



Instructions Club Pessary

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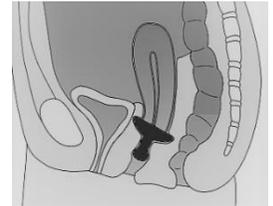
Components and storage: The traditional thick-walled Club Pessary is made of tissue-friendly silicone. It can be stored at room temperature at 1 to 30 °C protected from UV radiation without direct contact to reactive media like gas, ozone or mineral oil.

Indication: The Club pessary is used in patients with severe forms of vaginal and uterine prolapse (grade III-IV), where other ring-shaped pessaries can no longer withstand the pressure and/or a cube pessary increases stress incontinence. Experienced (uro-) gynaecologists indicate the application and should also follow these patients.

Teaching: In case a physician or health care provider has no experience in the handling, the device we recommend to take part in courses (online/hands-on), to visit our web site www.dr-arabin.de or to transfer the patients to an experienced physician with experience in conservative treatment of severe prolapse.

Sizes: Club pessaries are available in sizes from 50 mm to 90 mm according to their largest diameter. The pessary with the smallest circumference that stays should be inserted. In case of uncertainty to determine the size, we also provide fitting sets.

Use: Before application, the prolapsed organs must be re-positioned. If there are other viscera in the hernial sac besides the uterus, re-positioning into the abdominal cavity must be carefully performed with two hands. After inserting the pessary, the patient and the physician check whether the pessary adheres. The patient should first cough or press while lying down. By moving the stem, it is also possible to check whether the pessary sticks. It is advisable to explain the function of the handle to the patient and to let her feel it herself already directly after the insertion. If the patient feels comfortably, she should move for a short time for testing purposes. Before and during treatment the physician may recommend additional measures and discuss them with the patient. If possible, the patient should remove herself while pressing. **If this is too difficult for her**, because the relatively rigid pessary must be tilted while protecting the urethra the gynaecologist will change the pessary. It is recommended to ask the patient to urinate before leaving the ambulance-if this is too difficult, the pessary should be removed and a smaller (different) model should be chosen. The patient should be instructed to report all complaints - 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 4 weeks, to see if there are any signs of irritation, or allergic reactions. For this purpose, the pessary must be removed. It may happen that the size of the pessary is changed after the first fitting. The patient should then be instructed to have a further examination within one to two weeks. In case of a motivated patient who can remove and insert the device herself, follow-up examinations can be postponed at the discretion of the doctor.

At each follow-up examination, the pessary should be removed while the vagina is examined for erosions, pressure necrosis or allergic reactions. If defects are detected during the examination, the pessary should be replaced. For reasons of continuity of care, the same physician who placed the pessary should preferably care for the patient.

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 if the patient removes the pessary in the evening and re-inserts it in the morning. 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 go deeper and in the worst case dislocate. The patient should then be instructed to palpate the head of the pessary and, if necessary, to fix it in the vagina while pressing. Postmenopausal women with thin vaginal mucosa are more susceptible to vaginal ulcerations when using a pessary. Treatment with oestrogen cream can then make the vaginal mucosa more resistant to erosion, as oestrogen reduces inflammation and promotes epithelial maturation. Prolonged lying in bed and/or oestrogen deficiency can cause pressure problems of the vaginal mucosa. This is worst when a pessary is forgotten and can then be difficult to remove. The use of lubricant gel or oestrogen cream can then make it easier to remove the pessary. The physician in charge decides this. In case of absolute intolerance either a smaller Club pessary or another model, e.g. a cube pessary or tandem pessary can be chosen, which however should be changed daily.

Duration: The therapy is "short-term", i.e. the pessary can remain in place for up to 30 days without interruption. After a change and cleaning, it can be re-inserted only in the same patient.

Contraindications: Genital prolapse grade I-II that can be treated with ring or bowl pessaries. For patients who are in need of care or are unable to consider regular controls, it may be advisable to involve a nurse or family member in the management of the change. However, the attending physician should be consulted in case of pain, bleeding or pronounced discharge. An allergy to silicone is extremely rare, but would also be a contraindication. In case of active infections, including inflammatory diseases of the vagina or pelvis, any pessary is contraindicated until the infection is cured. Patients who do not understand, ignore or cannot follow advices should be supervised or 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 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.