ZSI 375 TECHNICAL MANUAL

Zephyr Surgical Implants

Version 4, Nov 2015

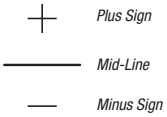
The ZSI 375 is a device composed of two separate functioning components:

- The Hydraulic Circuit (saline solution in blue)
- The Compensation Pouch (saline solution in purple)

The Hydraulic Circuit is responsible for the inflation and aspiration of the cuff, which is wrapped around the urethra, as the saline solution is circulated around the circuit by the pump button.

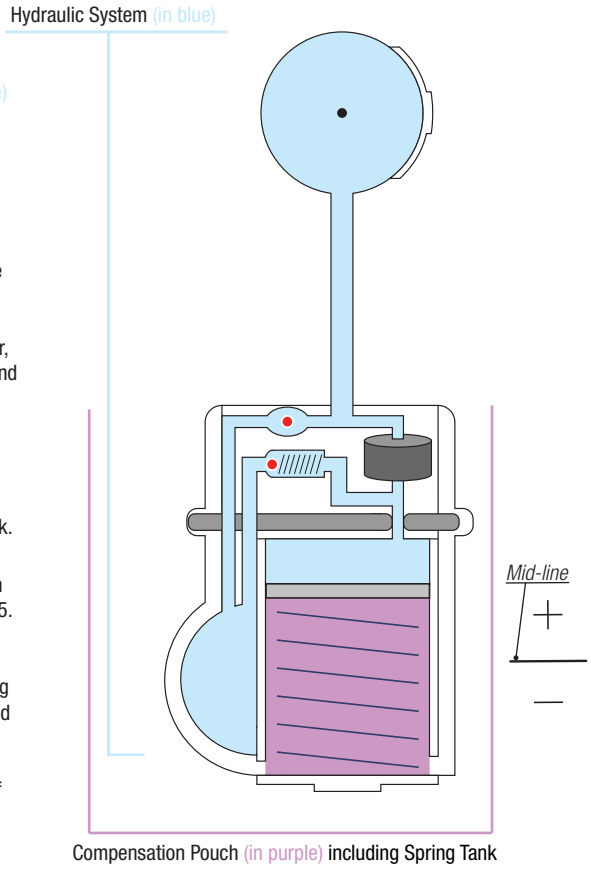
The Compensation Pouch is a sort of reservoir, which allows the Hydraulic Circuit to inflate and aspirate the cuff when the pump button is pushed.

The saline solution of the two components never comes in contact and is maintained separated by the piston within the Spring Tank.



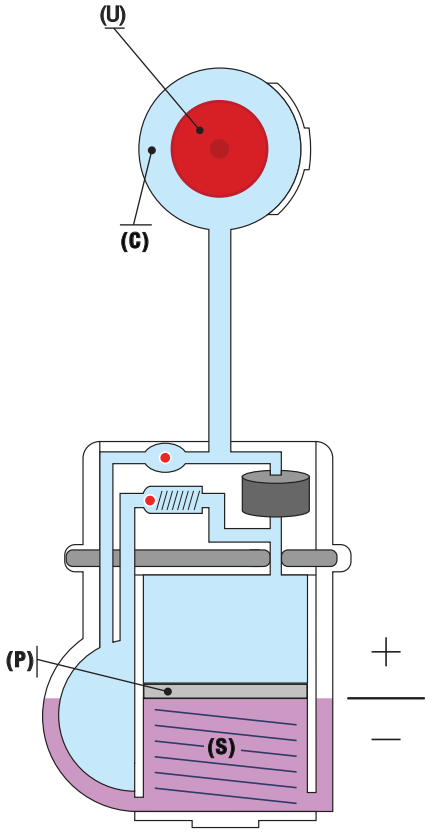
These three signs are found on the Pump Device of the ZSI 375.

Throughout this document notice the position of the Spring with respect to the *mid-line* and *minus sign*. What state the device is in can be easily identified by the relationship of the Spring and these given signs.



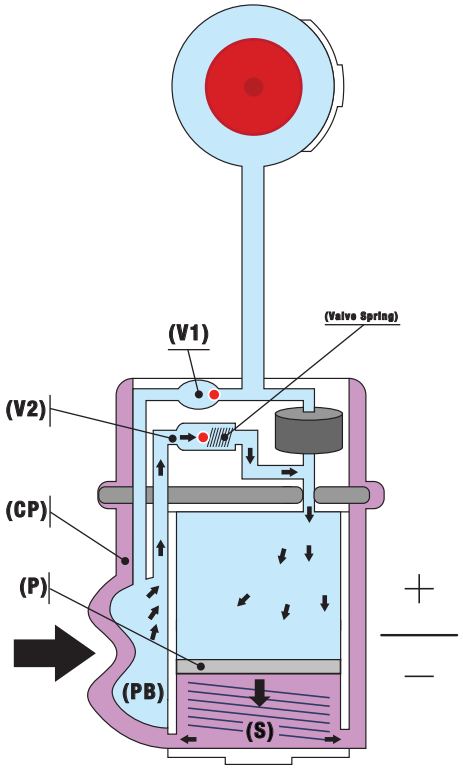
DEVICE ACTIVATED Patient is continent

The spring **(S)** is decompressed.
The piston is **(P)** raised.
Saline solution maintains optimal pressure on the Cuff **(C)** around the urethra **(U)**.



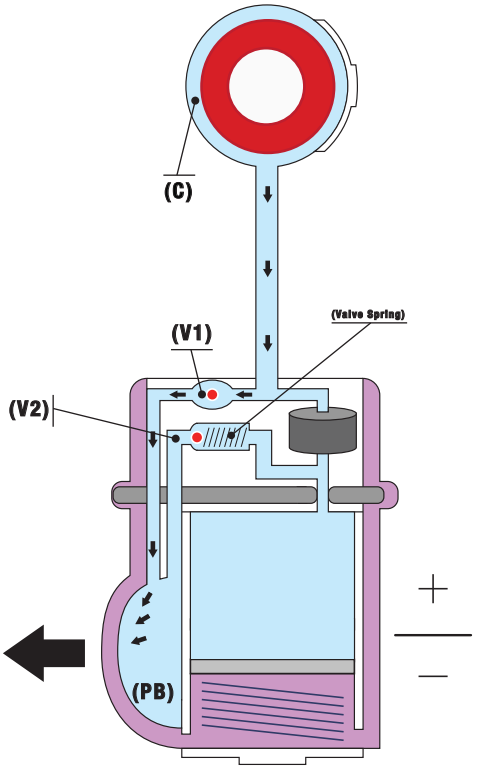
MICTURATION STEP 1

Patient presses Pump Button **(PB)** closing Valve #1 **(V1)** and opening Valve #2 **(V2)**. Valve #2 **(V2)** allows the flooding of saline solution into the Spring Tank **(ST)**, compressing the Piston **(P)** and the Spring **(S)**, in turn, flooding the Compensation Pouch **(CP)** with saline solution.



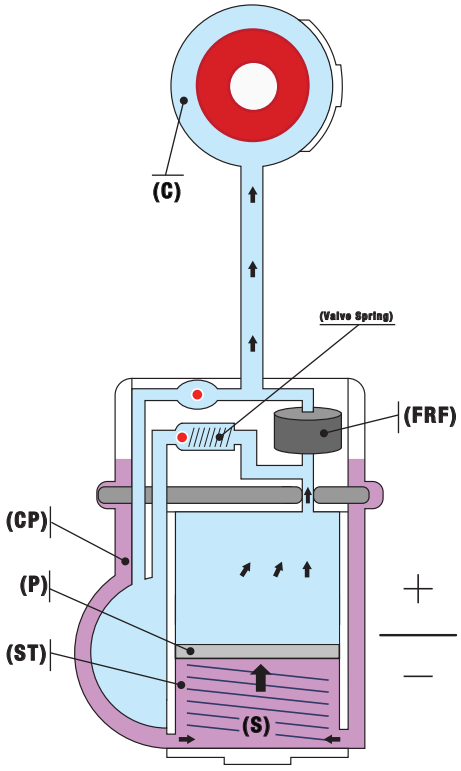
MICTURATION STEP 2

When the patient releases the Pump Button **(PB)** the negative pressure opens Valve #1 **(V1)** and closes Valve #2 **(V2)**, aspirating the saline solution from the Cuff **(C)** into the Pump Button **(PB)** pouch, releasing the Cuff pressure so patient can urinate.



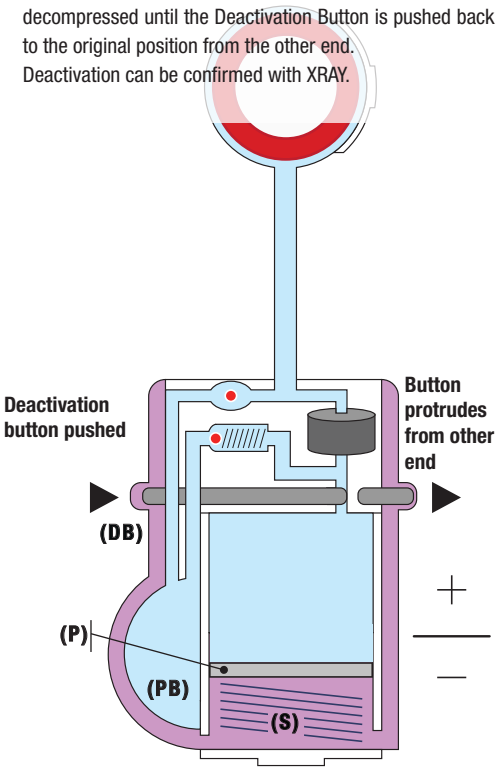
MICTURATION STEP 3

The Spring **(S)** begins pushing back the Piston **(P)**. The Piston floods back the saline solution into the Cuff **(C)**, compressing it. The Flow is regulated by the Flow Restriction Filter **(FRF)**.
The saline solution in the Compensation Pouch **(CP)** then returns into the Spring Tank **(ST)**.



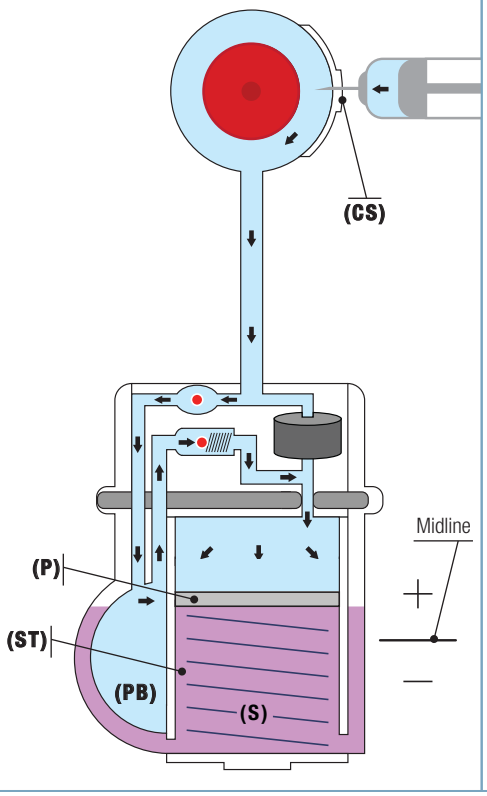
DEVICE DEACTIVATED

Device properly deactivated with decompressed cuff. Deactivation Button **(DB)** located above the Pump Button **(PB)**.
Follow micturation steps 1 and 2. At step 2, press Pump Button **(PB)** twice, at the end of which, when the Pump Button **(PB)** pouch is filled with saline solution from the Cuff, press the Deactivation Button **(DB)**. This maintains Piston **(P)** and Spring **(S)** compressed and the Cuff **(C)** decompressed until the Deactivation Button is pushed back to the original position from the other end.
Deactivation can be confirmed with XRAY.



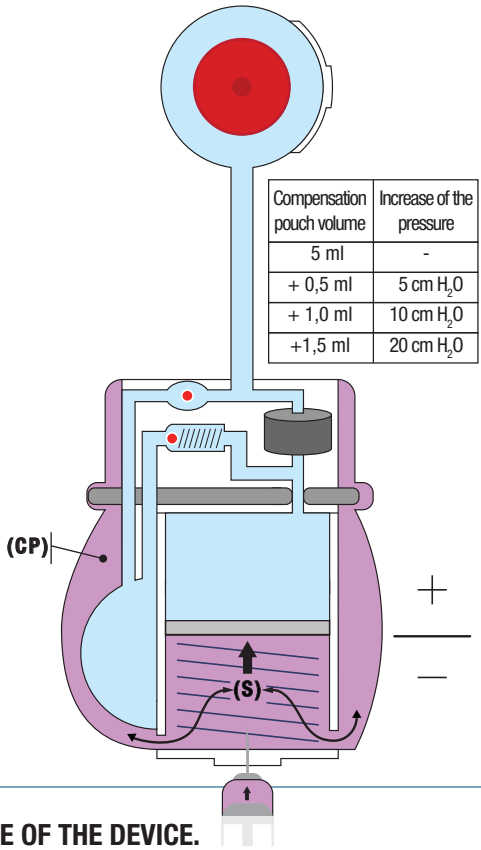
ADJUST SPRING POSITION

During implantation, if the Spring **(S)** needs to be adjusted, use syringe to inject saline solution through the Cuff Septum **(CS)**to bring the Spring **(S)** at Midline. Solution goes down the Cuff tube into Pump Button **(PB)** pouch and into Spring Tank **(ST)** 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 saline solution directly into Compensation Pouch **(CP)**. When more than 5 ml are injected, pressure is increased.
The device is then under the combined pressure of the Spring **(S)** and Compensation Pouch **(CP)**. The greater the volume of solution, the greater the pressure.

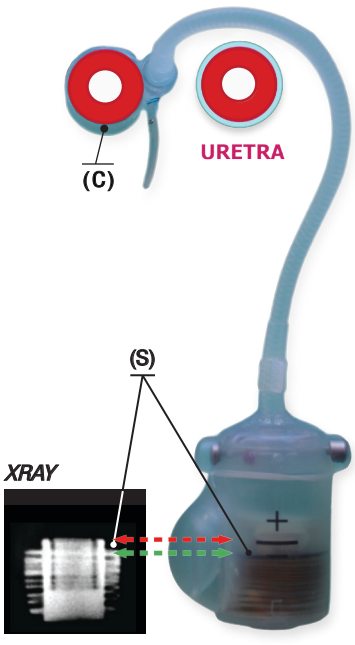


Compensation pouch volume	Increase of the pressure
5 ml	-
+ 0,5 ml	5 cm H_2O
+ 1,0 ml	10 cm H_2O
+1,5 ml	20 cm H_2O

THE POSITION OF THE SPRING IS DIRECTLY RELATED TO THE PRESSURE OF THE DEVICE.
EACH OF THE FOLLOWING EXAMPLES DEMONSTRATE DIFFERENT POSSIBLE STATES OF THE CUFF
(For more information about XRAY's, refer to Manual 'How to Perform an Xray')

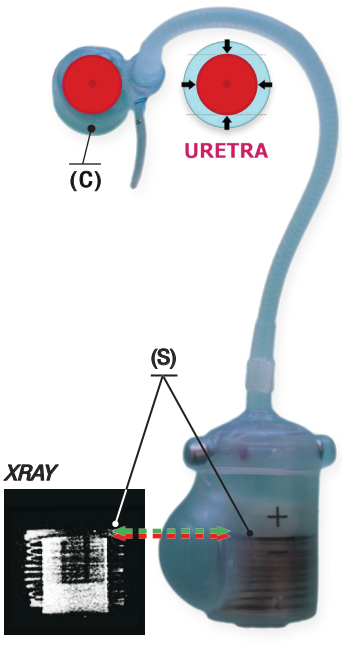
Device Deactivated

0- Spring **(S)** permanently compressed.
Cuff **(C)** permanently decompressed.
Urethra permanently decompressed.
Patient is incontinent

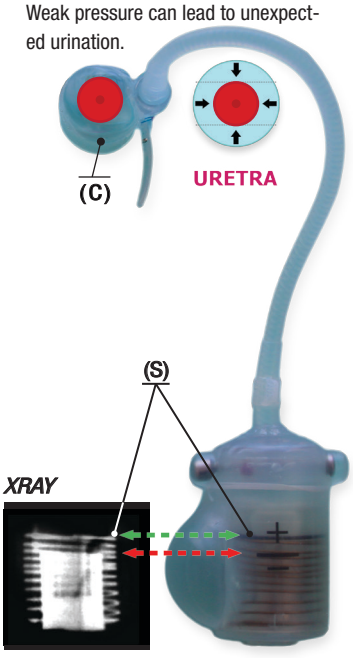


The following examples demonstrate an active and properly functioning device

1- Spring **(S)** aligned at mid-line.
Urethra healthy and compressed with a pressure of 90-100 H_2O.
Patient should be continent.



1bis- Spring **(S)** sits above the mid-line, meaning device lacks adequate pressure, and/or urethra is atrophied and/or bubbles remain in Hydraulic Circuit during preparation. Weak pressure can lead to unexpected urination.



1ter- Spring **(S)** looks completely decompressed, well above the mid-line.
Either:
- Device is leaking solution, and/or
- Urethra has atrophied, and/or
- Urethra has suffered necrosis.