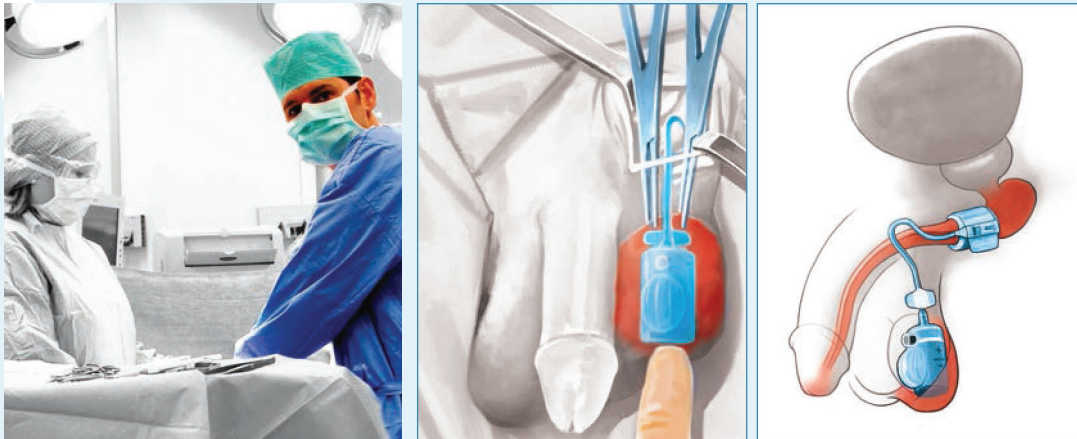


MANUAL *For Operating Room*

ARTIFICIAL URINARY SPHINCTER ZSI 375



NOTE

This document is a complementary checklist to the two training videos, which you can access and download from our website: ZSI 375 Training Video, ZSI 375 Functioning Protocol.

Please watch the videos before reading this document.

*ZSI 375 - English
Version 1 January 2015*



LOCAL DISTRIBUTOR

ZEPHYR SURGICAL IMPLANTS SARL

C/Ulmann, route des Jeunes 4
1227 Acacias
Switzerland

E-mail: contact@zephyr-si.com
www.zephyr-si.com

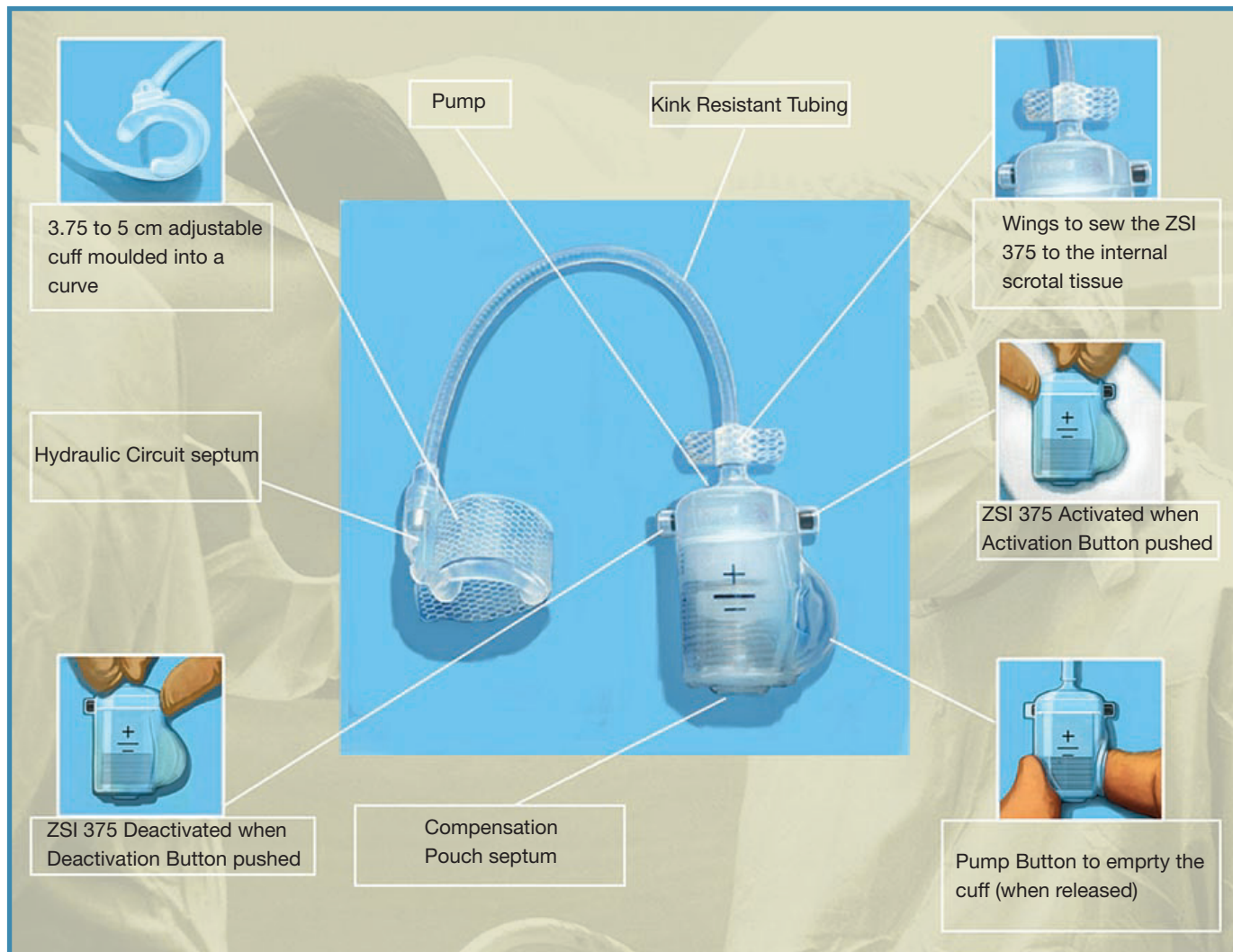


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ARTIFICIAL SPHINCTER ZSI 375

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 normal saline solution. It is designed to treat severe urinary incontinence secondary to an intrinsic urinary sphincter deficiency.



Packaging Contents



<p>1. Patient Implantation Form</p>	<p>2. Traceability Stickers</p>
<p>3. Instructions</p>	<p>4. Patient Implantation ID</p>

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 of bacteria.
- An antibioprohylaxis is necessary. Use antibiotic adapted to the bacteria of your region prior to the incision.

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 Foley catheter in order to drain the bladder.

PREPARATION OF THE SURGEON

- All surgeons use full gown, hood (no cap) and two pairs of gloves at all times.
- All surgeons should replace gloves after draping the area, before skin incision and before touching the device.

IRRIGATION OF THE IMPLANTATION SITE

- Before implanting the device, irrigate the scrotal pouch and the perineal incision with local antibiotics. Use Gentamycin 80mg pure or Cefotoxin.

PREPARATION OF THE DEVICE

- Change gloves before handling the device.
- Minimize time the device is exposed to open air as some bacteria are airborne.
- Dip the device in a bowl filled with antibiotic solution (Gentamycin 80mg or Cefotoxin).
- Place the device in clean gauze for the transit from the bowl to the implantation site.

PRECAUTION WITH PUMP

- During the preparation and implantation procedure, pump should be wrapped in a clean gauze; it must not touch the skin. Always remember that the skin is a source of microbes.

LAST PRECAUTIONS

- Final antibiotic irrigation with pure Gentamycin 80 mg is done with device installed.
- Remove/wash away the blood clots on the device. Blood clots are an ideal source for bacterial proliferation.
- 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 tissue separates the device cannot be exposed.

ANTIBIOPROPHYLAXIS

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

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

In case of an allergy, instead of CEFOTOXIN, you can use

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

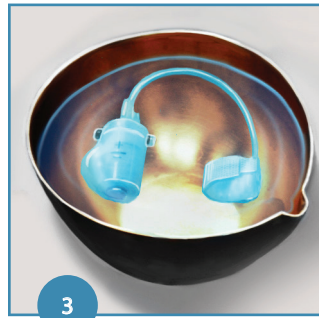
PREPARATION



1
Change gloves for preparation. Change gloves if any contact is made with the skin. Prepare a large and comfortable table.



2
There should be minimal contact with the device and only the urologist (or the product manager for preparation) should handle it.

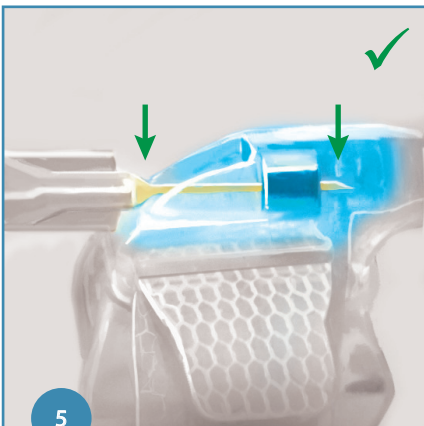


3
Place the device into normal saline solution with antibiotics. Minimize the time the device is exposed to open air.

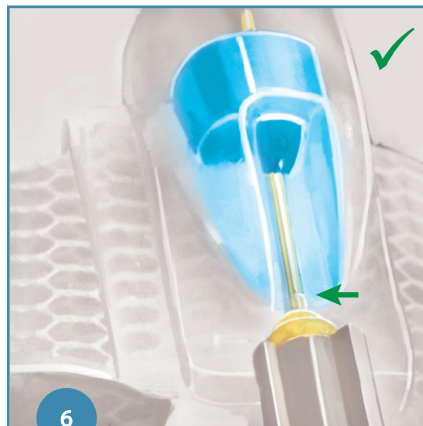


4
Prepare from the kit: One 5 ml syringe. One huber needle.

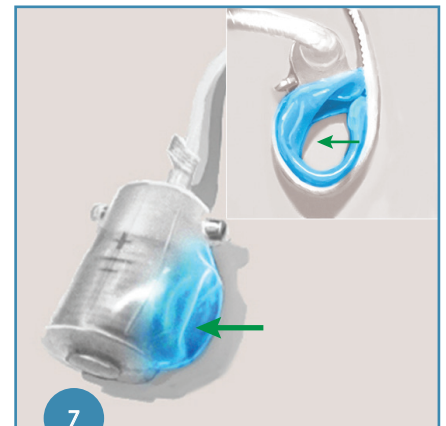
PREPARATION OF THE HYDRAULIC CIRCUIT



5
Place the needle in the slot and pierce the septum.



6
This is the correct position. Create a vacuum. Do not aspirate more than 5 ml.



7
Check that the cuff and the Pump Button are flat after performing the vacuum.



8
Inject 5 ml of normal saline solution. This is the correct position to aspirate the bubbles from the pump (look at the correct right hand fingers position). Remove the bubbles from the hydraulic circuit.

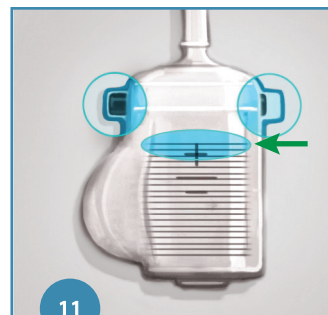


9
This is the correct position to aspirate the bubbles from the cuff.

PREPARATION OF THE COMPENSATION POUCH



10
Create a vacuum. Aspirate 5-6 ml. Inject 5 ml of normal saline solution. Do not remove the bubbles from the compensation pouch.

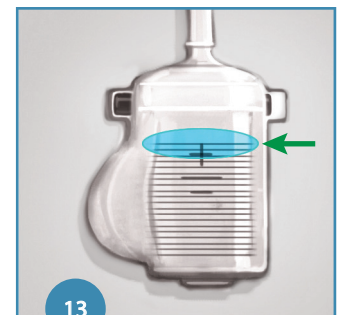


11
The device is prepared when the spring is above the "+" sign.



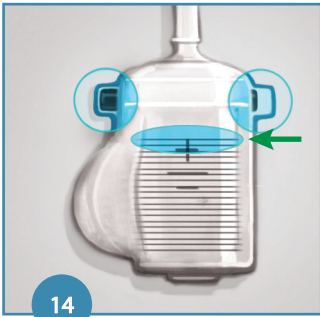
12
Press-Release 3 or 4 times until the spring is fully compressed.

TEST THE SPRING



13
Wait for the spring to return above the "+" sign. It takes 3 minutes. When it does the test has been successful.

PREPARATION OF THE CUFF FOR IMPLANTATION / DEACTIVATION

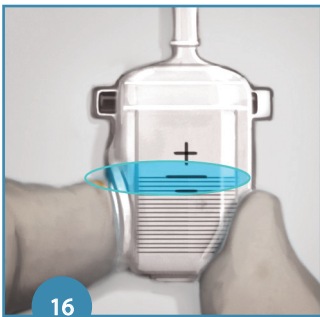


14 Spring released (device activated).



15 Cuff full (device activated).

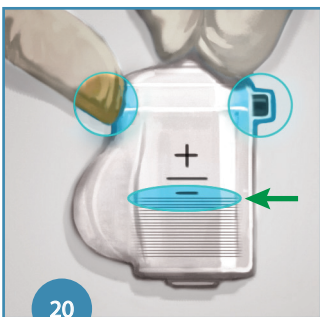
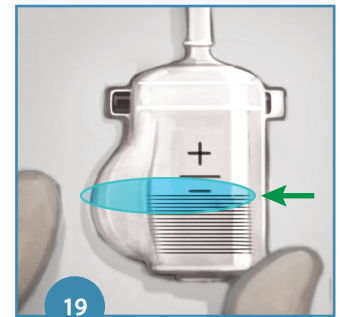
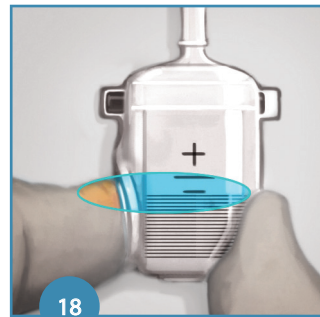
OUR GOAL NOW IS TO DEFLATE THE CUFF AND DEACTIVATE THE ZSI 375 TO KEEP THE CUFF FLAT



In order to deflate the cuff completely, aspirate the saline solution from the cuff to the tank of the pump unit. You will not be able to press any more once the spring is compressed.



Press and release 3 or 4 times until the spring is below the “-” sign.

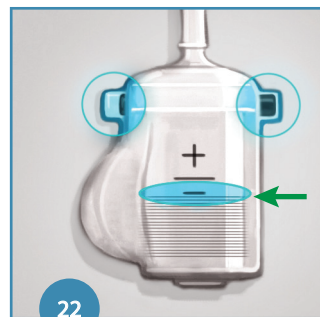


20 When the spring is below the “-” sign, press the deactivation button firmly.

(DEVICE DEACTIVATED)



21 Cuff must be deflated.



22 The spring is below the “-” sign. The cuff is flat. Wait 20 seconds to check that the ZSI 375 stays deactivated.

(DEVICE PROPERLY DEACTIVATED)

CORRECT POSITION OF THE SPRING: PICTURE 22. THE SPRING IS BELOW THE “-” SIGN.

IF THE SPRING IS NOT BELOW THE “-” SIGN SEE TROUBLE SHOOTING PAGE 10. PICTURE A22.

DISSECTION



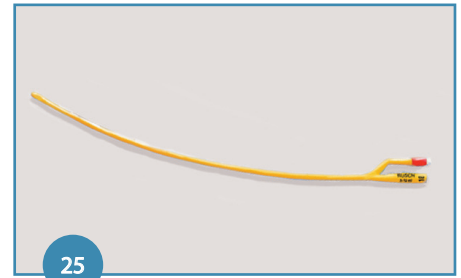
23

Instruments. Do not forget a large maier clamp.



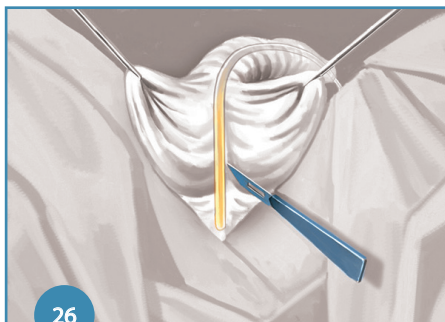
24

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



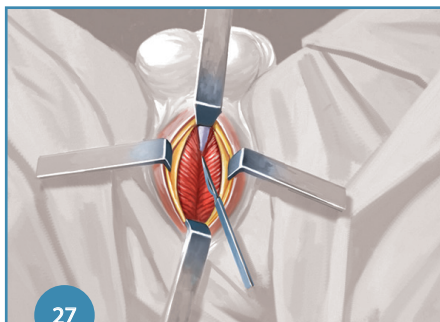
25

Install a size 16 Foley catheter (no smaller).



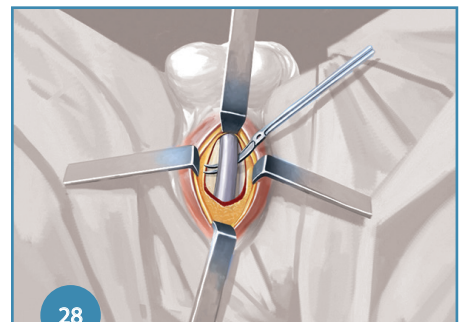
26

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



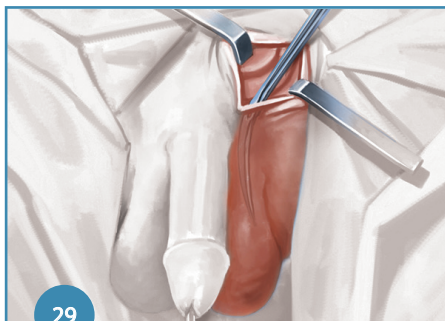
27

Dissect the fat and the bulbospongiosus muscle covering the urethra.



28

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



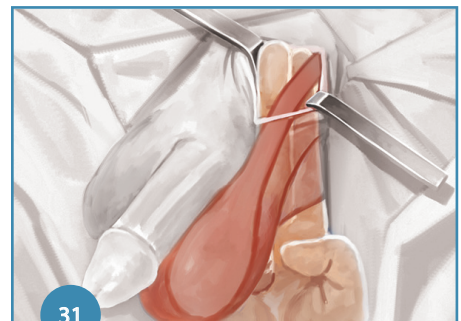
29

Perform an inguinal incision. It is easier to find the subdartos space from an inguinal incision than a scrotal incision.



30

Prepare a subdartos pouch for the pump unit with the scissors and the maier clamp. The subdartos pouch is the space used for orchidopexy.



31

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 of the testis.



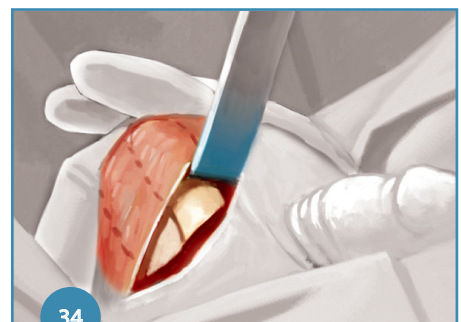
32

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



33

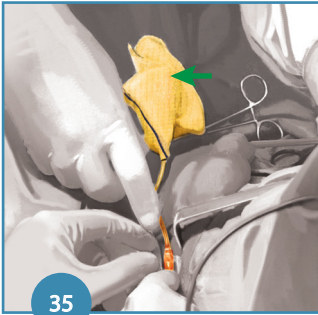
Check the passage. The sudartos pouch, which receives the pump unit, is between 2 layers: the dartos and the cremaster muscles. Enlarge the passage with 2 fingers so that pump unit may enter easily.



34

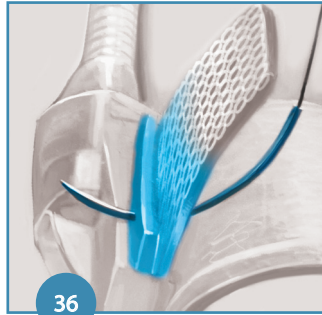
IMPLANTATION

IMPLANTATION OF THE CUFF / SUTURE OF THE CUFF



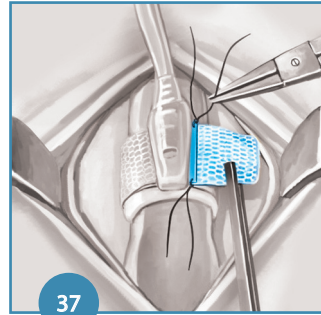
35

Install the deflated cuff and protect the pump with a gauze pad. The device should never come in contact with the skin.



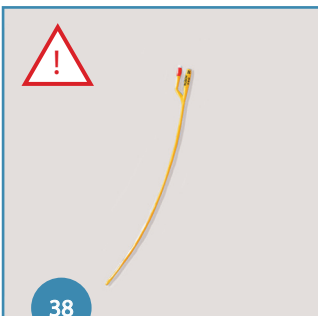
36

Suture the cuff to secure the closure, while the size 16 Fr Foley catheter is still calibrating the urethra.



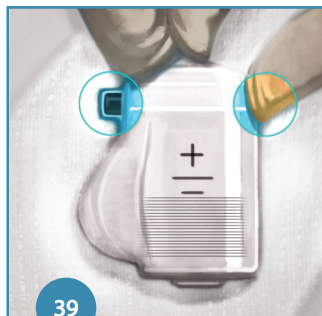
37

CONTROL OF THE ISSUED PRESSURE



38

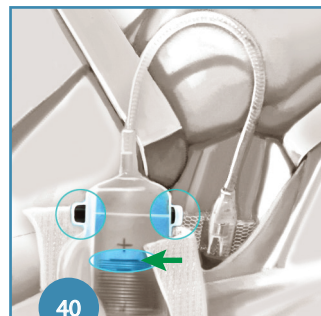
Remove the size 16 Fr Foley catheter.



39

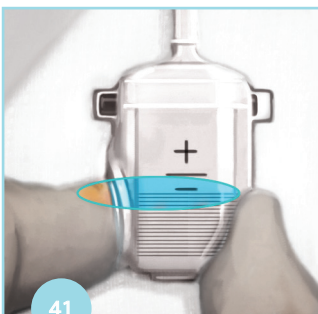
Press the activation button to activate the device in order to check that the correct pressure is delivered.

(DEVICE DEACTIVATED)



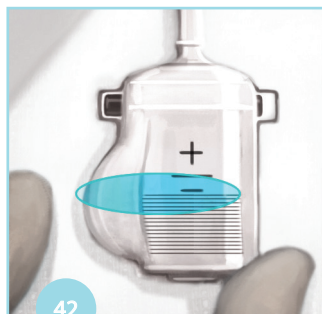
40

After pressing the activation button the spring will automatically go up and stop at the midline.



41

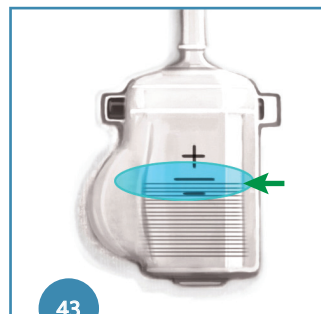
PRESS



42

RELEASE

TEST: CHECK THE DELIVERED PRESSURE AGAIN



43

The spring will come back just below the midline to achieve the correct delivered pressure. It takes **2 minutes**.

(DEVICE PROPERLY DEACTIVATED)

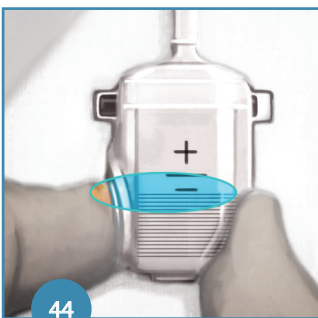
PICTURE 43 SHOWS THE CORRECT POSITION OF THE SPRING. THE SPRING IS JUST BELOW THE MIDLINE. THE ZSI 375 DELIVERS THE PROPER PRESSURE.

IF THE SPRING IS NOT BELOW THE MIDLINE, SEE TROUBLE SHOOTING PAGE 10. PICTURE A43 & D43.

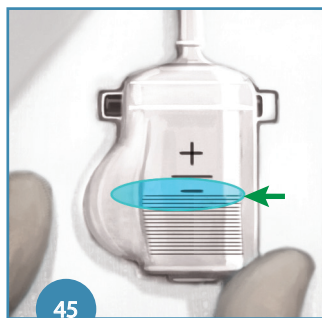
PICTURE 47 SHOWS THE CORRECT POSITION OF THE SPRING. THE SPRING IS JUST BELOW THE " - " SIGN. THE ZSI 375 IS PROPERLY DEACTIVATED, THE CUFF IS DEFLATED.

IF THE SPRING IS NOT BELOW THE " - " SIGN SEE TROUBLE SHOOTING PAGE 11. PICTURE A47.

DEACTIVATION BEFORE IMPLANTATION OF THE PUMP

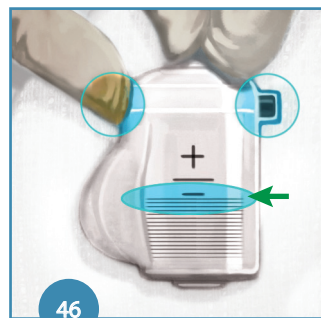


44



45

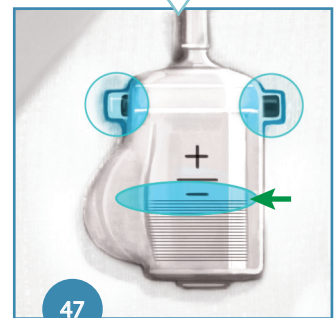
Press and release once or twice, until the spring is fully stressed and the cuff is deflated. We deflate the cuff and deactivate the ZSI 375 so that the cuff is not compressing the urethra during healing.



46

Firmly press the deactivation button.

(DEVICE DEACTIVATED)

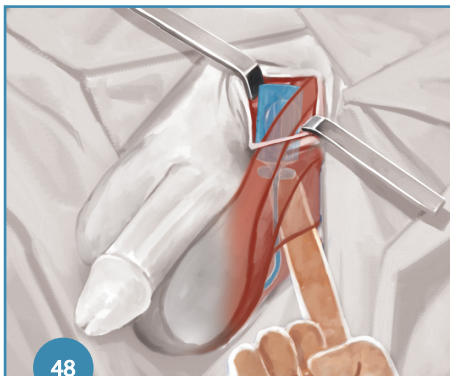


47

The spring is below the " - " sign. Wait **20 seconds** to be sure the ZSI 375 stays deactivated.

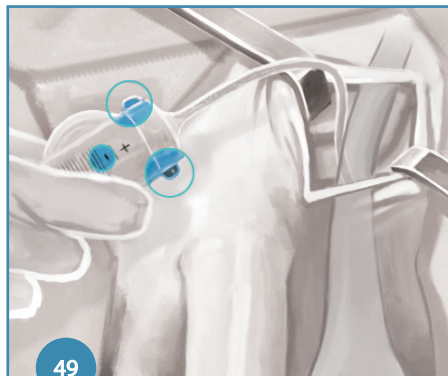
(DEVICE PROPERLY DEACTIVATED)

IMPLANTATION OF THE PUMP



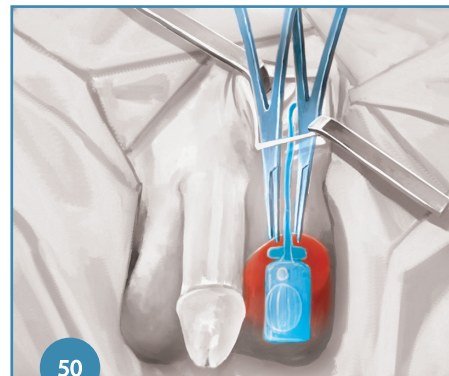
48

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



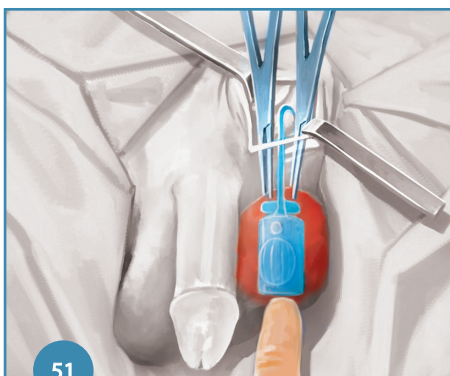
49

After this passage, check that device is still deactivated, and that the spring is below the “-” sign.



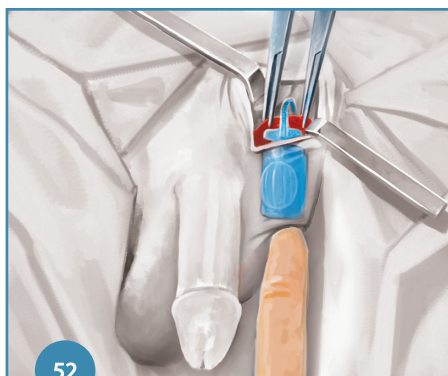
50

Insert the pump unit into subdartos pouch.

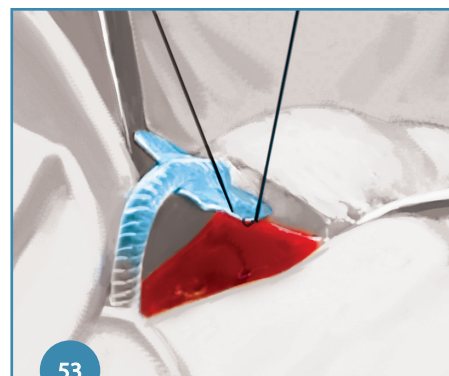


51

With the index finger push the pump upwards to expose the deep internal scrotal tissue. With two mosquito clamps, pick and pull out the deep internal scrotal tissue. Suture the butterfly to the deep internal tissue, so that the pump is not placed too high in the scrotum pouch. Insertion follows the same technique as implanting a testis prosthesis.

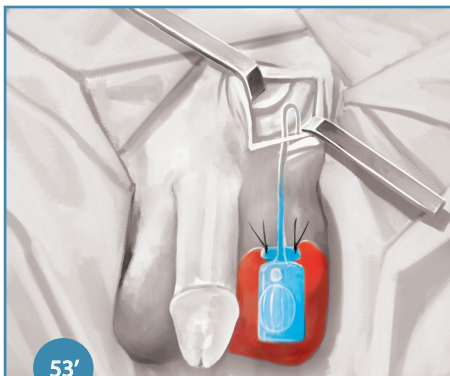


52



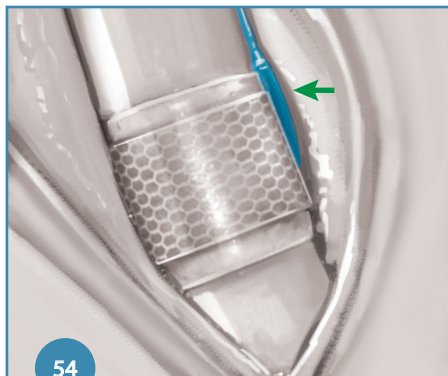
53

Use non absorbable suture to fix the wings into the deep internal tissue of the scrotal pouch.



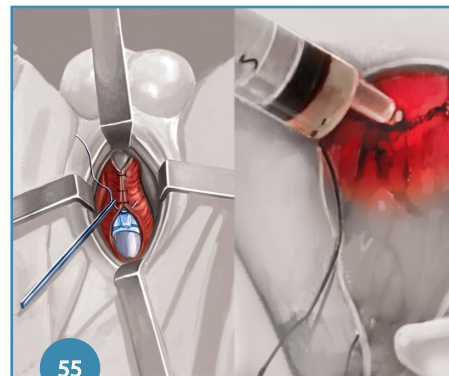
53'

Drop the device deep in the scrotum.



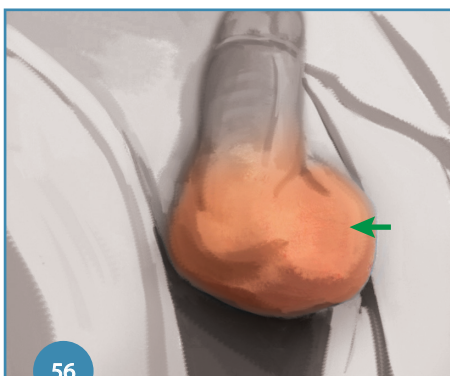
54

Turn the septum to the side. Check that the cuff pillow is properly installed.



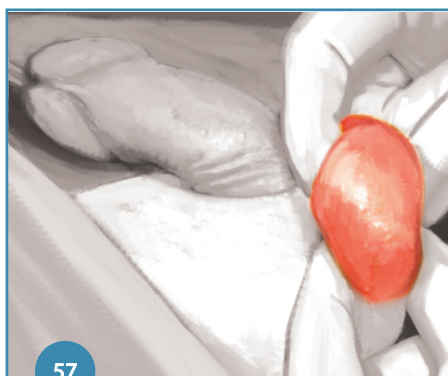
55

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



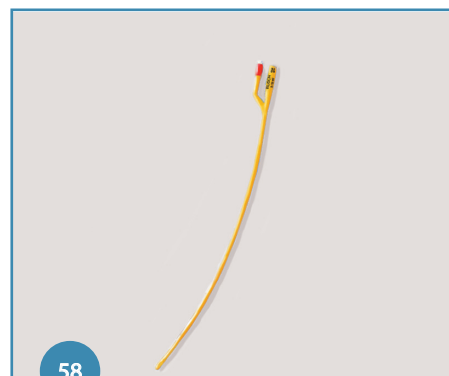
56

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



57

Because of the size and placement of the pump, the patient will easily find the pump.

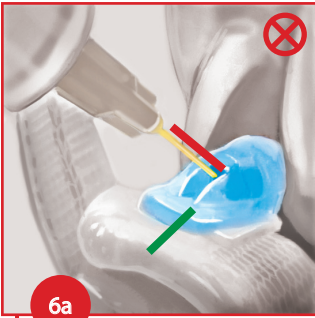


58

Install a size 12 Fr catheter for 24 hours.

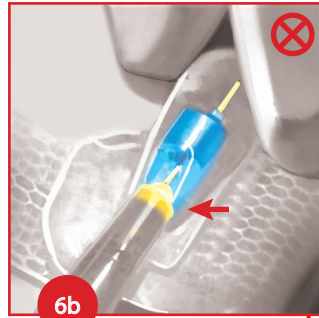
TROUBLESHOOTING

PREPARATION OF THE HYDRAULIC CIRCUIT



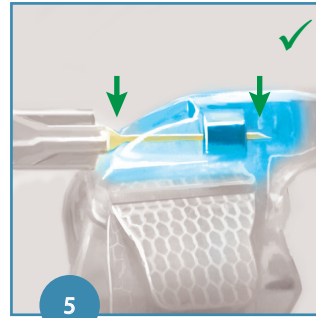
6a

This is not the correct angle. The needle is not in the slot.



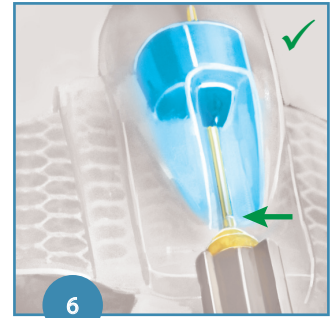
6b

This is not the correct angle. The needle is too far inside the slot.



5

Place the needle in the slot and pierce the septum again. Inject 4.5 ml of normal saline solution.

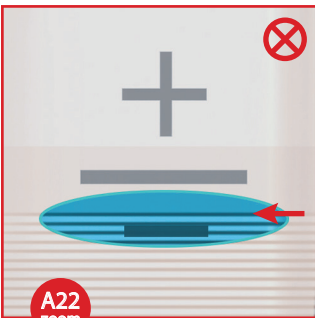


6

This is the correct position. Create a vacuum. Do not aspirate more than 5 ml.

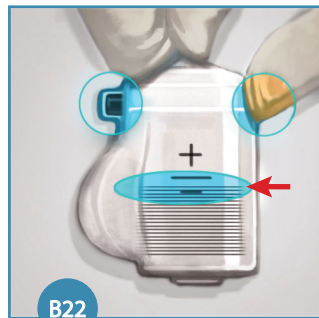
TROUBLESHOOTING

PREPARATION OF THE CUFF FOR IMPLANTATION / DEACTIVATION (From image 22)



A22 zoom

The spring is above the "+" sign. (DEVICE WRONGLY DEACTIVATED), NEXT TIME PRESS THE DEACTIVATION BUTTON FASTER.



B22

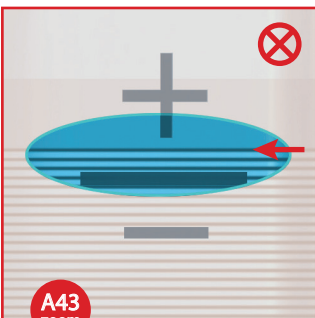
Press the activation button. (DEVICE IS NOW ACTIVATED. IT IS READY TO BE RE-DEACTIVATED)

REPEAT
PROCEDURE
FROM 14 TO 22

TROUBLESHOOTING

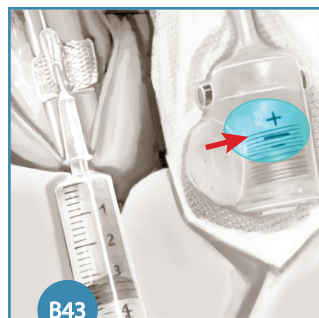
HOW TO CORRECT IT

CONTROL OF THE ISSUED PRESSURE (From image 43)



A43 zoom

The spring is above the midline: weak pressure is delivered.



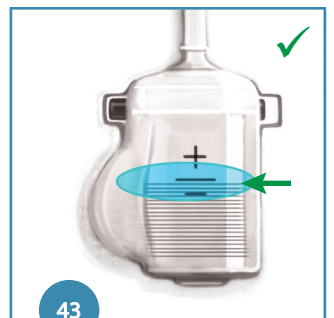
B43

Gently inject normal saline solution and wait for the spring to move down just below the midline position. Wait **20 seconds**. Check until the spring is stabilized just below the midline.



C43

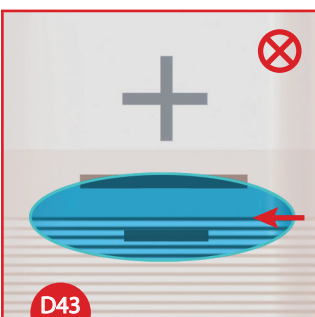
HOW TO CORRECT IT



43

The spring is just below the midline. The correct pressure is delivered into the cuff.

TROUBLESHOOTING



D43 zoom

If the spring is too far below the midline, too much saline solution is in the tank and you may have difficulties deflating the cuff.



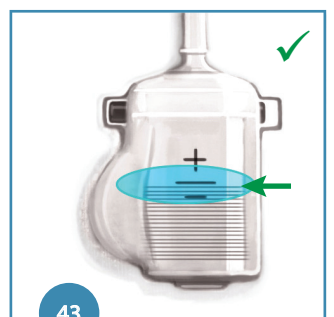
E43

Gently remove saline solution for the spring to move up just below the midline position. Wait **20 seconds** to check that the spring is well stabilized. Repeat the procedure if necessary.



F43

HOW TO CORRECT IT



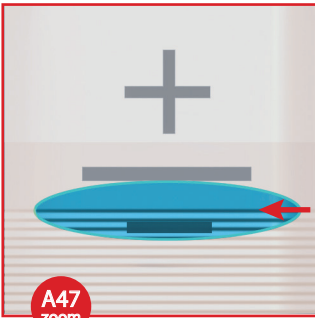
43

The spring is just below the midline. The correct pressure is delivered into the cuff.

TROUBLESHOOTING

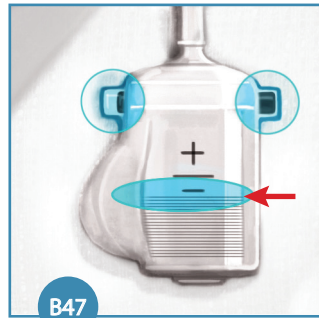
TROUBLESHOOTING

DEACTIVATION BEFORE IMPLANTATION (From image 47)



The spring is above the “-” sign.
(DEVICE WRONGLY DEACTIVATED), NEXT
TIME PRESS THE DEACTIVATION BUTTON
FASTER.

TROUBLESHOOTING

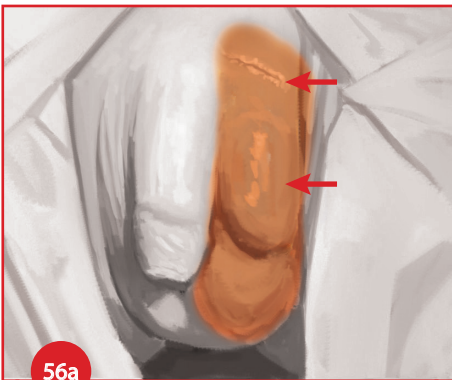


Press the activation button.
(DEVICE IS NOW ACTIVATED FOR THE
PROCEDURE TO BE REPEATED)

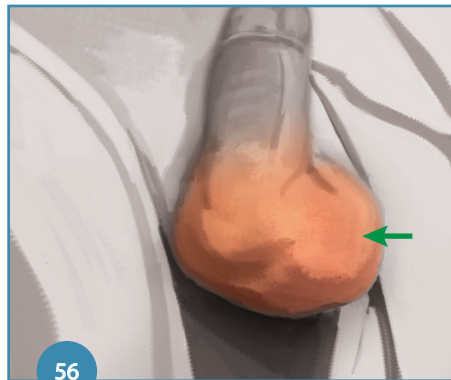
HOW TO CORRECT IT

REPEAT
PROCEDURE
FROM 44 TO 47

IMPLANTATION OF THE PUMP (From image 56)



The devices wings 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 not an aesthetic position. Insertion follows the same technique as implanting a testis prosthesis.



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

ACTIVATION AND GUARANTEE:

Properly complete the patient information form and send it back to ZEPHYR in order to activate the guarantee of mechanical failure. Do not forget to stick the traceability label of the ZSI 375 you have implanted.

Complete, in priority, the following information:

- Country, Hospital Name and Address
- Name of the urologist
- Date of implantation
- If possible name and telephone of the patient

Fax us or email us the document at: contact@zephyr-si.com.

Give the patient his implantation card

The bearer of this card has an implanted medical device

In case of emergency, phone: _____

Hospital: _____ Phone: _____

Dr: _____


Forename: _____

Last name: _____

Address: _____

State: _____

Country: _____



ZEPHYR Surgical Implants

Date of implantation: _____

Type of implanted medical device: **ZEPHYR Surgical Implants**
Urinary Artificial Sphincter
ZSI 375

REF: ZSI 375
REF: 3756

CE 042010 03786-033

ZEPHYR Surgical Implants, 13 rue Emile Decors, 69100, Villeurbanne, France

Place the traceability sticker here

FAX COMPLETED FORM TO: 00 33 (0) 4 72 11 36 81
ZSI 375/ ZEPHYR Surgical Implants 13 rue Emile Decors, 69100 Villeurbanne, France. contact@zephyr-si.com

PATIENT INFORMATION FORM

PATIENT NAME (LAST, FIRST, MIDDLE): _____ HOSPITAL: _____

DATE OF BIRTH: MONTH: _____ DAY: _____ YEAR: _____ STREET ADDRESS: _____

PATIENT ADDRESS: _____ CITY, STATE, POSTAL CODE, COUNTRY: _____

CITY, STATE, POSTAL CODE, COUNTRY: _____ HOSPITAL TELEPHONE: _____

INSURANCE CARRIER: _____ IMPLANTING HOSPITAL: _____

SOCIAL SECURITY NO.: _____ DATE OF SURGERY: MONTH: _____ DAY: _____ YEAR: _____

IN-PATIENT: OUT-PATIENT:

ETIOLOGY OF INCONTINENCE

POSTPROSTATECTOMY PHET-TUR NON-NEUROGENIC

NEUROGENIC SPINELUM-SINUSITIS Adult Trauma (Injury, Straddle Injury)

Spinal Trauma (Trauma/Fall) OTHER: _____

RECURRING INCONTINENCE

PROXIMAL LOCATION DISTAL LOCATION

PROXIMAL LOCATION DISTAL LOCATION

PAIN LOCATION

PATIENT DISEASE ACTOR (Please Explain): _____

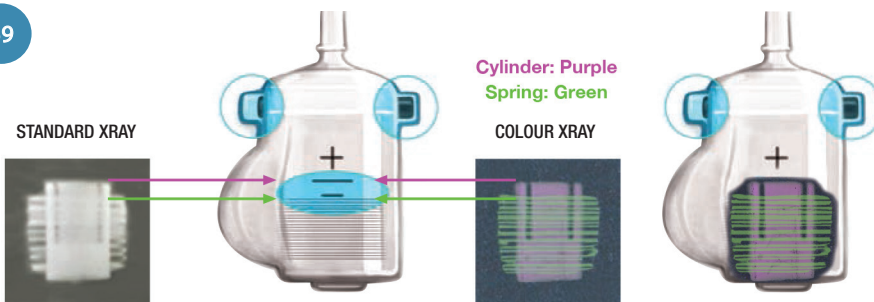
OTHER: _____

COMMENTS: _____

Component implanted: **ZEPHYR Surgical Implants**
Urinary Artificial Sphincter
ZSI 375
REF: 3756
CE 042010 03786-033

8 WEEKS AFTER

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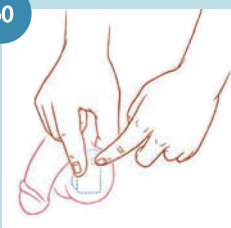


The Cylinders height has been designed to reach at the devices mid-line, making discernment easier when viewing an XRAY.

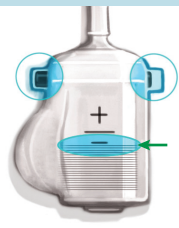
The Spring does not extend beyond the top of the Cylinder. It is compressed and remains compressed.
The device is properly deactivated.

The ZSI 375 is DEACTIVATED for 8 weeks after implantation: the tank is fully compressed, the cuff is deflated, the urethra is decompressed: the patient is incontinent. You can check that the ZSI 375 is deactivated with a scrotal radiography: the Spring is fully stressed; it sits below the top of the Cylinder.

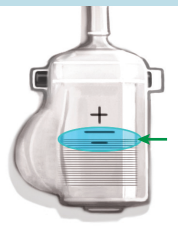
60



61



62

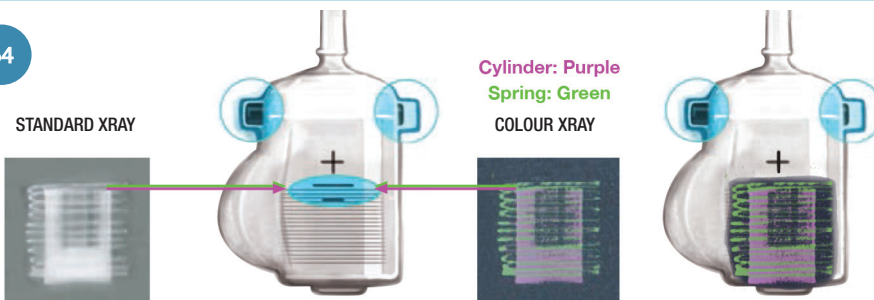


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To ACTIVATE the ZSI 375 after 2 months of healing, press the ACTIVATION BUTTON. The Spring is released and pushes the saline solution from the Spring tank to the cuff, drop by drop. Wait 120 seconds for the cuff to compress the urethra. The patient will be continent.

64



The Cylinders height has been designed to reach at the devices mid-line, making discernment easier when viewing an XRAY.

The Spring sits in line with the top of the Cylinder. It is decompressed and remains decompressed.
The device is properly activated.

The ZSI 375 is ACTIVATED: the Spring is decompressed and at the midline. The cuff is compressing the urethra: the patient is continent. You can check that the ZSI 375 is activated with a scrotal radiography: the Spring is decompressed; it sits in line with the top of the Cylinder.