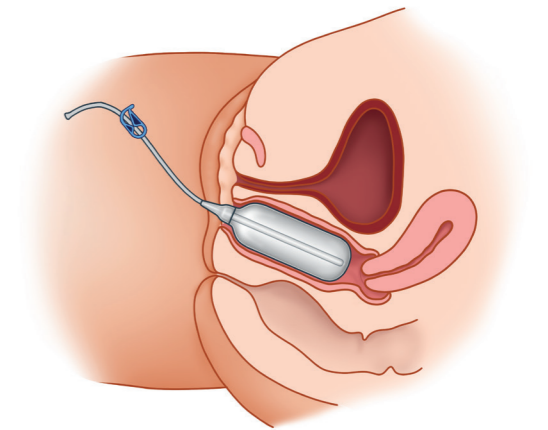




# ZSI 200 NS EXPANDER VAGINAL EXPANDER



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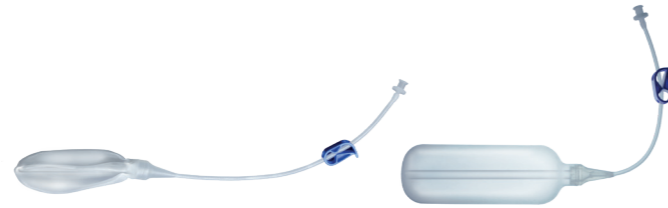
Instruction for use  
after radiotherapy

- One inflatable cylinder, two sizes.
- For more information, visit [www.zsimplants.ch](http://www.zsimplants.ch)

## ZSI 200 NS VAGINAL EXPANDER AFTER RADIOTHERAPY, INSTRUCTION FOR USE

### DESCRIPTION

The device is an inflatable cylinder with a clamp and a connector.  
The device is made of silicone.  
Lengths available: 90 mm & 120 mm  
Diameter inflated: 40 mm



### OBJECTIVE:

The treatment of gynaecological (vaginal, cervical or uterine), anal and rectal cancers commonly requires pelvic radiotherapy. Vaginal stenosis is a common side effect of pelvic radiotherapy and is characterised as an abnormal vaginal canal obstruction caused by scar tissue formation. The reported incidence of radiation-induced vaginal stenosis varies from 1.2% to 88%.<sup>1</sup>  
The ZSI 200 Vaginal Expander can prevent vaginal stenosis, vaginal adhesion and dyspareunia in patients who receive pelvic radiotherapy.

### INSTRUCTION FOR USE:

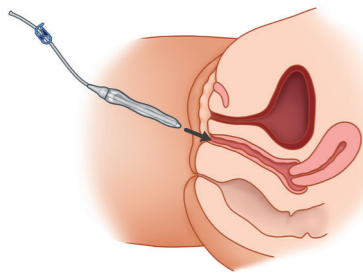
The patient can start using the ZSI 200 Vaginal Expander about 2-4 weeks after her last radiotherapy treatment, depending on when vaginal irritation has decreased. The practitioner will advise the patient when to start.

To use the ZSI 200 Vaginal Expander, it is recommended that the patient finds a place where she can lie down comfortably (e.g. a bed or a sofa) with the knees slightly bent and the feet flat. The legs should be shoulder-width apart; the aim being to easily reach the opening of the vagina with her own hand.

Prior to insertion, the use of a water-soluble lubricant is recommended; this should be applied to the ZSI 200 Vaginal Expander and around the entrance to the vagina. The patient should also relax their pelvic floor muscles.

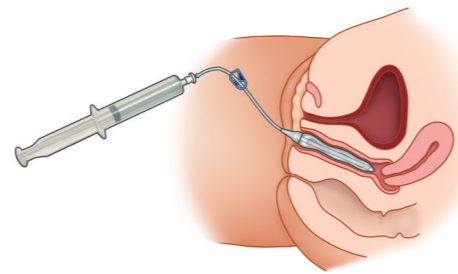
The recommended use of the ZSI 200 Vaginal Expander is the following:

1



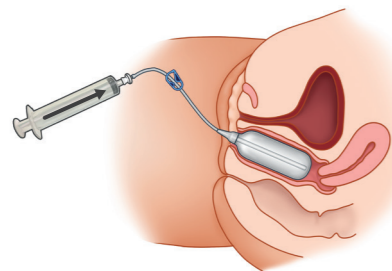
The deflated ZSI 200 Vaginal Expander should be inserted inside the vagina. It should be inserted as deeply as is comfortable, without forcing it. A hand mirror can be used to find the vaginal opening if needed.

2



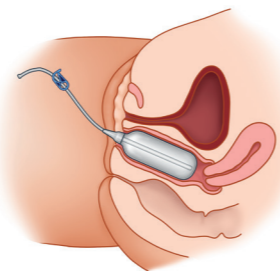
The ZSI 200 Vaginal Expander must be filled with water up to 100ml for the ZSI 200 L90 or 130ml for the ZSI 200 L120.

3



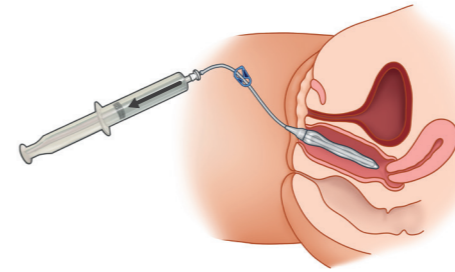
The tube must be clamped with the provided clamp so that water cannot escape. The syringe then can be removed.

4



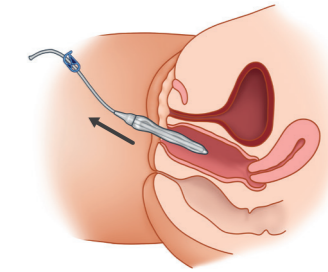
The patient should gently squeeze the ZSI 200 Vaginal Expander with her pelvic muscles (the Vaginal Expander shouldn't be squeezed so hard that the patient pushes it out), and then the patient should allow her muscles to relax. This process should be repeated a few times.

5



The syringe should be attached to the connector on the tube, the clamp should be open and the ZSI 200 Vaginal Expander emptied.

6



The ZSI 200 Vaginal Expander should be removed gently from the vagina.

It is common to use the ZSI 200 Vaginal Expander for c. 5–10 minutes at a time, 3-4 times a week.<sup>2,3</sup> The treatment is to be used for an indefinite time,<sup>2,3</sup> according to the need of each patient (sexual activity and/or clinical follow-up), given that vaginal narrowing can occur up to 3 years after treatment finishes.

### WARNING:

The patient should be made aware that, in case of any questions or problems, it is important she talks to her practitioner at her next appointment (e.g. she should seek medical help in case she experiences pain, discomfort, or bleeding during vaginal expansion).

**The Vaginal Expander must be filled with water. In no circumstances, should the device be filled with air; Air leakage can cause vaginal damage.**

### OTHER CONDITIONS:

ZSI 200 Vaginal Expander therapy can also help reduce adverse symptoms from many vaginal conditions, including:

- Vaginismus
- Dyspareunia
- Vulvodinia\*
- Vaginal atrophy
- Pelvic pain and chronic conditions resulting from menopause

\*Vaginal expander therapy can help reduce pain during sexual intercourse and can also alleviate symptoms from common vaginal conditions.

### SEXUAL INTERCOURSE:

The patient can have sexual intercourse 2 weeks after the radiotherapy treatment ends, unless she experiences a lot of bleeding or pain. If the patient has sexual intercourse, the use of the ZSI 200 Vaginal Expander might not be necessary. Its use should be resumed as soon as the patient stops having regular sexual intercourse (or any other penetration into the vagina).

It is important that the patient feels comfortable when having sexual intercourse. It is recommended that she talks to her sexual partner about changes and side-effects that she experiences.

### REFERENCES:

1. International Clinical Guideline Group. International Guidelines on Vaginal Dilatation after Pelvic Radiotherapy; National Forum of Gynaecological Oncology Nurses; Owen Mumford: Oxon, UK, 2012.
2. Guidelines on vaginal dilator use after pelvic radiotherapy, H. Jefferies, S. Hoy, R. McCahill, A. Crichton, sexual health, vol: 103, issue: 30, page: 28-29
3. Consensus for vaginal stenosis prevention in patients submitted to pelvic radiotherapy Sabrina Rosa de Lima Matos et al. PLOS ONE, <https://doi.org/10.1371/journal.pone.0221054> August 9, 2019