Instructions for Use of Vaginal Dilators (SD) for Health Care Providers & Patients

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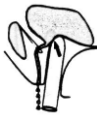
CE 0482

Components and storage: The so-called vaginal dilators are made of tissue-friendly silicone. They 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/purpose: Vaginal dilators are used to treat patients whose vagina needs to be widened for various reasons. An undesired constriction can occur after problematic suturing of an episiotomy during childbirth, after operations with reduction and/or scarring of the vagina and the aim is to stretch the vagina. It may make sense to prescribe several sizes for one patient.



Clinical benefit: Vaginal constrictions that are widened with vaginal dilators can be caused by malformations or postoperative complications.

Training: If a treating physician has little experience in pessary therapy, we recommend training by specialised colleagues (online/offline), a visit to our website (see above) or referral to an experienced colleague.

Sizes: Vaginal dilators are manufactured and used in five different sizes:

Starter	**15 mm diameter / 120 mm length**
Extra small:	**20 mm diameter / 120 mm length**
Small	**26 mm diameter/ 157 mm length**
Medium	**30 mm diameter/ 130 mm length**
Long	**37 mm diameter/ 135 mm length.**

Use/suitability: The attending physician recommends the appropriate sizes after the initial examination. Insertion in a relaxed position is made easier for the patient by applying creams to the pessary. These are prescribed by the treating gynaecologist. In general, the patient is instructed to insert the appliance herself. The type, frequency and duration of treatment is determined by health care provider, depending on the indication and the desired treatment goal. The vaginal dilators can also be inserted in the evening and left in place at night. The vaginal dilators should be used carefully, without provoking pain.

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 four weeks. It may be necessary to change the size of the vaginal dilator after the first fitting. If cracks or defects in shape or colour changes are detected on the surface, the pessary must be replaced. In a motivated patient who can demonstrate effective removal, insertion and care of the pessary, follow-up examinations may then be spaced further apart at the doctor's discretion.

Application/cleaning: Vaginal dilators are therapeutic products and may only be used by a single patient. Clean under running water without the use of disinfectants, until no traces of mucus or dirt particles are visible, a soft toothbrush can also be used if necessary. They should be stored hygienically in a clean tin if possible. We also provide tins for this purpose. We have evaluated disinfection and product compatibility with PERFEKTAN ACTIVE® from Dr Schumacher GmbH in order to adapt the correct model of class IIa urogynaecological pessaries. This means that size and/or models can already be adapted in outpatient clinics. This is rarely required for vaginal dilators.

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. However, a vaginal dilator is so short that this will rarely occur.

Duration of use: The therapy is "short-term", the pessary is only used during the dilation process and/or overnight, i.e. < 24 hours.

Contraindications: 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 vaginal dilator until the infection has subsided. Weakened patients and patients who do not understand advice, ignore it or cannot be followed up should not receive this therapy.

Warning: In case of pain, bleeding or extreme fluorine with odour, the attending 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 detected on the pessary, the device must be replaced at any time.

Disposal: Used and damaged silicone products can be disposed of in household waste in a low-germ condition. For disposal in medical facilities, the country-specific regulations must be observed.