CE 0482

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

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Components and storage: The urethral pessary is made of tissue-friendly silicone. The ring diameter is adjusted so it always takes the same force to fold it, regardless of size. This means small and large urethral pessaries have the same 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.

Indication/ intended patient/user population: The urethra pessary with metal treats patients with stress incontinence and possible cystocele and is indicated and monitored by a gynaecologist. The calotte (thickening on the pessary) is intended to move the transition between the bladder and urethra upwards and forwards, preventing the upper urethra from opening during 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 with the non-metallic urethra pessary, it is preferred in elderly patients with eventual vaginal atrophy and/or a narrow introitus since the ring diameter is more flexible and thinner. Other treatments than only pessary should be chosen



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

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 ring diameters from 45 mm to 100 mm. Insert the pessary with the smallest circumference that fits. Our fitting sets help you to determine the size.

Use/suitability: The attending physician will fit the pessary during the initial examination. Insert the pessary to provide the best continence when coughing while standing, while still allowing the bladder to empty without problems. You may need to change to a larger pessary later, as the pessary may no longer close the bladder sufficiently due to tissue loosening. When fitting, guide the ring through the posterior vaginal vault so the collet lifts the transition between the bladder and urethra by tilting upwards/forwards (image). Use stress (coughing, pressing, and movement) to test whether the pessary holds during initial insertion. Urethra pessaries are usually worn during the day, occasionally only during exertion (e.g. sport). The patient should remove the pessary in the evening and reinsert 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 epithelial and tissue build-up. Change the pessary while standing, with one leg 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 label information in case of complaints and for tracing.

Follow-up examination: After the first pessary insertion, re-examine the patient after one week (no later than four weeks). At each follow-up examination, remove the pessary, clean it with water, and examine the vagina for erosion, pressure necrosis, or allergic reactions. The pessary size may need to 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, replace the device. The same health care provider should preferably supervise the patient throughout treatment. In motivated patients who can effectively handle of the pessary, follow-up examinations can be spaced further apart at the patient's discretion. Her treatments should be chosen

Application/cleaning: The urethral pessary is a therapeutic product and should be used by only one patient. Clean it during changes in the doctor's surgery and at home when the patient removes the pessary in the evening and reinserts it in the morning. Clean the pessary under running water without adding disinfectant until no mucus or particles (dirt) are visible. If particles remain on the pessary under running water, use a soft brush (e.g., a toothbrush). Store the devices hygienically in a clean container, if possible. We recommend (and offer) a clean box for storing the device overnight. If 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 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. Oestrogen cream can make the vaginal mucosa more resistant to erosion by reducing inflammation and promoting epithelial maturation. Prolonged exposure and/or oestrogen deficiency can lead to pressure symptoms. This is most serious if a pessary is forgotten and becomes difficult to remove. Select a smaller urethral pessary in cases of absolute intolerance, and a different model (e.g., a urethral cup or cube pessary) if slippage is frequent. Daily changes by the patient can prevent tissue dilation 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: Grade III-IV prolapse should be managed with a cube or cup pessary. It may be advisable to involve a nurse or family member in changing the device for patients who require care or cannot change it regularly. If there is pain, bleeding, or heavy discharge, consult the healthcare provider. Silicone allergy is extremely rare but is also a contraindication. Active infections, including inflammatory diseases of the vagina or pelvis, preclude the use of a pessary until the infection has resolved. Patients who do not understand, ignore, or cannot follow advice should be closely monitored or not given a pessary. In purely neurogenic incontinence, other treatments should be considered.

Warning: The Urethra Pessary metal is classified as MR unsafe, therefore removal before any MR investigations is required. If you have pain, bleeding, or extreme fluorine with odour, consult the attending physician 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. Report serious complications to the manufacturer and, if necessary, to the responsible authorities.

Shelf life: The pessary has a shelf life of 10 years in its original packaging from the production date. We recommend using the pessary for three years after insertion. If you notice cracks, deformation, or colour changes on the pessary, replace the device immediately.

Disposal: Dispose of used and damaged silicone products in household waste in a low-germ condition. In medical facilities, consider country-specific regulations.