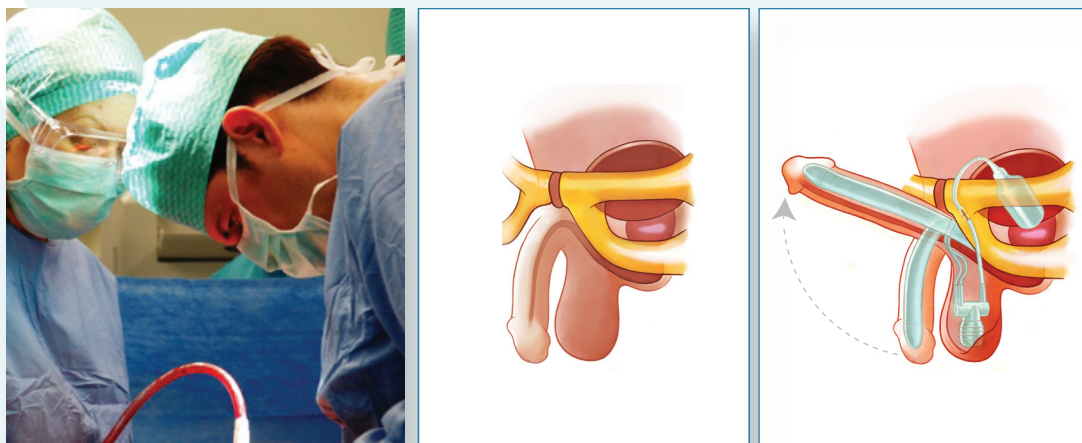


# MANUAL

*For Operating Room*

## HYDRAULIC PENILE IMPLANT ZSI 475



ZSI 475 - English V.11  
May 2013



LOCAL DISTRIBUTOR

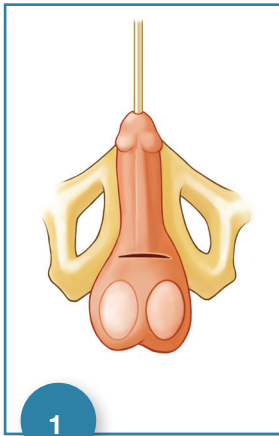
**ZEPHYR SURGICAL IMPLANTS SÀRL**

Route des Jeunes 4  
1227 Acacias (Geneva)  
SWITZERLAND

E-mail: [contact@zephyr-si.com](mailto:contact@zephyr-si.com)  
[www.zephyr-si.com](http://www.zephyr-si.com)

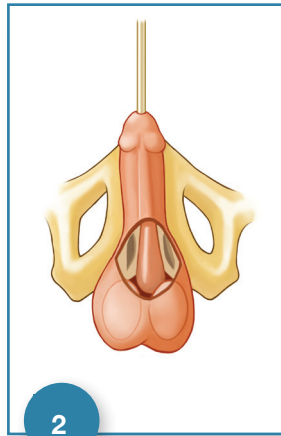


# PREPARATION OF THE PENIS, THE SCROTUM AND THE PELVIS FOR IMPLANTATION OF THE PENILE IMPLANT ZSI 475



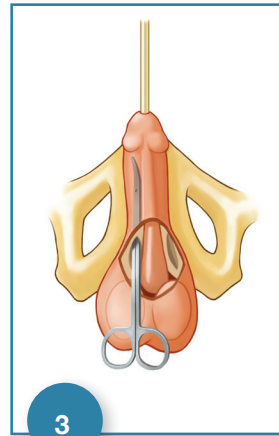
1

The patient is placed in a supine position. Insert a 16 Fr Foley catheter. Perform a peno-scrotal incision.



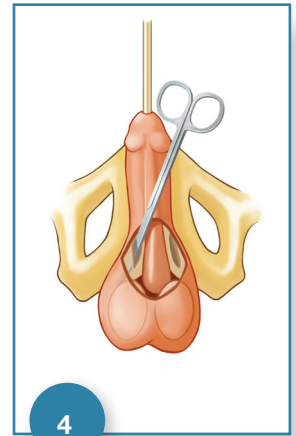
2

Expose the tunica albuginea of both corpus cavernosum to achieve deep exposure of the proximal corpora. Make an incision in each area.



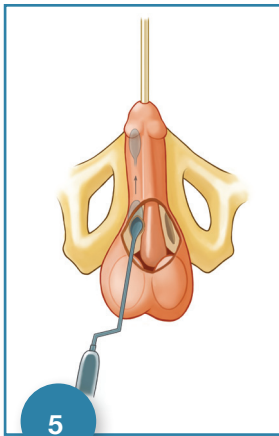
3

Carefully prepare the distal part of the corpus cavernosum with the scissors closed.



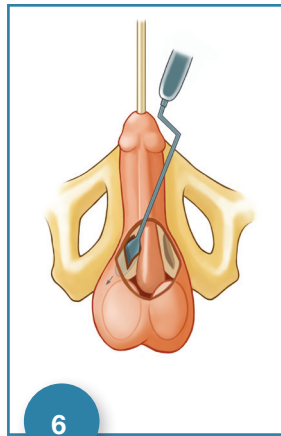
4

Carefully prepare the proximal part of the corpus cavernosum with the scissors closed.



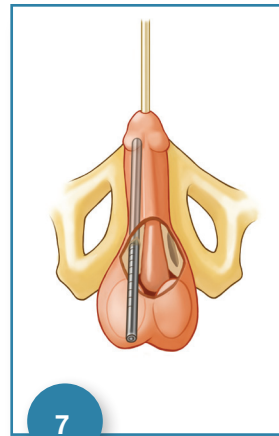
5

Dilate the distal part of the corpus cavernosum with dilators from 10 Fr Ch to 13 Fr Ch using Hegar candles.



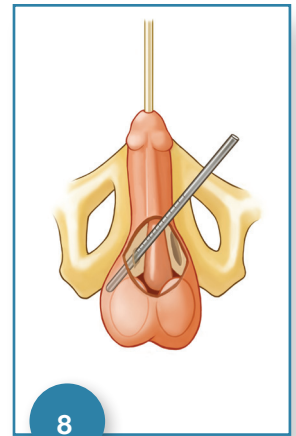
6

Dilate the proximal part of the corpus cavernosum with dilators from 10 Fr Ch to 13 Fr Ch using Hegar candles.



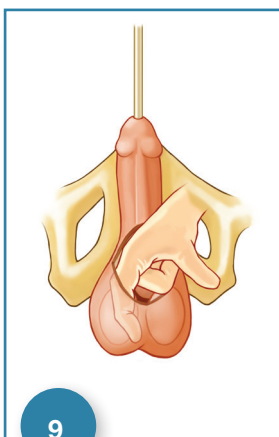
7

Measure the length of the distal part of the corpus cavernosum with the Introducer/ruler.



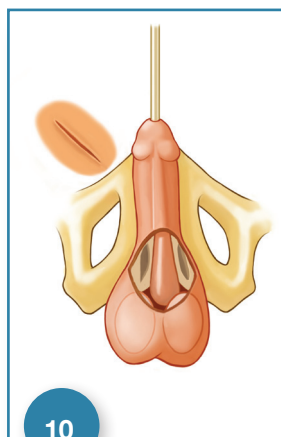
8

Measure the length of the proximal part of the corpus cavernosum with the introducer/ruler. Add the two measures for the total length of the corpus cavernosum.



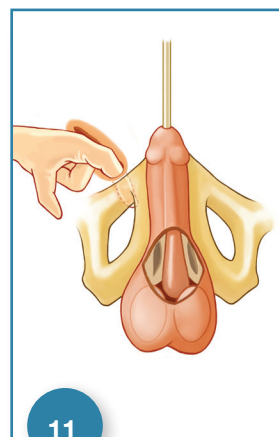
9

Prepare the scrotal pouch for the pump of the Penile Implant utilizing the subdartos pouch.



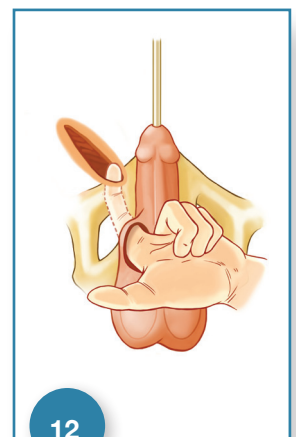
10

Perform an inguinal incision for the implantation of the reservoir in the pelvis.



11

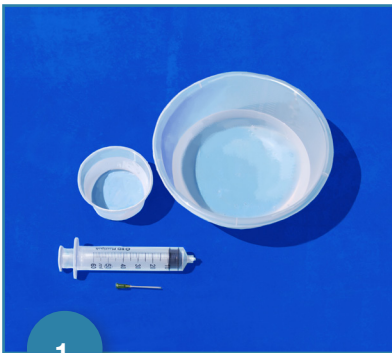
Follow the spermatic cord with the index finger to reach the pelvis. Then, create a space for the reservoir in the pelvis, beside the bladder.



12

To prepare for the passage of the armed tubing under the skin, join the peno-scrotal incision and the inguinal incision with a finger or dissect with a Kelly.

# PREPARATION OF THE CORPUS CAVERNOSUM PROSTHESIS AND THE PUMP



1

Supply and instrument requirements:  
 A bowl + saline solution,  
 A bowl + antibiotics,  
 A 60 ml syringe,  
 The cylindrical needle from the kit.



2

Change gloves. Only the surgeon should touch the device. Open the kit.



3

Prepare the corpus cavernosum prosthesis. Screw the inflatable distal part to the proximal parts and the pump.



4

Repeat the procedure with the second inflatable distal part.



5

Squeeze the pump to fill the assembling with normal saline solution.



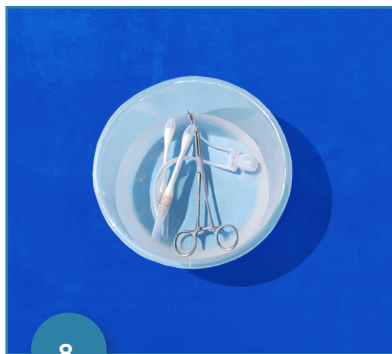
6

Remove the air and the saline solution from the prosthesis squeezing the valve and the inflatable parts at the same time.



7

Place a clamp on the tubing, avoiding the return of air back into the assembling.



8

Minimize the time the device is in open air. Plunge the assembling in antibiotics. The assembling is ready to be implanted.



## PREPARATION OF THE RESERVOIR



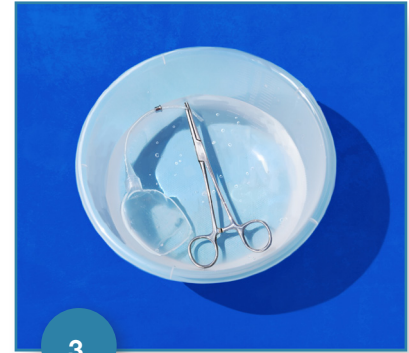
1

With the 60 ml syringe and the cylindrical needle, inject normal saline solution in the reservoir. Remove the air and the saline solution from the reservoir.



2

Place a clamp on the tubing to avoid air returning in the reservoir.



3

Plunge the reservoir in antibiotics. The reservoir is ready to be implanted.

## IV

## PREPARATION OF THE NEEDLE AND THE INTRODUCER



1

Place the suture into the eye of the needle and go through the hole of the inflatable distal part.

**Warning:** do not pierce the inflatable distal part.



2

Remove the needle. Repeat the same procedure with the second inflatable cavernous distal part.



3

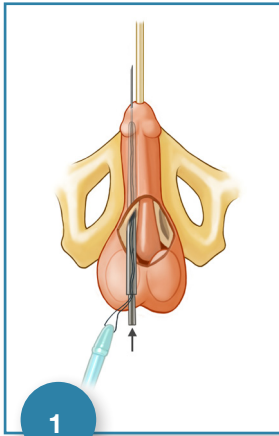
Place the two ends of the thread into the eye of the needle.



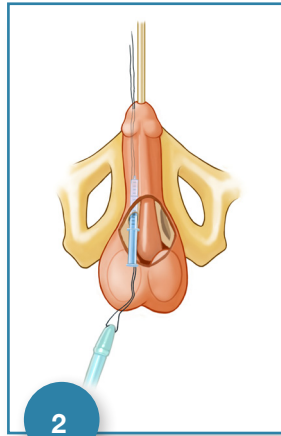
4

Introduce the bottom of the needle and the thread in the introducer. Push with the spatula to introduce the needle completely.

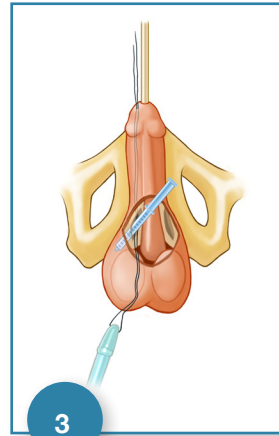
## IMPLANTATION OF THE PENILE IMPLANT



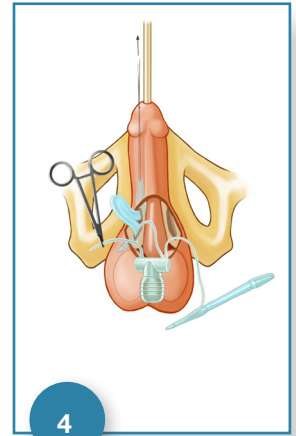
**1**  
Place the introducer into the corpus cavernosum. Push the needle through the glans penis with the piston. Pull up the needle and remove the introducer.



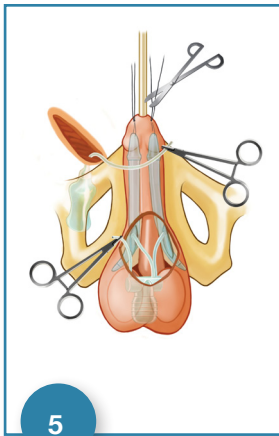
**2**  
Inject local antibiotics in the distal part of the corpus cavernosum.



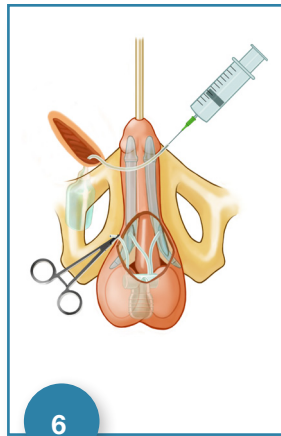
**3**  
Inject local antibiotics in the proximal part of the corpus cavernosum.



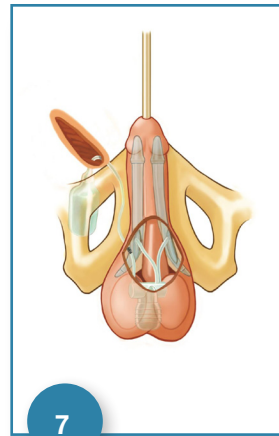
**4**  
Introduce the prosthesis into the corpus cavernosum. First the proximal part, then the distal part. With the thread, pull up the distal part of the prosthesis into the corpus cavernosum.



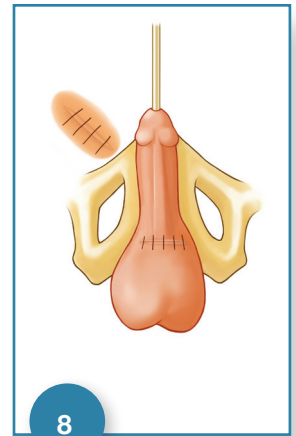
**5**  
Place the reservoir into the pelvis and the Pump into the scrotum. Cut the thread and remove them.



**6**  
Fill the reservoir with a maximum of 80 ml.



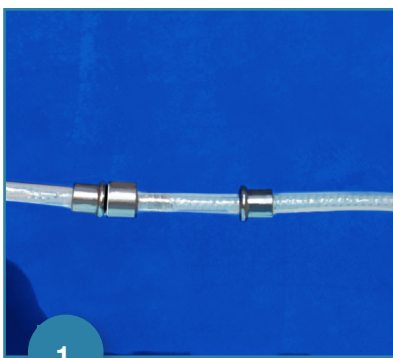
**7**  
Pass the armed tubing under the skin, through the passage. Connect the armed tubing together.



**8**  
Close and remove the Foley catheter after 24 Hours.

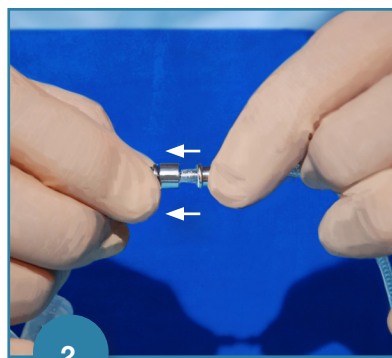
## CONNECTION OF THE ARMED TUBINGS

To ease the connection, soak the armed tubing, the connector and the rings with saline solution.



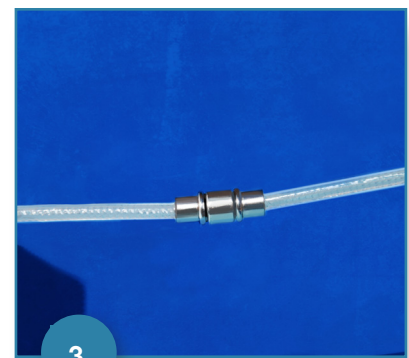
**1**

Connect the armed tubing with the connector.



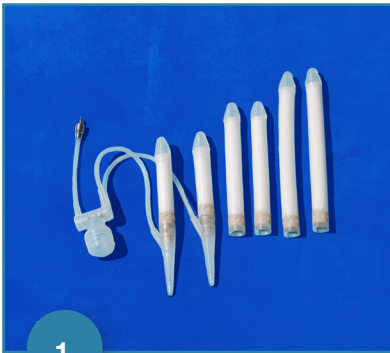
**2**

With your fingers, push the ring to the connector, to secure the connection.



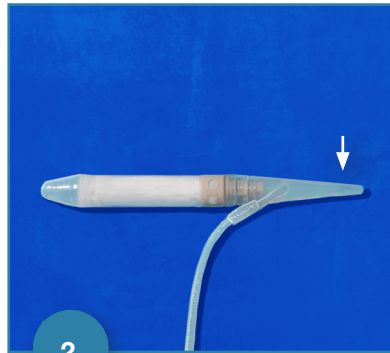
**3**

The reservoir is connected with the pump.



1

Three inflatable pairs of distal cavernous prosthesis are available: 13, 16 and 19 cm.



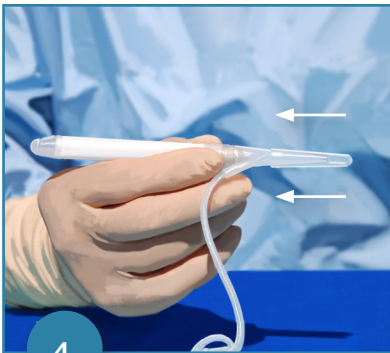
2

If a 12 cm is required : cut 1 cm of the proximal part of the cavernous corpus prosthesis at the mark.



3

To increase the length, proximal and distal extensor are available.



4

For length between 13 cm to 21 (19 cm + 3) use proximal extensor of 1, 2, 3 cm.



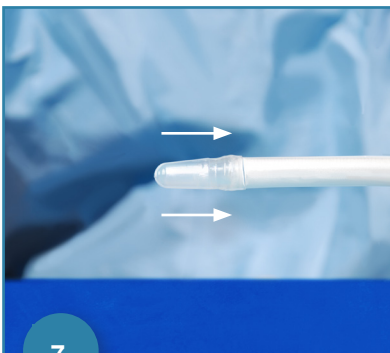
5

For length over 21 cm, use distal extensor of 1 or 2 cm. Turn the Clap inside out.



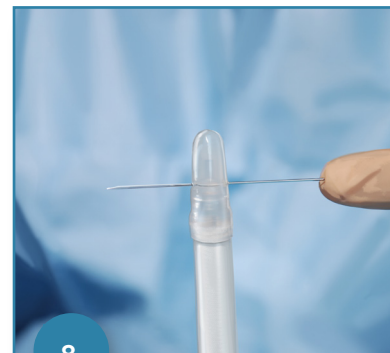
6

Place the distal extensor , with the flap inside out, over the top of the inflatable part. Soak the extensor and the inflatable part to ease the connection.



7

Push back in place the flap, over the inflatable part.



8

Pierce the extensor flap with the needle to go through the hole of the distal part with the thread.

## EXAMPLE:

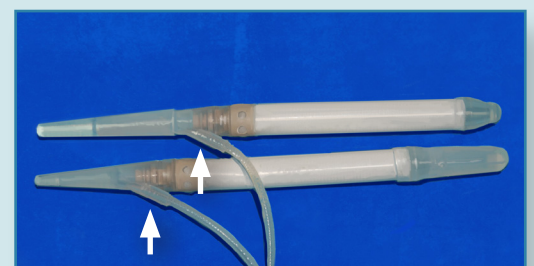
**Length of 17 cm :** use the 16 cm inflatable distal part + 1 proximal or distal extensor of 1 cm.

**Length of 15 cm :** use the 13 cm inflatable distal part + 1 proximal or distal extensor of 2 cm. Or Use the 16 cm inflatable distal part and cut 1 cm of the proximal part of the cavernous corpus prosthesis.

**Length of 24 cm :** use the 19 cm inflatable distal part + the 3 cm proximal extensor + the 2 cm distal extensor.

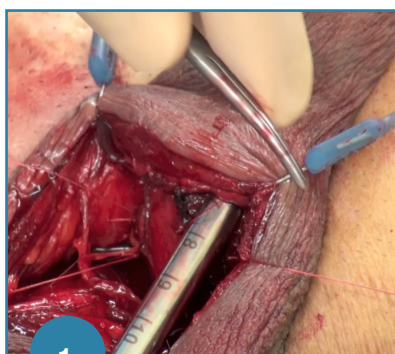
**For more than 24 cm** add more proximal and distal extenders.

>> Picture:  
Same length with proximal or distal extensor. The armed tubing exit is not at the same level.





## IMPLANTATION HIGH LIGHT



1

Measure the length of the distal part and proximal part of the corpus cavernosum with the introducer/ruler. The threads are the reference line to take the measure.



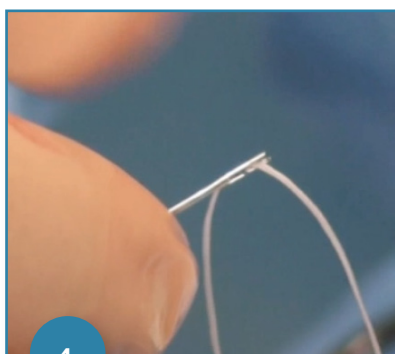
2

Pass the thread into the hole of the distal part of the prosthesis. You do not need a needle.



3

To avoid contact of the implant with the skin and the drape, use the upper part of the blister as a trail.



4

The needle has a special eye, you just need to push the thread into its eye to ease the assembling.



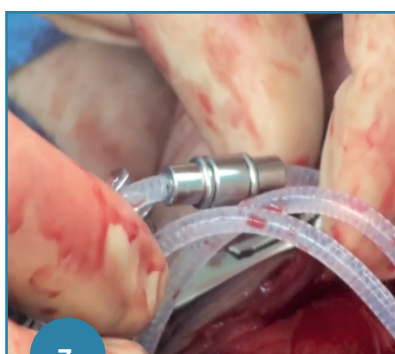
5

With the index finger, follow the spermatic cord to the inguinal space and pierce the transverse fascia to reach the pelvis. Open a space for the reservoir.



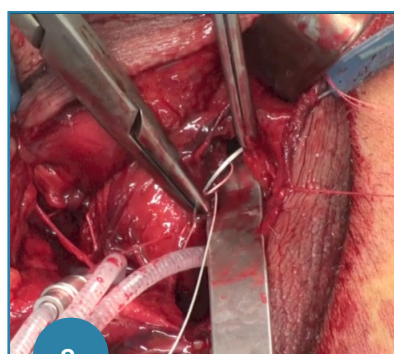
6

Push the reservoir into the pelvis through the passage previously made by the index finger.



7

To ease the connection, soak the armed tubing, the connector and the rings with saline solution.



8

Use the spatula to not pierce the inflatable distal part during closure.



9

Applied clean pressure to the scrotum and the penis for 24 hours.

# ACTIVATION OF THE GUARANTEE:

Properly complete the patient information form and send it back to ZEPHYR in order to activate the guarantee for mechanical failure. Do not forget to stick the traceability label of the ZSI 475 you have implanted.

Fax us or email us the document at: [contact@zephyr-si.com](mailto: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 : .....

Dr : ..... Phone: .....


Forename : .....

Last name : .....

Address : .....

State : .....

Country : .....



ZEPHYR Surgical Implants SÀRL

Date of implantation ..... / ..... / .....

(m/d/y)

Type of implanted medical device

**PENILE IMPLANT**

**ZSI 475**

ZF 6301

**PLACE THE TRACEABILITY LABEL STICKER HERE**

ZEPHYR Surgical Implants SÀRL, Route des Jaunes 4, 1227 Acacias Geneva SWITZERLAND

**FAX COMPLETED FORM TO: +41 22 327 1027**  
**ZSI 475/ ZEPHYR Surgical Implants** rue du Conseil-Général 14, CH - 1205 Geneva, Switzerland [contact@zephyr-si.com](mailto:contact@zephyr-si.com)

**PATIENT INFORMATION FORM**  
 IMPIANT PENILE ZEPHYR - FICHE D'INFORMAZIONI DEL PAZIENTE - FORMULAIRE D'INFORMATION DU PATIENT - PATIENTEN INFORMATIONSBLATT  
 PROFILI DEL PENILE ZEPHYR - MODULO DI INFORMAZIONI DEL PAZIENTE - FORMULÁRIO DE PENS - ZEPHYR - FORMULÁRIO DE INFORMAÇÃO DO PACIENTE

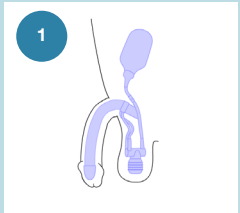
<b>PATIENT NAME</b> (LAST) (FIRST) (MIDDLE) <small>NOI DE PAZIENTI - NOME DEL PAZIENTE - NOME DEL PAZIENTE - NOMME DEL PAZIENTE</small>	<b>HOSPITAL</b> <small>HOSPITAL - HOSPITAL - HOSPITAL - HOSPITAL</small>
<b>DATE OF BIRTH</b> (DAY) (MONTH) (YEAR) <small>DATA DI NASCITA - GIORNO DEL Mese - ANNO DI NASCITA - TAGLIA DI NASCITA</small>	<b>STREET ADDRESS</b> <small>INDIRIZZO - STRASSE - ADRESSE - ADRESSE</small>
<b>PATIENT ADDRESS</b> <small>INDIRIZZO DI ABITAZIONE - INDIRIZZO DEL PAZIENTE - INDIRIZZO DEL PAZIENTE</small>	
<b>CITY, STATE, POSTAL CODE, COUNTRY</b> <small>CITTA' - STATO - CODICE POSTALE - CATEGORIA PAESE</small>	
<b>HOSPITAL TELEPHONE N°</b> <small>NUMERO TELEFONO OSPEDALE - TELEFONO DEL PAZIENTE</small>	
<b>INSURANCE CARRIER</b> <small>COMPAGNIA DI ASSICURAZIONE SANITARIA - ASSICURAZIONE SANITARIA</small>	<b>IMPLANTING SURGEONS</b> <small>CHIRURGI E ATTI PRECEDENTI AL RISPONDERE - IMPIANTAZIONE</small>
<b>LAST CONSULTATION DATE</b> <small>ULTIMO VISITO</small>	<b>FIRST CONSULTATION DATE</b> <small>PRIMO VISITO</small>
<b>SOCIAL SECURITY NO.</b>	<b>DATE OF SURGERY</b> (DAY) (MONTH) (YEAR) <small>DATA DELL'INTERVENTO - GIORNO DEL Mese - ANNO</small>
<b>FOR HOSPITAL USE - IMPRINT PATIENT I.D. CARD ABOVE</b> <small>RESERVE AL USAGE DE L'HOSPITAL - SPOURVE NE MERE</small>	
<b>IN-PATIENT</b> <input type="checkbox"/> <small>IN-PATIENT - IN-PATIENT - IN-PATIENT - IN-PATIENT</small>	
<b>OUT-PATIENT</b> <input type="checkbox"/> <small>OUT-PATIENT - OUT-PATIENT - OUT-PATIENT - OUT-PATIENT</small>	

Component implanted

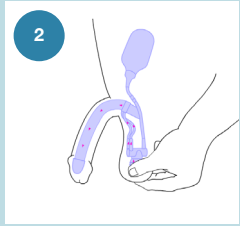
**PLACE THE TRACEABILITY LABEL STICKER HERE**

ZF62v1

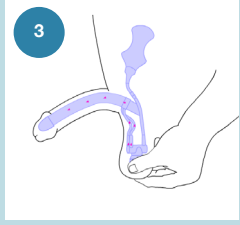
## 8 WEEKS AFTER IMPLANTATION



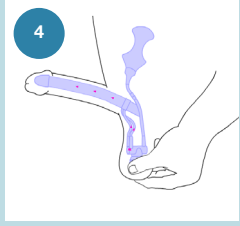
Penile cylinders are empty, the penis is flaccid.



Pressing the pump, the cylinders are filled to produce an erection.



Press the pump until the penis is suitably rigid.



By pressing the valve at the top of the pump, cylinders are flushed in the tank, so that the penis becomes flaccid again.

## OBSERVATIONS:

The diameter of the cylinders increase + 20% when inflated.

