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

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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 (1 to 50°C), protected from UV radiation, and without direct contact with reactive media such as gas, ozone, or mineral oil.

Indication/ intended patient/user population: The Hodge pessary is used to treat urinary incontinence or pelvic organ prolapse when other models cannot be tolerated. Frequently, this can be caused by previous operations or rare genital malformations. The aluminium core allows individual adjustment of the shape. It is assumed that the patient still has (albeit reduced) pelvic floor strength. The health care provider indicates the device, or referes the patient to a colleague. The aim of treatment is to reduce the patient's prolapse or incontinence symptoms, also combined with additional measures, and to prevent incontinence from deteriorating.



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 should also be trained to change the pessary by the health care provider or through additional information on our website (see above).

Sizes: Hodge pessaries are available in sizes from 55 mm to 90 mm in diameter. Insert the pessary with the smallest circumference that fits. Since the device can be folded, it does not need special adaptation kits.



Use/suitability: Do not prescribe a pessary "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 hormone therapy, either before or alongside pessary use. This can make insertion and changing easier and support epithelial and tissue build-up. The patient should change the pessary while standing, with one leg 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. To remove it, 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. Patients and/or health care providers should keep the label information in case of complaints and for tracing.

Follow-up examination: After the first insertion, re-examine the patient 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 the pessary's size and shape must be changed 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 on examination, replace the pessary. The same doctor should preferably care for the patient throughout the treatment. If a motivated patient 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 a therapeutic product and may be used by only **one** patient. Clean it under running water without disinfectants. Carefully remove any mucus or blood residue with a soft toothbrush. We recommend (and offer) using 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". The most common side effect is increased discharge, possibly with odour. This can be minimised by using an acidic vaginal gel and/or a lubricating cream, which also prevents itching. The pessary may move deeper during a bowel movement. The patient should then be instructed to feel for the ring and reposition it in the vagina. Postmenopausal women with thin vaginal mucosa are more susceptible to vaginal ulceration when using a pessary. 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 becomes difficult to remove. If the pessary is intolerable, select a different size or model. 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 be reused only with the same patient.

Contraindications: Grade III-IV prolapse should be managed with a cube or cup pessary. Consider involving a nurse or family member to change the device for patients who require care or cannot change it regularly. If there is pain, bleeding, or heavy discharge, consult the healthcare provider. Silicone allergy is extremely rare but is also a contraindication. Active infections, including inflammatory diseases of the vagina or pelvis, preclude the use of a pessary until the infection has resolved. Patients who do not understand, ignore, or cannot follow advice should be closely monitored or not given a pessary. For purely neurogenic incontinence, consider other treatments.

Warning: The Hodge Pessary is classified as MR unsafe, therefore removal before any MR investigations is required. If you have pain, bleeding, or severe discharge with odour, consult the responsible physician 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. Report serious complications to the manufacturer and, if necessary, to the responsible authorities.

Shelf life: The pessary has a shelf life of 10 years in its original packaging from the production date. We recommend using the pessary for three years after insertion. If you notice cracks, deformation, or colour changes, replace the pessary immediately.

Disposal: Dispose of used and damaged silicone products in household waste in a low-germ condition. In medical facilities, consider country-specific regulations.