

## FAQ

### Are there any side effects?

If your patient suffers from vaginal dryness, the device may cause some irritation or chafe on the labia or inside the vagina. If your patient feel it chafing or if they know they have a sensitive vulva, they can try applying some water-based lubricant to see if that helps.

### Can Efemia Bladder Support be used with a coil?

Yes.

### How many times can the product be reused?

The device can be reused as many times as needed, up to 16 hours per day during the 3 month lifetime of the product.

### How do I know which size I should use?

It's best simply to test and see, starting with the smallest size. If it doesn't work for your patient and they still leak or it feels uncomfortable, recommend them to go up a size. And, even if the smallest size does work for them, it might be an idea to try a larger size for comparison's sake. Smaller doesn't always mean more comfortable.

# efemia bladder support



## About the product

Efemia Bladder Support is a medical device that is inserted in the vagina to reduce urine leakage caused by stress urinary incontinence. Efemia is reusable and you can use it for up to 16 hours per day for 3 months. It is easy to clean with water and soap and can also be boiled.



Effective



Comfortable



Sustainable

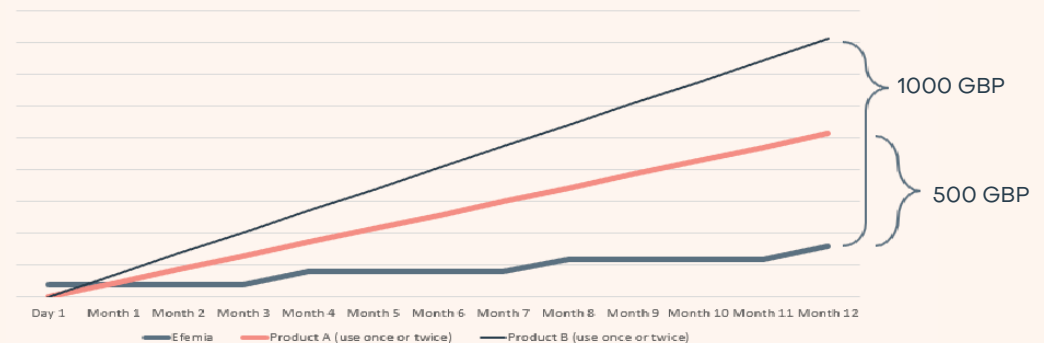
## A sustainable option

The production of one Efemia Bladder Support is equivalent to a day's consumption of single use incontinence pads (4 pads on average) in terms of carbon footprint. Switching from incontinence pads to Efemia Bladder Support saves an annual average of 46 kg CO2 eq and reduces the amount of household waste with up to 29 kg per year.



## Efemia Bladder Support compared to disposable bladder supports

Even though the initial cost of Efemia Bladder Support is higher than the two disposable alternatives in the graph below, Efemia is the more economical alternative after already about half a month to one month. In one year, you can save between 500-1000 GBP per patient.

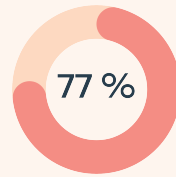


## Design

The development and design behind Efemia Bladder Support is based on the integral theory, the same scientific theory as the most common surgical methods for stress urinary incontinence, TVT. Efemia is designed to support the urethra through the vaginal wall by the two support rings. The rings support the "urethral knee" located at the mid urethra when the urethra and bladder neck drop at elevated abdominal pressure. The two support rings have the same distance as the width of the TVT sling. The length of the Bladder Support stem is designed so that the support rings are situated in the same position as the TVT sling. The handle holds the device at the right position, preventing it from gliding too far in to the vagina. The shape of the rings ensures that it is always effective, regardless of the direction in which the handle points, thus minimising user errors.

## Clinical evidence

The safety and performance of Efemia Bladder Support was evaluated in a randomized, controlled clinical investigation, including 97 women. The study confirmed that the device achieved its primary performance objective to reduce leakage (median reduction during provocation tests 77%). The observed side effects were mild and transient. Thus, the benefit-risk-analysis for the device can conclude that the risk of encountering any side-effects and the severity of these are found to be acceptable in relation to the benefits the user gains from the device performance.



Median reduction during provocation tests



Read the study here!

## Post market surveys

The user acceptance of Efemia has been evaluated in both older (average age 55 years) and younger (average age 36 years) age groups, during daily life and during exercise such as weightlifting, cross-fit and running. The studies showed a high user acceptance. An average of 72% of the 130 participants reported that they were likely to continue using Efemia (median rating on a scale 0-10 of 8).



7/10 likely to continue using Efemia



8/10 likely to recommend Efemia to a friend

## Sizes

Efemia Bladder Support is available in three different sizes: 30 mm, 35 mm and 40 mm. You start by prescribing the Starter Kit, including all three sizes, and the woman gets to try them out herself at home during activities when she is experiencing leakage. When she has found which size works for her, she gets prescribed a single size every three months.

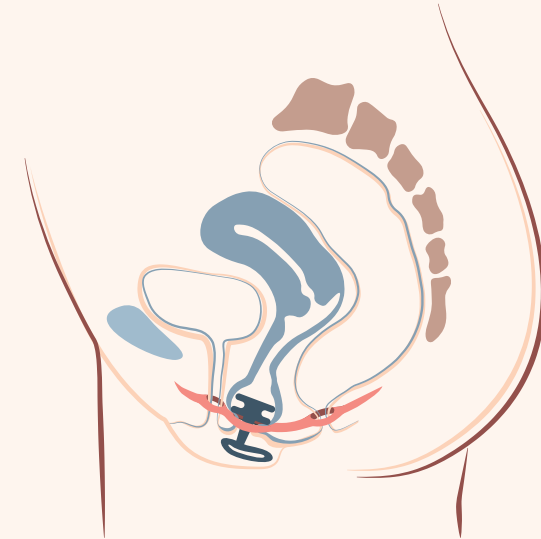
30 mm



35 mm



40 mm



The right size is essential for the best comfort and efficiency

## Material

- 100% medical grade pure silicone
- Soft and flexible, but is sufficiently stable to support the urethra during periods of increased abdominal pressure
- The material is durable and resilient so it can withstand the vaginal environment
- Contains no heavy metals, flame retardants, phthalates, bisphenols, fluorinated compound, PFAS, colourants, antibacterial substances, latex or animal proteins
- The material is tested for biocompatibility and conforms to the standards for medical devices, ISO10993-1:2018 and USP class IV

Precautions: 18+. Do not use if pregnant.