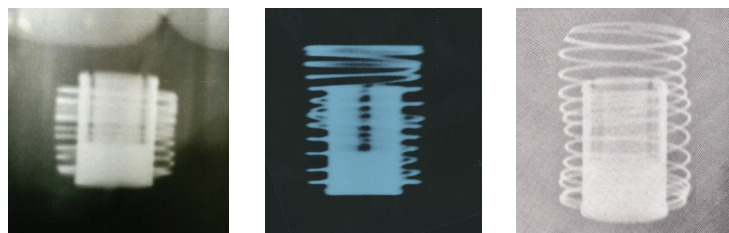


1. PERFORM A RADIOGRAPY

If the patient is experiencing incontinence after the device has been implanted, perform an X-ray to obtain a better understanding of the state of the spring which will allow you to deduce the state of the pressure in the cuff.

The X-ray image of the device should come out like these examples. The device in clear profile, the spring easy to identify, the cylinder clear to see.

For more information about how to perform, read and understand the state of the spring from an X-ray image, please consult the 375 How to Perform and Read an X-ray Manual.



2. INCREASE DEVICE PRESSURE THROUGH THE COMPENSATION POUCH

Note 1: The pressure of the ZSI 375 can be increased by injecting 0.5 to 2ml of saline solution directly into the compensation pouch. It should always be the Urologist's responsibility to administer the increase of pressure, as it is a medical matter. The patient should also be aware that increasing the pressure of the device could possibly lead to urethral atrophía, erosion and/or necrosis.

Note 2: Before any increase of device pressure, an evaluation should be made of the patient to clearly understand their incontinence. It is essential to understand the patient's level of incontinence before the device was implanted and how far from social continence he is today, (0-1 pad per day).

An increase of pressure should only be performed after a Urologist has evaluated the patient and advises that such action should be taken. Inject 0.5 to 2ml of saline solution into the compensation pouch to increase device pressure. The amount of saline solution injected should be recorded.

REMEMBER

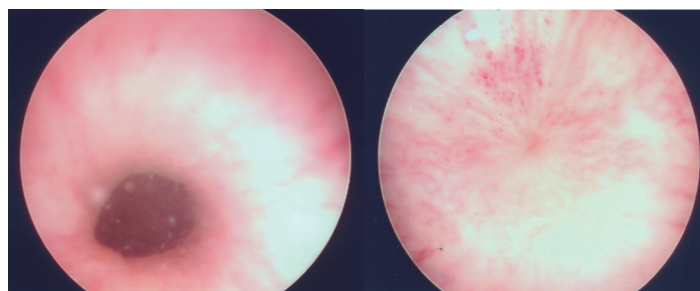
A Huber needle should be used for all injections concerning the device

Compensation pouch volume	Increase of the pressure
5 ml	-
+ 0,5 ml	5 cm H ₂ O
+ 1,0 ml	10 cm H ₂ O
+1,5 ml	20 cm H ₂ O



3. PERFORM A CYSTOSCOPY

If the patient is still not continent or his situation has not improved sufficiently, perform a cystoscopy. Look for the good functioning of the cuff and for an urethral erosion.



4. CALIBRATE THE SPRING AT INITIAL POSITION FOR OPTIMAL PRESSURE

If the patient is still not continent or his situation has not improved sufficiently, it probably means that the spring is too decompressed and should be positioned back into its optimum position, in line with the top of the cylinder. To do so, saline solution must be injected directly into the hydraulic circuit. This means that the patient must undergo another operation to have the pressure of the device increased.

If so, the saline solution that was injected into the compensation pouch must be removed before any saline solution is injected into the hydraulic circuit.

REMOVING ADDED SALINE SOLUTION FROM THE COMPENSATION POUCH

Using a Huber needle remove the previously added saline solution from the compensation pouch.

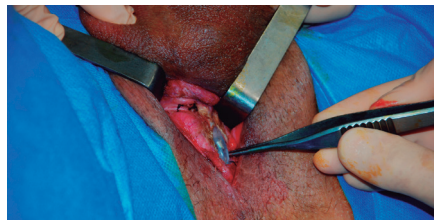
We strongly recommend that you note the amount of saline solution added into the compensation pouch. If for some reason you forget and/or the notation is lost, you can pierce the septum of the compensation pouch with a Huber needle, without the syringe, and the extra added saline solution will drip out until the pressure balances the spring back at the mid-line.



SPRING ADJUSTMENT SHOULD BE DONE IN THE OPERATING ROOM



1. Place the patient in lithotomy position. Use the approved preoperative scrubbing procedure to clean the patient. Prepare and drape for a perineal incision and pin-point the position of the cuff through the perineal skin.



2. With the electric bistoury perform a perineal incision by dissecting the tissue to uncover the septum of the cuff. Do not be afraid of damaging the silicone. It needs 200° Celsius to melt.

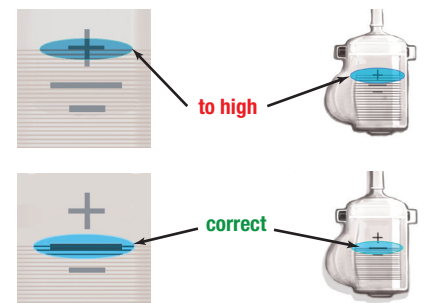


3. Push the pump unit through the incision that has just been made in the perineal area and open the tissues covering the pump unit using the electric bistoury only.

ADJUSTMENT OF PRESSURE

The pressure of the ZSI 375 can be increased by positioning the upper part of the spring in line with the mid-line sign or just a fraction below.

1. Fill a syringe with saline solution, one equipped with a 25 gauge HUBER needle.
2. Clean the septum of the cuff with saline solution.
3. Pierce the septum of the cuff.
4. Inject saline solution until device reaches normal pressure of 90-100cm H2O, until the upper part of the spring is placed in line with the mid-line sign, or, just a fraction below.
5. Remove the HUBER needle.
6. Check that you can empty the cuff by pressing the pump button.
7. Place the pump unit back in the scrotal pouch. Suture the scrotal pouch and the perineal incision to complete the procedure.



If incontinence still persists, inject the 1 or 2ml of saline solution back into the compensation pouch.