CE 0482

Instructions for Use of the Dr. Arabin Urethra Bowl Pessary (USP) for Health Care Providers & Patients

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Components and storage: The Urethra Bowl Pessary pessary is made of tissue-friendly silicone. The pessary can be stored at room temperature at 1 to 50 °C protected from UV radiation without direct contact with reactive media such as gas, ozone or mineral oil.

Indication/ intended purpose: The Urethral Bowl Pessary is used to treat patients with stress incontinence and/or cystocele. A stable pelvic floor is required. The calotte (thickening on the pessary) is intended to move the transition between the bladder and urethra upwards and forwards and thus prevent the upper urethra from opening under stress situations such as coughing or movement (image). This is intended to prevent urine from entering the urethra, which favours the effect on urge incontinence or a mixed form of stress and urge incontinence. Compared to the urethral pessary, this pessary slips less frequently.

Clinical benefits: The pessary supports the transition between the bladder and urethra and can therefore alleviate stress incontinence and reduce the likelihood of urinary incontinence occurring. It also supports the vaginal walls in the case of milder prolapse.

Training: If a treating physician has little experience in pessary therapy, we recommend training (online/hands-on), visiting our website (see above) or referral to experienced colleagues.

Sizes: Urethral shell pessaries are measured according to the diameter of the shell. They are available in sizes from 55 mm to 90 mm in diameter. The pessary with the smallest circumference that holds straight should be inserted. If you are unsure of the size, our fitting sets can help.

Use/suitability: The attending physician will fit the pessary during the initial examination. The pessary should be inserted which achieves the best continence when coughing and standing and which still allows the bladder to be emptied without problems. It may be necessary to switch to a larger pessary after some time, as the pessary no longer closes the bladder sufficiently due to loosening of the tissue. When fitting, the pessary is guided through the posterior vaginal vault so that the calotte lifts the transition between the bladder and urethra by tilting upwards/forwards (image). Stress such as coughing, pressing and movement should be used to test whether the pessary holds during the initial insertion. Urethral shell pessaries are usually worn during the day, occasionally only during exertion (e.g. sport). We recommend that the patient removes the pessary in the evening and reinserts it in the morning. Stress incontinence does not require treatment during the night anyway. The treating doctor may recommend further measures, such as prior or parallel hormone therapy. These can make it easier to insert and change the pessary and support the build-up of epithelium and tissue. It is best to change the pessary while standing, whereby one leg can be placed on a chair. If this is too difficult, the change can also be carried out with the legs slightly apart while standing against a wall or lying down. During removal, the patient pulls on the ring part with her index finger. If the patient is unable to urinate, the pessary should be removed and a smaller (different) model selected. Even if an operation is planned, the Urethral Bowl Pessary can be regarded as a "trial pessary" for or against surgical treatment. The patient should be instructed to report any discomfort - including urination/defecation - immediately during pessary therapy**.** Patients and/or health care providers should keep the information on the label in case of complaints.

Follow-up examination: After the first insertion of the pessary, the patient should be re-examined after one week (at the latest after four weeks). At each follow-up examination, the pessary should be removed and cleaned with lukewarm water while the vagina is examined for erosions, pressure necrosis or allergic reactions. It may happen that size of the pessary must be adapted after the first fitting. The patient should then have another examination after one to two weeks. If cracks or other defects are detected in the material, the pessary must be replaced. The patient should preferably be monitored by the same health care provider for the duration of the treatment. In the case of a motivated patient who demonstrates effective handling of the pessary, follow-up examinations can be spaced further apart at the patient's discretion.

Application/cleaning: The urethra bowl pessary is labelled as a therapeutic product and may only be used by **one** patient. It is cleaned under running water without the use of disinfectants. Any mucus or blood residue can be carefully removed with a soft toothbrush. The devices should be stored hygienically in a clean container if possible. We recommend (and offer) to use a clean box to store the device overnight. 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 an acidic vaginal gel and/or a lubricating cream, which also prevents itching. During a bowel movement, the pessary may become deeper and, in the worst case, dislodge. The patient should then be instructed to feel the pessary and fix it back up in the vagina. Postmenopausal women with a thin vaginal mucosa are more susceptible to vaginal ulceration when using a pessary. Treatment with oestrogen cream can make the vaginal mucosa more resistant to erosion, as oestrogen reduces inflammation and promotes epithelial maturation. Prolonged use and/or oestrogen deficiency can lead to pressure symptoms in the vaginal mucosa. This is most serious if a pessary is forgotten and may then be difficult to remove. In the case of absolute intolerance, a smaller Urethra Bowl Pessary should be chosen, and in the case of frequent slippage, a different model, e.g. a cup or cube pessary, which should be changed daily. To prevent tissue expansion and pressure discomfort patients are advised to change the Urethral Bowl Pessary daily.

Duration of use: The therapy is "short-term", i.e. the pessary can remain in place continuously for up to 30 days, thereafter, it should be removed and cleaned.

Contraindications: Prolapse III-IV. Grade I, purely neurogenic incontinence. It may be advisable to involve a carer or family member in the changing process for patients who require care or are unable to change regularly. In the event of pain, bleeding or pronounced fluoride, however, the attending physician should be consulted. A silicone allergy is extremely rare, but it 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 advice, ignore it or cannot be followed up should not be given a pessary.

Warning: In case of pain, bleeding or extreme fluorine with odour, the attending physician must be consulted as soon as possible. Although creams and gels improve treatment with pessaries, the compatibility of these products with the pessary material has not been 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. We recommend using the pessary for three years after insertion. 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. For disposal in medical facilities, the country-specific regulations must be observed.