

## **Instructions Cube Pessary (perforated/unperforated)**

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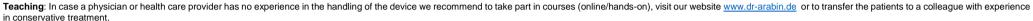
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Components and storage: The cube pessary is made of tissue-friendly silicone with a button and firmly welded thread to facilitate changing. The pessary can be stored at room temperature at 1 to 30 °C protected from UV radiation without direct contact to reactive media like gas, ozone or mineral oil.

Indication: The non-perforated version allows a better adhesion and resistance as compared to the perforated version, which is easier to handle for patients during changes.

In general, the cube pessaries are used for more severe degrees of vaginal prolapse. In case of prolapse grade III-IV, the prolapsed organs should be carefully reposed (picture). The cube pessaries holds the prolapse better than most other devices because it adheres to the vaginal wall by building up a kind of vacuum effect. Therefore, it does not need an intact pelvic floor. Cube pessaries are also indicated for the treatment of micturition disorders, complaints during sexual intercourse and before surgery.



Sizes: The size of the cube pessary depends on the edge length of the cube. There are 10 different sizes available with a minimum edge length of 25mm (size 0) up to a maximum edge length of 75mm (size 9). The correct size selection by a treating physician is a prerequisite for a secure hold and a comfortable use. The cube should be large enough so that it sits/adhesively holds well during pressing, coughing and movements. A cube that is too large can press on the bladder or intestine and make removal more difficult. Treatment should always begin with a cube that adheres/fits well both when coughing and when pressing. After a few days or weeks, it may be necessary to change the pessary size (usually to a smaller model).

**Use:** The physician adjusts the pessary during the initial examination. The patient herself removes the device in the evening and re-inserted in the morning after initial instruction by health care providers. This allows that the vaginal walls may recover overnight. In some cases, however, it may be useful to use the pessary at night to prepare the tissue before surgery. However, this should only be done on medical indication. In case of a severe prolapse grade, III and IV a smaller pessary can be used at night for patients in need of care, but always in agreement with the treating physician. It is advised to cover the edges by a crème when inserting the cube. This will not only result in a gliding effect, but – when oestrogen crème is used, also in better blood circulation of the mucous tissue. The choice of cream should be discussed with the treating gynaecologist.

To insert the cube, the foot is placed on a chair or the edge of the bed, similar to the insertion of a tampon. It may also be sufficient to insert the pessary with spread legs, leaning against a wall or lying down if necessary. In doing so, push the cube as far as possible into the vagina. Only then the pessary will fit correctly and will not cause any pressure problems. To remove the pessary pull down the cube by the thread - best in different directions, if necessary also with light pressing - until a resistance is felt by the pelvic floor muscles. With the index and/or middle finger, the accessible edges of the pessary should be moved in a way that the existing vacuum is released. If the patient cannot urinate, but also if incontinence is intensified by the pessary, the device should be removed and a smaller (different) model should be chosen. The patient should be instructed to report all complaints as soon as possible.

Follow-up examination: After the first insertion, the patient should be examined after about one week (at the latest after four weeks). At each follow-up examination, the pessary should be removed and cleaned and the vagina examined to exclude erosions, necrosis or allergic reactions. Sometimes the size of the pessary is changed after the first fitting. The patient should then have another examination after one to two weeks. If defects are detected on the pessary, the device must be replaced. The patient should preferably be cared for by the same doctor for the duration of the treatment. If the patient is motivated and can prove effective handling of the pessary, follow-up examinations can be further apart at her discretion.

Application/Cleaning: This cube pessary is called a therapeutic product and may only be used by a single patient. The pessary is cleaned by running water without using disinfectants and if necessary by a soft toothbrush.

Side effects/ complications: Although pessaries are a safe form of treatment, they are a "foreign body". Therefore, the most common side effect is increased discharge and possibly smell. This side effect can be reduced by using additional measures (creams, hygiene). During bowel movement the pessary can go deeper (picture above right). The patient should be instructed to palpate the pessary and then fix it in the vagina again (picture top middle). Postmenopausal women are more prone to vaginal mucosal injuries. By promoting epithelial maturation, treatment with oestrogen cream can make the vaginal mucosa more resistant to erosion. Prolonged lying in bed and/or oestrogen deficiency can lead to pressure problems of the vaginal mucosa. This is worst when a pessary is forgotten. In case of intolerance another model, e.g. a cup or club pessary, can be chosen. This is then decided by the doctor. If the thread is dislocated, the pessary should be removed as soon as possible, if necessary by a doctor. In women who have a hidden form of bladder weakness ("larvae incontinence") wearing a pessary can increase urinary incontinence. In these cases, it should be discussed whether it is necessary to change to another model (urethra or urethral pessary). In the case of patients in need of care or anxious patients, a nurse or family member can be involved in the handling of the change. In case of bleeding or serious infections, a physician must be consulted as soon as possible.

Duration: The therapy is "short-term" (< 30 days). However, our recommendation is to remove the pessary every evening before going to sleep. It may only be re-used only by the same patient in the morning

Contraindications: For patients who are in need of care or are not able to change the pessary regularly, a nurse or a family member can be integrated into the changing process. An allergy to silicone is extremely rare but would also be a contraindication. Active infections, including inflammatory diseases of the vagina or pelvis, rule out the use of a pessary until the infection has disappeared. Patients who do not understand, ignore or cannot follow advice should not receive a pessary.

Warning: In case of pain, bleeding or extreme discharge with smell the physician in charge should be consulted as soon as possible. Although several crèmes are additionally indicated to improve the therapeutic effects, we have not tested the compliance of the material with these substances, but never heard of any compliants or complications. Serious complications should be reported to the manufacturer and, if necessary, to the responsible authorities.

Shelf life: The pessary has been assigned a shelf life of 10 years from the date of production. After insertion, we recommend not to continue the therapy with the same device for more than 3 years. In case there are defects, changes of the form or colour the pessary should be replaced.

Disposal: Used or damaged silicone products can be disposed of in household waste in a low-germ state. For disposal in medical facilities, the country-specific regulations must be followed

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