Instructions for Use of the Cup Pessary (KP) for Health Care Providers & Patients

CE 0482

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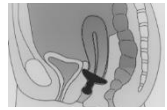
Components and storage: The traditional Cup Pessary is made of thick-walled, tissue-friendly silicone. During development, we have increasingly applied softer silicone for better usability. The pessary can be stored at temperatures between 1 and 50°C protected from UV radiation without contact with reactive media such as gas, ozone or mineral oil. The perforations allow the outflow to pass through

Indication/ intended purpose: The cup pessary is used to treat patients with severe forms of vaginal and uterine prolapse (grade III-IV) where other pessaries cannot withstand the pressure and/or a cube pessary increases stress incontinence. An experienced (uro-) gynaecologist, who monitors the success of the treatment, makes the indication.

Clinical benefit: In severe forms of prolapse (grade III-IV) and simultaneous treatment failure of other pessaries, the cup pessary can reduce stress incontinence and, above all, severe prolapse symptoms by supporting the pelvic floor organs and creating a vacuum effect under the symphysis.

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



Sizes: Cup pessaries are measured according to the diameter of the shell. They are available in sizes from 50 mm to 90 mm in diameter. The pessary with the smallest circumference that holds straight should be inserted. If you are unsure of the size, our fitting sets can help.

Use/suitability: A pessary should not be prescribed "blindly". The prolapsed organs may need to be pushed back before application. If the hernia sac contains viscera other than the uterus, repositioning in the abdominal cavity must be carried out carefully with two hands**.** After inserting the pessary, the patient and doctor check whether the pessary adheres. The patient initially coughs or presses while lying down. By moving the handle, it can be checked whether the pessary adheres. It is advisable to explain the significance of the stem to the patient and to let her feel the handle herself in the examination chair. If the patient has a good feeling, she should move around for a short time to test it. When inserting the pessary and during treatment, the treating doctor may recommend additional measures such as the use of creams and local oestrogen therapy. This should be discussed with the patient. The patient herself can remove the pessary. To do this, she grasps the pessary by the cap of the stem and pulls the pessary out while pressing. If this process is too difficult for the patient, it is recommended that the gynaecologist changes the pessary, as the pessary must be tilted at the pelvic floor while protecting the urethra during removal. Patients and/or health care providers should keep the information of the label in case of complaints.
We offer a video on our website (see above) to further support the changing process, see also the QR code on the right:
It is also recommended to ask the patient to urinate before leaving the practice. If she is unable to do this, the pessary must be removed and a smaller (different) model selected. The patient must be instructed to report any discomfort - including urination/defecation - immediately during pessary therapy.

Follow-up examination: After the first insertion of the pessary, we recommend a follow-up examination after one or at the latest four weeks to rule out any signs of irritation or pressure points. The pessary must be removed for this purpose. It may be necessary to change the size of the pessary after the first fitting. In these cases, a further short-term follow-up examination must be carried out after one to four weeks at the latest. In the case of a motivated patient who can demonstrate effective removal, insertion and care of the pessary, follow-up examinations can be spaced further apart at the doctor's discretion. The pessary must be removed at each follow-up visit in order to examine the vagina for erosion, pressure necrosis or allergic reactions. The same doctor should preferably care for the patient for the duration of the treatment.

Application/ cleaning: The cup pessary is labelled as a therapeutic product and may **only** be used **on a single patient**. Cleaning takes place during the change in the doctor's surgery and only 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 (e.g. from unintentional contact with other materials or dirt) are visible. If particles remain on the pessary under running water, a soft brush (e.g. toothbrush) can be used to remove them**.** We recommend (and offer) to use a clean box to store the device overnight, i fit may be removed. In case 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 urogynecological 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. These side effects can be minimised by using an acidic vaginal gel and/or a lubricating cream to prevent itching. During a bowel movement, the pessary can become deeper and, in the worst case, dislodge. **In these cases, the patient can** feel the head of the bulb and hold it in place in the vagina while pushing. Postmenopausal women are more susceptible to vaginal ulceration when using a pessary. Treatment with oestrogen cream can make the vaginal mucosa more resistant to erosion, as oestrogen reduces inflammation and promotes epithelial maturation. Prolonged use and/or oestrogen deficiency can lead to increasing discomfort... This can happen if a pessary is forgotten and may then be difficult to remove. The use of lubricant or oestrogen cream can also make it easier to remove the pessary. This is decided by the health care provider. In the case of absolute intolerance, either a smaller cup pessary or another model, e.g. a cube or tandem pessary, can be selected, which should, however, be changed daily.

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. After cleaning and interruption of therapy, it can only be reinserted in the same patient.

Contraindications: Prolapse I-II degree, which can be treated with other models. For patients who require care or are unable to regularly change devices, it is recommended that a nurse or family member is involved in the changing process. An allergy to silicone is an extremely rare contraindication. Active infections and chronic inflammatory diseases of the vagina or pelvis preclude the use of a pessary until the infection has disappeared. Patients, who do not understand or ignore advice should be actively followed or should not receive a cup pessary.

Warning: In case of pain, bleeding or extreme discharge with odour, the health care provider must be counselled 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.

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.