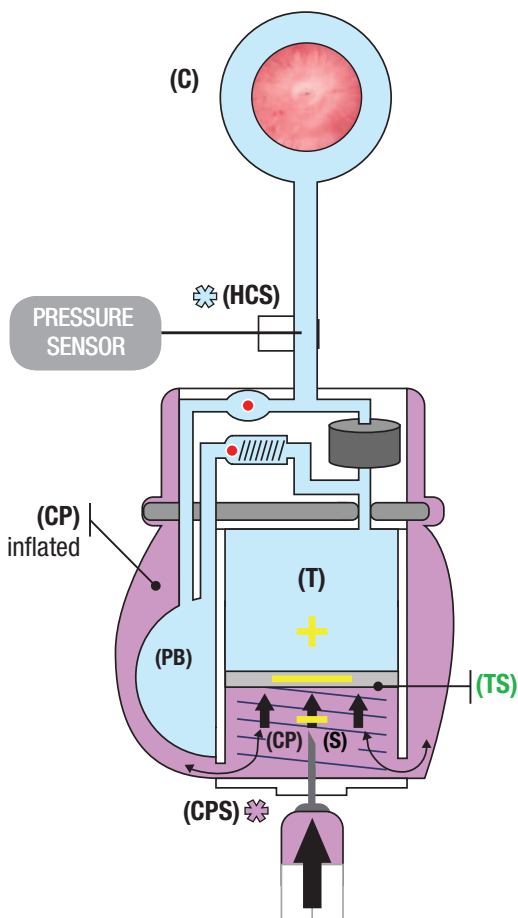
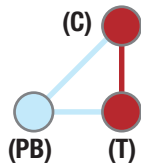


D. ISSUED PRESSURE ADJUSTMENT MECHANISM

BEFORE ANY PRESSURE ADJUSTMENT SPRING MUST BE LEVEL WITH MID-LINE

INCREASING THE PRESSURE

Saline Solution injection into the Compensation Pouch (CP)
Cuff pressure > 90 cmH₂O +/- 5 cmH₂O



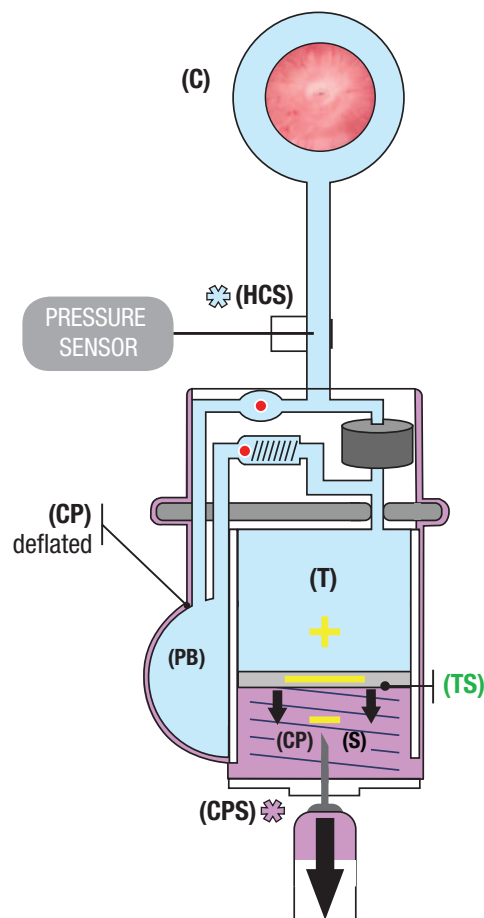
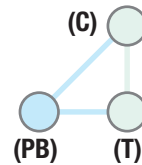
The ZSI 375 is under the combined pressure of the Spring (S) and the Compensation Pouch (CP) inflated.

The greater the volume of Sterile Saline Solution 0.9% injected, the stronger is the pressure in the Cuff.
Before injecting Sterile Saline Solution 0.9% the Top of the Spring (TS) has to be level with the Mid-line.
The Top of the Spring (TS) will not move significantly visually under X-Ray or Fluoroscopy.
Control the added pressure with the Pressure Sensor.

⊗ (HCS): Hydraulic Circuit Septum

DECREASING THE PRESSURE

Saline Solution removal from the Compensation Pouch (CP)
Cuff pressure < 90 cmH₂O +/- 5 cmH₂O



Removal of Saline Solution from Compensation Pouch (CP) leads to negative pressure.

The ZSI 375 is then under Spring (S) pressure and aspiration from negative pressure of the Compensation Pouch (CP).
The Top of the Spring (TS) will not move significantly visually under X-Ray or Fluoroscopy. If the surgeon keeps on removing Saline Solution from the Compensation Pouch, the negative pressure will aspirate the Piston downwards to 00 cmH₂O. The drop in pressure must be under Pressure Sensor control.

⊗ (CPS): Compensation Pouch Septum

Do not control the issued pressure with a syringe connected to the Pressure Sensor. Tests showed an underestimation of the issued pressure due to micromotion of the syringe piston.



Surgeons must have extensive experience with the technology and implantation of the ZSI 375 before attempting this procedure.



ADVANCED COURSE VIDEO

11 OPTIONAL - PRESSURE SELECTION WITH PRESSURE SENSOR
1:23 minutes video

DIRECT ACCESS



www.zsimplants.ch
(fast access to videos)

ZSI ARTIFICIAL URINARY SPHINCTER - ZSI 375 1:23 minutes Video n°11
INCORPORATED PRESSURE SELECTION WITH PRESSURE SENSOR

SPEED X3

* TO HAVE AN ACCURATE MEASURE OF PRESSURE, ALWAYS PRESS AND RELEASE THE PUMP BUTTON/BULB THEN WAIT FOR 3-4 MINUTES (THIS INCLUDES THE 2-3 MINUTES FOR THE SPRING TO RETURN TO THE MID-LINE). THIS IS BECAUSE THE NEEDLE PIERCING THE SEPTUM IS VERY THIN AND PRESSURE TRANSMISSION AND BALANCE TAKES TIME.

There are 2 types of Artificial Urinary Sphincter, based on how pressure is provided:

(1) by a spring.

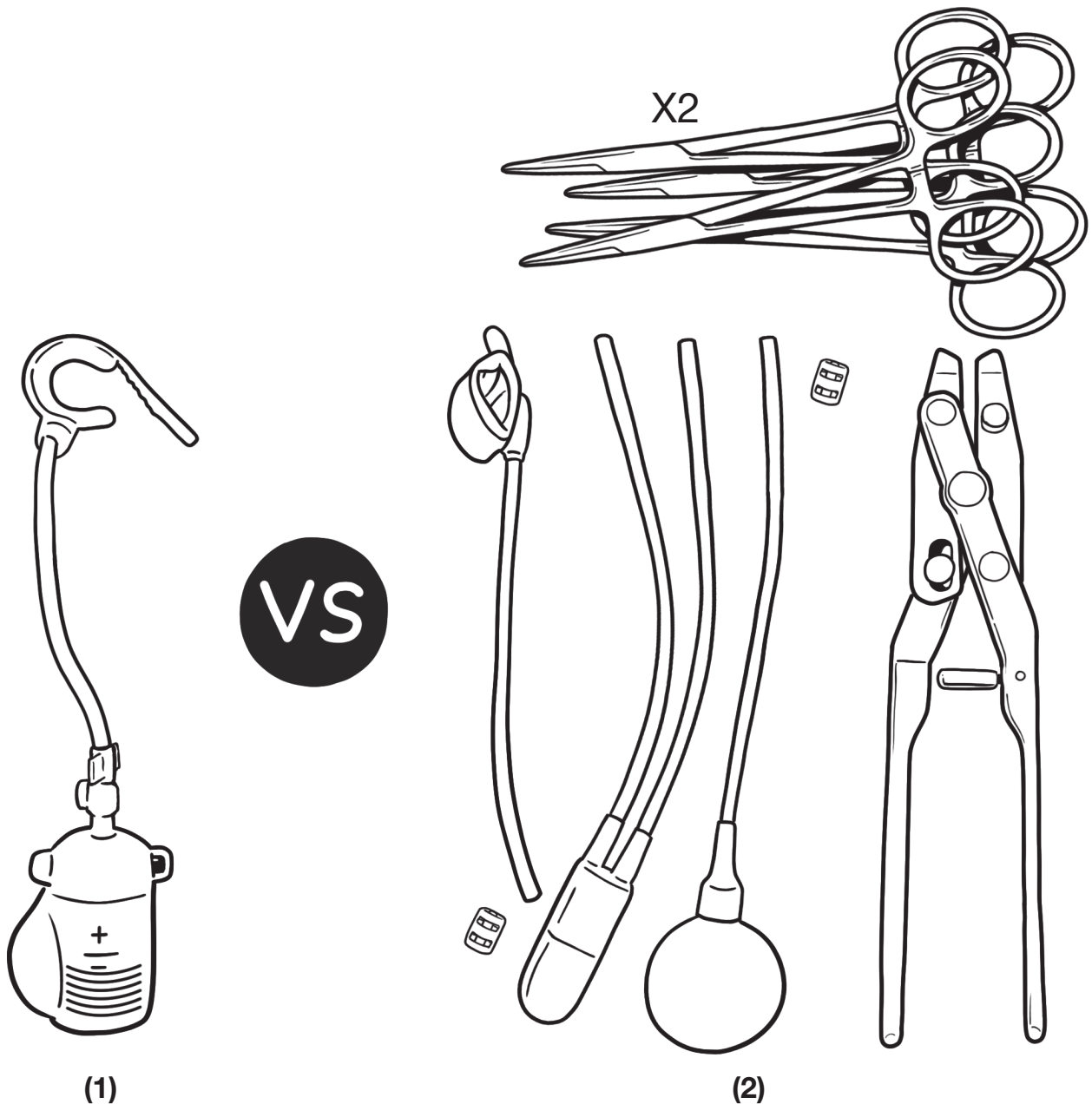
(2) by a pressure regulating balloon.

Presentation of the main differences after implantation.

IX

ARTIFICIAL URINARY SPHINCTERS TYPES

ARTIFICIAL URINARY SPHINCTERS TYPES	65
1. ZSI 375 CUFF DESIGN	66
A - CUFF VISUAL COMPARISON	66
B - FLAT CUFF CLOSED, NOT ZSI 375 CUFF DESIGN	66
C - CIRCULAR CUFF CLOSED, ZSI 375 CUFF DESIGN	66
2. PRESSURE COMPARISON BETWEEN TWO TYPES OF ARTIFICIAL URINARY SPHINCTERS	67
A - PRESSURE REGULATING BALLOON SYSTEM.....	67
B - ZSI 375 SPRING SYSTEM.....	67



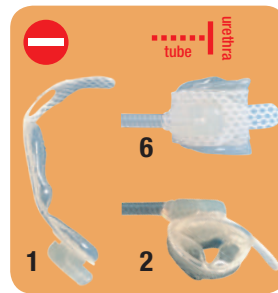
A - CUFF VISUAL COMPARISON

Visual comparison of two different Cuffs available in the market:

- The flat Cuff **1**, clamp Cuff design (when closed). **2**
- The circular Cuff **3**, ZSI 375 Cuff design (when closed). **4**

Tubing angle

- ZSI 375 Ergonomic tubing design parallel to urethra with reinforcement of tubing. **5**
- Flat Cuff with tubing perpendicular to urethra increasing elbow with no tubing reinforcement. **6**



FLAT CUFF
open and closed
clamp Cuff design



CIRCULAR CUFF
open and closed
ZSI 375 Cuff design

B - FLAT CUFF CLOSED, NOT ZSI 375 CUFF DESIGN

The flat Cuff closes around the urethra like a high pressure clamp. Pinching leads to higher risk of ischaemia.

The weakness of the flat cuff design is shown by silicone fracture at the angle junctions * causing leakage and subsequent loss of pressure.

ZSI has not selected this Cuff design.



FLAT CUFF CLOSED
clamp Cuff design



FLAT CUFF CLOSED
clamp Cuff design

C - CIRCULAR CUFF CLOSED, ZSI 375 CUFF DESIGN

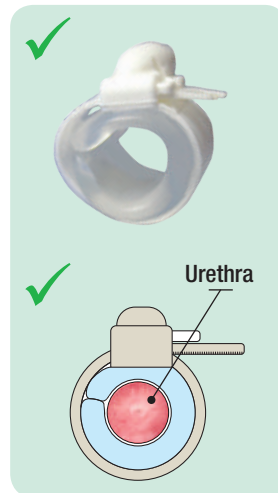
ZSI selected a circular Cuff design because of the following advantages:

- Organic curve shape.
- Controlled pressure around the urethra.
- No kink in the silicone as the Cuff is closed, no risk of fracture leading to leakage.

ZSI 375 is adjustable to fit all sizes of urethra from 4 to 6 cm overlapping is engineered by design.

No need to measure the urethral circumference with the ZSI 375 Cuff.

See page 27, images 35, 36, 37 and the page 29 'A - CONTROL OF THE ISSUED PRESSURE'.



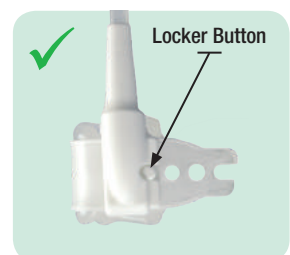
ZSI 375 CIRCULAR CUFF
with inflatable cushion end
to end for large circumference



ZSI 375 CIRCULAR CUFF
with cushion ends overlapped
for narrow circumference



ZSI 375 CUFF OPEN



ZSI 375 CUFF LOCKED
Circumference 4.5 cm

The Cuff has a fast Lock Button.

Surgeons can tighten the Cuff around the urethra the way they prefer. Urethra is calibrated by a 16 Fr Ch Foley Catheter.

- Hole 1: 4 cm (circumference).
- Hole 2: 4.5 cm (circumference).
- Hole 3: 5 cm (circumference).
- Hole 4: 5.5 cm (circumference).
- Notch 5: 6 cm (circumference) fixed only by suture.

2. PRESSURE COMPARISON BETWEEN TWO TYPES OF ARTIFICIAL URINARY SPHINCTERS

Today, there are two systems of Artificial Urinary Sphincters (AUS) available on the market. One system works with a Pressure Regulating Balloon and the other is the ZSI 375 which works with a Spring System. Both Artificial Urinary Sphincters are composed of a Cuff squeezing the urethra, a Pump and a Pressure Regulating System.

COMPARISON OF ISSUED PRESSURE

H₂O = water
cmH₂O = mbar

A - PRESSURE REGULATING BALLOON SYSTEM

The normal issued pressure of the Pressure Regulating Balloon System is 60-70 cmH₂O, but this is the pressure of the Cuff before it has been implanted. Two other factors must be considered that impact the pressure of the Cuff around the urethra after implantation.

I) The pressure of the pelvis

The pressure of the pelvis increases the pressure of the Pressure Regulating Balloon System from about 10 to 15 cmH₂O, and at other times, even more. There have been some recorded cases where the registered pressure was as high as 180 cmH₂O. *

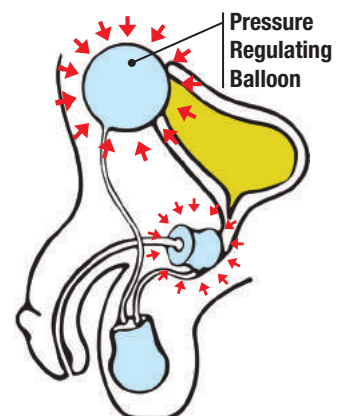
II) The difference in height between the Pressure Regulating Balloon and the Cuff

The difference in height between the Cuff and the Pressure Regulating Balloon increases the pressure in the Hydraulic Circuit from about 10 to 15 cmH₂O.

Summary: The normal pressure of 60-70 cmH₂O is valid before the device is implanted. Upon implantation, considering all given factors, the pressure of the Cuff comes to:

$$\begin{aligned} & 60-70 \text{ cmH}_2\text{O} \text{ (pressure of the Balloon)} \\ & + 10 \text{ to } 15 \text{ cmH}_2\text{O} \text{ (pressure of the pelvis)} \\ & + 10 \text{ to } 15 \text{ cmH}_2\text{O} \text{ (difference in height between Balloon and Cuff)} \\ & = 80 \text{ to } 100 \text{ cmH}_2\text{O} \text{ (final pressure of the Cuff)} \end{aligned}$$

* Issued pressure with a 60-70 cmH₂O Pressure-Regulating Balloon could be greater than 100 cmH₂O when implanted: Th. Riper, J. Pierre-Velcin, Comparative study of urodynamic tests after AMS 800 and ZSI 375 insertion, Urologia Journal, 10.5301/uj.

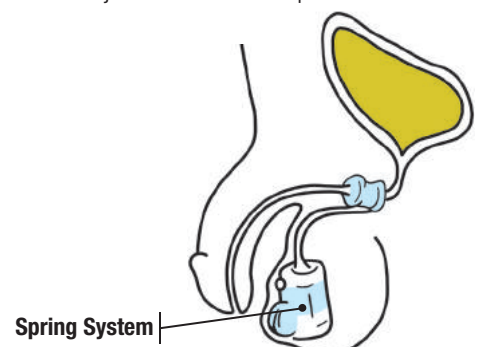
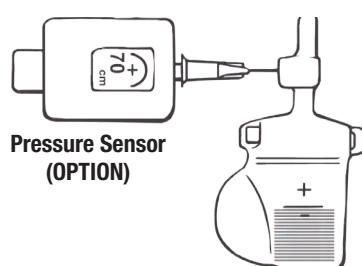


B - ZSI 375 SPRING SYSTEM

Summary: The Spring is not influenced by the pelvis and abdominal pressure since the ZSI Pump Unit is positioned in the scrotum. To reach continence, the standard pressure of the ZSI 375 Spring System must be equivalent to the Pressure Regulating Balloon system with additional pelvic pressure (0 to 15-20 cmH₂O). The ZSI 375 is supplied with an issued pressure of 90 cmH₂O +/- 5 cmH₂O when the Top of the Spring (TS) is level with the Mid-line and the Compensation Pouch is not under pressure.

The Cuff pressure of the ZSI 375 can be adjusted as desired by the surgeon, though this is rarely needed or performed.

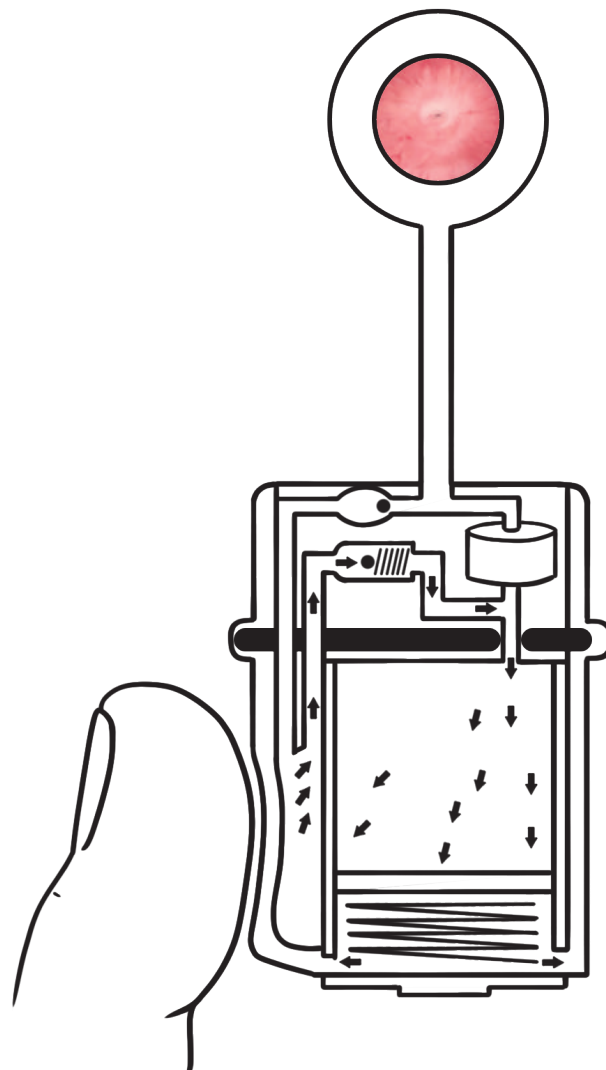
- It can be decreased to 0 cmH₂O with Saline Solution removed from the Compensation Pouch. See PRESSURE ADJUSTMENT page 60-61-62-79.
- It can be increased up to >120 cmH₂O with Sterile Saline Solution 0.9‰ injected into the Compensation Pouch. See PRESSURE ADJUSTMENT page 60-61-63-66-67-68-69.



This section of the manual aims to comprehensively explain all the functions and features of the ZSI 375.

Although some of the explanations may be repeated, the various diagrams, drawings and photos provide useful additional information.

TECHNOLOGY IN DETAILS	69
1. ZSI 375 MECHANISM OVERVIEW	70
2. DEACTIVATION BEFORE IMPLANTATION.....	74
A - DEACTIVATION GENERAL PROTOCOL.....	74
B - DEACTIVATION BEFORE CUFF IMPLANTATION (EXPLAINED WITH PICTURES).....	75
C - DEACTIVATION BEFORE CUFF IMPLANTATION (EXPLAINED WITH DRAWING).....	76
3. DEACTIVATIONS AFTER CUFF IMPLANTATION.....	77
A - ISSUED PRESSURE CONTROL AND DEACTIVATION DURING PROCEDURE	77
B - DEACTIVATION AFTER PROCEDURE.....	78
B1 - AFTER PROCEDURE - DEACTIVATING THE ZSI 375, FOR EXAMPLE TO INSERT A CATHETER	78
B2 - DEACTIVATION USING THE DEACTIVATION BUTTON.....	78
B3 - EMPTYING COMPENSATION POUCH (EMERGENCY).....	79
4. ACTIVATION	80
5. MICTURITION.....	82



1. ZSI 375 MECHANISM OVERVIEW


Page 88, 89 - Video 0 - Video 1 - Video 2 - Video 3 - Video 4 - Video 5 - Video 10

The ZSI 375 is a device composed of two separate functioning components:

- The Hydraulic Circuit (Saline Solution in blue)
- The Compensation Pouch (Saline Solution in purple).

The Hydraulic Circuit is responsible for the inflation and deflation of the Cuff (C). Saline Solution (blue) runs in the Hydraulic Circuit under the Pump Button command (PB).

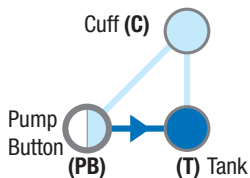
The Compensation Pouch is a type of reservoir. Saline Solution in this reservoir (purple) compensates the Piston (P) motion. The Saline Solution of the two components never come into contact and are kept separated by the Piston.

 The Saline Solution flow is regulated by the Flow Restriction Filter (FRF). It takes 2 to 3 minutes for the Saline Solution to pass from the Tank to the Cuff through the FRF. The patient is then continent again.

How does the FRF work?
The FRF has a helical design which regulates the flow of the Saline Solution.



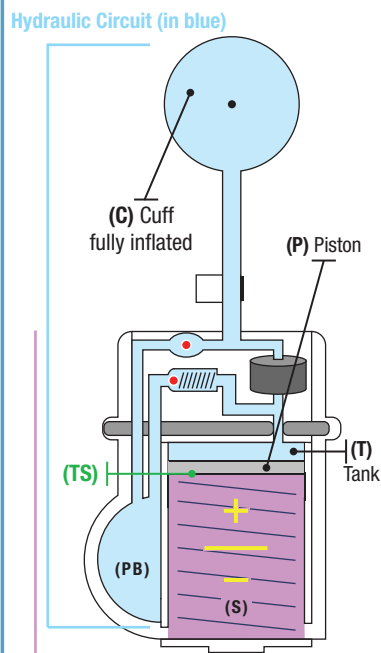
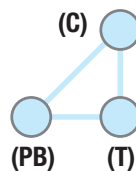
SCHEMATIC VIEW OF THE HYDRAULIC CIRCUIT SALINE SOLUTION (HCSS) FLOW INSIDE THE ZSI 375



- LEGEND**
- HCSS blocked
 - No HCSS flow
 - HCSS flowing
 - HCSS volume increasing
 - HCSS volume decreasing
 - No change in HCSS volume
 - No HCSS (Empty)
 - HCSS under extra pressure

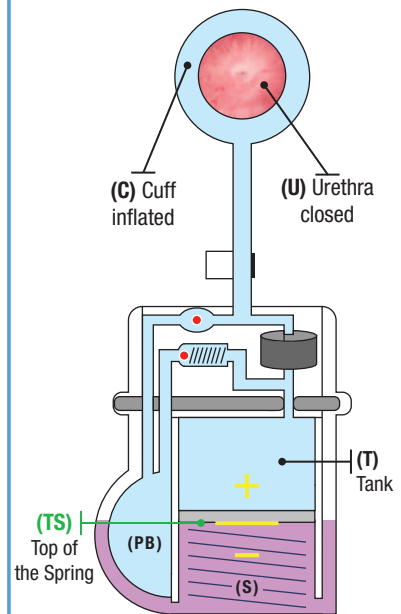
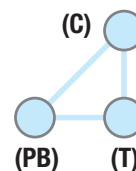
DEVICE ACTIVATED (without urethra)

The ZSI 375 is delivered Activated in a sterile bag of Saline Solution: The Top of the Spring (TS) is high because there is no urethra and consequently, nothing prevents the Spring from pushing the Saline Solution into the Cuff. Remember: There is a relation between the (TS) position and the volume of Saline Solution in the Cuff.



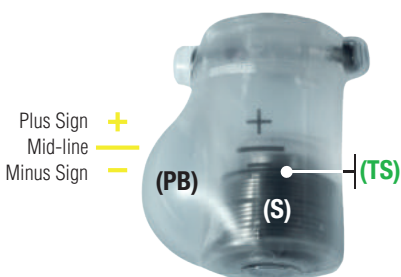
DEVICE ACTIVATED (Patient is continent)

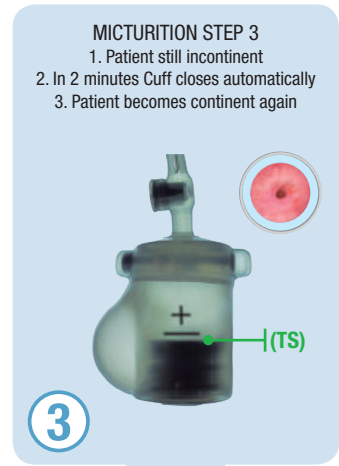
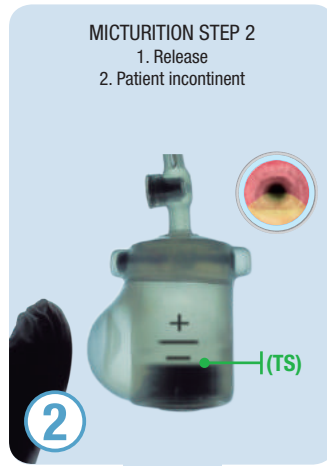
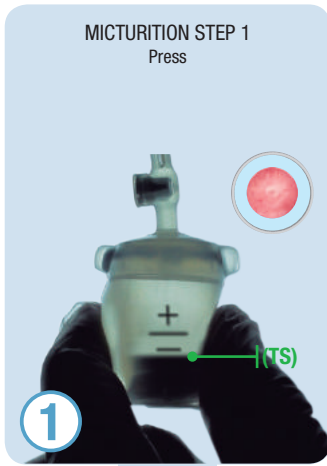
The Spring (S) is decompressed and the urethra occupies space which prevents the Spring from rising up fully; some Saline Solution remains in the Tank. Top of the Spring (TS) is raised at level with Mid-line. Saline Solution maintains optimal pressure on the Cuff (C) around the urethra (U).



DEVICE DEACTIVATED (with empty Cuff)

These three signs are found on the Pump Device.

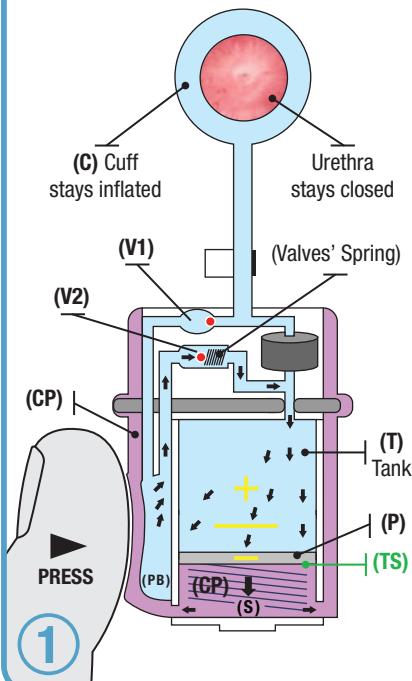
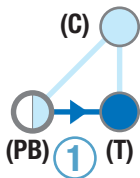




MICTURITION STEPS

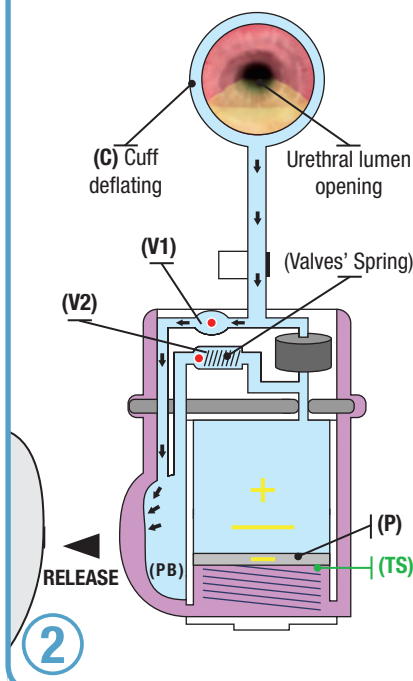
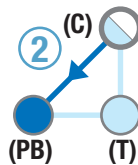
MICTURITION STEP 1

Patient presses Pump Button (PB) closing Valve (V1) and opening Valve (V2). Valve (V2) allows the flooding of Saline Solution (blue) into the Tank (T) compressing the Piston (P) and the Spring (S), in turn, flooding the Compensation Pouch (CP) with Saline Solution (purple).



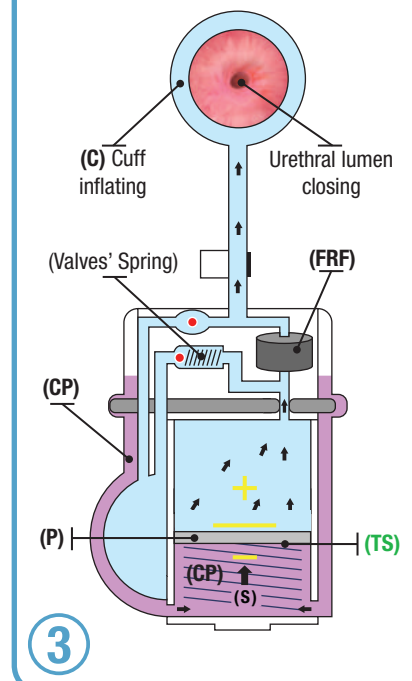
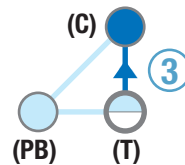
MICTURITION STEP 2

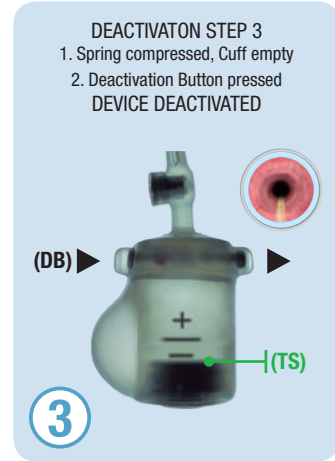
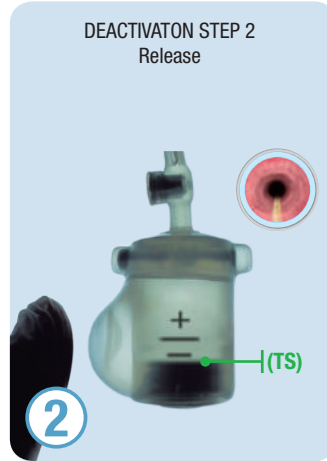
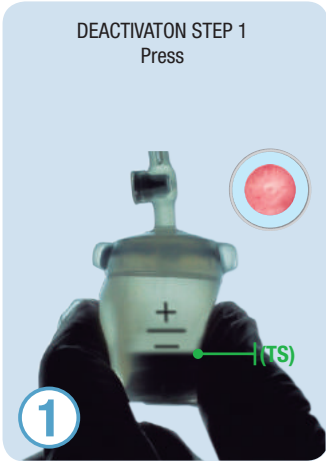
When the patient releases the Pump Button (PB) the negative pressure opens Valve (V1) and closes Valve (V2), aspirating the Saline Solution from the Cuff (C) into the Pump Button (PB), releasing the Cuff pressure so patient can void urine.



MICTURITION STEP 3

The Spring (S) begins pushing back the Piston (P). The Piston refloods the Saline Solution into the Cuff (C), compressing the urethra. The flow is regulated by the Flow Restriction Filter (FRF). The Saline Solution in the Compensation Pouch (CP) (purple) returns under the Piston (P). Patient becomes continent again after 2 minutes.

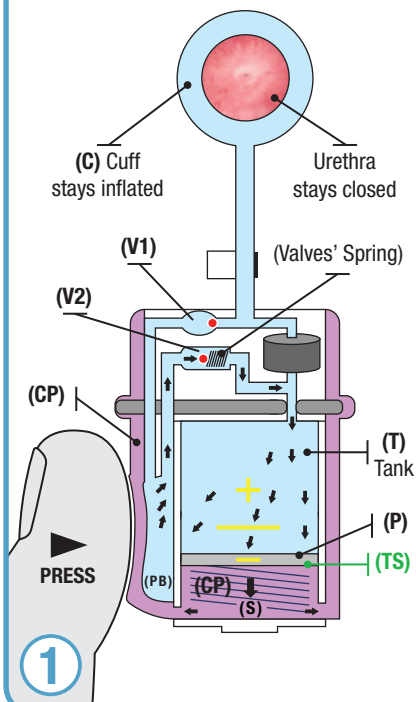
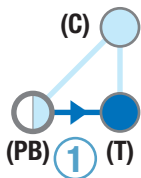




DEACTIVATION STEPS (AFTER IMPLANTATION)

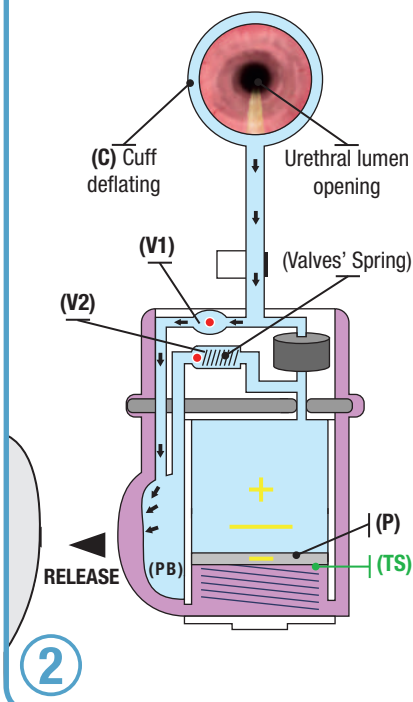
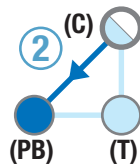
DEACTIVATION STEP 1

Press the Pump Button (PB) closing Valve (V1) and opening Valve (V2). Valve (V2) allows the flooding of Saline Solution (blue) into the Tank (T) compressing the Piston (P) and the Spring (S), in turn, flooding the Compensation Pouch (CP) with Saline Solution (purple).



DEACTIVATION STEP 2

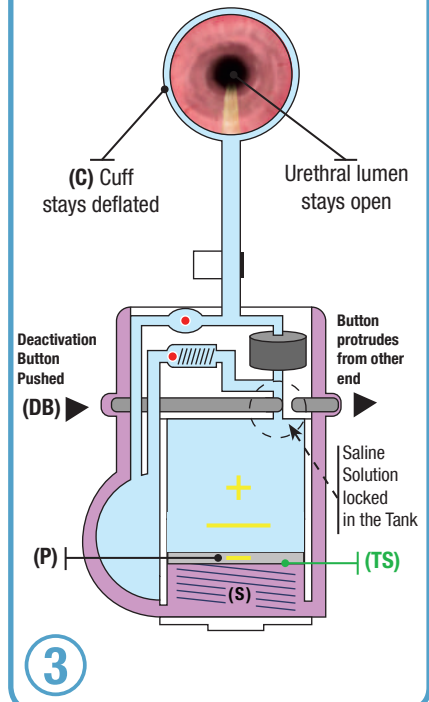
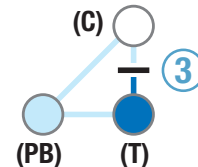
Release the Pump Button (PB) the negative pressure opens Valve (V1) and closes Valve (V2), aspirating the Saline Solution from the Cuff (C) into the Pump Button (PB), releasing the Cuff pressure so patient can void urine.

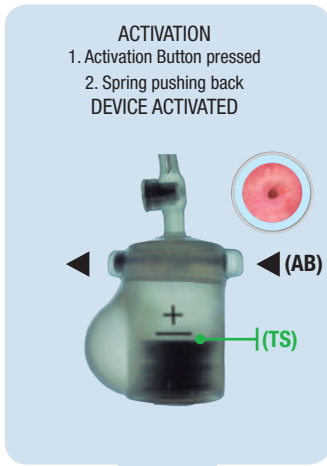


DEVICE DEACTIVATED STEP 3

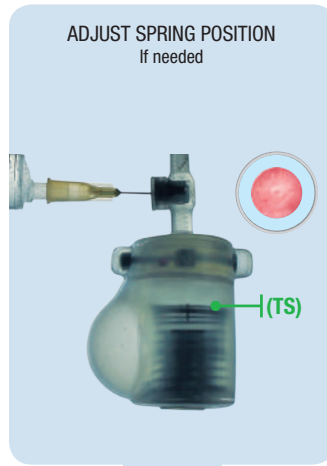
(patient incontinent)

Follow step 1 and step 2 to empty the Cuff. Then, the Deactivation Button (DB) is pressed to lock the Hydraulic Circuit with the axle (grey). This maintains Piston (P) and Spring (S) compressed and the Cuff (C) empty until the Activation Button is pushed from the other end. Deactivation can be confirmed with X-Ray by looking at the Top of the Spring (TS) position at Minus Sign.

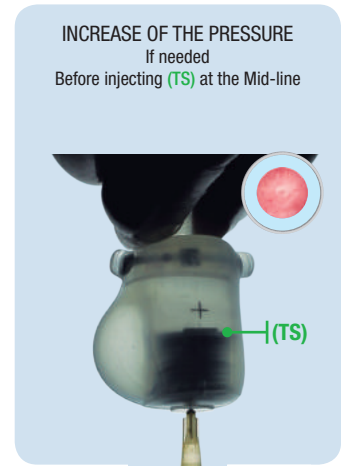




ACTIVATION (1 STEP)



ADJUSTMENTS (IF NEEDED)



DEVICE ACTIVATED

The Activation Button (**AB**) is pressed to unlock the Hydraulic Circuit with the axle (grey). The Spring (**S**) begins pushing back the Piston (**P**). The Piston reflows the Saline Solution into the Cuff (**C**), compressing the urethra. The flow is regulated by the Flow Restriction Filter (**FRF**). The Saline Solution in the Compensation Pouch (**CP**) (purple) returns under the Piston (**P**).

ADJUST SPRING POSITION

If the Top of the Spring (**TS**) needs to be adjusted because it is too high, use syringe to inject Sterile Saline Solution 0.9% through the Hydraulic Circuit Septum (**HCS**) to bring the Spring (**S**) to the Mid-line. Solution goes down the Cuff tube into Pump Button (**PB**) and into Tank (**T**) compressing the Piston (**P**) and Spring (**S**) to desired level.

INCREASE OF THE PRESSURE

Post-Surgery, the pressure in the device can be increased if necessary by injecting Sterile Saline Solution 0.9% directly into Compensation Pouch (**CP**). The device is then under the combined pressure of the Spring (**S**) and Compensation Pouch (**CP**). The greater the volume of Saline Solution the greater the pressure in Cuff. The Spring (**S**) gains extra force, but it will never visually move. Before injecting: the Top of the Spring (**TS**) has to be at the Mid-line.

2. DEACTIVATION BEFORE IMPLANTATION

 Page 88 - Video 1

A - DEACTIVATION GENERAL PROTOCOL

QUESTION:

Mechanically what is the difference between Deactivation before and after the implantation ?

ANSWER:

The number of times you press and release the Pump Button.

GENERAL DEACTIVATION PROTOCOL

STEP 1

Press and release the Pump Button until the cuff is flat and the Spring fully compressed.

STEP 2

Remove your thumb from the Pump Button.

STEP 3

Check that the Spring is fully compressed, and the Top of the Spring is level with the minus '-' sign.

STEP 4

Press the Deactivation Button firmly before the Spring rises.

STEP 5

Wait 20 seconds. Now check that the spring stays compressed at the minus '-' sign.

B - DEACTIVATION BEFORE CUFF IMPLANTATION (EXPLAINED WITH PICTURES)

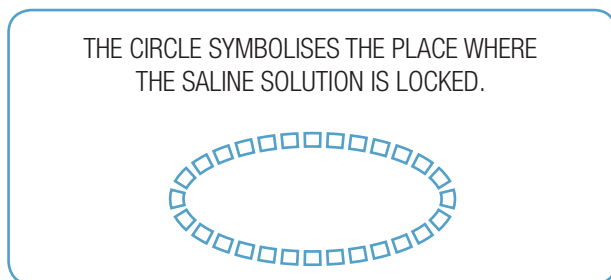
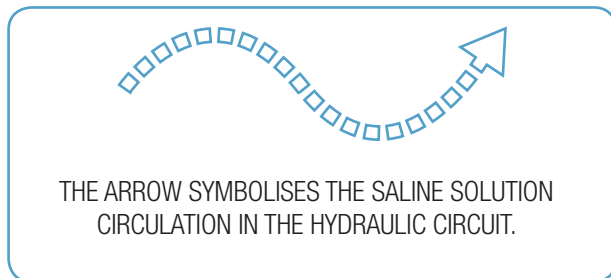
DEVICE IS PROVIDED ACTIVATED (PICTURE 0)

- CUFF FULL OF SALINE SOLUTION.
 - TANK PARTIALLY EMPTY.
 - SPRING RELEASED OVER PLUS '+' SIGN.
 - ACTIVATION BUTTON PRESSED. *
- (Activation Button is on opposite side to the Pump Button).

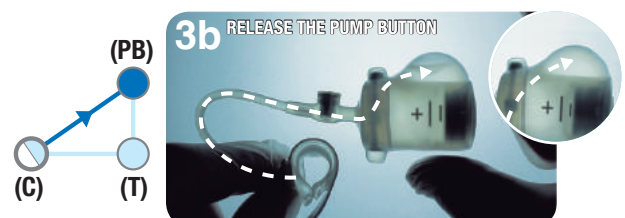
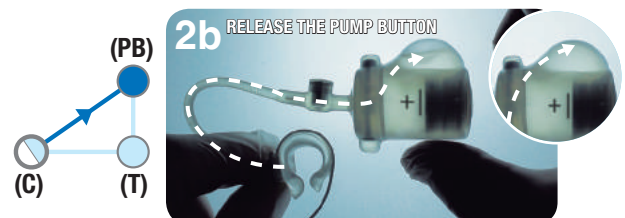
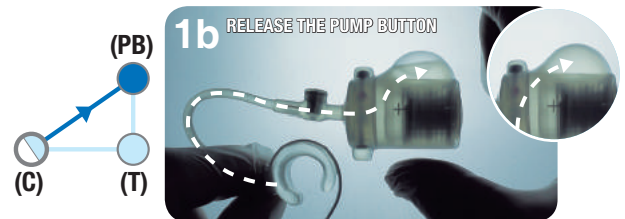
REMEMBER (PICTURES 1a, 1b, 2a, 2b, 3a, 3b):

a- PRESSING THE PUMP BUTTON FILLS THE TANK.

b- RELEASING THE PUMP BUTTON DEFLATES THE CUFF.



- CUFF EMPTY AND TANK FULL.
 - TOP OF THE SPRING (TS) COMPRESSED UNDER OR LEVEL WITH MINUS '-' SIGN.
 - PRESS THE DEACTIVATION BUTTON. *
- (Deactivation Button is on same side as the Pump Button)
- DEVICE IS PROPERLY DEACTIVATED (PICTURE 4)**



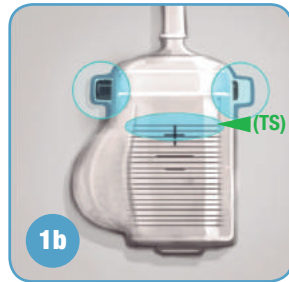
C - DEACTIVATION BEFORE CUFF IMPLANTATION (EXPLAINED WITH DRAWING)

PREPARATION OF THE CUFF FOR IMPLANTATION/DEACTIVATION: DEFLATION OF THE CUFF AND DEACTIVATION

When you place the Cuff around the urethra, it must be deflated.
 Pictures guide how to deflate the Cuff and Deactivate the device before implantation.



1a Cuff Inflated (device Activated).



1b Spring released (device Activated).

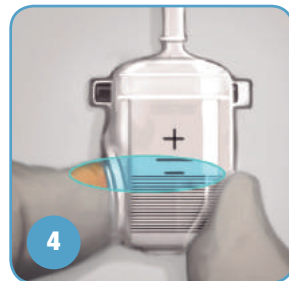
THE AIM IS TO DEFLATE THE CUFF AND DEACTIVATE THE ZSI 375 TO KEEP THE CUFF FLAT



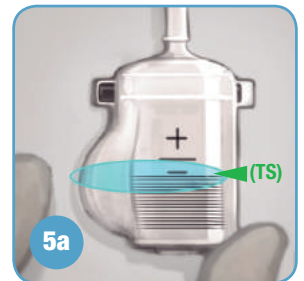
2 Press the Pump Button. The Saline Solution will go from the Pump Button to the Tank.



3 Release the Pump Button. The Saline Solution will go from the Cuff to the Pump Button.



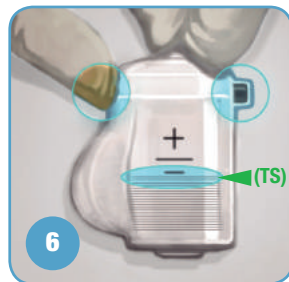
4 Repeat the process by pressing and releasing the Pump Button again.



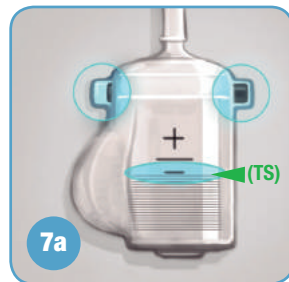
5a When the Spring is fully compressed, you will no longer be able to press the Pump Button.



5b Cuff should now be empty/flat.



6 While the Top of the Spring (TS) is level with the Minus '-' sign, remove finger from Pump Button and press the Deactivation Button **firmly**.



7a The Cuff is flat. The Top of the Spring (TS) is level with the Minus '-' sign. Wait **20 seconds** and check that the ZSI 375 stays Deactivated, with (TS) still level with the Minus '-' sign.



7b Cuff should stay empty/flat.

IT IS NORMAL THAT THE BULB OF THE PUMP BUTTON IS INFLATED WHEN THE DEVICE IS DEACTIVATED.

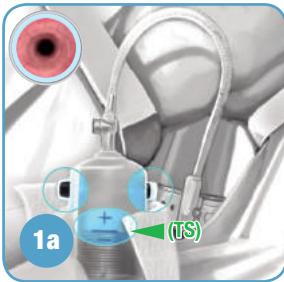


3. DEACTIVATIONS AFTER CUFF IMPLANTATION

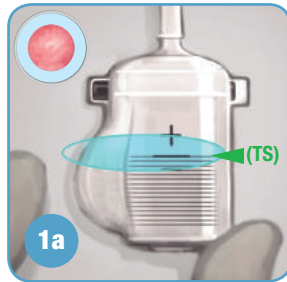
Page 88, 89 - Video 1 - Video 9

A - ISSUED PRESSURE CONTROL AND DEACTIVATION DURING PROCEDURE

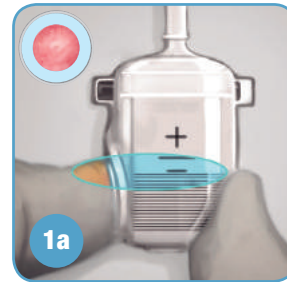
Pictures guide how to control issued pressure, deflate the Cuff and Deactivate device during implantation.



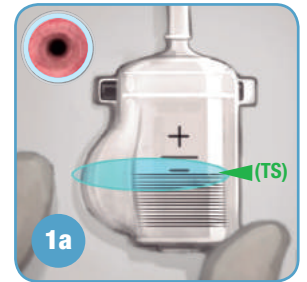
The Cuff is implanted around the urethra. Device Activated and ready to be tested.



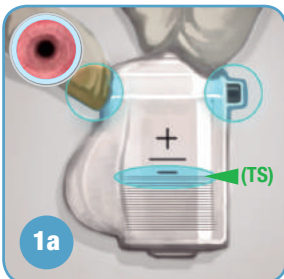
Top of the Spring (TS) is level with Mid-line. Device is receiving proper pressure. Cuff ready to be deflated and device to be Deactivated.



Press and release once or twice the Pump Button to empty the Cuff before Deactivation.

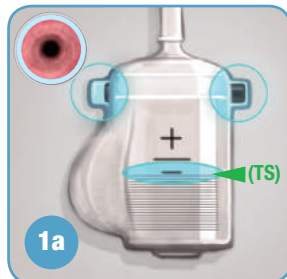


The Cuff is empty, the Tank is full, the device can be Deactivated for 8 weeks to ease urethral healing.



While the Top of the Spring (TS) is level with Minus '-' sign, press the Deactivation Button **firmly**.

DEVICE DEACTIVATED



The Top of the Spring (TS) is level or below Minus '-' sign. Wait **20 seconds** to be sure that the ZSI 375 has been properly Deactivated.

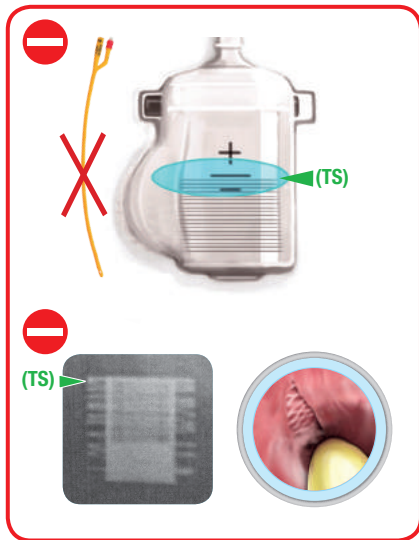
DEVICE PROPERLY DEACTIVATED

THE CUFF IS DEFLATED.
THE DEVICE IS PROPERLY DEACTIVATED.
YOU CAN NOW IMPLANT THE PUMP UNIT,
SUTURE THE WINGS, THE PERINEAL AND
INGUINAL INCISION.

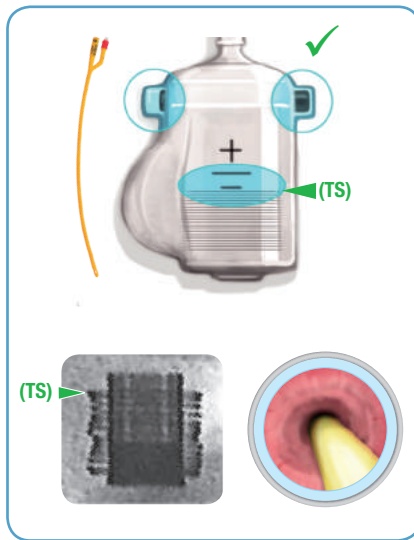
**DO NOT DEACTIVATE
WITH CUFF INFLATED
AND SPRING RELEASED
(it will lead to urethral erosion)**

B - DEACTIVATION AFTER PROCEDURE

— B1 - AFTER PROCEDURE - DEACTIVATING THE ZSI 375, FOR EXAMPLE TO INSERT A CATHETER

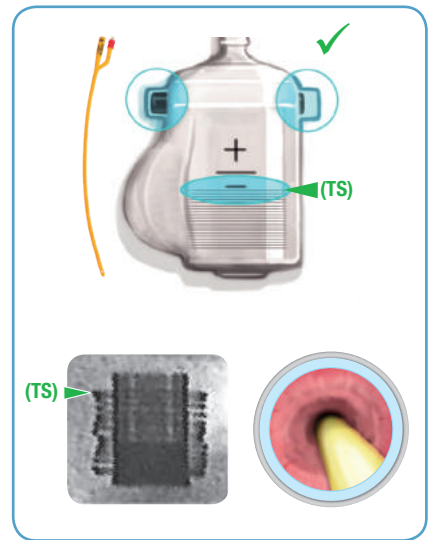


Never insert any urethral Catheter while the Artificial Urinary Sphincter is Activated. It will lead to urethral erosion.



STANDARD DEACTIVATION
See B2 page 78

Insert a urethral catheter only when the device is properly Deactivated. Confirm Deactivation with an X-Ray.

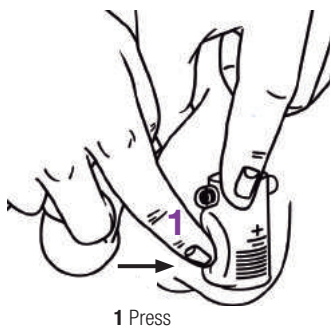
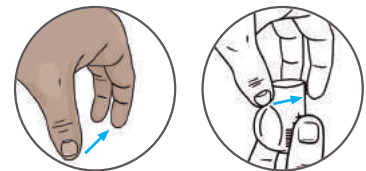


EMERGENCY DEACTIVATION
See B3 page 79

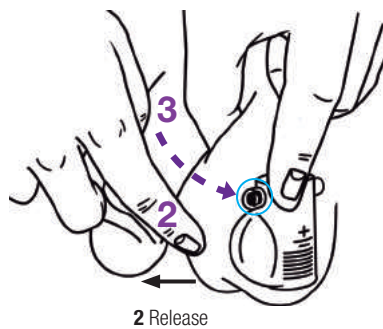
— B2 - DEACTIVATION USING THE DEACTIVATION BUTTON

Deactivation can be performed post surgery through patient scrotum (Deactivation post surgery is required for insertion of an urethral catheter). Press and Release the Pump Button twice to deflate the Cuff. Then press the Deactivation Button to lock Saline Solution into the Tank. Spring position can be checked with X-Ray. Top of the Spring (TS) must be compressed below the Top of the Cylinder to confirm a flat Cuff status.

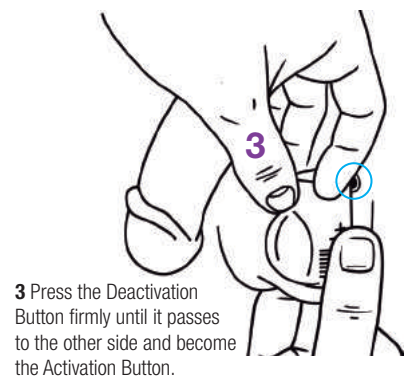
Best position for fingers for Deactivation (or Activation)
Fingers in a pliers position provides stability and effective pinch strength.



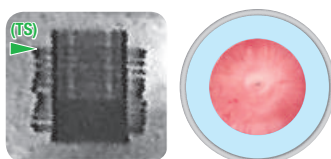
1 Press



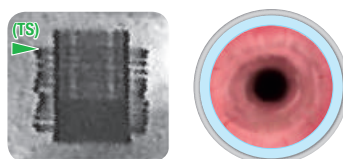
2 Release



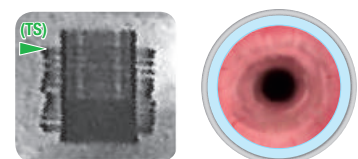
3 Press the Deactivation Button firmly until it passes to the other side and become the Activation Button.



Pump Button pressed



Pump Button released



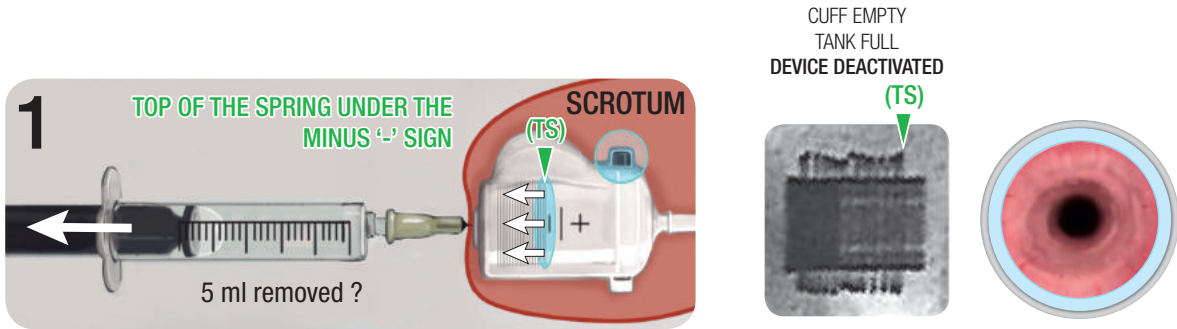
X-RAY SHOWING:
CUFF EMPTY
TANK FULL
DEVICE DEACTIVATED

— B3 - EMPTYING COMPENSATION POUCH (EMERGENCY)

1 In cases such as scrotal inflammation, standard Deactivation with the Deactivation Button might be difficult. ZSI recommends an emergency Deactivation protocol:

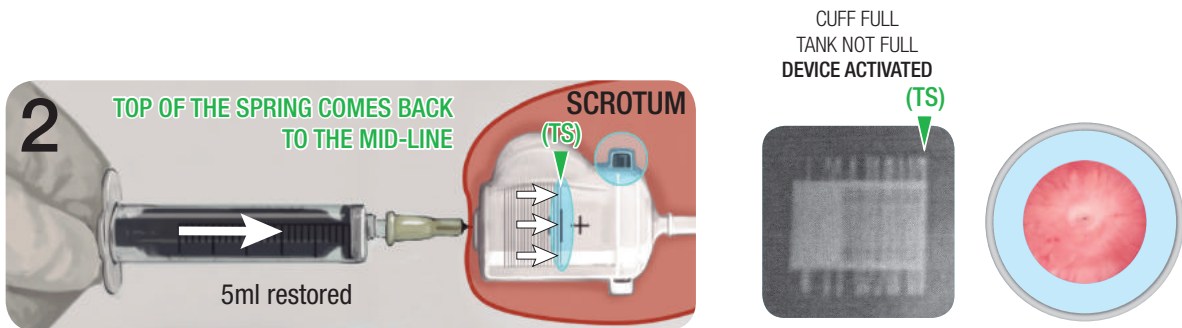
Pierce the Compensation Pouch Septum and remove around 5 ml of Saline Solution from the Compensation Pouch. The negative pressure in the Compensation Pouch will draw the Top of the Spring down and will deflate the Cuff. There is no need to press the Deactivation Button. X-Ray or Fluoroscopy will confirm proper Deactivation.

If not Deactivated, aspirate more Saline Solution.



2 To re-Activate the device, inject the same volume of Sterile Saline Solution 0.9‰ extracted previously for emergency Deactivation. The negative pressure will disappear and the Spring will return to its initial position.

When the needle passes through the skin of the scrotum, a few drops of blood may also be injected into the Compensation Pouch - this is normal and won't cause any damage to the ZSI 375 as the Compensation Pouch is not in contact with the Hydraulic Circuit.



A Huber needle should be used for all injections concerning the device.

Contact ZSI for Huber needle references if needed.



Huber point needle.
No risk for the silicone Septum.



Standard bevel point needle. Risk to damage the silicone Septum. It can create a core/tunnel in the silicone with leakage consequences.

4. ACTIVATION

Page 88 - Video 2

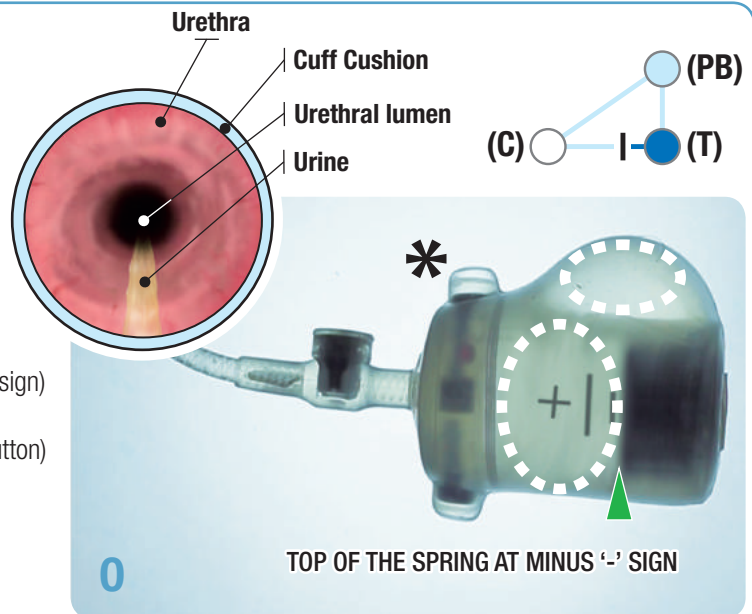
Remember, there is a relation between Spring position and Cuff filling:

- when Cuff is empty, Tank is full with Spring down at Minus '-' sign.
- when Cuff is full, Tank is partially empty with Spring at Mid-line or over Mid-line.

STATE 0

DEVICE DEACTIVATED
URETHRA OPEN
PATIENT INCONTINENT

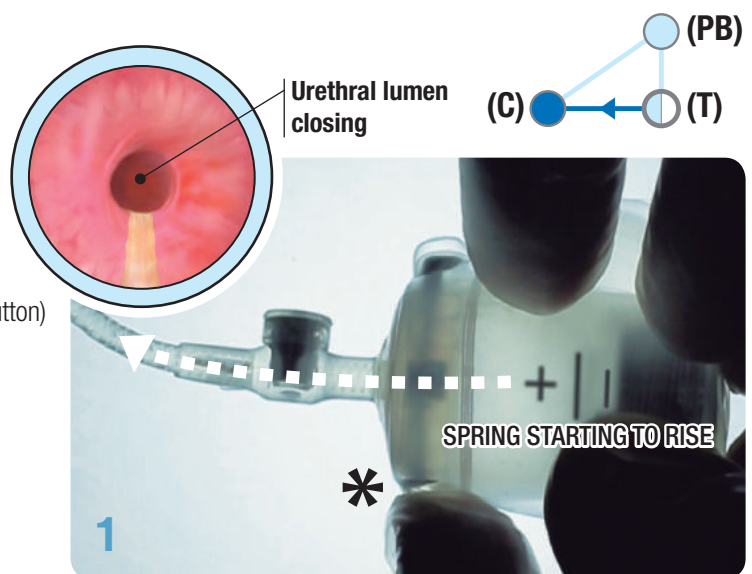
- Cuff deflated, urethra open.
- Tank full of Saline Solution.
- Top of the Spring (TS) compressed (under Minus '-' sign)
- Deactivation Button pressed. *
- (Deactivation Button is on same side as the Pump Button)
- Circulation of Saline Solution locked.
- Patient is incontinent.



STATE 1

ACTIVATION OF THE DEVICE
UNLOCKING THE HYDRAULIC
CIRCUIT

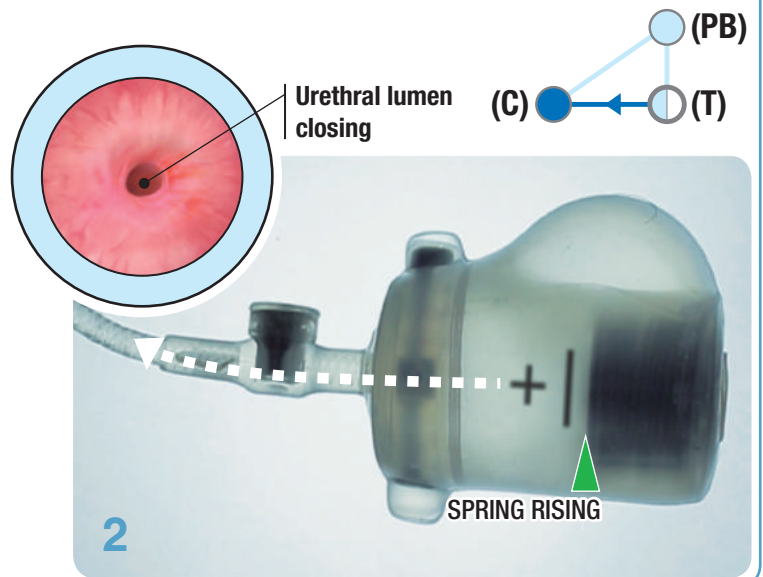
- ACTIVATION BUTTON PRESSED. *
- (Activation Button is on opposite side to the Pump Button)
- Circulation of Saline Solution unlocked.
- Patient is still incontinent.



STATE 2

DEVICE ACTIVATED SPRING RISING

- Spring rising, Saline Solution is pushed from the Tank to the Cuff.
- Cuff inflates slowly.
- Patient is still incontinent.

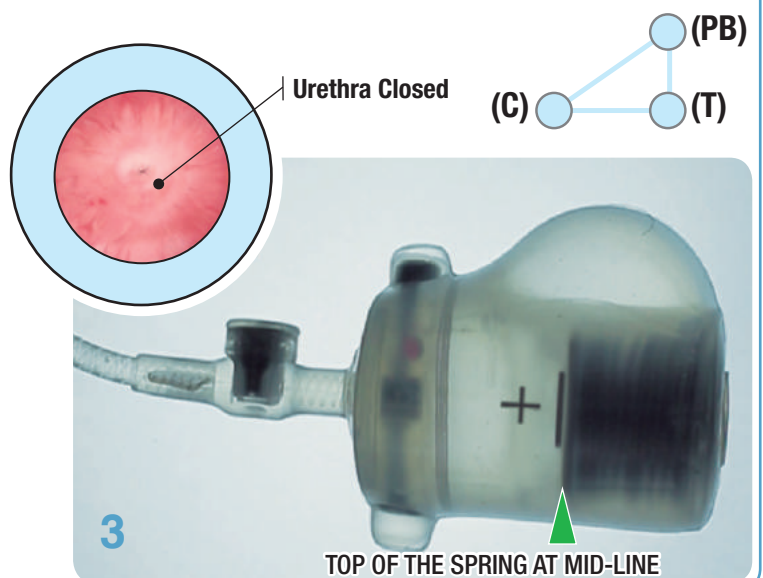


STATE 3

CUFF INFLATED SPRING STABILIZED PATIENT CONTINENT

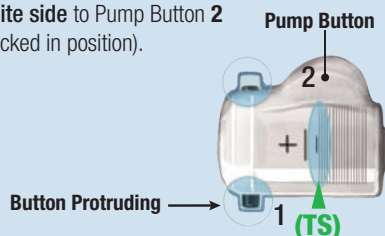
AFTER 2 OR 3 MINUTES

- Cuff inflated closing urethra.
- Tank partially empty.
- Spring maintains Saline Solution under pressure.
- No more circulation of Saline Solution.
- Patient is continent.



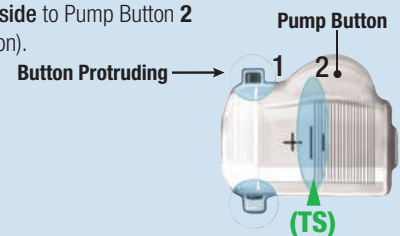
HOW TO RECOGNISE DEVICE **DEACTIVATED**

Button 1 Protruding **opposite side** to Pump Button 2 (Spring compressed and locked in position).



HOW TO RECOGNISE DEVICE **ACTIVATED**

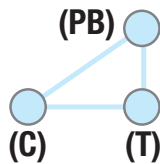
Button Protruding **1 same side** to Pump Button 2 (Spring not locked in position).



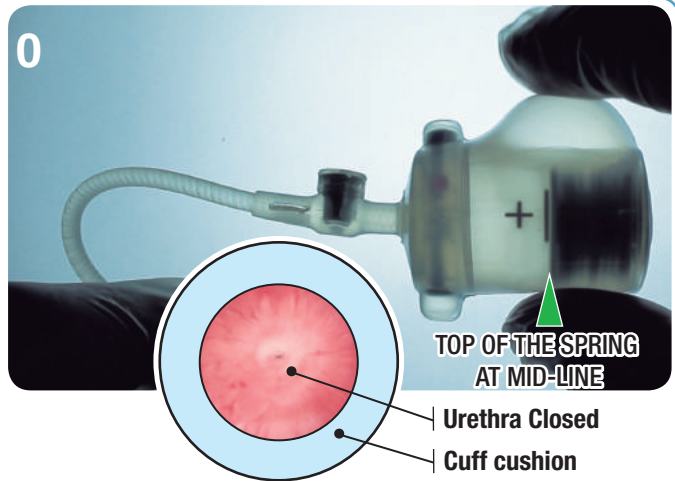
TIME BEFORE CUFF CLOSURE:
150 SECONDS ± 30 SECONDS

STATE 0

DEVICE ACTIVATED
PATIENT CONTINENT
URETHRA CLOSED

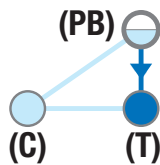


- Cuff inflated closing the urethra.
- Tank partially empty.
- Spring maintains Saline Solution under pressure.
- No Saline Solution circulation.
- Patient is continent.

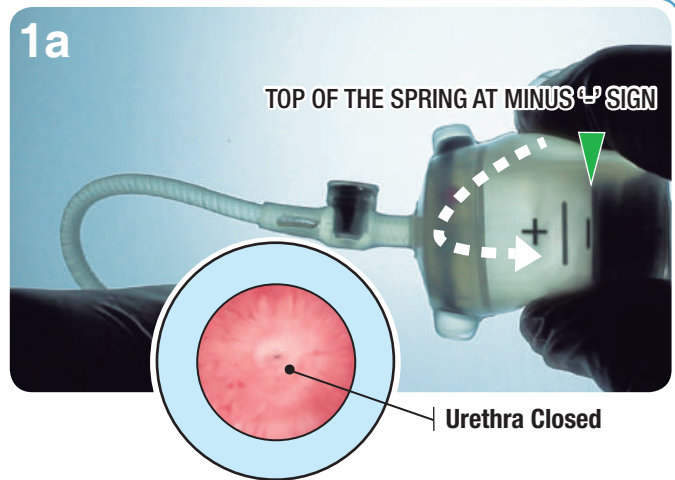


STATE 1a

OPENING OF THE CUFF FOR
MICTURITION 1

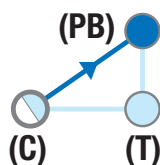


- Cuff inflated closing the urethra.
- Index finger presses the Pump Button: Saline Solution is pushed from the Pump Button to the Tank. A Valve blocks the passage of the Saline Solution to the Cuff.
- Patient is still continent.

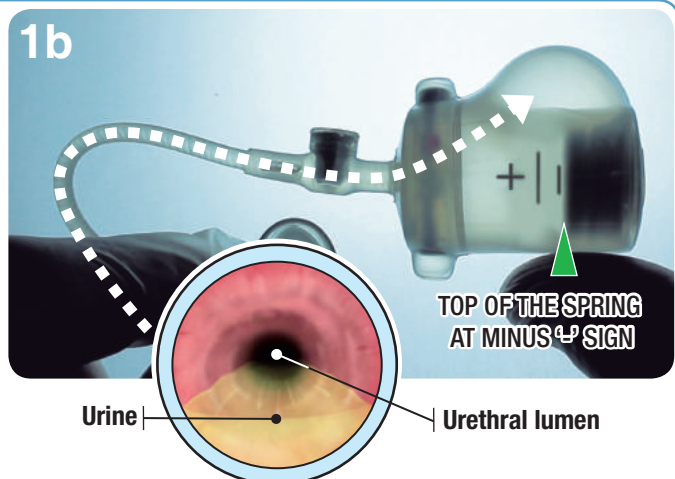


STATE 1b

OPENING OF THE CUFF FOR
MICTURITION 2

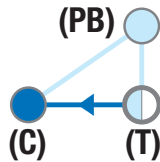


- Pump Button released.
- Saline Solution is aspirated from the Cuff to the Pump Button. A Valve blocks the passage to the Tank.
- Wait for the Pump Button to be 100% filled before pressing the Pump Button a second time or the Cuff will not be properly deflated.
- Cuff is empty and urethra open, patient can void urine. Patient gets 2 to 3 minutes to void.

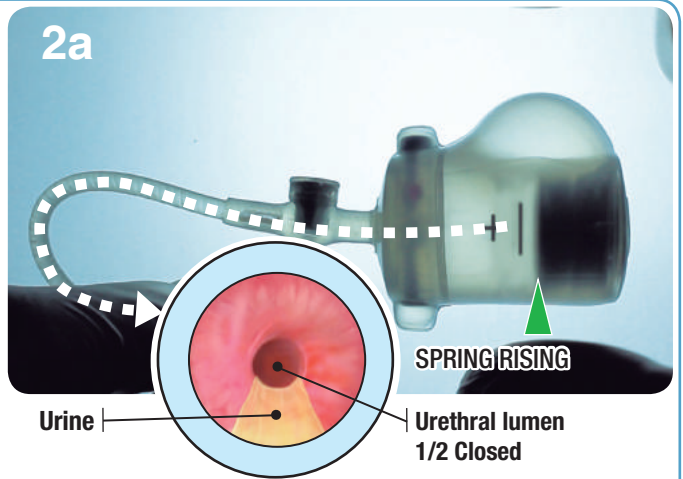


STATE 2a

DURING MICTURITION CLOSING OF URETHRA 1

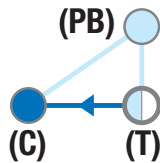


- Spring automatically rises slowly during micturition, pushing Saline Solution from the Tank to the Cuff through a flow restriction filter.
- Cuff inflates slowly, drop by drop.
- Cuff is still partially open.

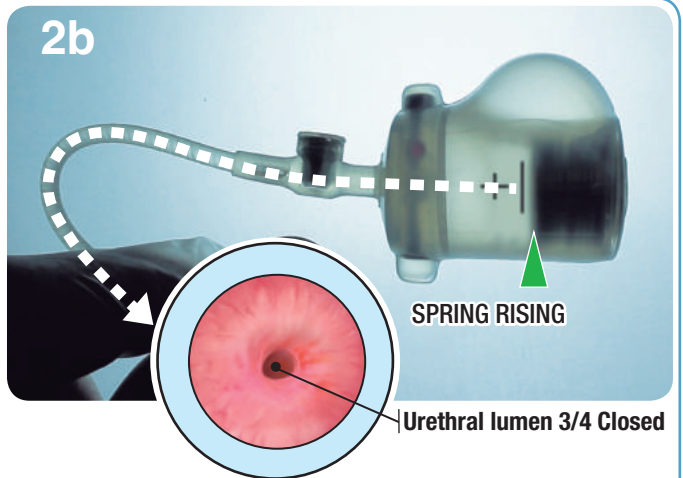


STATE 2b

DURING MICTURITION CLOSING OF URETHRA 2

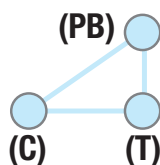


- Spring keeps rising slowly pushing Saline Solution from the Tank to the Cuff.
- Cuff inflates slowly, drop by drop, almost closing the urethra.
- Cuff is still partially open.

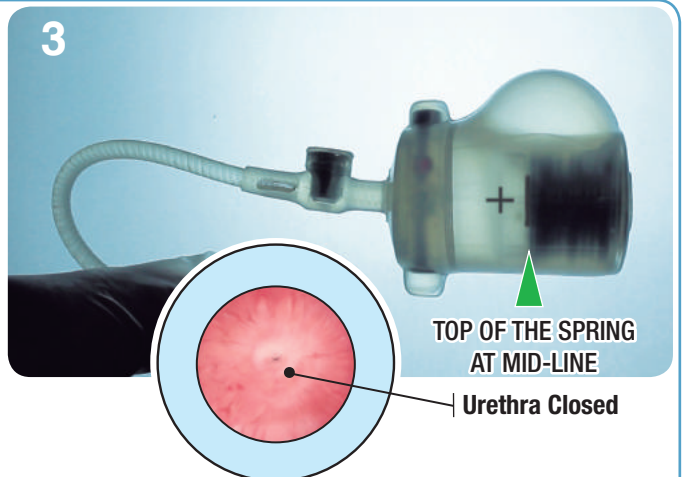


STATE 3

PATIENT CONTINENT AGAIN URETHRA CLOSED



- Cuff inflated closing urethra.
- Tank is partially empty.
- Spring maintains Saline Solution under pressure, it must be level with Mid-line or just under Mid-line.
- No more Saline Solution is circulating.
- Automatic Cuff closure lasts 2 to 3 minutes, enough time for the patient to empty his bladder.
- Patient is continent again.



XI

AVAILABLE ON ZSI WEBSITE: PUBLICATIONS AND TRAINING VIDEOS

AVAILABLE ON ZSI WEBSITE: PUBLICATIONS AND TRAINING VIDEOS.....	85
1. PUBLICATIONS.....	86
2. COMPLEMENTARY VIDEOS	88
0 - FUNCTIONING (HOW TO URINATE).....	88
1 - DEACTIVATIONS	88
2 - ACTIVATION	88
3 - TOP OF THE SPRING ADJUSTMENT AFTER CUFF IMPLANTATION	88
4 - TOP OF THE SPRING ADJUSTMENT POST SURGERY.....	88
5 - SPRING STRENGTH POST SURGERY.....	89
6 - CUFF SIZE	89
7 - EXCESS OF SALINE SOLUTION IN THE HYDRAULIC CIRCUIT.....	89
8 - EXTRA SALINE SOLUTION IN THE COMPENSATION POUCH.....	89
9 - EMERGENCY DEACTIVATION	89
10 - HYDRAULIC MECHANISM (HOW TO URINATE)	89



1. PUBLICATIONS

ALL PUBLICATIONS ARE AVAILABLE AT:

www.zsimplants.ch

<https://www.zsimplants.ch/en/products-en/incontinence/zsi-375-en/publications>

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DIRECT ACCESS



First publication presented in 2012.
Including learning curve period.
(FRANCE)

BJUI ZSI 375 Artificial Urinary Sphincter for male urinary incontinence: a preliminary study

Frederic Staerman*, Christophe G-Llorens*,†, Priscilla Leon* and Yves Leclerc*

*Department of Urology, Polyclinique Les Bleuets, Reims, and †Department of Urology, Clinique d'Epemay, Epemay, France

UJ

ISSN 0391-5603

Urologia 2017; 00 (00): 000=000
DOI: 10.5301/uj.5000271

ORIGINAL RESEARCH ARTICLE



First publication about Artificial Urinary Sphincters, Cuff pressure after insertion and Activation.
(FRANCE)

Comparative study of urodynamic tests after AMS 800 and ZSI 375 insertion

Thomas Ripert, Jean Pierrelcin
Polyclinique de Courfancy, Reims - France

UJ

ISSN 0391-5603

Urologia 2017; 00 (00): 000=000
DOI: 10.5301/uj.5000246

REVIEW



First multicentre publication including learning curve period.
(INTERNATIONAL)

Multicentre experience with ZSI 375 Artificial Urinary Sphincter for the treatment of stress urinary incontinence in men

Ireneusz Ostrowski¹, Mariusz Blewniewski², Frank Neugart³, Burkhard von Heyden⁴, Oscar Selvaggio⁵, Francesco Iori⁶, Steve Foley⁷, Manuel Fernández Arjona⁸, Alejandro Carvajal Obando⁹, Tobias Pottek¹⁰

- ¹ Department of Urology, Specialist Hospital, Pulawy - Poland
- ² Department of Urology, District Specialist Hospital, Lodz - Poland
- ³ Urology Practice, Baden-Baden - Germany
- ⁴ Urology Practice, Galdorf - Germany
- ⁵ Department of Urology, Ospedale Riuniti, Foggia - Italy
- ⁶ Department of Urology "U. Bracci", University Hospital Polyclinic Umberto I, Rome - Italy
- ⁷ Department of Urology, The Royal Berkshire NHS Foundation Trust, Reading - UK
- ⁸ Department of Urology, Henares University Hospital, Community of Madrid - Spain
- ⁹ San Vicente University Hospital Foundation, Medellín, Antioquia - Colombia
- ¹⁰ Department of Reconstructive Urology, Vivantes Urban Hospital, Berlin - Germany

UJ

ISSN 0391-5603

Urologia 2017; 00 (00): 000=000
DOI: 10.5301/uj.5000243

REVIEW



First implantations follow-up report including learning curve period.
(FRANCE - GERMANY)

Urinary Artificial Sphincter ZSI 375 for treatment of stress urinary incontinence in men: 5 and 7 years follow-up report

Christophe Llorens¹, Tobias Pottek²

- ¹ Urology Practice, Saint Brice Courcelles - France
- ² Reconstructive Urology, Vivantes Urban Hospital, Berlin - Germany

First Latin American publication including learning curve period.
(COLOMBIA)

EMJ EUROPEAN MEDICAL JOURNAL
EUROPEAN MEDICAL JOURNAL

EFFICACY OF THE ARTIFICIAL URINARY SPHINCTER ZSI 375 FOR TREATMENT OF POST-RADICAL PROSTATECTOMY INCONTINENCE IN PATIENTS WITH INTRINSIC SPHINCTER DEFICIENCY: A PRELIMINARY STUDY

*Alejandro Carvajal Obando¹, Federico Gaviria Gil², Álvaro Gutiérrez Martínez³, Luis Fernando Echeverry Molina⁴, Juan Carlos Castaño Botero⁵

- ¹ Hospital Universitario San Vicente Fundación, Medellín, Antioquia, Colombia
- ² Hospital Pablo Tobón Uribe Calle, Medellín, Antioquia, Colombia
- ³ Urobosque Centro Urológico, Bogotá, Cundinamarca, Colombia
- ⁴ Fundación SaluVite, Cali, Colombia
- ⁵ Clínica Universitaria CES, Medellín, Colombia

*Correspondence to sexualidadyfertilidad@gmail.com



0% infections publication in
50 ZSI 375 implantations including
the learning curve period.
(POLAND)

Second Latin American publication from
one urological center. including learning
curve period.
(CUBA)

First AUA (American Urology Association)
ZSI 375 data presentation. Including
learning curve period.
(SPAIN)

ZSI 375 multicentre experience since 2009.
84.40% of patients were considered as
presenting a social continence (0 to 1 pad
per day) and 8.25% of men improved.
Including the learning curve period.
(EUROPE)



Four-year follow-up on a Zephyr Surgical Implants 375 artificial urinary sphincter for male urinary incontinence from one urological centre in Poland

Ireneusz Ostrowski¹, Janusz Ciechan¹, Emil Sledz¹, Wojciech Dys¹, Tomasz Golabek², Piotr L. Chłosta²

¹Department of Urology and Urological Oncology, Regional Specialist Hospital, Puławy, Poland
²Department of Urology, Jagiellonian University, Medical College, Cracow, Poland

Citation: Ostrowski I, Ciechan J, Sledz E, Dys W, Golabek T, Chłosta PL. Four-year follow-up on a ZSI 375 artificial urinary sphincter for male urinary incontinence from one urological centre in Poland. Cent European J Urol. 2018; 71: 320-325.



Empleo del esfínter urinario artificial ZSI 375 en la incontinencia urinaria masculina

Use of the ZSI 375 artificial urinary sphincter in men with urinary incontinence

Isis Emérita Pedro Silva¹ Raúl Escudero¹ Lenin Moreno¹

¹Hospital Clínico Quirúrgico "Hermandades Ameyjeiras" La Habana, Cuba.



Multicentre Experience with the Refillable Artificial Urinary Sphincter ZSI 375 PF

Padilla-Fernández B1, González-López R², Resel-Folkersma L³, Garde-García H⁴, Hernández-Hernández D¹, Madurga-Patuel B⁴, Lorenzo-Gómez M F⁵, Moreno-Sierra J⁵, González-Enguita C², Castro-Díaz D M¹

1. Dept of Urology, University Hospital of the Canary Islands (Spain).
2. Dept of Urology, Fundación Jiménez Díaz University Hospital (Spain).
3. Dept of Urology, Hospital Clínico San Carlos (Spain).
4. Dept of Urology, University Hospital Puerta del Mar - Cádiz (Spain).
5. Dept of Urology, University Hospital of Salamanca (Spain).



Preliminary outcomes of the European multicenter experience with the ZSI 375 artificial urinary sphincter for treatment of stress urinary incontinence in men.

Ireneusz Ostrowski¹, Tomasz Golabek², Janusz Ciechan¹, Emil Śledź¹, Mikołaj Przydacz², Wojciech Dys¹, Mariusz Blewniewski³, Burkhard von Heyden⁴, Tobias Pottke⁵, Frank Neugart⁶, Giuseppe Carrieri⁷, Oscar Selvaggio⁷, Francesco Iori⁸, Manuel Fernandez Arjona⁹, Steeve Foley¹⁰, Christophe Llorens¹¹, Waldemar Rózański¹², Piotr L. Chłosta¹³

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⁵Department of Reconstructive Urology, Vivantes Urban Hospital, Berlin, Germany
⁶Urology Practice, Baden-Baden, Germany
⁷Department of Urology, Ospedali Riuniti, Foggia, Italy
⁸Department of Urology, University Hospital Policlinic Umberto I, Rome, Italy
⁹Department of Urology, Hospital de Henares, Madrid, Spain
¹⁰Department of Urology, Reading, United Kingdom
¹¹Department of Urology, Reims, France
¹²Department of General, Oncological and Functional Urology, II Clinic of Urology, Łódź, Poland
¹³Department of Urology, Jagiellonian University, Medical College, Cracow, Poland

Publications up to November 2019 are listed above.
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www.zsimplants.ch

ADDITIONS

2. COMPLEMENTARY VIDEOS

10 ZSI 375 KEY FEATURE VIDEOS AND COMPLEMENTARY VIDEOS ARE AVAILABLE AT:

www.zsimplants.ch (fast access to videos) 

<https://www.zsimplants.ch/en/products-en/incontinence/zsi-375-en/training-videos>

- ZSI 375 SURGICAL PROCEDURE
- ZSI 375 FUNCTIONING

Available on WhatsApp ask your ZSI representative.

 www.zsimplants.ch
(fast access to videos)

DIRECT ACCESS 



ESSENTIAL KNOWLEDGE VIDEO
0 - FUNCTIONING (HOW TO URINATE)
1:06 minutes video

DIRECT ACCESS 



ESSENTIAL KNOWLEDGE VIDEO
1 - DEACTIVATIONS
1:17 minutes video

DIRECT ACCESS 



ESSENTIAL KNOWLEDGE VIDEO
2 - ACTIVATION
41 seconds video

DIRECT ACCESS 



ESSENTIAL KNOWLEDGE VIDEO
3 - TOP OF THE SPRING ADJUSTMENT
AFTER CUFF IMPLANTATION
50 seconds video

DIRECT ACCESS 



ESSENTIAL KNOWLEDGE VIDEO
4 - TOP OF THE SPRING ADJUSTMENT
POST SURGERY
1:04 minutes video

DIRECT ACCESS 

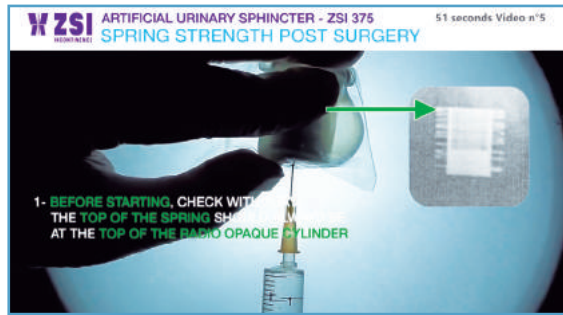


ESSENTIAL KNOWLEDGE VIDEO

5 - SPRING STRENGTH POST SURGERY

51 seconds video

DIRECT ACCESS



ADVANCED COURSE VIDEO

6 - CUFF SIZE

1:04 minutes video

DIRECT ACCESS

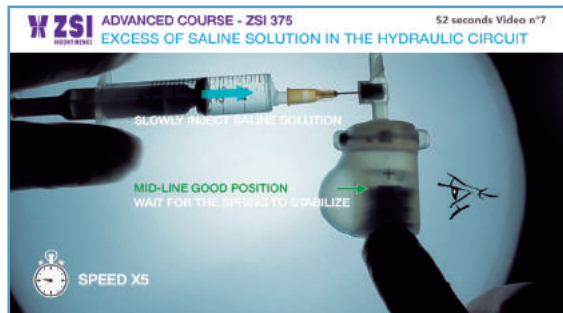


ADVANCED COURSE VIDEO

7 - EXCESS OF SALINE SOLUTION IN THE HYDRAULIC CIRCUIT

52 seconds video

DIRECT ACCESS

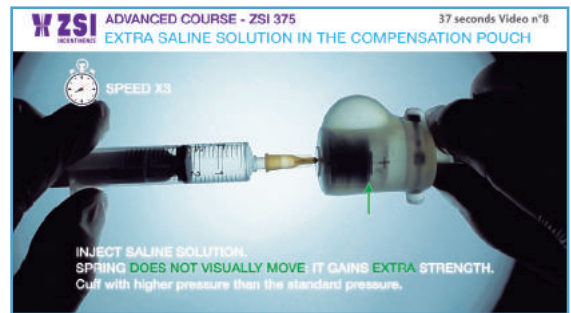


ADVANCED COURSE VIDEO

8 - EXTRA SALINE SOLUTION IN THE COMPENSATION POUCH

37 seconds video

DIRECT ACCESS



ADVANCED COURSE VIDEO

9 - EMERGENCY DEACTIVATION

1:03 minutes video

DIRECT ACCESS

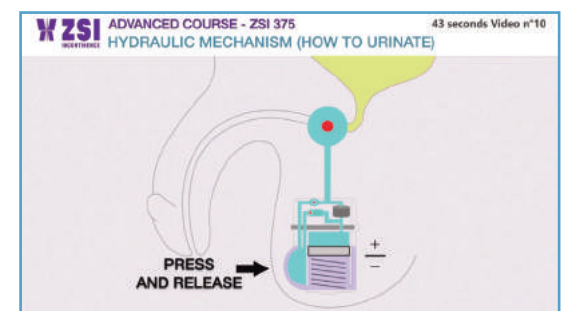


ADVANCED COURSE VIDEO

10 - HYDRAULIC MECHANISM (HOW TO URINATE)

43 seconds video

DIRECT ACCESS



Special dedication

To our parents who gave us the values which made ZSI possible:

- *If you do something, do it well, otherwise do not do it.*
- *When you do something well, check if you can do it better. Review improvement later and improve again. Do not hesitate to always improve what you have done.*

Disclaimer statement

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Artificial Urinary Sphincter ZSI 375

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This manual is the result of 12 years of experience and continual improvement of the Artificial Urinary Sphincter ZSI 375. It is the first manual of its kind: written both for Urologists specialising in male urinary incontinence and also for patients, to better understand the functions of the ZSI 375. It offers detailed, technical and illustrated information for readers. This may help to further improve the level of success of the implantation procedures and patient follow up.

ZSI works continuously to ease the daily life of patients suffering from moderate to severe urinary incontinence and to bring the best support to surgeons with the ideal Artificial Urinary Sphincter.

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