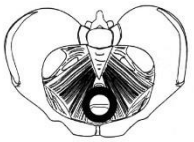
Instructions Ring Pessaries

CE 0482
MED/CERT
EN ISO 13485

Dr. Arabin GmbH & Co KG
Alfred-Herrhausen Str. 44, D-58455 Witten
Tel: +49 2302 189214 www.dr-arabin.de info@dr-arabin.de

Components and storage: The ring pessary is made of tissue-friendly silicone. The compression of the ring is adjusted so that the same hand craft is needed to fold it independently of the size. Therefore, small and large ring pessaries do not differ in their resistance. 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.

Indication: The ring pessary is used to treat patients with milder forms of genital prolapse (grade I-II) and/or stress incontinence. The indication is given 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. By reducing the pressure of the descent the device may also prevent the development of stress incontinence. The therapy with the ring pessary 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 Ring Pessary can also be used as a "preparation" if an operation is planned in the long term.



Teaching: In case a physician or health care provider has no experience with pessary treatment we recommend to take part in courses (onlinre/hands-on) or to visit our home page www,.dr-arabin.de.

Sizes: Ring pessaries are measured according to the diameter, they are available in sizes from 50 mm to 100 mm diameter. The pessary with the smallest circumference that holds should be inserted. In case of uncertainty in the determination of the size our fitting sets can be used for support.

Use: The treating physician/ gynaecologist will indicate the pessary on an outpatient basis during an initial examination. By short attempts of coughing, pressing and movement, it can be tested whether the pessary holds and relieves the discomfort by pressure.. After the test the position should be checked again.

The pessary can be changed relatively easily by the patient, i.e. it can be removed in the evening and reinserted in the morning. The physician may recommend further measures such as preceding or parallel hormone therapy. This can facilitate the insertion and change of the pessary and, if necessary, support the recovery of epithelium and tissue. It is best for the patient to change the pessary while standing. 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 down. When inserting the ring, the patient should make sure that the compressed ring is first inserted into the posterior vaginal vault and then pushed forward and upwards. During removal, the patient pulls the ring with her index finger on the ring part. The fixation of a pulling thread can be helpful. If the patient cannot urinate, the pessary should be removed and a smaller (different) model should be chosen. The patient should be instructed to report all serious symptoms - including urination/defecation 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. Sometimes the size of the pessary is changed after the first fitting. The patient should then be instructed again to have a further examination within one to two weeks. If tears or other defects are found while examining the pessary, the device has to be replaced. The patient should preferably be cared for by the same physician for the duration of the treatment. In case of a motivated patient who can prove an effective handling of the pessary, follow-up examinations can be prolonged.

Application/Cleaning: The club pessary is a therapeutic product to be used solely for one patient. The device is cleaned by running water and eventually some mild soap, during the change in the ambulatory or at home when the patient removes the pessary in the evening and re-inserts it in the morning. The use of additional disinfectants is not recommended. There should be no rests of discharge or dirt. In exceptional cases, a soft toothbrush can be used for cleaning.

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 descend or even dislocate. The patient should then be instructed to palpate the ring and fix it back up in the vagina. Postmenopausal women with thin vaginal mucosa are more susceptible to vaginal ulceration when using a pessary. Treatment with oestrogen cream can prevent the vaginal mucosa from erosion, as oestrogen reduces inflammation and promotes epithelial maturation. Prolonged therapy and/or oestrogen deficiency can lead to pressure problems of the vaginal mucosa. The worst case is when a pessary is forgotten and then difficult to remove. In case of absolute intolerance either a smaller ring pessary can be chosen, or another model, e.g. a bowl or cube pessary, should be chosen, which has to be changed on a dialy basis. This will be decided by the physician/gynaecologist. The ring pessary can also be changed on a daily basis by the patient herself which may prevent an expansion of the lateral vaginal tissue.

Duration: The therapy is "short-term", i.e. the pessary can remain in place for up to 30 days without interruption, thereafter, it is removed and cleaned. It may only be re-used by the same patient.

Contraindications: Genital prolapse grade III-IV which are better treated with cube or club pessaries. 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 or change. However, if pain, bleeding or pronounced discharge is present, the attending physician should be consulted.

Allergic reactions to silicone are extremely rare, but would also be a contraindication. Active infections, including inflammatory diseases of the vagina or pelvis, are contraindications until recovery. Patients who do not understand, ignore or cannot follow advice should not receive a pessary.

Warning: In case of pain, bleeding or extreme discharge with smell the physician in charge should be consulted as soon as possible. Although several crèmes are additionally indicated to improve the therapeutic effects, we have not tested the compliance of the material with these substances, but never heard of any complaints or complications. Serious complications should be reported to the manufacturer and, if necessary, to the responsible authorities.

Shelf life: The pessary has been assigned a shelf life of 10 years from the date of production. After insertion we recommend not to continue the therapy with the same device for more than 3 years. In case there are defects, changes of the form or colour the pessary should be replaced.

Disposal: Used or damaged silicone products should be packed and be disposed in household waste in a low-germ state. For disposal in medical facilities the country-specific regulations must be considered.