Instructions Urethra Pessary

CE 0482
MED/CERT
EN ISO 13485

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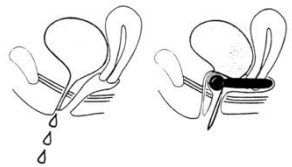

Components and storage: The urethra pessary is made of tissue-friendly silicone. It consists of a thickening to support the urethra and a ring part. The compression of the ring is adjusted so that the same hand craft is needed to fold it independently of the size. The product can be stored at room temperature at 1 to 30 ° C protected from UV radiation without direct contact with reactive media such as gas, ozone or mineral oil. Previous models contained a metal inlay which should be mentioned before an MRI, CT or at airport controls. Nevertheless, some patients still prefer this model which can then be produced on special request.
Indication: The Urethra pessary is used to treat patients with stress incontinence and eventually, with a cystocele. The device is indicated by (uro-)gynaecologists and the success of the therapy is further controlled by them. A still (albeit reduced) intact pelvic floor is assumed for the patients. The calotte (thickening) is intended to shift the transition between bladder and urethra upwards and forward and thus prevent the upper urethra from opening under stress situations such as coughing or movement (picture). This should prevent urine from entering the urethra, which has a positive effect on urge incontinence or a mixed form of stress and urge incontinence.The therapy with the Urethra pessaries has the aim to cure or reduce the patient's complaints of prolapse, also in combination with additional measures like pelvic floor training and/or drug therapy. The Urethra pessary can also be used before an operation to observe the consequences.
Teaching: In case a physician or health care provider has no experience in the handling of the device we recommend to take part in courses (online/hands-on), visit our website www.dr-arabin.de or to transfer the patients to an experienced physician with experience in conservative treatment.
Sizes: Urethra pessaries are available in sizes from 45 mm to 100 mm according to the ring diameter. The pessary with the smallest circumference that stays is applied. Size determination may be easier by the support of our fitting sets.
Use: The treating physician indicates and inserts the pessary during the initial examination. The pessary that achieves the best continence when coughing in a standing position should be inserted, but the patient should still be able to empty her bladder without problems. It may be necessary to change to a larger pessary after some time because the pessary might not close the bladder sufficiently due to softening of the connective tissue. During fitting, the ring is placed through the posterior vaginal vault so that the calotte lifts the transition between bladder and urethra by tilting it upwards/forward (picture). During the initial examination, it should be tested whether the pessary holds during coughing, pushing and movement.

Urethra pessaries are usually used during the day or only occasionally during stress (e.g. sports). It is recommended that the patient removes the pessary in the evening and reinserts it in the morning. Stress incontinence does not require therapy during the night anyway. The physician may recommend further measures such as hormone therapy to support insertion and removal of the pessary. The device may be best changed in a supine position. One leg can be placed on a chair, if this is too difficult, it can also be done by spreading the legs slightly while standing against a wall or lying. During removal, the patient pulls on the ring part with her index finger. The fixation of a thread can be helpful. If the patient cannot urinate, the pessary should be removed and a smaller (different) model should be chosen. Even if an operation is planned, the Urethra Pessary can be considered as an "experimental pessary" for or against an operative therapy. The patient should be instructed to report serious symptoms - during pessary therapy immediately.
Follow-up examination: After the first insertion of the pessary, the patient should be examined after one week (at the latest after four weeks). At each follow-up examination the pessary should be removed and cleaned with warm water while the vagina is examined for erosions, necrosis or allergic reactions. Often the size of the pessary is changed after the first fitting. The patient should then have another examination after one to two weeks. If defects are detected, the pessary has to be replaced. The patient should preferably be cared for by the same physician for the duration of the treatment. If the patient is motivated and can prove effective handling, follow-up examinations can be further postponed.
Application/ Cleaning: This urethra pessary is a therapeutic product and may only be used by one single patient. The pessary should be cleaned by running water without using disinfectants. The use of additional disinfectants is not recommended. After cleaning there should be no rests of discharge or any other substances. Exceptionally, a soft toothbrush can be used

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 smell. This side effect can be minimized by using an acid vaginal gel and/or a fat cream and thus also prevent itching. During bowel movement the pessary can descent and in the worst case dislocate. The patient may then palpate the pessary and fix it higher in the vagina again. Postmenopausal women with thin vaginal mucosa are more susceptible to vaginal ulcerations when using a pessary. Treatment with oestrogen cream can make the vaginal mucosa more resistant to erosion, as it reduces inflammation and promotes epithelial maturation. Prolonged lying in bed and/or oestrogen deficiency can lead to pressure problems of the vaginal mucosa. This is worst when a pessary is forgotten and can then be difficult to remove. In case of absolute intolerance either a smaller ring pessary can be chosen, in case of frequent dislocation another model, e.g. a urethra bowl or cube pessary, should be chosen. A daily change by the patient prevents an expansion of the tissue of the lateral vaginal walls.

Duration: 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. It may only be re-used by the same patient.

Contraindications: Genital prolapse grade III-IV, pure neurogenic incontinence, For patients who are in need of care or who are not able to ensure a regular change, it may be advisable to integrate a nurse or a family member into the handling. However, if pain, bleeding or pronounced discharge is present, the attending physician should be consulted.
An allergy to silicone is extremely rare, but would also be a contraindication. Active infections, including inflammatory diseases of the vagina or pelvis are a contraindication until the patient recovers. Weakened patients who do not understand, ignore or cannot follow advice should be supervised or not receive a pessary.

Note: Serious complications should be reported to the manufacturer and, if necessary, to the responsible authorities.
Disposal: Used or damaged silicone products can be disposed in household waste in a low-germ state. For disposal in medical facilities the country-specific regulations must be observed.