Instructions for Use of the Dr. Arabin Tandem Pessary (unperforated/perforated, TP/TPP)

CE 0482

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Components and storage: The Tandem Pessary consists of two coupled cube pessaries made of tissue-friendly silicone with a button and a thread to facilitate changing. 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.

Indication/ intended purpose: Only advanced forms of genital prolapse (grade III-IV) are treated with the tandem pessary. The vacuum or suction cup effect of the tandem pessary provides greater resistance than cube pessaries. The non-perforated form holds better than the perforated form, which is easier to change and allows discharge to drain. The Tandem Pessary can be used to treat severe and individually specialised forms of genital prolapse with a specific anatomy because the sizes of the cubes can be selected individually.

Clinical benefits: In the case of scars or deviations, tandem pessaries can adapt to anatomical features. In the case of prolapse of internal organs, the tandem pessary returns the organs to their original position. Indications for treatment also include bladder emptying disorders, discomfort during sexual intercourse and pre-operative preparation with oestrogen cream, as well as stress incontinence, whereby the pessary can be placed at different heights. With the tandem pessary, the lowered organs can be returned to their original position even more safely than with a single cube pessary (image). They are also suitable for scar loosening of vaginal constrictions. Other indications include bladder emptying disorders, discomfort during sexual intercourse and preoperative treatment.

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 must also be trained in changing the pessary by health care provider or through additional information on our website.

Sizes: The sizes of the cubes of the tandem pessary depend on the edge length of the cubes. There are six different sizes of individual cubes available for the combination, with a minimum edge length of 25 mm (size 0) up to a maximum edge length of 50 mm (size 5). Correct selection is a prerequisite for an effective pain-free use. The combinations should be large enough to adhere well when pressing, coughing and moving. Large combinations are more difficult to remove. During treatment, adjusting the pessary sizes (usually to a smaller model) may be necessary.

Use/suitability: A pessary should not be prescribed "blindly". The health care provider adjusts the pessary on an outpatient basis during the initial examination. Tandem Pessaries are removed by patients in the evening and reinserted in the morning. This allows the vaginal walls to recover overnight. It is advantageous to apply an oestrogen cream over 2-3 edges of the cubes when inserting the device to improve gliding and care of the vaginal tissue. The choice of cream should be discussed with the health care provider.

To insert the pessary, patients can place a foot on a chair or the edge of the bed, similar to inserting a tampon; it may also be sufficient to insert the pessary while standing or lying down with legs apart. To remove, the vacuum is released **with** the index and/or middle finger, whereby the accessible edges of the pessary are moved to release the vacuum. The pessary is then removed by gently pulling. If the patient is unable to urinate or if the pessary aggravates incontinence, the device should be removed and a different model selected. The patient should be instructed to immediately report any adverse symptoms during pessary therapy.

Patients and/or health care providers should keep the information on the label in case of complaints. **We offer a video on our website (see above) to support the change, see also QR code on the right:**

Follow-up examination: After the first insertion, the patient should be re-examined after approximately one week. The vagina should be examined for erosions or necrosis. It may be necessary to adapt the sizes after the treatment. The patient should then be examined again after one to two weeks. If defects in shape and colour of the material are detected, the pessary must be replaced. The same health care provider should preferably supervise the patient for the duration of the treatment. If motivated, patients can effectively handle the device, and follow-up examinations may be spaced further apart at the patient's discretion.

Application/ cleaning: The Tandem Pessary is designated as a therapeutic product and may only be used by a single patient. It is cleaned under running water without the use of disinfectants. Any mucus or material residue can be carefully removed with a soft toothbrush without loosening or tearing out the button. . 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. 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 additional measures (creams, hygiene). During a bowel movement, the pessary may protrude (top right image). The patient can push the pessary higher again. Postmenopausal women are more susceptible to mucosal injuries. Prolonged use and/or oestrogen deficiency can lead to pressure problems in the vaginal mucosa. In post-menopausal women, oestrogen-containing creams (suggested 2x/week) and fat creams (suggested 5x/week) help to prevent mucosal erosions. If the string should break, the pessary should be removed as soon as possible. The cube pessary can cause urinary incontinence in women who have a hidden bladder weakness ("larvated incontinence"). A physician must always be consulted in the event of bleeding, pain or serious infections. If the Tandem pessary is not tolerated, a different model, e.g. a cup pessary, can be selected. If the thread dislocates, the pessary must be removed as soon as possible by health care providers. In women who have a hidden form of bladder weakness ("larvated incontinence"), the pessary can increase urinary incontinence. In these cases, other treatment options should be considered. For patients who require care or are anxious, a carer or family member can be involved in handling the change,

Length of stay: The therapy is "short-term" (< 30 days). **However, we recommend changing the pessary every evening**! It may only be reused by the same patient.

Contraindications: For patients who require care or are unable to change regularly, a carer or family member can be involved in the changing process. In the event of pain, bleeding or infection, the attending physician should be consulted. A silicone allergy is extremely rare, but it 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 subsided. Patients who do not understand advice, ignore it or cannot be followed up should not be given a pessary.

Warning: In case of pain, bleeding or serious infection, the health care provider 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 the original packaging of 10 years from the production date. We recommend using the pessary for 6 months after insertion. If cracks, deformation or colour changes are observed within the material, the pessary must be replaced at any time.

Disposal: Used and damaged silicone products can be disposed of at home in the household waste in a low-germ state. In medical facilities, the country-specific regulations must be considered.