Instructions for Use of the Dr Arabin Cube Pessary (non-perforated/perforated, WP/WPP) for Health Care Providers & Patients

CE 0482

Dr Arabin GmbH & Co KG Sales: A.-Herrhausen-Str. 44, D-58455 Witten Tel: +49 2302 189214 Mail: info@dr-arabin.de/ www.dr-arabin.de
Training/Design/Science: Koenigsallee 36 14193 Berlin/ GF: Prof. Dr.med. Dr.h.c. mult. Birgit

Components and storage: The cube pessary is made of tissue-friendly silicone with a button and welded thread to facilitate changing. The pessary can be stored at all temperatures between 1 and 50 °C protected from UV radiation without direct contact with reactive media such as gas, ozone or mineral oil.

Indication/ intended purpose: The cube pessary is primarily used to treat advanced forms of prolapse of the internal organs (grade III-IV), regardless of age or whether the pelvic floor is stable. The cube pessary holds better than other pessaries due to its vacuum or suction cup effect. **The non-perforated form has a better hold than the perforated form. However, the latter is easier to change, somewhat gentler on the mucous membrane and allows fluorine to drain out.**

Clinical benefit: In the case of scars or deviations, the pessary can adapt to anatomical features. In the event of prolapse of internal organs, the cube pessary returns the organs to their original position (image). Other indications for treatment include bladder emptying disorders, discomfort during sexual intercourse and previous operations as well as stress incontinence. The pessary can be placed at different heights depending on the symptoms.

Training: If a treating doctor has little experience in pessary therapy, we recommend training (online/hands-on)visiting the website (see above) or referral to experienced colleagues. The patient herself must also be trained in changing the pessary either by the doctor or additional media such as offline/online information.

Sizes: The size of the cube pessary depends on the edge length of the cube. There are 10 different sizes available, ranging from a minimum edge length of 25 mm (size 0) to a maximum edge length of 75 mm (size 9). The correct size selection by a treating physician is a prerequisite for secure support and pain-free use. The cube should be large enough so that it adheres well when pressing, coughing and moving. A cube that is too large can press on the bladder or bowel and make removal more difficult. After a few days or weeks, it may be necessary to change the size of the pessary (usually to a smaller model). If the vagina is constricted, the larger models are used.

Use/ follow-up:: A pessary should not be prescribed "blindly". The health care provider usually fits the device during the initial examination. After initial instruction by a doctor or other specialist, cube pessaries are removed by the wearer herself every evening and reinserted in the morning. This allows the vaginal walls to recover overnight. It is advantageous to apply an ointment over 2-3 cube edges before inserting the cube. In addition to a lubricating effect this improves tissue circulation and helps to build up normal vaginal flora. The choice of cream or ointment should be discussed with the treating gynaecologist (see below). To insert the cube, place the foot on a chair or the edge of the bed, similar to inserting a tampon. It may also be sufficient to insert the pessary with your legs apart, leaning against a wall if necessary, or lying down. The cube is pushed into the vagina until the pessary is seated correctly without causing pressure discomfort or urine leakage. To remove the pessary, the vacuum of the cube must first be released. This can be achieved by moving the pessary back and forth in different directions and, if necessary, supported by gentle pressing. Alternatively, the vacuum can be released by moving the accessible edges of the pessary with the index and/or middle finger. The thread is only used as a guide or aid to remove the pessary with a constant light pull.

Patients and/or health care providers should keep the information of the label in case of complaints

To further support the change process, we recommend a video on our website (see above), see also QR code on the right:
If the patient is unable to urinate after pessary application or if incontinence is aggravated by the pessary, the pessary should be removed and a smaller (different) model selected. The patient should be instructed to report any discomfort - including urination/defecation - immediately during pessary therapy

Follow-up examination: After the pessary has been prescribed for the first time, the patient should be re-examined after approx. one week (at the latest after four weeks). The vagina is examined for any erosions, pressure necrosis or allergic reactions. If the size is modified, the patient should be examined again after one to two weeks. If cracks or defects are found on the pessary, the pessary must be replaced. It is recommended that the patient is best cared for by the same doctor for the duration of the treatment. In the case of a motivated patient who confirms effective handling of the pessary, follow-up examinations can be spaced further apart at the patient's discretion.

Application/cleaning: The cube pessary is labelled as a therapeutic product and may only be used by a single patient. It is cleaned under running water without the use of disinfectants. Any mucus or material residue can be carefully removed with a soft toothbrush without loosening or tearing out the button. We recommend (and offer) to use a clean box to store the device over night. In case our adjustment rings are used to choose the right size providers should consider our evaluation for cleaning and sterilisation. Our class IIa products such as urogynaecological devices may also be used to choose the right model because they have been evaluated for cleaning and disinfection and for compatibility with PERFEKTAN ®ACTIVE by Dr. Schumacher GmbH. This means that the size and/or the model can already be adapted in outpatient clinics.

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 odour. This side effect can be minimised by using additional measures (creams, hygiene). During a bowel movement, the pessary may descent. In this case, patients may replace the devices by pushing them up again. Postmenopausal women are more susceptible to vaginal mucosal injuries. By promoting epithelial maturation, treatment with oestrogen cream can make the vaginal mucosa more resistant to erosion. Prolonged use and/or oestrogen deficiency can lead to pressure problems in the vaginal mucosa. For women after the menopause, oestrogen-containing creams (suggested 2x/week) and fat creams (suggested 7x/week) help to prevent mucosal erosions. If the string should detach and the patient cannot remove the device, she should ask for medical help to remove and replace the device. The cube pessary can cause urinary incontinence in a few women with "larvated incontinence". In such cases the patients should always ask for professional advice. Similarly, professional support is necessary in case of bleeding, pain or serious infections.

Duration: The therapy is "short-term" (< 30 days). **It is medically recommended to remove the pessary every evening and reinsert it in the morning**!

Contraindications: For patients who require care or are unable to change devices on a regular basis, a nurse or family member can be involved in the changing process. An allergy to silicone is an extremely rare contraindication. Active infections, including inflammatory diseases of the vagina or pelvis, preclude the use of a pessary until the infection has disappeared. Patients who do not understand advice, ignore it or cannot be followed should not receive a pessary where self-management is mandatory. As a general rule, if regular changing cannot be ensured, the cube pessary is contraindicated. In this case, alternatives should be discussed with the health care providers.

Warning: In the event of pain, bleeding or serious infections, the attending physician must be consulted as soon as possible. Creams and gels improve the success of treatment. However, the compatibility of these products with the pessary has not been specifically tested. Serious complications caused by the product should be reported to the manufacturers, who will then forward them to the responsible authorities following a risk-based approach.

Shelf life: The pessary has a shelf life in its original packaging of 10 years from the production date. After the first insertion of the pessary, it should be possible to use it for at least 6 months. If cracks, deformation or discolouration occur during inspection of the pessary, the pessary must be replaced at any time.

Disposal: Used and damaged silicone products can be disposed of in household waste in a low-germ condition. In medical facilities, the country-specific regulations must be followed.