

Instructions for Use 1/2 Efemia Bladder Support

Intended Use

Efemia is a medical device intended to temporarily reduce stress induced urine leakage in women by supporting the mid-urethra through the vaginal wall.

Stress Incontinence

Stress urinary incontinence (SUI) is defined as involuntary leakage on effort or exertion, or on sneezing or coughing. The condition is not defined by the amount or the frequency of leakage. Many experience incontinence as a social and hygienic problem. SUI may also cause irritation, eczema and infections in the genital area, caused by the repeated exposure to urine.

Recommendations for Use/

Device Description

Efemia is a reusable vaginal insert made from medical grade silicone. It is intended to be used to temporarily alleviate involuntary urine leakage caused by stress incontinence.

It can be used continuously for up to 16 hours a day or on occasions when you might expect an episode of SUI.

The device is available in 3 diameter sizes (30, 35 and 40 mm) for best comfort and performance. You might have to try more than one size to find which one offers most comfort and effective reduction of incontinence. Some women may also have a degree of pelvic organ prolapse which might make the device hard to fit.

You might experience that the device causes friction on the labia or mucosa, and this might lead to irritation or chafing. Such experiences are highly individual. It might be because the area around your vulva and/or your vagina is dry or extra sensitive. If you already know you are extra sensitive in these areas, or experience any irritation or chafing, you can try using some water-based lubricant with the device.

Do Not Use Efemia

If you are pregnant, the effects of the device during pregnancy have not been studied.



Precautions

- Use water based lubricant to avoid discomfort from use if you are extra sensitive in the vulvar and/or vaginal areas.
- Reduce use of the device if you experience any physical reactions related to the device that are not transient. Please seek medical attention if the reaction does not pass despite reduced use.

Instructions for Use 2/2 Efemia Bladder Support

OPERATING PRINCIPLE:

1. Before Use

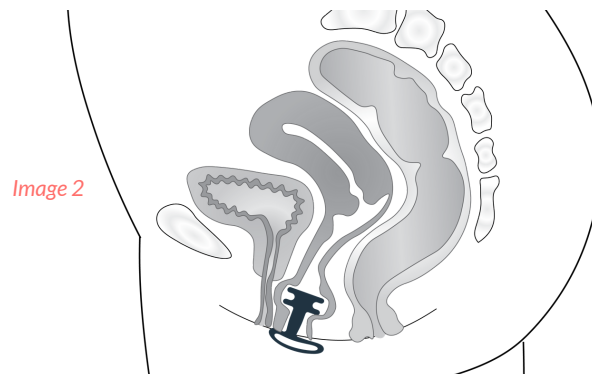
- Make sure your bladder is empty and wash your hands with soap and water.
- Take the device out of the packaging and rinse it with water. This reduces friction and makes it easier to insert into the vagina.
- Find a comfortable position, if standing, slightly bending the knees may help.

2. Inserting Device

- Hold Efemia so that the back of the handle (See image 1) points towards the perineum. Insert the device into your vagina at a slightly upward angle.
- Push the device in until the handle rests tight up against your pubic bone/perineum (see image 2.) Allow the labia to cover the handle.

3. Removing the Device

- If possible, empty your bladder before removal.
- Grip the outer part of the handle and pull gently, but steadily until the device comes out.



4. Cleaning the Device

Clean the device using any of the following methods:

- Rinse with water for immediate reuse.
- Boil in water for 10 minutes and allow to air dry.
- Cleanse with water and soap, preferably a soap for intimate use. Rinse thoroughly to remove all soap and allow to air dry.

5. Device Replacement

Replace the device every 3 months.

DISPOSAL

Discard the device as a non-recyclable item according to local regulations. The primary packaging can be recycled as plastic and the secondary packaging as cardboard according to local regulations.

MANUFACTURER

Invent Medic Sweden AB
Scheelevägen 2, SE-223 81 Lund, Sweden
efemia@inventmedic.com
www.inventmedic.com

CE 0402