‘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
Zephyr Surgical Implants

- ***ZSI** is the **only European manufacturer** of artificial urinary sphincters and of malleable and inflatable penile implants, as solutions for male urological problems (incontinence), sexual complications (Erectile Dysfunction), and gender identity procedures (prostheses for trans men and women).*

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

PRODUCTS

The hydraulic / inflatable penile implant in three components (PI) ZSI 475 is a solution for problems related to erectile dysfunction and impotence.

A malleable / semirigid penile implant for men. ZSI 100 is a solution for problems related to erectile dysfunction and impotence.

ZSI offers solutions adapted for plastic surgery to satisfy the specific demands of transsexual / transgender men and women.

A hydraulic / inflatable penile implant of three components for trans men ZSI 475 FTM

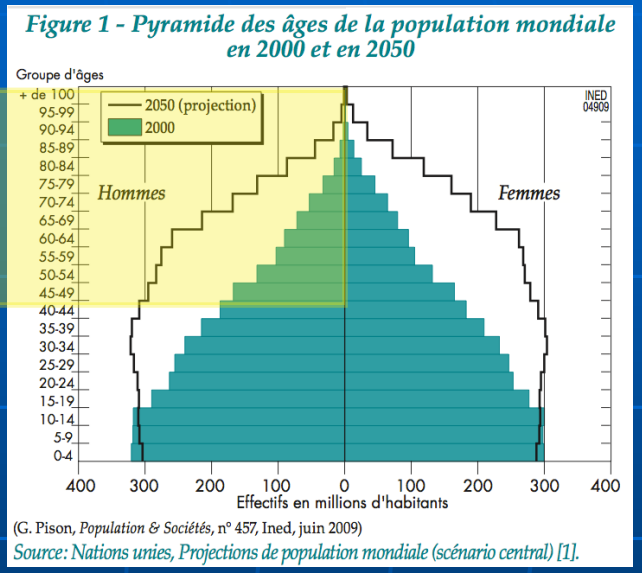
A malleable / semirigid penile implant for trans men ZSI 100 FTM

A malleable / semirigid implant for metoidioplasty for trans men ZSI 100 D4

MALE INCONTINENCE

Prostate Cancer
Population who can be concerned

POPULATION WHO CAN BE CONCERNED BY THE PROSTATE CANCER:
٤٥years old to ١٠٠ years old



The masculine population world wide is getting older every year:

More prostate cancer and radical prostatectomy every year :

Consequences

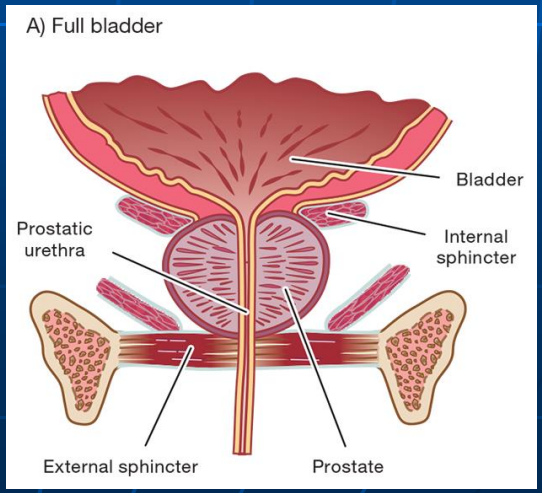
- More severe incontinence
- More impotence

Some French statistics

65 000 000 INHABITANTS
60 000 PROSTATE CANCER / YEAR
16 400 PROSTATECTOMY / YEAR
2 000 MEN WITH SEVERE INCONTINENCE / YEAR

REASONS FOR SEVERE INCONTINENCE

- RADICAL PROSTATECTOMY
- TURP
- EXTERNAL BEAM RADIATION
- NERVE PROBLEMS (DIABETES)



MALE INCONTINENCE

- Go for a bit of walk
- Spend time with family and friends
- Learn new things
- JUST GO OUT

MALE INCONTINENCE

How to deal with male incontinence???

- PADS:

Smelly, Diaper Rush, bulky, uncomfortable, …

MALE INCONTINENCE

How to deal with male incontinence???

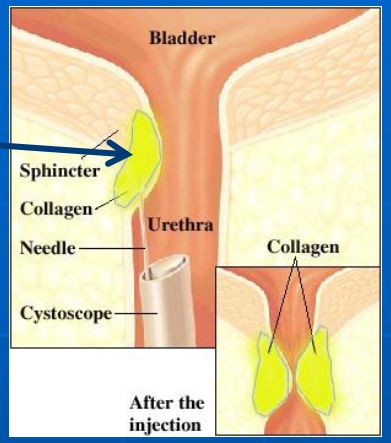
- PENILE SHEATS/ condom with catheter

- PENILE CLAMP

Male incontinence treatment options

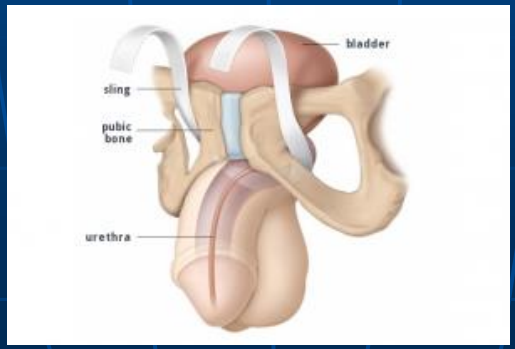
- BULKING AGENT INJECTION

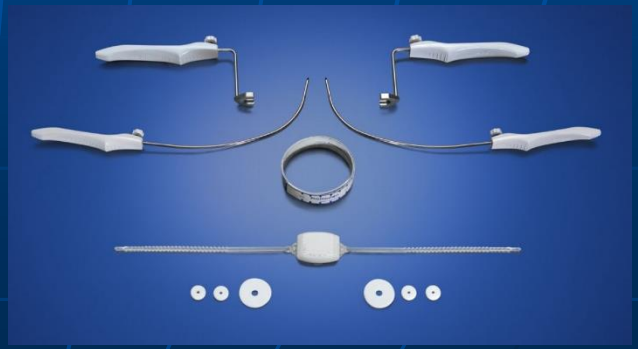
(Light +/- moderate incontinence)



- MALE SLING (Light +/- moderate incontinence)

- Urethral injury during trocar passage,
- Infection,
- Moderate perineal pain,
- Bleeding with hematoma,
- Erosion,
- Urinary retention





ARTIFICIAL URINARY SPHINCTER

It has several drawbacks including:

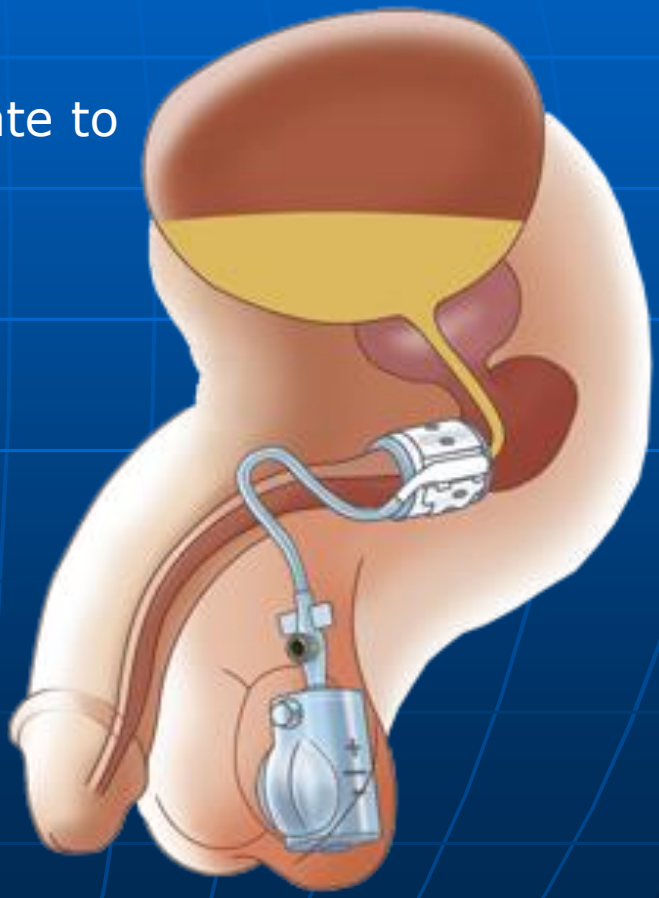
- Complexity of the procedure
- Significant cost
- No option to adjust the issued pressure of the device
- Inability to re-adjust the cuff in case of urethral atrophy
- Infection,
- Mechanical failure,

ARTIFICIAL URINARY SPHINCTER

In effort to improve the disadvantage of the Artificial Urinary Sphincter, ZSI 375 has recently been developed by urologists.

A technological breakthrough for moderate to severe male incontinence

Improving the lives of patients with urinary incontinence who must use protectors or towels, Penilex, penile cases, urinary catheters, and/or urinary collectors or bags.



ZSI 375

ZSI
Zephyr Surgical Implants

ARTIFICIAL URINARY SPHINCTER

- ONE-PIECE DEVICE
- EASY TO IMPLANT
- NO PREPARATION (Pre-filled/ Pre-connected, Ready for implant)
- ADJUSTABLE CUFF
- CIRCULAR CUFF
- PRESSURE CONTROLED
- Easy control of the device with X-Ray
- EASY TO USE
- COST EFFECTIVE
- LONG TERM GUARANTEE

ZSI 375 Activation Button
Opposite side to the Pump Button

Kink Resistant Tubing

Wings

Hydraulic Circuit Septum

Receiving slot

ZSI 375 Deactivation Button
Same side as the Pump Button

Temporary Extension Tab for easy Cuff implantation; will be removed after Cuff implantation around the urethra.

Pump Unit

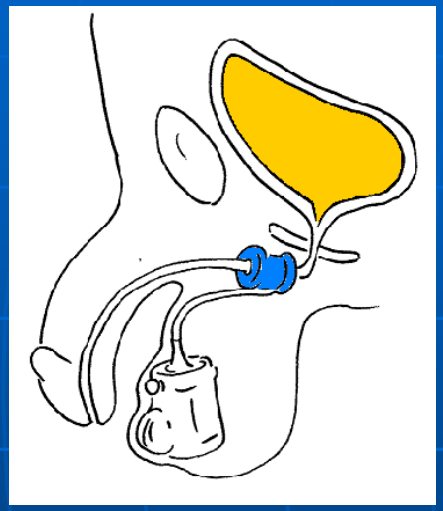
4 to 6 cm adjustable Cuff moulded into a curved shape

Cuff Pillow

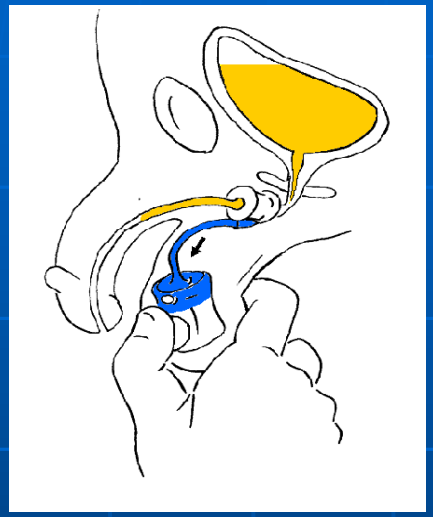
Compensation Pouch Septum

Pump Button to empty the Cuff after pressing and releasing it

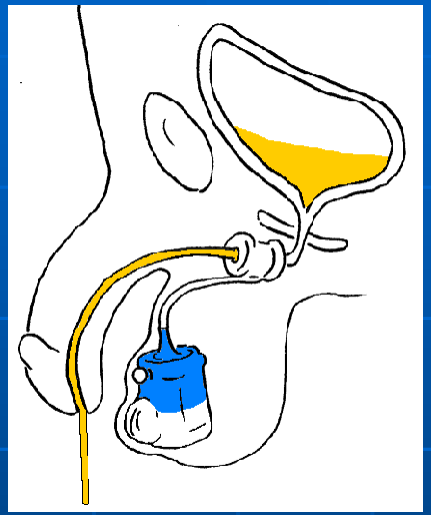
FUNCTIONING



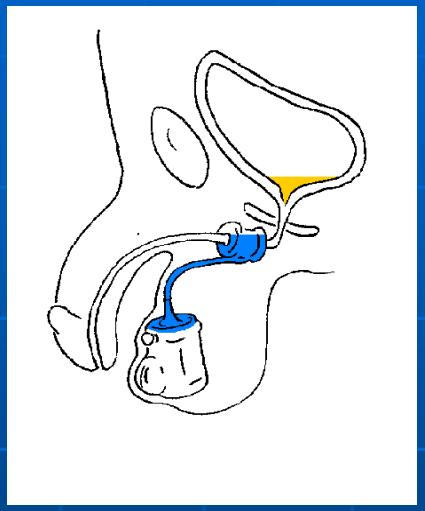
1) The cuff squeezes the urethra, the patient is continent



2) The patient squeezes and releases the Pump button to deflate the cuff.

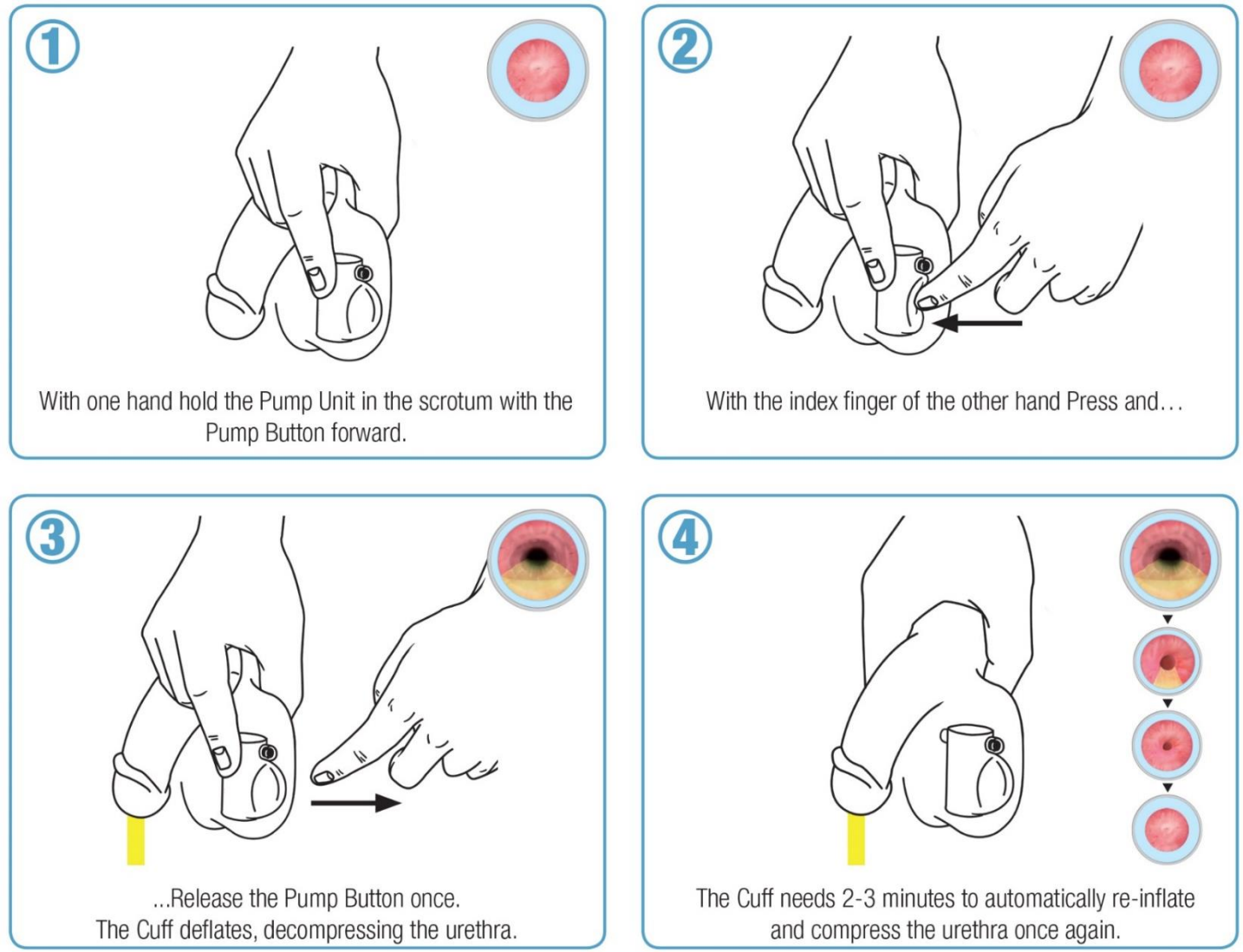


3) The patient urinates.

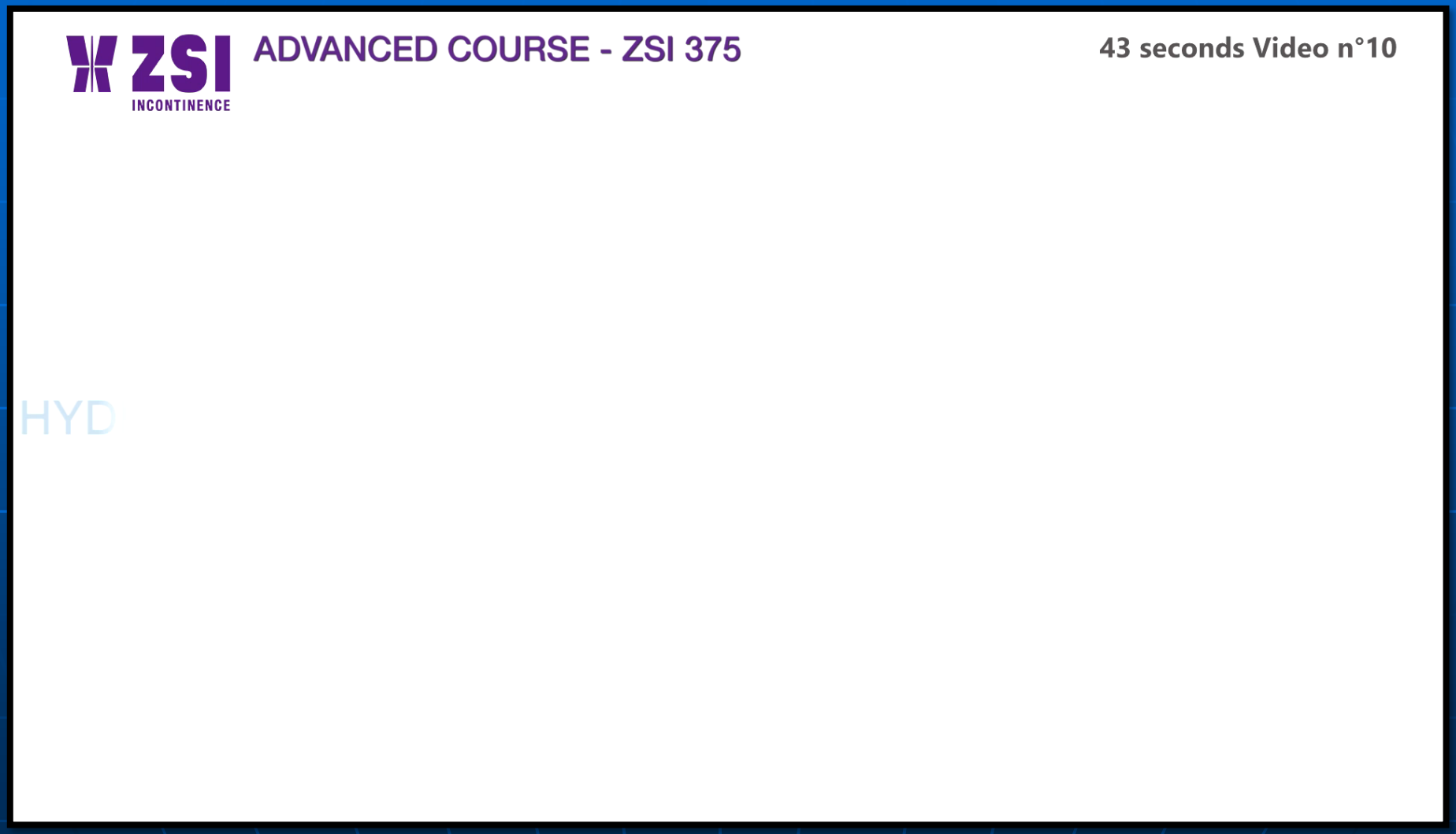


Automatically the cuff inflates and closes the urethra again.

FUNCTIONING



FUNCTIONING



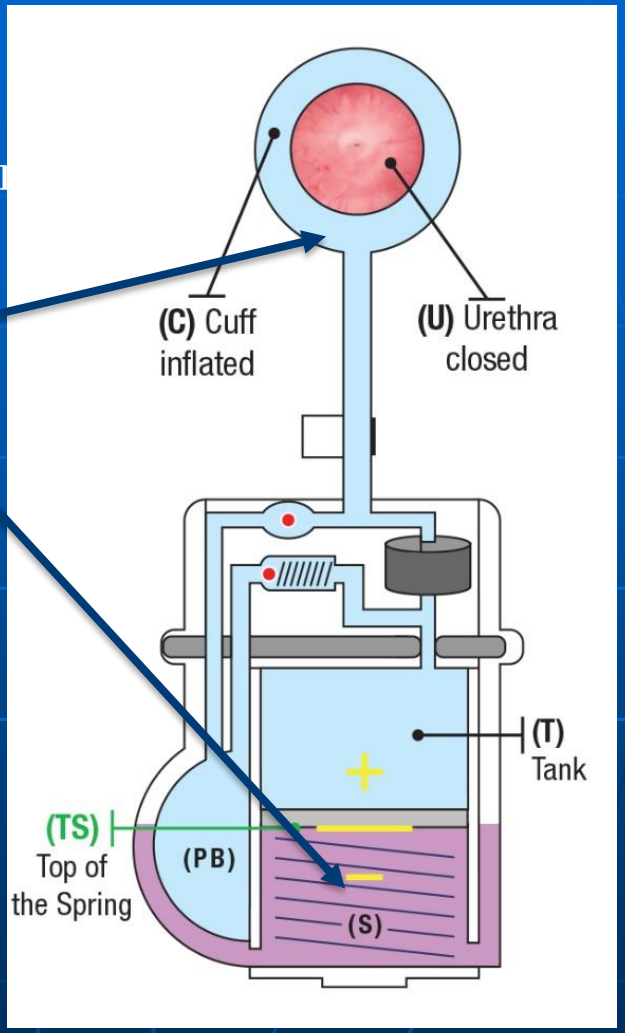
FUNCTIONING

ZSI 375 is filled with normal saline solution.

There are TWO compartments separated by the piston

(1) Hydraulic Circuit
(2) Compensation Pouch Circuit

The two circuits are separated by a piston.
They are never in contact with each other.
The piston can go up an down in the tank.

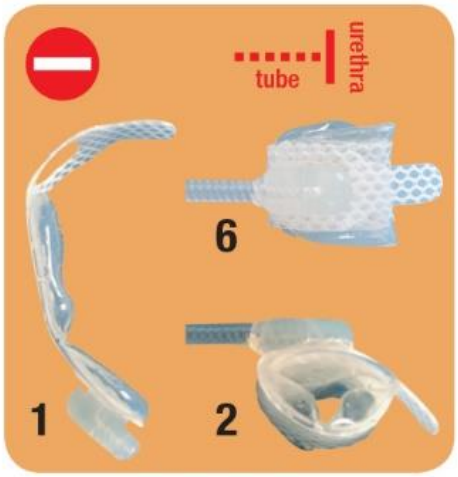


CUFF

ZSI
Zephyr Surgical Implants

FLAT CUFF CLOSED
clamp Cuff design

FLAT CUFF CLOSED
clamp Cuff design



FLAT CUFF
open and closed
clamp Cuff design

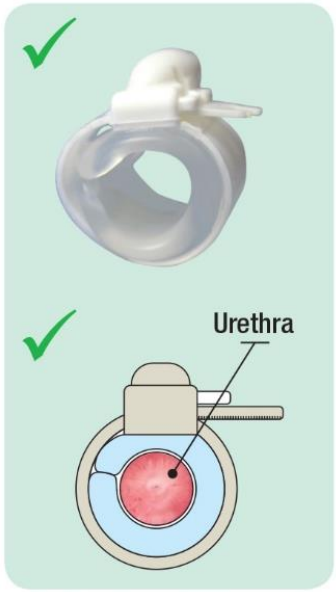
ZSI 375 CUFF

ADJUSTABLE: From 4, 4.5 , 5, 5.5 to 6 cm

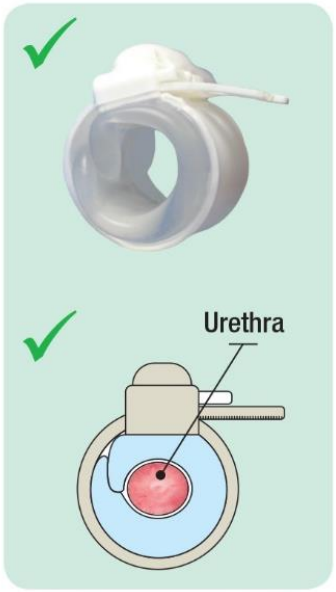
MOULDED IN CURVE

CLOSURE BY BUTTONS

CIRCULAR CUFF
open and closed
ZSI 375 Cuff design



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



ZSI 375 CIRCULAR CUFF
with cushion ends overlapped
for narrow circumference

PUMP SIGNS

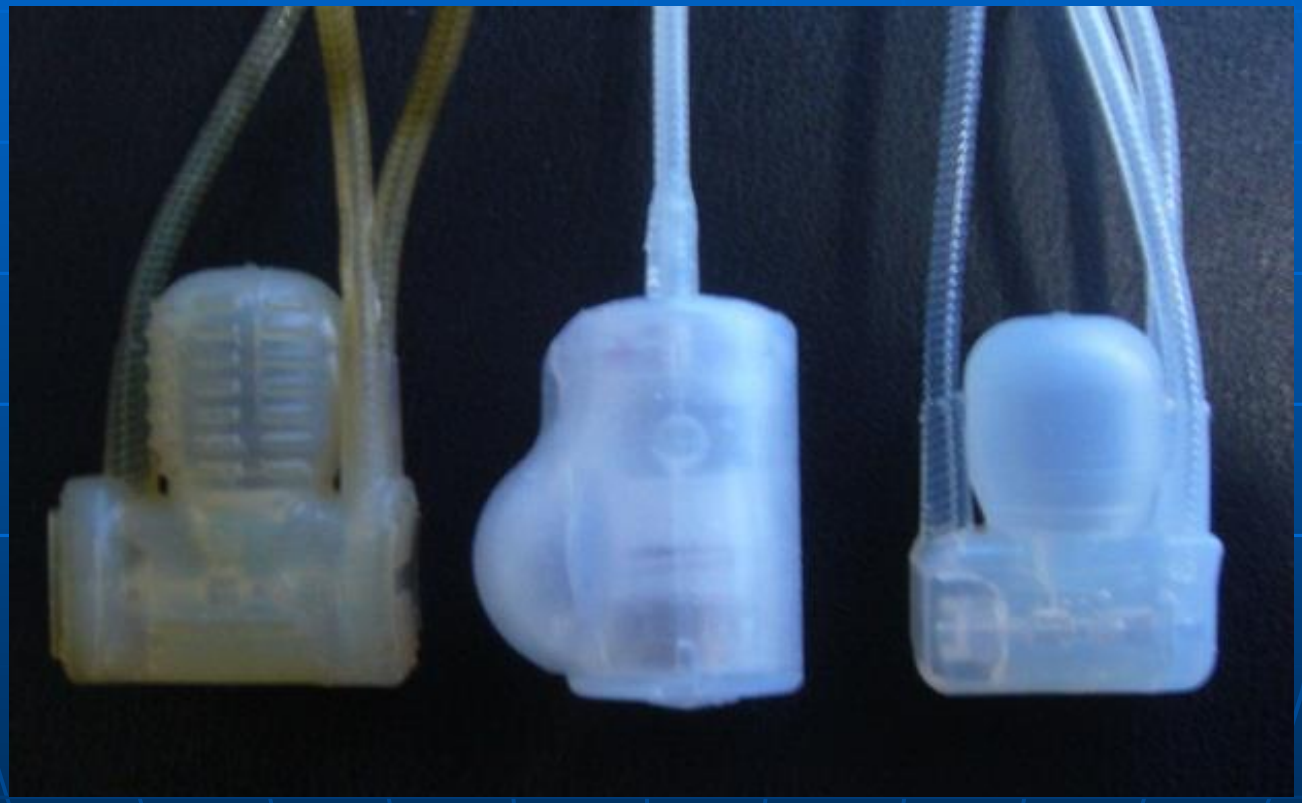
PLUS SIGN

Mid-Line

Minus Sign

Spring Level

PUMP SIZE



ZSI 375

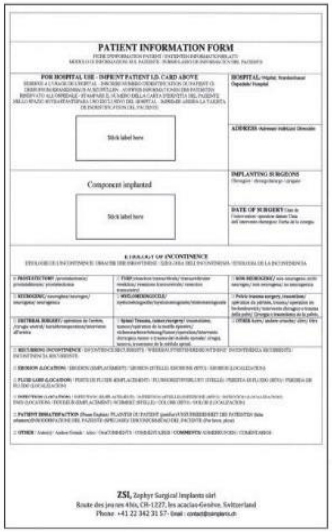
ARTIFICIAL URINARY SPHINCTER

ONLY 1 BOX

1 - ZSI 375 packed in Saline Solution delivered sterile

2 - Two Huber needles of 24 Gauge delivered sterile

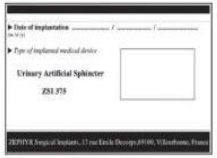
3 - Patient Implantation Form to activate guarantee



4 - Traceability Stickers

5 - Instructions

6 - Patient Implantation ID



THE PRESSURE IN THE CUFF TO REACH CONTINENCE

STRONG ENOUGH **TO BLOCK THE BLADDER PRESSURE**

BLADDER PRESSURE: From 0 to 30/ 35 cm H2O

WEAK ENOUGH **TO LET THE BLOOD GOING THROUGH THE URETHRAL TISSUE**

ARTERIAL BLOOD PRESSURE: 90 / 140 mmHg

Or 122,4 / 190,4 cm H2O

(1 mmHg= 1.36 cm H2O)

ZSI 375 PRESSURE :90-100 cm H2O

THE PRESSURE IN THE CUFF TO REACH CONTINENCE

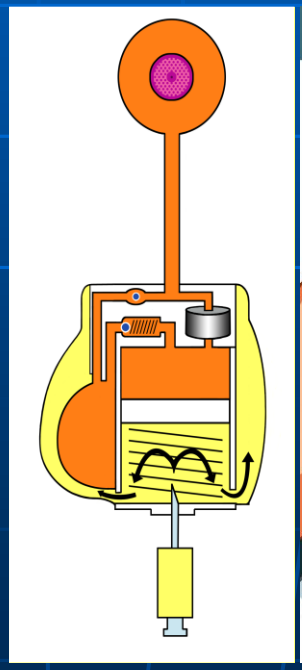
Increase of the pressure At the office:

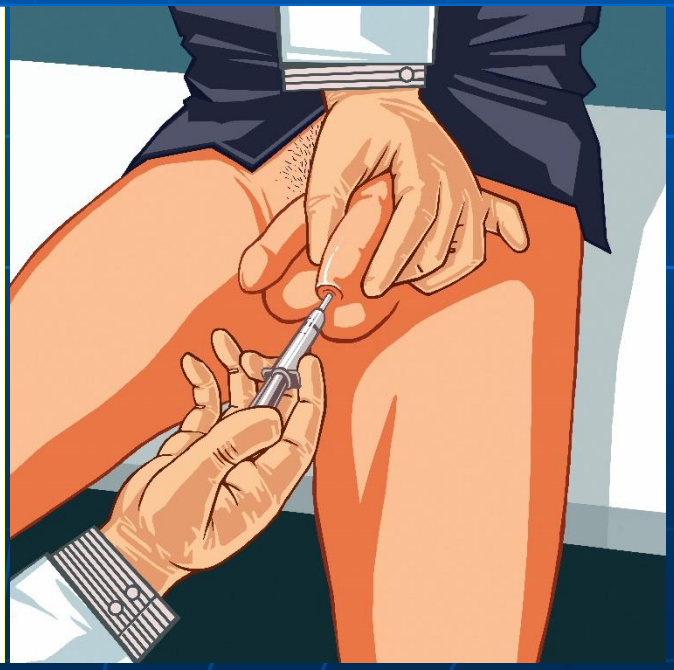
Scrub the scrotum,

Inject 1ml saline solution : Increase the pressure 10 cm H2O

2 ml: 20 cm H2O

3 ml: 30 cm H2O





The more you increase pressure,

The more risk of urethral erosion.

SURGICAL PROCEDURE

Simple and rapid procedure,
less invasive
No need to mesure the urethra
less pain, under skin surgery
No prepration,
No connections,
Shorter anesthesia and lighter aneathesia reducing risk
Possibility of one day hospitalization

ZSI
Zephyr Surgical Implants

ZSI 375

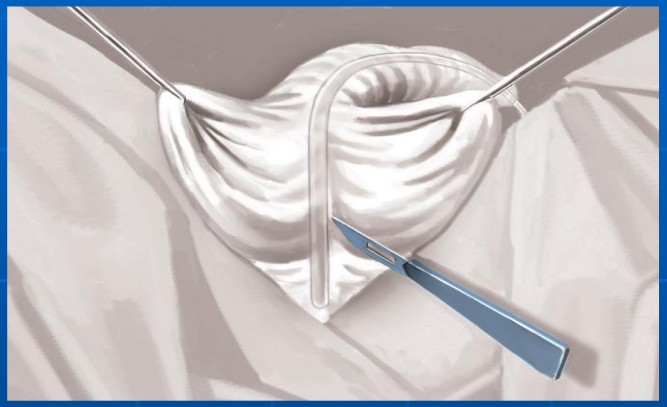
URINARY ARTIFICIAL SPHINCTER SURGICAL PROCEDURE

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

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.

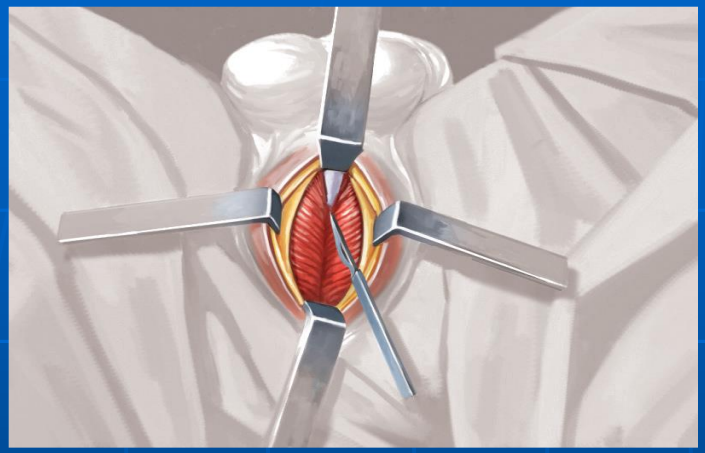
1. DISSECTION

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

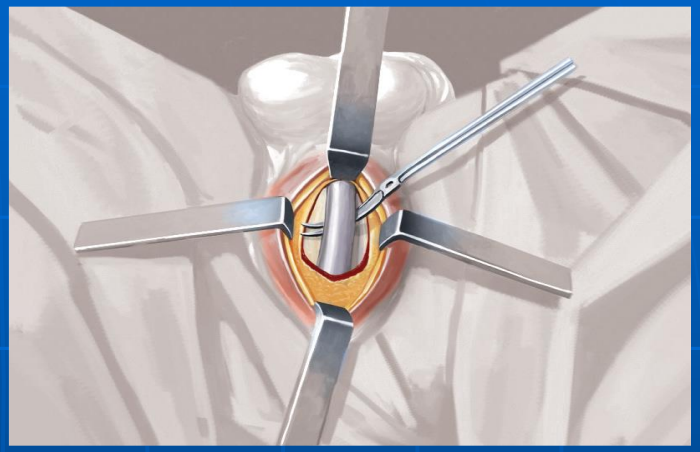


Perform a perineal incision. The Foley catheter helps to identify the urethra during dissection

1. DISSECTION

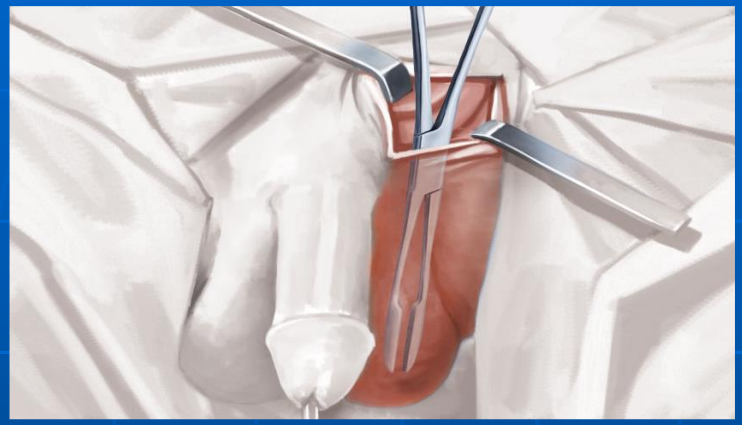


Dissect the fat and the bulbospongiosus muscle covering the urethra.

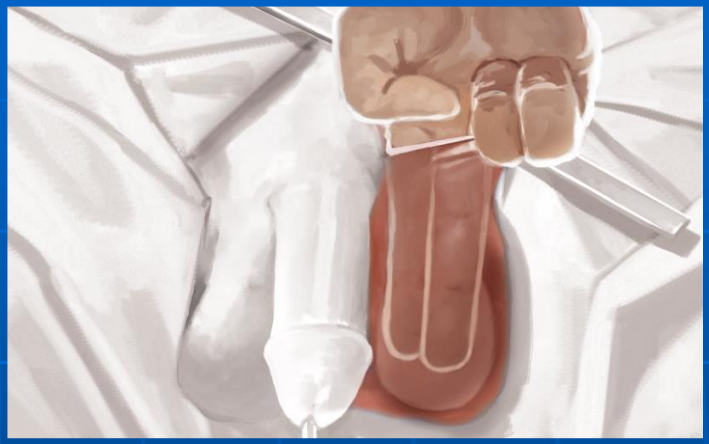


Dissect two centimetres of the urethra that is surrounded by the corpus spongiosum.

1. DISSECTION

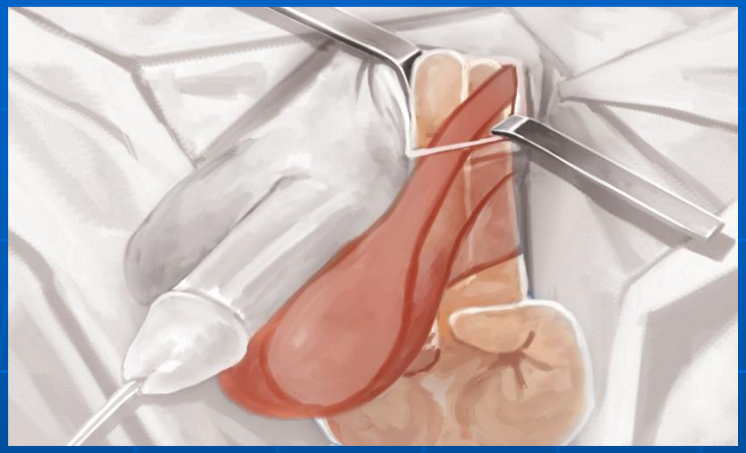


Perform an inguinal incision. It is easier to find the subdartos space from an inguinal incision rather from a scrotal incision. It is easier to create a deep, large pouch with a Maier clamp.

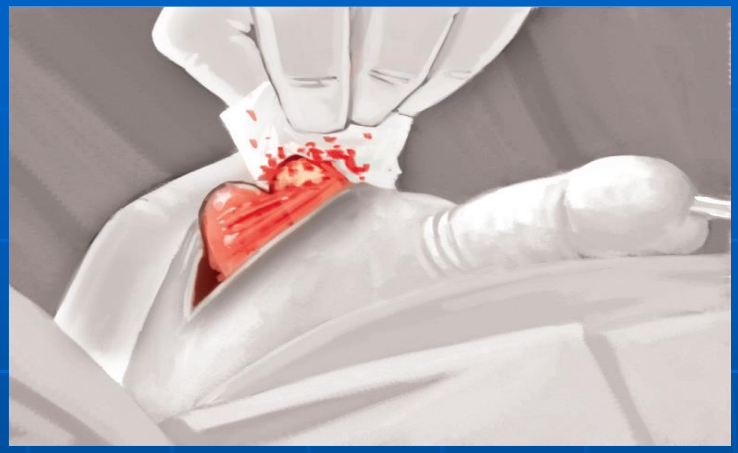


Prepare a subdartos pouch for the Pump Unit with the scissors and the maier clamp. The subdartos is between 2 layers: the dartos and the cremaster muscles (same as for orchidopexy).

1. DISSECTION

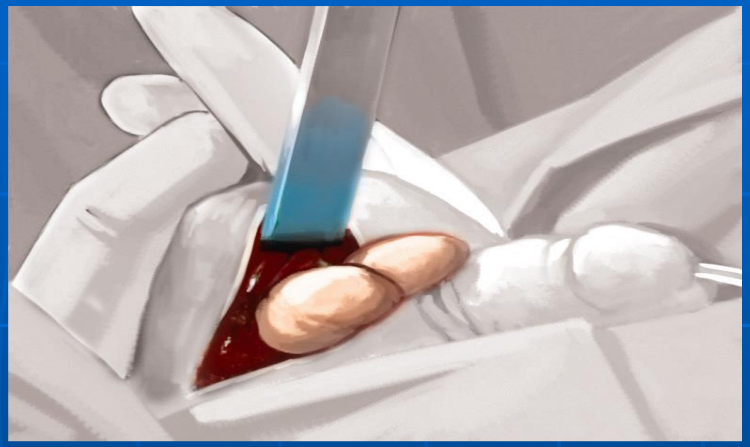


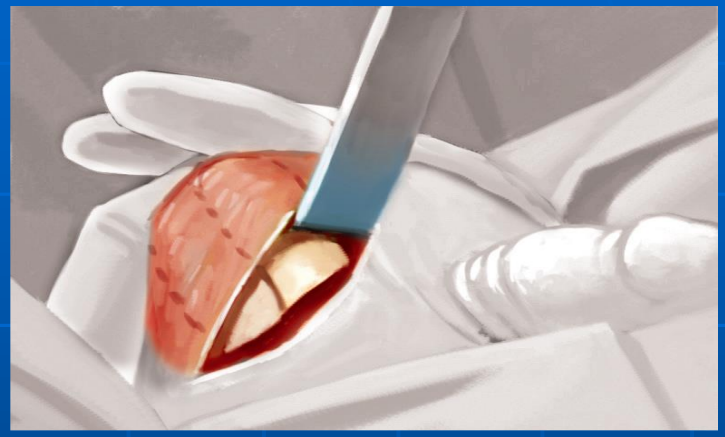
Open the passage between the perineal incision and the inguinal incision with the index and the middle fingers. Stay parallel to the urethra. The passage is behind the spermatic cord.



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

1. DISSECTION





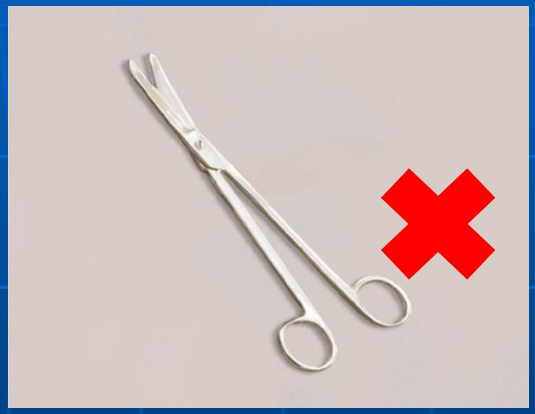
- Check the passage.
- The subdartos pouch, which receives the Pump Unit, is between 2 layers: the dartos and the cremaster muscles.
- Enlarge the passage with 2 fingers so that the Pump Unit may enter easily.

2. ZSI 375 PREPARATION BEFORE IMPLANTATION

A - REMOVING THE ZSI 375 FROM ITS PACKAGING LIQUID

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

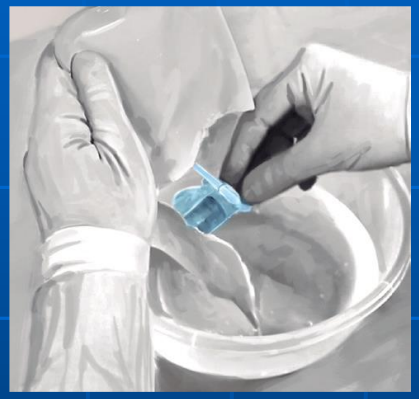
There should be minimal contact with the device and only the surgeon should handle it.



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

2. ZSI 375 PREPARATION BEFORE IMPLANTATION

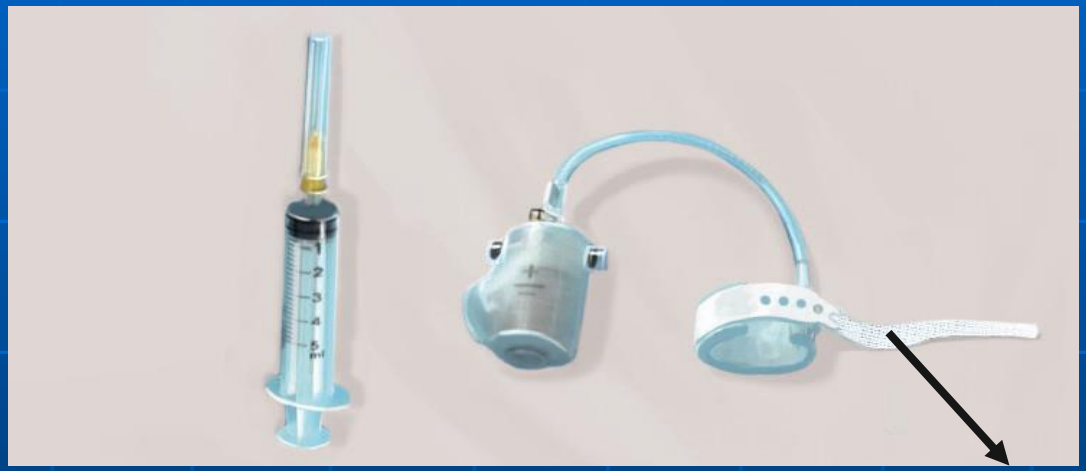





Open the bag and remove the device carefully into the first bowl full of Sterile Saline Solution 0.9‰. The ZSI 375 arrives Pre-filled and Activated. Prepare a second bowl filled with Sterile Saline Solution 0.9‰, and antibiotics to clean the device of its packaging liquid.

2. ZSI 375 PREPARATION BEFORE IMPLANTATION

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



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.

2. ZSI 375 PREPARATION BEFORE IMPLANTATION

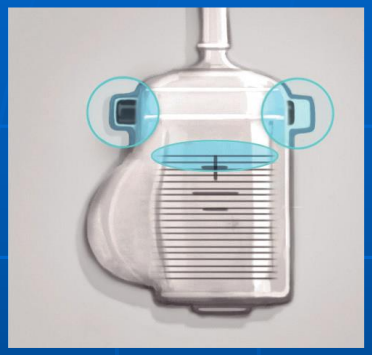
B - TEST THE SPRING

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

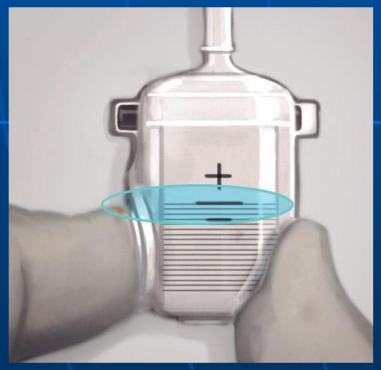
Wait for the Top of the Spring (TS) to return above the Plus '+' sign.

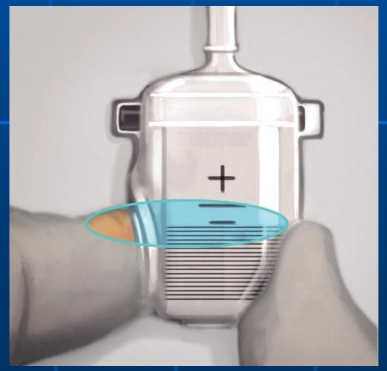
2. ZSI 375 PREPARATION BEFORE IMPLANTATION

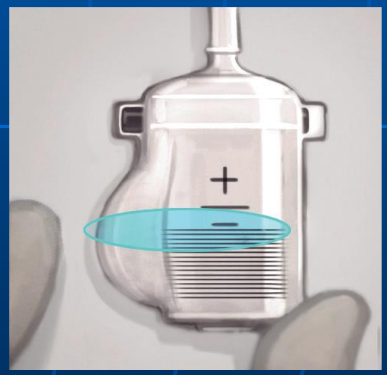
C - PREPARATION OF THE CUFF FOR IMPLANTATION / DEACTIVATION WITH CUFF EMPTY



- Spring released (ZSI 375 Activated).
- Cuff full (ZSI 375 Activated).



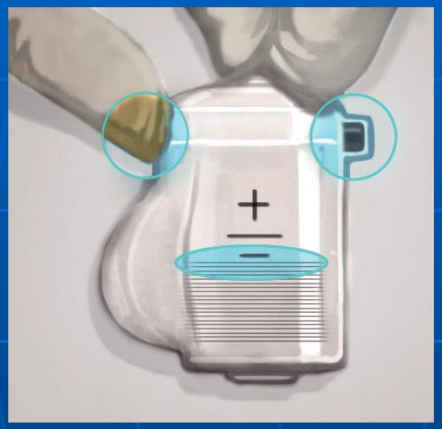




In order to deflate the Cuff completely, aspirate the Saline Solution from the Cuff to the Tank of the Pump Unit by **pressing and releasing** the Pump Button. Once the Spring is fully compressed, you will not be able to press the Pump Button any further.

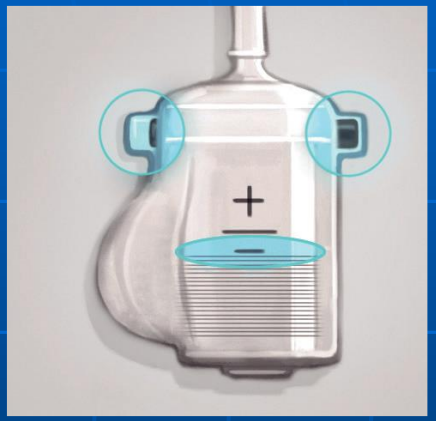
2. ZSI 375 PREPARATION BEFORE IMPLANTATION

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



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

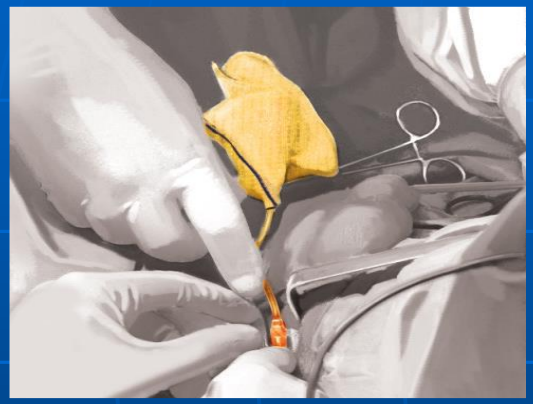
Cuff must be deflated.



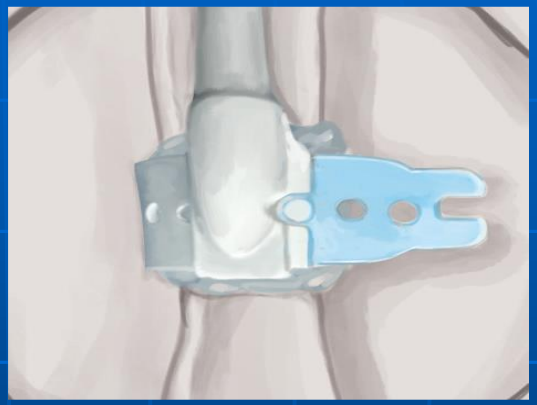
- The Top of the Spring (TS) is below the Minus '-' sign.
- The Cuff is flat.
- Wait 20 seconds to check that the ZSI 375 keeps Deactivated.

3. IMPLANTATION

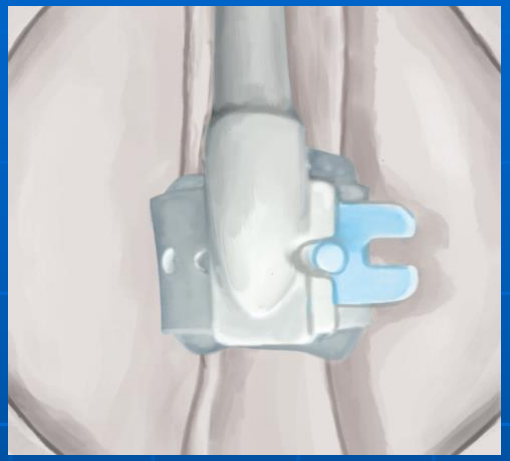
A - IMPLANTATION OF THE CUFF/LOCKING THE CUFF



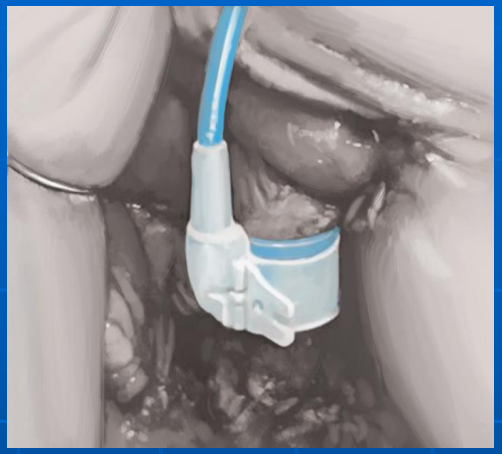
- Install the deflated Cuff and protect the Pump with a gauze pad.
- The device should never come in contact with the skin.
- Remove the Temporary Extension Tab after implantation.



- Fit the Cuff around the urethra.
- The 16 Fr/Ch Foley Catheter calibrates the urethra and prevents it from being tightened excessively.



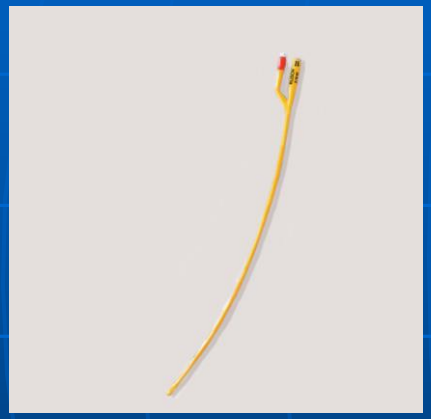
You can also keep the Cuff more loose around the urethra, but you will probably have to adjust the volume of Saline Solution in the Hydraulic Circuit; this will move the Spring to the Mid-line.



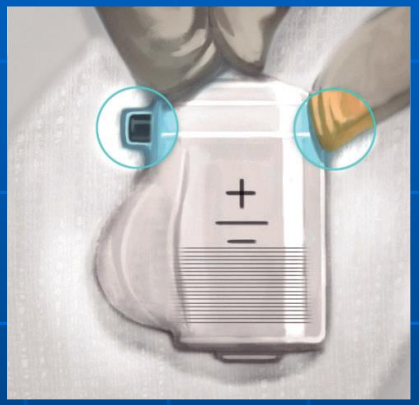
Tighten the Cuff with the 16 Fr/Ch Foley catheter to calibrate the urethra. When the Cuff is closed, it must be able to be rotated towards both the right side and the left side of the urethra.

3. IMPLANTATION

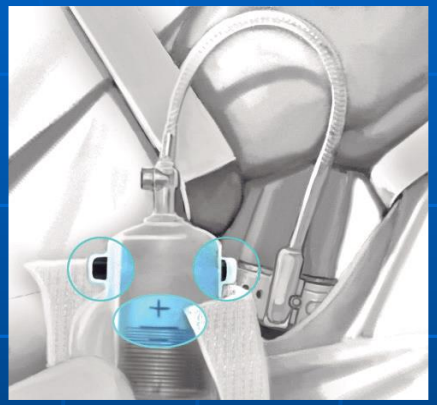
B - CONTROL OF THE CUFF ISSUED PRESSURE



Remove the size 16 Fr/Ch Foley catheter.

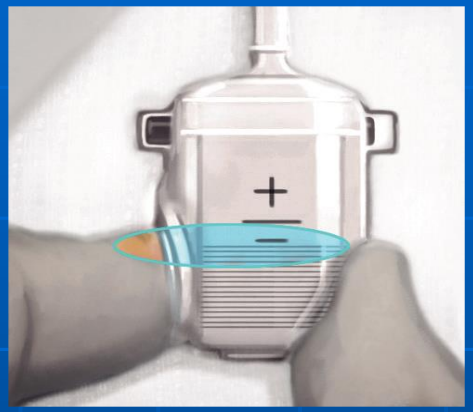


Press the Activation Button to Activate the device to check that the correct pressure is delivered.

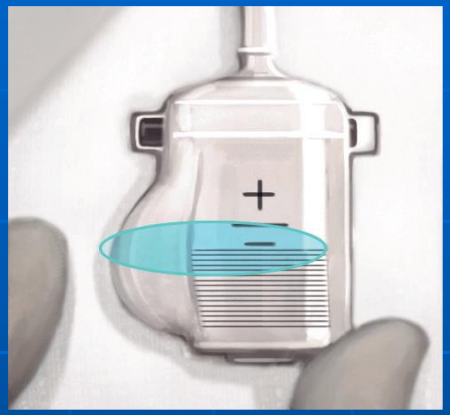


After pressing the Activation Button, the Top of the Spring (TS) will automatically Rise. Wait for at least two minutes

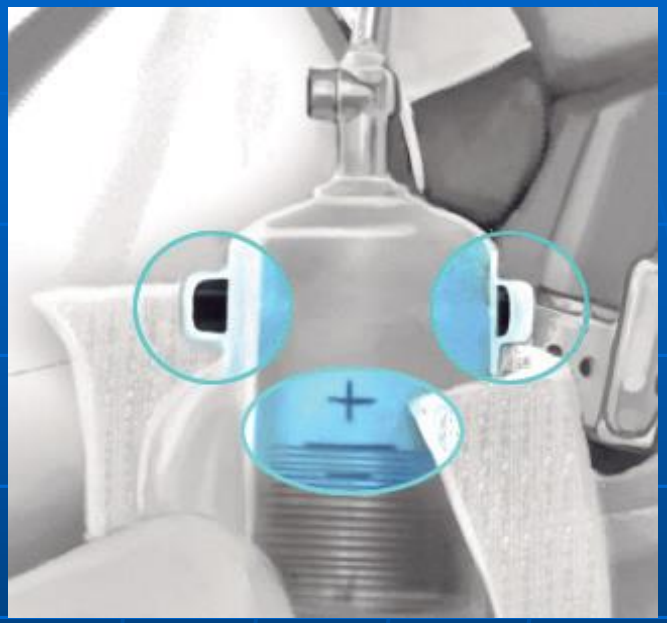
TEST: CHECK THE DELIVERED PRESSURE AGAIN



PRESS

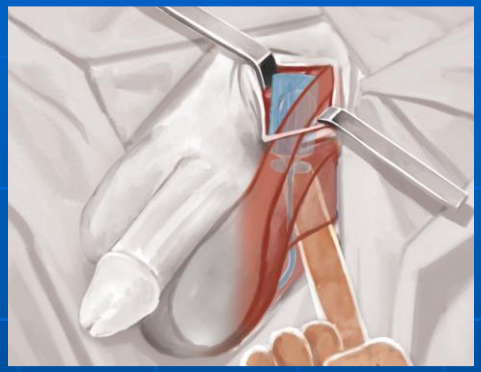


RELEASE

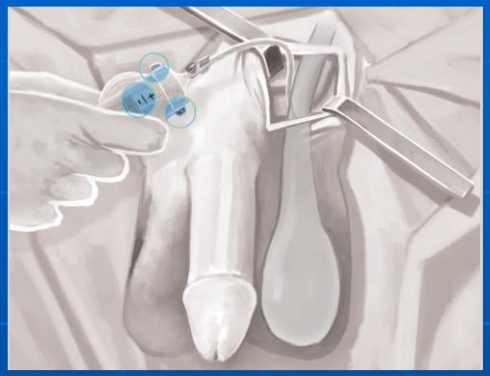


With the urethra in the Cuff, the Top of The Spring (TS) should stop just below or level with the Mid-line

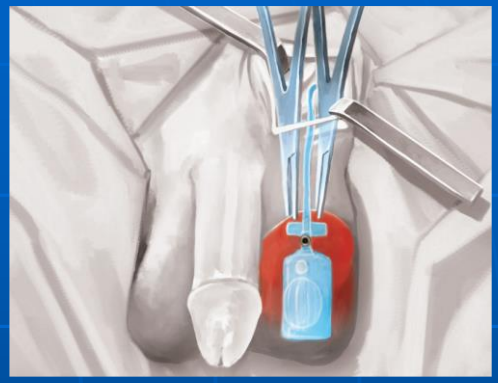
D - IMPLANTATION OF THE PUMP AND WINGS SUTURING



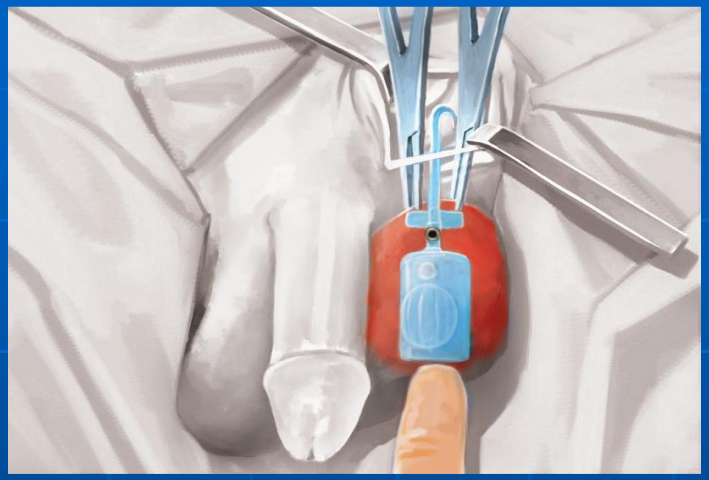
Pump Unit passage from the perineal incision to the inguinal incision.

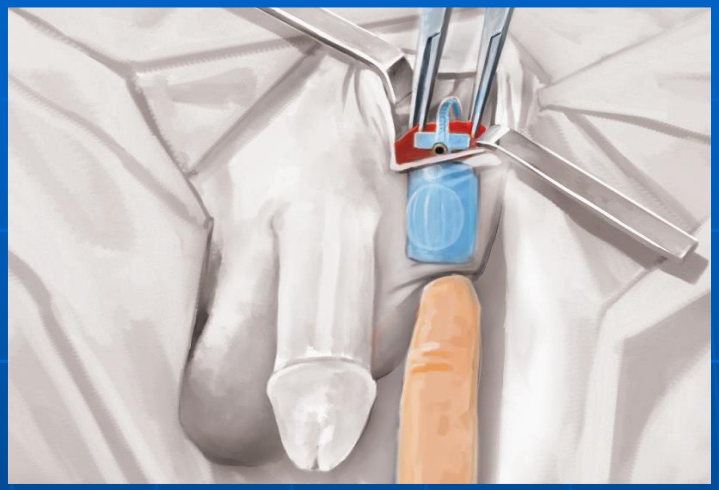


After this passage, check that device is still Deactivated, and that the Spring is below the Minus '-' sign.

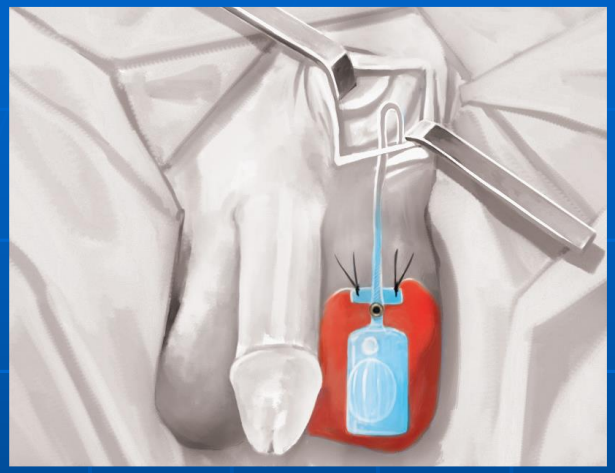


Insert the Pump Unit into subdartos pouch.

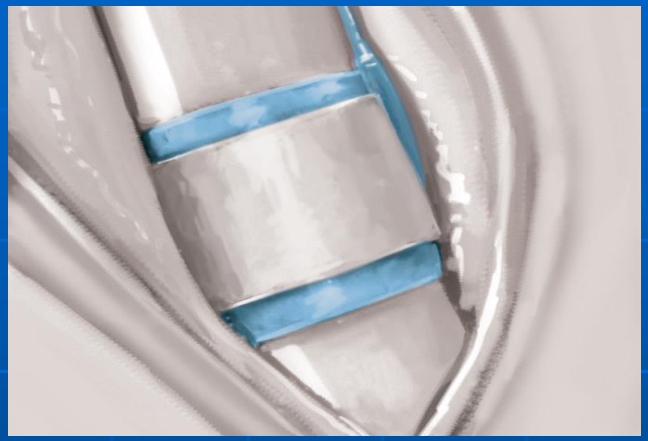




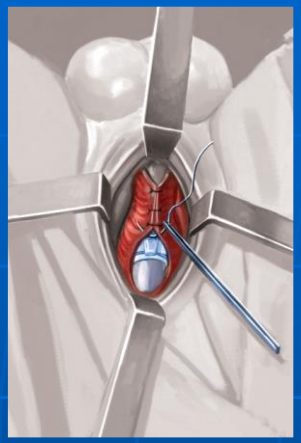
- With the index finger push the Pump Unit upwards to expose the deep internal scrotal tissue. With two mosquito clamps, pick and pull out the deep internal scrotal tissue.
- Suture the Wings to the deep internal tissue, so that the Pump Unit is not placed too high in the Scrotum pouch.
- Insertion follows the same technique as implanting a testicular prosthesis



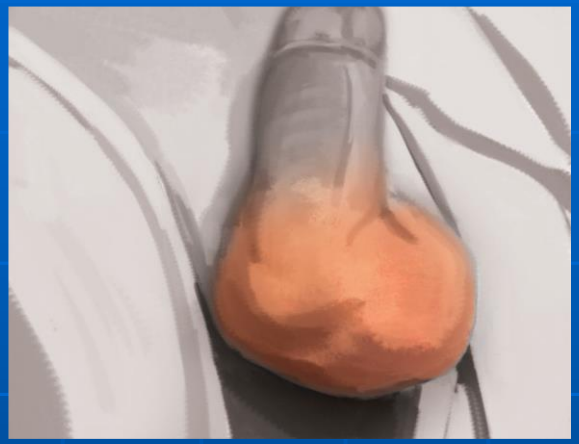
Drop the Pump Unit deep in the scrotum.



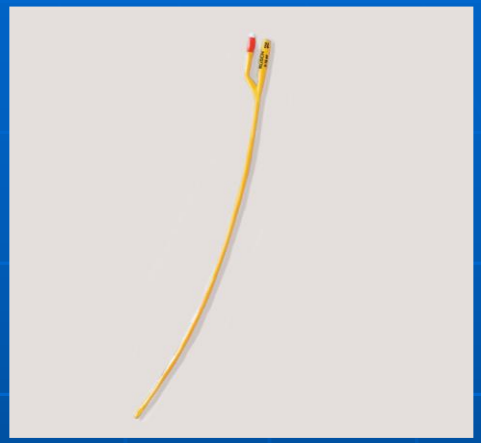
Turn the Cuff to the side. Check that the Cuff pillow is properly installed.



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



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



Install a size 12 Fr/Ch Foley catheter for 24 hours

THANKS FOR YOURE ATTENTION