



Instructions for use
Silicone pessary: bowl-shaped urethral



INSTRUCTIONS FOR USE SILICONE PESSARY: BOWL-SHAPED URETHRAL

DESCRIPTION

Silicone pessary: bowl-shaped urethral has a form of a bowl with a nub of oval form and a large central opening. Pessaries are manufactured from elastic biologically inert silicone.

Silicone pessary: bowl-shaped urethral is supplied in the following sizes (outer diameter): 55, 60, 65, 70, 75, 80, 85, 90 mm.

The size is indicated on the product and on the label.

MODE OF ACTION

Pessary is inserted into the vagina and creates an additional support for pelvic organs. This restores topographical-anatomical interrelation between the pelvic organs and eliminates/decreases the manifestations of prolapse.

The nub on the rim of the ring is meant for the additional fixation of urethrovesical segment.

INDICATIONS

Conservative (non-surgical) correction of genital prolapse, complicated by stress urinary incontinence (N 81.0 – 81.9, R 32 in accordance with ICD-10).

Simulation of the results of operative correction of stress urinary incontinence, including the operative treatment using mesh prosthesis.

CONTRAINDICATIONS

Allergic reactions to pessary material.

RELATIVE CONTRAINDICATIONS

Inflammatory diseases of female pelvic organs, bleeding from genital tracts.

COMPLICATIONS/SIDE EFFECTS

During the process of treatment with the help of silicone pessary the development of inflammatory diseases of female pelvic organs is possible.

WARNINGS

The product should not be used by other patients.

Pessary should be stored at room temperature.

It is unacceptable to start using it after the expiry date indicated on the pack of the product.

It is not allowed to use the product in case of presence of damage (cuts, cracks, etc.) on the surface of the product.

Pessary is supplied non-sterile. Before the first use the treatment of pessary is required.

The pessary can be sterilized with steam (temperature regime 121 °C, not less than 15 minutes) or hot air (temperature 160 °C, exposure time 2 hours). After the treatment the product should cool to room temperature.

For reuse the pessary should be washed with running water with a detergent (liquid soap). During the washing it is possible to use a soft brush. Then the pessary should be treated with an antiseptic solution for skin and mucous membranes (Octenisept or similar) during 1 minute and rinsed again with running water.

The material properties allow the repeated treatment of the product.

CHOICE OF PESSARY SIZE

The choice of pessary is carried out by obstetrician-gynecologist individually in accordance with the anatomic features of a patient.

The primary fitting of pessary is carried out in lithotomy position of the patient (on the gynecological examination chair) with filled urinary bladder. For treatment must be used the pessary with the smallest diameter which eliminates/decreases the manifestations of prolapse. In case of correctly fitted size of pessary there must be a small clearance between the product and the vaginal wall (10 – 15 mm, width of finger phalanx). The correctness of fitting must be evaluated during the tension of abdominal muscles (for example, during coughing, straining) and in motion.

Pessary must not fall out during straining, must not cause difficulties during urination and must not cause pain feelings in the vagina.

It is necessary to teach the patient to extract and when possible to insert the pessary by herself.

INSERTION AND EXTRACTION OF PESSARY

Before the insertion of the pessary the prolapsing organs must be returned to their anatomically correct position.

Pessary is taken out of the pack (fig. 1), the treatment of pessary is carried out (see above). In order to facilitate the procedure of insertion the pessary is lubricated with a small amount of lubricant (Durex or similar), squeezed and in squeezed state inserted into the vagina (fig. 2). Then the pessary is turned in such a way, so that the cervix uteri (vaginal vault) would be placed in the opening of the pessary (fig.3).

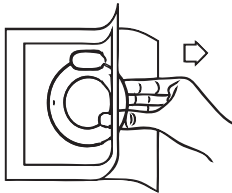


Fig. 1

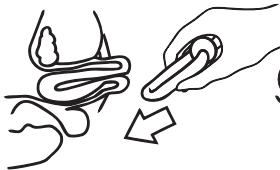


Fig. 2

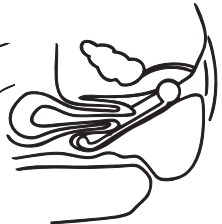


Fig. 3

For the extraction of the pessary it is necessary to clench the product with fingers, squeeze it a little bit and in squeezed state to take it out of the vagina. Owing to the elastic properties of silicone the discomfort of the patient during the insertion/ extraction of the pessary is minimal.

FOLLOW-UP OF PATIENTS

During the use of pessary it is necessary to undergo regular gynecological examinations (at least once in 6 months). The duration of the continuous use of pessary is determined individually and on the average amounts to 20-25 days. The practice of using pessary only for the period of physical activity is possible (using at daytime and extraction for the night).

There were identified no specific side effects in case of proper use of the pessary. The possible development of inflammatory process (non-specific reaction to the foreign body) requires pessary extraction and sanitation. After the end of sanitation further use of silicone pessary is possible.

RECOMMENDATIONS FOR PATIENTS

After the pessary is inserted make sure that there are no unpleasant sensations, difficulties with urination, and the pessary does not fall out when straining. In case of occurrence of pain in the vagina or if the product falls out, it is necessary to use a pessary of a different size.

Try to extract and install a pessary independently under the supervision of a gynecologist. While using the pessary it is advisable to visit a gynecologist. The frequency of visits is set individually. This is necessary to assess the effectiveness of treatment, the choice of the optimum time of continuous use of pessary. At home the cleaning of the product is carried out by thorough washing with running water with detergent. After the cleaning it is necessary to treat the pessary during 1 minute with an antiseptic solution for skin and mucous membranes (Octenisept or similar) and rinse once again with running water. Sometimes during the use of pessary the development of vaginal inflammation is possible. For the prevention of inflammatory complications it is necessary to comply with the recommendations of the doctor, hygiene and terms of continuous pessary use.

In case of appearance of complications/side effects it is necessary to consult a doctor immediately.

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