Instructions for Use of the Ring Pessary (RP) for Health Care Providers & Patients

CE 0482

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Components and storage: The Ring Pessary is made of tissue-friendly silicone. The compression of the rings is adjusted by the diameter so that the same hand force is required to fold each size.
This means that small and large ring pessaries do not differ in their resistance. The pessary can be stored at room temperature at 1 to 50°C protected from UV radiation without direct contact with reactive substances.
media such as gas, ozone or mineral oil.

Indication/ intended purpose: The ring pessary is used to treat patients with milder forms of genital prolapse and/or stress incontinence. The treatment is indicated and monitored by the health care provider. The ring 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.

Clinical benefits: In milder forms of prolapse, the pessary returns the urethra to its original position and can thus alleviate stress incontinence and reduce the likelihood of later stress incontinence.

Training: If a health care provider has little experience in pessary therapy, we recommend training by specialised colleagues (online/hands-on), a visit to our website (see above) or a referral to a specialist.
with experience in conservative therapy.

Sizes: Ring pessaries are available in sizes from 50 mm to 100 mm in diameter. The pessary with the smallest circumference that holds straight should be inserted. If you are unsure about the size, our customisation sets can help.

Use/suitability: A pessary should not be prescribed "blindly". The health care provider adapts the device on an outpatient basis during the initial examination. The patient should use coughing, pressing and movement to test whether the device holds. The pessary is relatively easy for the patient to change, e.g. to remove in the evening and reinsert in the morning. Additional creams make it easier to insert and change the pessary and - if necessary - support the vaginal epithelium and tissue. It is best to change the pessary while standing, whereby one leg can be placed on a chair. If this is too difficult, it can also be done with the legs slightly apart while standing against a wall or lying down. During insertion, the patient should ensure that the compressed ring is first inserted into the posterior vaginal vault and then the ring is pushed forwards and upwards. When removing the ring, the patient pulls on the ring with her index finger. If the patient is unable to urinate, the pessary should be removed and a smaller (different) model selected. The patient should be instructed to report any discomfort, including urination/defecation, immediately during pessary therapy.Patients and/or health care providers should keep the information on the label in case of complaints.

Follow-up examination: After the first insertion of the pessary, the patient should be re-examined after one week (at the latest after four weeks). At each follow-up examination, the pessary should be removed and cleaned while the vagina is examined for erosions, or pressure necrosis. If the size of the pessary is changed after the first fitting, the patient should have another examination carried out within one to two weeks. If cracks or defects in shape or colour are found when the pessary is examined, the pessary must be replaced. The patient should preferably be cared for by the same health care provider 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.

Application/cleaning: The ring 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 odour. This side effect can minimised by using an acidic vaginal gel and/or a lubricating cream, which also prevents itching. During a bowel movement, the pessary may become deeper and, in the worst case, dislodge. The patient should then be instructed to feel the ring and fix it back up 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 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 absolute intolerance, either a smaller ring pessary or - in the case of frequent slippage - a different model, e.g. a cup or cube pessary, can be selected, which should, however, be changed daily. Daily changes by the patient prevent tissue expansion and pressure discomfort.

Duration of use: The therapy is "short-term", i.e. the pessary can stay in place for up to 30 days without interruption, after which it is removed and cleaned. The same patient may only reuse it.

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 odour, the responsible 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 its original packaging of 10 years from the production date. We recommend using the pessary for three years after insertion. If during the inspection of the pessary
If cracks, deformations or colour changes occur, 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.