Instructions for Use of the Dr Arabin Hybrid Pessary normal (AHPN) /soft (AHPS) for Health Care Providers & Patients

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CE 0482

Components and storage: The hybrid pessary is made of tissue-friendly silicone. The pessary can be stored at all temperatures between 1 and 50 °C protected from UV radiation without direct contact with reactive media such as gas, ozone or mineral oil.

Indication/ intended purpose: The hybrid pessary is used to treat genital prolapse of internal organs, regardless of age. Hybrid pessaries lie ventrally on the symphysis and thus provide good support for cystoceles even in case of avulsion. The recesses in the lateral walls create a vacuum or suction cup effect. In tensile force measurements, the hold of these pessaries was approximately 5 times higher than with conventional models. The egg-shaped contour makes it easy to insert and change the pessary and ensures less overstretching of the vaginal side walls than round pessaries. In contrast to the cube pessary, the pessary is open on the inside so that discharge or blood can drain more easily. It can even be used with a tampon. The pessary was primarily developed for early pelvic floor dysfunction caused by lesions of the levator muscle, which are associated with an enlargement of the vaginal opening. Its purpose is to support internal organs and relieve pressure and incontinence problems that also occur during pregnancy and the postpartum period or when other pessaries do not hold properly.

Clinical benefits: In the event of a prolapse, the pessary returns the internal organs to their original position and can thus alleviate stress incontinence. In the case of scars or abnormalities, the pessary can adapt to anatomical features and can be used before and after surgery and in combination with electrostimulation or physiotherapy.

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

Sizes/degree of hardness: The size of the pessary is specified according **to the length diameter** and currently consists of dimensions between 55 and 80 mm in 5 mm increments. The size is selected by the health care provider. The most commonly used sizes are 60, 65 and 70 mm. The pessary should be large and firm enough to adhere well when pressing, coughing and moving. The frontal narrow part should lie above the symphysis. A pessary that is too large or too small can slip under the symphysis and then be less effective. The pessary can be ordered with **NORMAL and SOFT consistency**, each adapted to the individual situation. It is possible for patients to initially wear the soft pessary in everyday life and then insert the more stable pessary in stressful situations such as physical activity or sports..

Use/suitability: A pessary should not be prescribed "blindly". The health care provider fits the pessary during the initial examination and shows the patient how to use it who then can start her own therapy, i.e. she can remove the pessary in the evening and reinsert it in the morning. This allows the vaginal walls to recover at night. Before inserting the device, a cream can be applied to the edges of the upper surface for better care of the mucous membrane. For women before the menopause, pH-stabilising creams (e.g. Vagisan.®), after the menopause, a fat cream can be used daily and an oestrogen cream 2-3 times/week. The choice of cream should be discussed with the physician in charge. The pessary is initially placed with the firmer part facing upwards and the flaps facing downwards. This can be adjusted individually for each woman. Some women find it more comfortable if the soft tabs point upwards. To insert the pessary, place your foot on a chair or the edge of a bed or bathtub (make sure it is non-slip!), as you would when inserting a tampon. Alternatively, the pessary can be inserted with the legs spread apart or lying down. The product should be squeezed with the left hand, so that the wider side is inserted backwards into the vaginal opening first. Once the pessary has come to rest completely in the vagina, the pessary is pushed further upwards (e.g. with the right index finger) until the rear part **sits** high in the vagina **and the front part sits above the symphysis**. Finally, the pointed end is tilted upwards by approx. 45°. This is the only way to ensure that this part is supported by the symphysis so that the tabs can automatically attach themselves to the lateral walls. To remove the device, it is best to insert the middle or index finger into the vagina in the same position until the patient can hook the front part, move it briefly back and forth in different directions and then remove it. If urination problems, incontinence or pressure symptoms occur, the pessary should be replaced with a smaller/other model. The patient should report any discomfort during therapy. If the pessary does not hold sufficiently, a larger or different model should be considered. If the pessary is used during pregnancy, labour and rupture of the membranes must be ruled out before. The pessary must be removed at the onset of labour and rupture of the membranes. If there is an indication to apply the pessary after the birth, placental remnants must be excluded by transvaginal sonography and and documented in the files. In addition, infections, suture dehiscence and oedema formation must be ruled out before therapy. Patients and/or health care providers should keep the information of the label in case of complaints.

For support, we offer a video on our website (see above), see also QR code on the right:

Follow-up examination: After the pessary has been prescribed for the first time, the patient should have a follow-up examination after approximately one week (four weeks at the latest)**.** The vagina is examined for any erosion, pressure lesions or irritation. If the size is modified, the patient should be re- examined again after 1-4 weeks. It is recommended that the patient is cared for by the same health care provider for the duration of the treatment. In the case of a patient who confirms adequate handling of the pessary, follow-up examinations can be spaced further apart.

Application/cleaning: The Hybrid 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. They should be stored hygienically in a clean container if possible. We recommend (and offer) to use a clean box to store the device over night. 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". The most common side effects are increased discharge and possibly odour. These can be reduced by using additional measures (creams, hygiene). The pessary may descent during bowel movement. The patient should be instructed to repose the pessary higher again. Postmenopausal women are more susceptible to mucosal injuries. Prolonged uninterrupted use and/or oestrogen deficiency can lead to pressure complaints of the vaginal mucosa. To prevent mucosal erosion, the use of oestrogen-containing creams (suggested 2x/week) and fat creams (suggested 7x/week) helps women after the menopause. A physician must always be consulted in the event of bleeding, pain or serious infections.

Duration of treatment: The therapy is "short-term" (< 30 days). **It is recommended to remove the pessary every evening and reinsert it in the morning.**

Contraindications: For patients who require care or are unable to change devices regularly, a nurse or family member can be involved in the changing process. An allergy to silicone is an extremely rare contraindication. Active infections, including pelvic inflammatory disease, preclude the use of the pessary until the infection has disappeared. In pregnant women, active labour, onset of labour and premature rupture of the membranes, post partum placental remnants, vaginal oedema formation or suture dehiscence are contraindications. Patients who do not understand advices about the handling or cannot be followed up should not be given a pessary.

Warning: In the event of pain, bleeding or serious infections, the responsible health care provider must be consulted immediately. Creams and gels improve the success of treatment. The compatibility of these products with the pessary has not been specifically 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 been assigned a shelf life of 10 years from the production date in its original packaging. After the first insertion of the pessary, the pessary should last at least 12 months. If cracks, deformation or discolouration occur during inspection of the pessary, the pessary must be replaced.

Disposal: Used and damaged silicone products can be packaged and disposed of with household waste. In medical facilities, the country-specific regulations must be observed.