

Dr. Arabin Instructions for Use of Fitting Sets (AP) for Health Care Providers (60482

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Components and storage: The fitting sets consist of 3 x 4 thin rings made of very soft, tissue-friendly silicone. Compared to our therapeutic ring pessaries, the rings are much easier to compress and are green to distinguish them from the blue therapeutic pessaries. The set can be stored at room temperature at 1 to 30 °C protected from UV radiation without direct contact with reactive media such as gas, ozone or mineral oil.

Indication/ intended purpose: The fitting set is used to adjust the correct size of round pessaries, hodgepodge, bowl, sieve bowls, urethra or urethral bowls, club pessaries) and indirectly also of hybrid and cube pessaries. We offer a table for conversion to the correct cube size (right).

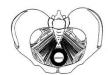
Clinical benefit: The aim of the application sets is to objectify the size selection of the indicated pessaries. Experienced colleagues, however, often appreciate this from the clinical constellation alone.

Training: If a health care provider has limited experience in pessary therapy, we recommend training (online/hands-on), visiting our website (see above) or referral to experienced colleagues.

Sizes: The following 4 ring sizes are combined in a total of 3 sets:

pessaries:

Small: 45 / 50 / 55 / 60 mm Medium 65 / 70 / 75 / 80 mm Large: 85 / 90 / 95 /100 mm



Use: The compressed soft ring is inserted into the posterior vaginal vault and then pushed forwards. The doctor tests which size is suitable by exertion such as coughing, pressing and movement. The pessary with the smallest circumference that holds straight should be inserted. After the test, the fit should be checked again and the pessary removed again after fitting.

Health care providers should keep the information of the label in case of complaints.

Side effects/complications: No side effects have been described to date with the short fitting (< 60 minutes) in an outpatient facility.

Duration of use: As the rings of the set may only be used in an outpatient facility, the duration of use is < 1 hour

Contraindications: An allergy to silicone is extremely rare, but would be a contraindication. Rings of the fitting set are not intended for therapy.

Conversion table applicable for the fitting of cube

Ring size	Cube pessary size
45-50 mm	Size 0 - 25 mm
55 - 60 mm	Size 1 - 29 mm
60 - 70 mm	Size 2 - 32 mm
70 - 75 mm	Size 3 - 37 mm
80 - 85 mm	Size 4 - 41 mm
from 90 mm	Size 5 - 45 mm

Reprocessing: Medical facilities should follow the manufacturer's instructions in accordance with Table B1 of EN-ISO 17664—2017 for re-using the devices. These can be found on our website (see above) /Information. There you will also find an evaluated process for reprocessing, i.e. cleaning and sterilisation, by a certified laboratory. For all Class I and Ila products we also offer an evaluated process of cleaning and of disinfection with PERFEKTAN ® ACTIVE from Dr. Schumacher GmbH.

Note: 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 three years after insertion. If cracks, deformation or discolouration occur during inspection of the pessary, the pessary must be replaced at any time

Disposal: For disposal in medical facilities, the country-specific regulations must be considered.