Instructions for use of Bowl and Sieve Bowl Pessary for Health Care Providers and Patients

CE 0482

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Components and storage: The sieve bowl or bowl pessary is made of tissue-friendly silicone, which is easily foldable. It can be stored at room temperature at 1 to 50°C protected from UV radiation without direct contact to reactive media like gas, **ozone or mineral oil.** The perforated version allows a better passage of discharge.

Indication/intended use: The bowl or sieve bowl pessary is used to treat patients with milder forms of vaginal and uterine prolapse and/or stress incontinence. The treatment is indicated and monitored by the health care provider. The bowl pessary can also be used to reduce prolapse symptoms in combination with additional measures such as physiotherapy, medication, biofeedback or before and after an operation.

Teaching: In case a 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: Bowl pessaries are available in sizes from 55 mm to 95 mm diameter. The pessary with the smallest circumference that holds straight should be inserted. Our fitting sets might support to find the right sizes.

Use/Suitability: The physician in charge adjusts the pessary during the initial examination. The patient should cough, push and move to realize whether the pessary stays in place. The pessary can be changed relatively easily by the patient herself, i.e. it can be removed in the evening and reinserted in the morning. The health care provider may recommend further treatments such as estrogen crèmes, which can facilitate the insertion, change of the pessary, and support the restoration of the mucous tissue. The patient better to change the pessary while standing and one leg is 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 bowl, the patient should make sure that it is compressed and inserted into the vaginal vault and then unfolded. During removal, the patient pulls the bowl through the central opening with her index finger. 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 complaints as soon as possible.

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 and the vagina examined to exclude erosions, necrosis or allergic reactions. Often, 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. If defects or changes of shape or color are observed, the pessary has to be replaced. The patient should preferably be cared for by the same health care provider for the duration of the treatment. In case of a motivated patient who can prove an effective removal, insertion and care of the pessary, follow-up examinations can be further apart at the doctor's discretion.

Application/Cleaning: The (sieve) bowl pessary is labelled as a therapeutic product and may only be used by a single patient. Cleaning takes place during the change in the outpatient unit and 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 toothbrush can be used for cleaning. We recommend (and offer) using a clean box to store the device overnight. In case our adjustment rings are used to choose the right size, providers should consider our evaluation for cleaning and sterilisation. To adapt the right model of urogynaecological devices in outpatient units we offer sets (only for adaption), which have been evaluated for disinfection with PERFEKTAN®ACTIVE by Dr.Schumacher GmbH, allowing that size and/ models can already be adapted individually before use.

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 reduced by using an acid vaginal gel and/or a fat cream and thus prevent itching. During a bowel movement, the pessary can descend. The patient should be instructed to palpate the bowl 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 estrogen cream can make the vaginal mucosa more resistant to erosion, as estrogen reduces inflammation and promotes epithelial maturation. Prolonged lying in bed and/or estrogen deficiency can lead to pressure problems of the vaginal mucosa. This is worse 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 slipping, another model, e.g. a cup or cube pessary, should be chosen, which needs be changed daily. The health care provider will then decide on this - a daily change by the patient prevents an expansion of the tissue and pressure problems.

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, which should be treated with cube or club pessaries. For patients who require care or are unable to ensure regular changes, a nurse or a family member may be integrated into the change process. In case of pain, bleeding or pronounced discharge, a specialist should be consulted. A silicone allergy is extremely rare, but it would also be a contraindication. Patients who do not understand, ignore or cannot follow advice should not receive a pessary. Active infections, including inflammatory diseases of the vagina or pelvis, preclude the use of a pessary until the infection has subsided.

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 compatibility 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 continuing 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.