

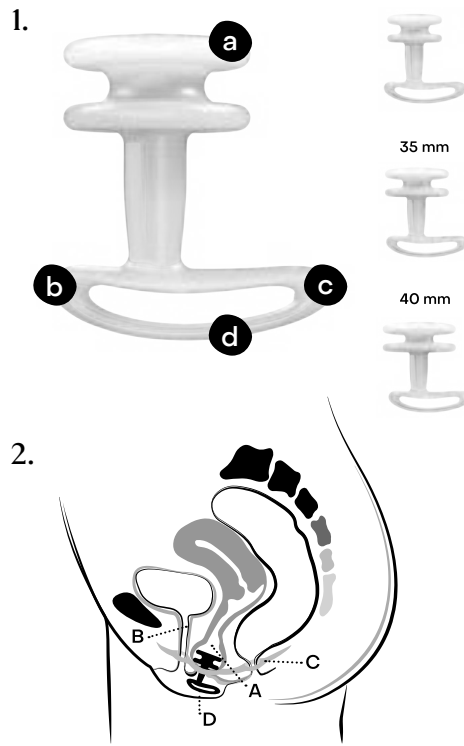
efemia

bladder support



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L2: www.hma.eu/human-medicines/national-contacts.html



English	Svenska	Dansk	Norsk	Deutsch	Nederlands
Manufacturer	Tillverkare	Fremstiller	Produsent	Hersteller	Fabrikant
Use-by date	Används före	Anvendes inden	Brukets innenside	Verfallsdatum	Gebruiksduur
Catalogue number	Katalognummer	Katalognummer	Katalognummer	Bestellnummer	Catalogusnummer
Caution	Försiktighet	Forsigtig	Forsiktig	Warnung	Let op
Unique device identifier	Unik enhets-identifikator	Unik udbyr-identifikator	Unik enhets-identifikator	Produktidentifikationsnummer	Uniek identi-ficatie-merk
Consult instructions for use	Se bruks-anvisningen	Se brugsan-visningen	Se bruks-anvisningen	Gebrauchsan-weisung	Readpleeg de instructies voor gebruik
Medical device	Medicinteknisk produkt	Medicinsk udstyr	Medicinsk utstyr	Medizinprodukt	Medisch hulpmiddel
Batch code	Batchcod	Batchcode	Partilcode	Chargennummer	Batchcode
Recycling	Återvinning	Gembrug	Resirkulering	Wiederverwendbar	Recycling
Information	Information	Information	Informasjon	Hinweis	Informatie

Use

Efemia Bladder Support is a medical device intended to temporarily reduce stress induced urine leakage in women, 18 years and older, 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

- The Efemia Bladder Support is a reusable vaginal insert made of medical grade silicone. It is intended to be used to temporarily alleviate involuntary urine leakage caused by stress incontinence.
- It can be used on occasions when you expect an episode of SUI, or you can wear it for up to 16 continuous hours per 24 hour-period.
- The device is available in 3 sizes 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. It may take a few tries to find what works best for you.
- Although it is not required, you can remove the device before emptying your bladder or bowels if you want to.

Some women may 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 occurring 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 and use some water-based lubricant with the device.

Do not use Efemia Bladder Support

If you are pregnant.

⚠ Precautions

- Use water-based lubricant to avoid discomfort from use if you are 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.

If you experience any problems with the device or its use, please inform us! Any serious incident that has occurred in relation to the device should be reported to us (L1) and the competent authority (L2).

Disposal

Discard the device as a non-recyclable item according to local regulations.

About Efemia

Efemia is a health and wellbeing brand for women from Invent Medic Sweden. Learn more about us and our products at: www.efemia.se

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 drinking 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 the device so that the back of the handle (see image 1c) points down towards the rear. Insert the device into your vagina at a slightly upward angle, similarly to a tampon.
- Push it in until the handle rests tight up against your body so the labia cover the handle. Make sure the support rings are completely through the vaginal opening and above the pelvic floor (see image 2C).

3. Removal

- 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

Clean the device using one of the following methods (whichever you prefer):

- Rinse thoroughly with drinking water. This works well if you need to reuse the device straight away.
- Boil in drinking water for 10 minutes and allow to air dry.
- Cleanse with drinking water and soap, preferably a soap for intimate use. Make sure you clean the entire device. Rinse thoroughly to remove all soap and allow to air dry.

We do not recommend using anything else but soap along with drinking water to clean your device. If you see any visible soil, we recommend cleaning it once more according to the instruction.

5. Device replacement

Replace the device every 3 months.

Image 1: a. Support rings b. Front c. Back d. Handle

Image 2: A. Vagina B. Urethra C. Pelvic Floor D. Efemia Bladder Support