Instructions for Use of the Urethra Pessary (UP) for Health Care Providers & Patients

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Components and storage: The urethral pessary is made of tissue-friendly silicone. The diameter of the ring is adjusted so that the same force is always required to fold it, regardless of the size. This means that small and large urethral pessaries do not differ in their resistance. It 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. Earlier models still had a metal core. This must be pointed out during MRI examinations and during checks at airports. If patients were used to this model, it can still be ordered separately.

Indication/ intended purpose: The urethra pessary is used to treat patients with stress incontinence and/or milder forms of genital prolapse (possibly a cystocele). The calotte (thickening on the pessary) is designed to support the transition between the bladder and urethra upwards, preventing the upper urethra from opening under stress situations such as coughing or physical stress, even reducing symptoms in mixed forms of stress and urge incontinence. The treatment is indicated and monitored by the health care provider.

Clinical benefits: The pessary supports the transition between the bladder and urethra and can thus alleviate stress incontinence and reduce the likelihood of urge incontinence occurring.

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

Sizes: Urethra pessaries are available in sizes from 45 mm to 100 mm diameter of the ring part. The pessary with the smallest circumference that holds should be inserted. Our fitting sets help you to determine the size.

Use/suitability: The attending physician will fit the pessary during the initial examination. The pessary should be inserted that achieves the best continence when coughing while standing and at the same time allows the bladder to be emptied without problems. It may be necessary to change 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 ring 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. Urethra pessaries are usually worn during the day, occasionally only during exertion (e.g. sport). It is recommended 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, e.g. hormone therapy. These can make it easier to insert and change the pessary and support the build-up of epithelium and tissue. The pessary is best changed while standing, whereby one leg can be placed on a chair. If this is too difficult, the pessary can also be changed with the legs slightly apart while standing against a wall or lying down. When removing the pessary, the patient pulls on the ring with her index finger. It can be helpful to hold a pull string in place. If the patient is unable to urinate, the pessary should be removed and a smaller (different) model selected. Even if surgery is planned, the urethral pessary can be seen 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, cleaned with water and the vagina examined for erosion, pressure necrosis or allergic reactions. It is possible that the size of the pessary must be changed after the first fitting. The patient should then be examined again after one to two weeks. If cracks or defects in shape or colour are detected on the pessary, the device must be replaced. The same health care provider should preferably supervise the patient for the duration of the treatment. In motivated patients who can effectively handle of the pessary, follow-up examinations can be spaced further apart at the patient's discretion.

Application/cleaning: The urethral pessary is labelled as a therapeutic product and may only be used by a single patient. Cleaning takes place during the change in the doctor's surgery and at home when the patient removes the pessary in the evening and reinserts it in the morning. The pessary is cleaned under running water without the addition of disinfectant until no mucus or material particles (dirt) are visible. If particles remain on the pessary under running water, a soft brush (e.g. a toothbrush) can be used. 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. To adapt the right model of urogynaecological devices in outpatient units we offer sets (only for adaption), which have been evaluated for disinfection with PERFEKTAN®ACTIVE by Dr.Schumacher GmbH, allowing that size and/ models can already be adapted individually before use.

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 to prevent itching. The pessary may become deeper during a bowel movement. 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 this reduces inflammation and promotes epithelial maturation. Prolonged exposure and/or oestrogen deficiency can lead to pressure symptoms. This is most serious if a pessary is forgotten and may then be difficult to remove. A smaller urethral pessary should be selected in the event of absolute intolerance, and a different model, e.g. a urethral cup or cube pessary, should be selected in the event of frequent slippage. A daily change by the patient can prevent dilation of the tissue and pressure discomfort.

Duration of use: The therapy is "short-term", i.e. the pessary can remain in place for up to 30 days without interruption, after which it is removed and cleaned. The same patient may only reuse it.

Contraindications: Genital prolapse grade III-IV, which should be treated with cube or club pessaries. For patients who require care or are unable to ensure regular changes, a nurse or a family member may be integrated into the change process. In case of pain, bleeding or pronounced discharge, a specialist should be consulted. A silicone allergy is extremely rare, but it would also be a contraindication. Patients who do not understand, ignore or cannot follow advice should not receive a pessary. Pure neurogenic incontinence is not an indication for a pessary. Active infections, including inflammatory diseases of the vagina or pelvis, preclude the use of a pessary until the infection has subsided.

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 colour changes are observed on the pessary, the device 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 considered.