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*femicare*

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# Instructions for use

## Pessaries



## General information

**About these instructions for use:** This document is intended for both doctors and medical professionals as well as patients and serves to ensure that the pessary is used safely and as intended. This document must be carefully read and understood by every patient using the pessary before first use. If you have any further questions, please contact the manufacturer, tic Medizintechnik GmbH & Co. KG. This document is part of the pessary and must be available to the patient at all times. Extracts are not permitted.

Instructions for use suitable for blind and visually impaired people (e.g. in MS Word format [read aloud function]) as well as a version in simple language can be provided upon request.

**Intended use/indications:** Thanks to the flexible and tissue-friendly medical-grade silicone, the pessary can usually be inserted and removed easily by the patient. Before first use, the patient must be instructed in handling by a qualified person. The exact intended use of each pessary type can be found on the back of these instructions for use.

**How to use:** After receiving instructions from a doctor or medical professional during initial use, the patient can change the pessary independently at home. Unless otherwise prescribed, the pessary should always be inserted every morning and removed every evening (short-term use according to the legal definition of duration of use: between 60 minutes and < 30 days).

It is recommended to insert the pessary while standing. To do this, place one foot on a stool, for example. If this is too difficult, you can insert your pessary while lying down or leaning against a wall with your legs slightly spread. For optimum fit and to avoid pressure discomfort, please read the detailed instructions for use for your pessary type on the back of these instructions for use.

To facilitate insertion of the pessary, it may be beneficial to apply a suitable lubricant to its surface. After consultation with the treating physician, an ointment containing oestrogen may be used, which can also improve tissue blood flow and promote the development of a normal vaginal flora.



**Caution:** Before using creams containing hormones, please be aware of the risks and side effects, which you can find in the corresponding package insert, and consult your doctor or pharmacist. The pessary is to be used by only **one** patient.

**Cleaning/Sterilisation:** Before first use, we recommend manual cleaning at home with a mild, pH-neutral and mucous membrane-friendly soap solution. After each use, the pessary should be cleaned (depending on the degree of soiling) under running drinking water or with a suitable soap solution. If the pessary is heavily soiled, it can be boiled for 10 minutes at 100 °C. Rinse with plenty of water after each cleaning to remove any soap residue. After cleaning, gently dry the pessary with a cloth. The pessary should be checked for damage after cleaning and replaced if necessary. For hygienic reasons, we recommend replacing the pessary after 6 months of use at the latest. No pre-cleaning/disinfection/sterilisation is required. Do not use acidic/alkaline cleaners!

**Size:** *femicare* pessaries are available in different sizes. The selection of the correct size is made by the attending physician, as this is essential for a secure fit and comfortable use. The correct size and optimum hold are usually tested through stress such as coughing, straining and movement, after which the fit of the pessary should usually be checked again by the doctor. A size should be chosen with which the pessary does not cause any pressure or pain. It may be necessary to change the pessary size after some time (days or weeks).

**Storage:** The pessary should be stored at room temperature within the specified limits (see packaging) and protected from UV radiation. The surface and size of the pessary must be checked before each use. In case of tearing, the pessary must be replaced *immediately*.

**Application limitations:** It is advisable to involve a treating nurse or family member in advising and instructing patients who require care or are anxious about using the pessary.

**Side effects:** If infections occur during use of the pessary, discontinue treatment and consult your doctor *immediately*. In case of pain, injury, changes in sensation and bodily functions, allergies and intolerances, as well as pressure discomfort occurring during use, remove the pessary and consult your doctor immediately. Pressure discomfort can lead to irritation or pressure necrosis in the vaginal area. If you have any problems inserting, wearing, or removing the pessary, consult your physician. The physician can assess the fit and size of the pessary and offer guidance.

The residual side effects identified from the literature on pessaries after implementation of all risk-reducing measures are: bacterial vaginosis, fungal infection, colpitis/vaginitis, urosepsis, urinary tract infection, allergy, silicone intolerance, pressure discomfort, skin lesions caused by thread (with cube pessaries), irritable bowel syndrome, constipation, difficulty defecating, latent incontinence becomes visible, irritable bladder, incomplete bladder emptying, difficulty urinating, cervical, uterine and/or intestinal prolapse and strangulation, uterine migration, vaginal atrophy, vaginal bleeding, vaginal erosions, vaginal granulation tissue, vaginal constipation, vaginal ulcers, fistulas, increased vaginal discharge, irritation of the vaginal wall/mucosa, itching, lower abdominal or back pain, pain during defecation, perforation of the bowel or bladder, injury to the vaginal wall, small bowel prolapse, odour, bowel and ureteral obstruction.

**Contraindications:** Contraindications include the simultaneous use of pessaries and other medical devices in the treatment area, vaginal

infections/inflammations or bleeding of unknown origin, menstruation, persistent vaginal or cervical cancer, use after radiotherapy of the vaginal tissue, severely atrophic vaginal tissue that has not responded to previous oestrogen treatment, a vaginal cavity that is too small or too narrow, recognisable synthetic vaginal mesh erosions, and if the woman is unable to comply with regular follow-up care and manage the pessary independently.

**Clinical benefit:** Use of the pessary in cases of *genital prolapse* to provide support.

**Note on reporting incidents:** The pessary is a certified and approved medical device. Therefore, please report all serious incidents and injuries related to the product to the manufacturer and the competent national authority (in Germany – Federal Institute for Drugs and Medical Devices (BfArM)).

**Environmentally friendly disposal:** The pessary can be disposed of in general household waste. The national legal regulations applicable in your country regarding the environmentally friendly disposal of silicone/plastic and packaging must be observed.

**Material:** Medical-grade silicone

**Age restriction:** Adults

## (Thick) Ring Pessary



### Intended use/Indications

The ring pessary can be used to treat mild prolapse symptoms and/or stress incontinence. By repositioning the prolapse and providing sub-urethral support, the ring pessary can prevent or even remedy stress incontinence. The patient must have sufficient pelvic floor capacity, even if it is reduced.

Thick ring pessaries have a larger surface area due to their increased circumference. This also increases their contact surface, which reduces the risk of pressure damage.

### Application:

To ensure that the pessary sits correctly and does not cause any pressure discomfort, the pessary should first be pressed together into the posterior vaginal fornix when inserting it and then the ring should be pushed upwards and forwards.

To remove it, grasp the ring pessary with your index finger and pull it out.

## (Sieve) Bowl Pessary



### Intended use/Indications

The bowl pessary can be used to treat mild prolapse and/or stress incontinence. The patient must have sufficient pelvic floor capacity, even if it is reduced. The broad contact surface of the bowl on the pelvic floor enhances adhesion.

Sieve bowl pessaries are the same as bowl pessaries, but have a number of holes that make the drainage of secretions easier.

### Application:

To ensure that the pessary sits correctly and does not cause any pressure discomfort, the pessary should first be compressed and inserted into the posterior vaginal fornix and then the cup should be unfolded upwards/forwards.

To remove the pessary, grasp it with your index finger through the hole in the bowl. To facilitate removal, the pessary should first be squeezed together with the fingers and then gently pulled out.

## Urethra (Bowl) Pessary



### Intended use/Indications

The urethral pessary can be used to treat various degrees of stress incontinence and/or prolapse. The local thickening (calotte) of the urethral pessary is intended to shift the transition between the bladder and urethra upwards/forward. To prevent urine from entering the urethra during stress such as movement or coughing, a urethral ring can be inserted into the vagina.

Compared to the ring-shaped urethral pessaries, urethra bowl pessaries slip less often.

### Application:

To ensure that the pessary fits correctly and does not cause pressure discomfort, the calotte should be positioned behind the pubic bone under the upper urethra.

To remove the urethral pessary, slide the calotte to the side and grasp with your index finger the ring part or through the bowl hole.

## Cube Pessary (perforated)



### Intended use/Indications

The cube pessary can be used to treat various degrees of prolapse of the vagina, uterus, bladder or bowel, pelvic floor weakness or stress incontinence. To return the prolapsed organs to their original position, this type of pessary is inserted through the vagina. A perforated pessary facilitates the drainage of secretions.

The respective edge length of the cube indicates the corresponding size. Small pessaries are recommended for vaginal prolapse, and larger ones for vaginal narrowing. The pessary should fit well in the vagina, but should not press on the bladder or bowel, as this may make removal difficult.

### How to use:

The cube pessary should be removed daily so that the vaginal walls can recover overnight. To prepare the tissue before surgery, it may be useful to use the pessary at night as well, provided this has been prescribed by the attending physician. After consultation with the doctor, a smaller cube pessary can also be used overnight for patients in need of care.

To ensure a correct fit and to avoid pressure discomfort, push the pessary as far into the vagina as possible. Important: The thread of the pessary must point towards the vaginal opening! If the thread breaks, the pessary must be removed by a doctor as quickly as possible.

To remove the pessary, pull the cube down on the thread until you feel resistance from the pelvic floor muscles. The thread must not be pulled abruptly. This can be achieved by pulling in different directions and, if necessary, by gently pressing. You must move the now accessible edges with your fingers in such a way that the existing vacuum is released. The pessary can then be removed from the vagina while maintaining the tension on the thread.

Cube pessaries stay better in place in the vagina than other types of pessaries thanks to their suction cup effect. Unperforated ones can withstand greater pressure, while perforated pessaries are easier to insert & remove.





### Adverse effects with using a pessary

During pessary therapy, symptoms such as problems with urination/ bowel movements or (in the case of a cube pessary) worsening of existing incontinence may occur.

Please report any symptoms you experience ***immediately*** to your health-care provider so that a smaller pessary can be inserted if necessary.

## Other products

### Our recommendation:

Take a closer look at the lubricants, cleansers, and creams that are optimally tailored to your pessary therapy and recommended by the manufacturer. For more information, please visit our website!

For more information about our *femicare* pessaries,  
please refer to our website:



[www.femicare.shop](http://www.femicare.shop)



Patient survey



Instructions/e-IFU



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