Instructions for Use of the Dr Arabin Hodge-Pessary (HP) for Health Care Providers & Patients

Dr Arabin GmbH & Co KG Sales: A.-Herrhausen-Str. 44, D-58455 Witten Tel: +49 2302 189214 Mail: info@dr-arabin.de/ www.dr-arabin.de
Training/Design/Science: Koenigsallee 36 14193 Berlin/ GF: Prof. Dr.med. Dr.h.c. mult. Birgit Arabin

CE 0482

Components and storage: The Hodge pessary is made of tissue-friendly silicone and a core of flexible aluminium, which allows the pessary to be deformed in all directions. It can be stored at room temperature at 1 to 50°C protected from UV radiation without direct contact with reactive media such as gas, ozone or mineral oil.

Indication/intended purpose: When the Hodge pessary was developed, the focus was on "lifting the uterus", an indication that has lost its significance today. The aluminium core allows individual adjustment. A Hodge pessary is now only used in individual cases for the treatment of urinary incontinence if other models cannot be tolerated due to previous operations. The Hodge pessary is preferably used to treat older patients (with less pressure discomfort even after a longer period of use) with prolapse symptoms with or without incontinence. It is assumed that the wearer still has (albeit reduced) pelvic floor strength. The indication is given by the treating doctor or referred to a colleague. By repositioning the prolapse, it can also prevent the development of stress incontinence. The aim of treatment with the Hodge pessary is to reduce the patient's prolapse symptoms, also in combination with additional measures.

Clinical benefit: The aim of treatment with the Hodge pessary is to reduce the patient's prolapse symptoms, also in combination with additional measures, if other pessaries cannot be fitted. By repositioning the prolapse, the pessary can also prevent the development of stress incontinence.

Training: If a treating physician has little experience in pessary therapy, we recommend training (online/hands-on), visiting the website (see above) or referral to experienced colleagues.
The patient herself should also be trained in changing the pessary by the health care provider or additional information on our website (see above).

Sizes: Hodge pessaries are available in sizes from 55 mm to 95 mm in diameter. The pessary with the smallest circumference that holds should be inserted. Since the device can be folded it does not nee special adaptation kits.

Use/suitability: A pessary should not be prescribed "blindly". The treating doctor fits the pessary and tests whether it holds by coughing, pressing and moving. The pessary is relatively easy for the patient to change, i.e. to remove in the evening and reinsert in the morning. The attending physician may recommend further measures, such as prior or parallel hormone therapy. This can make it easier to insert and change the pessary and support the build-up of epithelium and tissue. It is best for the patient to change the pessary while standing, whereby one leg can be placed on a chair. If this is too difficult, the pessary can also be inserted with the legs slightly apart while standing against a wall or lying down. When inserting the pessary, the patient should ensure that it is placed in the posterior vaginal vault. During removal, the patient pulls the pessary with her index finger. If the patient is unable to urinate, the pessary must be removed and a different model selected. The patient should report any discomfort during pessary therapy immediately.

Patients and/or health care providers should keep the information of the label in case of complaints

Follow-up examination: After the first insertion, the patient should be re-examined after one week (at the latest after four weeks). At each follow-up examination, the pessary is removed while the vagina is examined for erosion or pressure necrosis. Sometimes it is necessary to change the size and shape of the pessary after the first fitting. The patient should then have another examination carried out within one to two weeks. If cracks or other defects are found when the pessary is examined, the pessary must be replaced. The same doctor should preferably care for the patient for the duration of the treatment. In the case of a motivated patient who can demonstrate effective removal, insertion and care of the pessary, follow-up examinations may be spaced further apart at the doctor's discretion.

Application/cleaning: The Hodge pessary is labelled as a therapeutic product and may only be used by **one** patient. It is cleaned under running water without the use of disinfectants. Any mucus or blood residue can be carefully removed with a soft toothbrush. We recommend (and offer) to use a clean box to store the device overnight. 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. This side effect can be minimised by using an acidic vaginal gel and/or a lubricating cream, which also prevents itching. The pessary may become deeper during a bowel movement. The patient should then be instructed to feel the ring and fix it back in the vagina. Postmenopausal women with a thin vaginal mucosa 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 pressure symptoms in the vaginal mucosa. This is most serious if a pessary is forgotten and may then be difficult to remove. In the case of intolerance, either a different size or model should be selected. Daily replacement by the patient prevents tissue expansion and pressure discomfort.

Duration of use: The therapy is "short-term", i.e. the pessary can remain in place continuously for up to 30 days, after which it is removed and cleaned. It may only be reused within the same patient.

Contraindications: Prolapse Grade III-IV should be better treated with a cube or cup pessaries. It may be advisable to involve a nurse or family member in the changing process for patients who require care or are unable to change devices regularly. In the event of pain, bleeding or pronounced discharge, the health care provider 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, preclude the use of a pessary until the infection has disappeared. Patients who do not understand advice, ignore it or cannot be followed should be closely monitored or not given a pessary.

Warning: In case of pain, bleeding or extreme discharge with odour, the responsible physician must be consulted 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.

Shelf life: The pessary has a shelf life in its original packaging of 10 years from the production date. We recommend using the pessary for three years after insertion. If cracks, deformation or colour changes are observed, the pessary must be replaced at any time.

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.