



Dr. Arabin dare to care Dr. Arabin GmbH & Co KG Sales / Information: A.-Herrhausen-Str. 44, D-58455 Witten Tel: +49 2302 189214 info@dr-arabin.de www.dr-arabin.de

Dr. Arabin GmbH & Co KG Teaching/Design/Science: Koenigsallee 36 14193 Berlin/ CEO / PRRC: Prof. Dr.med. Dr.h.c. mult. Birgit Arabin

Components and storage: The Dr. Arabin Hybrid Pessary is made of tissue-friendly silicone. 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 Hybrid Pessary is used to treat pelvic dysfunction associated with genital prolapse and/or urinary incontinence, regardless of age or whether the pelvic floor can bear weight. Hybrid pessaries are ventrally placed on top of the symphysis and thereby support cystoceles. The recesses built into the walls and the resulting vacuum effect stabilizes the devices laterally. By verification through tensile force measurements these devices resisted ca. 5 times better to traction or pressure than conventional models. The oval egg-shaped form allows the pessary to be inserted flexibly and makes it an ideal device for selfmanagement. The fact that it is centrally open -unlike the cube pessary-, means that discharge or menstrual blood can drain more easily and a tampon can be used simultaneously. The devices were specially developed for early lesions of the pelvic floor such as in case of avulsion with subsequent hiatal enlargement caused by detachment of the levator muscle. The general intended purpose is to provide non-invasive support for internal organs, thereby alleviating pressure or incontinence problems even during pregnancy and thereafter and in all cases, where other devices are not satisfying.

Clinical benefit: In the event of genital prolapse, the pessary returns the internal organs to their original position; this can also be useful before and after operations. Treatment indications also include stress incontinence or bladder emptying disorders, where the pessary can be placed at different heights. In the case of scars or deviations, the pessary can adapt to anatomical features and can be used before and after operations or combined with electrotherapy or physiotherapy in case these are indicated.

Training: If a physician has no experience in pessary therapy, we recommend training (online/hands-on), visiting the website www.dr-arabin.de or referral to experienced colleagues.

The patient herself should be trained in changing the pessary either by her health care provider or by additional media such as offline/online information.

Sizes and hardness: The size of the pessary is specified according to the length and is currently available with a maximal length between 55 and 80 mm in 5 mm increments. The wall thickness and material determine the compression capacity. The most commonly used sizes are 60, 65 and 70 mm. The pessary should be large and stiff enough so that it adheres well when pressing, coughing and moving. The front narrow part must lie above the symphysis: a pessary that is too large can slip under the symphysis and then tend to dislocate. After a few days or weeks, it may be advisable to change the pessary size or grade of hardness (decide between normal and soft).

The device exists in two degrees of hardness (NORMAL and SOFT). In general, patients should start with a soft version, if the prolapse is more severe or in case of physical stress they may change to a normal hardness. Use/suitability: The health care provider fits the pessary after prescribing the hardness and size during the initial examination. The patient should "self-manage" her daily therapy thereafter, e.g. the patient learns to remove the pessary in the evening and reinsert it in the morning. This allows the vaginal walls to recover overnight. It is advantageous to apply a cream over the pessary when inserting it. This not only has a lubricating effect but also, depending on the cream prescribed, improves blood flow to the tissue or cares for the vaginal mucosa. For younger women before menopause, wetting with water or cream during insertion may be sufficient: after menopause, it is advisable to use lubricating cream daily and estrogen cream twice a week. The choice of cream should be discussed with the treating healthcare provider.

To insert the pessary, we advise to place one foot on a chair or the edge of the bed in a similar way to inserting a tampon. It may also be sufficient to insert the pessary with legs spread apart, leaning against a wall or lying down, until the pessary is seated correctly without causing pressure discomfort or urine leakage. The pessary should first be placed over the symphysis with the tip handle, then the rear part is pushed upwards. Most women find it more comfortable to have the soft flaps facing upwards, but it can also be inserted so that the firmer part faces upwards and the flaps face downwards. To remove the pessary, you must first release the vacuum on the walls, preferably by moving it back and forth in different directions, if necessary with a slight squeeze, until resistance from the pelvic floor muscles can be felt by moving the accessible arms of the pessary with the index and/or middle finger so that the pessary is released. If urination problems occur or incontinence increases, the pessary should be removed and a smaller or 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 have another examination 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 may be spaced further apart at the patient's discretion.

Application/cleaning: The Hybrid 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. Storage should be hygienic.

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 minimized by using additional measures (creams, hygiene). The pessary may become deeper during a bowel movement. The patient should be instructed to fix the pessary higher again. Postmenopausal women are more susceptible to vaginal mucosal injuries. By promoting epithelial maturation, treatment with estrogen cream can make the vaginal mucosa more resistant. Prolonged use and/or estrogen deficiency can lead to pressure symptoms in the vaginal mucosa. For women after menopause, estrogen-containing creams (recommended 2x/week) and fat creams (recommended 5x/week) help to prevent mucosal erosion. A doctor must always be consulted in the event of bleeding, pain or serious infections.

Duration of treatment: The therapy is "short-term" (< 30 days). The medical recommendation is to remove the pessary every evening and reinsert it in the morning. It may only be used by the same patient.

Contraindications: For patients who require care or are unable to change regularly, a carer or family member can be involved in the changing process. A silicone allergy is extremely rare, but would also be a contraindication. Active infections, including inflammatory diseases of the vagina or pelvis, preclude the use of a pessary until the infection has subsided. Patients who do not understand the advice, ignore it or cannot be followed up should not be given a pessary and should discuss with their doctor whether they need to change to a different model or undergo a different treatment.

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, but the compatibility of these products with the pessary has not been specifically tested. Serious complications attributable to the pessary should be reported to the manufacturer and, if necessary, the responsible authorities.

Shelf life: The pessary has been assigned a shelf life of 10 years from the production date in its original packaging. After the first insertion of the pessary, the pessary should last at least 6 months. If cracks, deformation or discoloration occurs during the inspection of the pessary, the pessary must be replaced at any time.

Disposal: Used and damaged silicone products can be disposed of at home in the household waste, wrapped up in a low-germ bag. In medical facilities, country-specific regulations must be observed.

REV 06/ Date: 01.01.2025 -Instructions for Dr. Arabin Hybrid Pessaries