

## INSTRUCTIONS FOR USE **Conservative Pelvic Organ Pessary** CPOP-065, CPOP-070, CPOP-075, CPOP-080, CPOP-085

Disposable Single Patient Use.

Read and become familiar with all instructions, warnings, and cautions in this instruction leaflet before using this product.

**Sterile:** This product is sterile in the unopened, undamaged package.

**Description:** A vaginal pessary made of clear medical grade silicone.

### INDICATIONS FOR USE

This device is indicated to be placed in the vagina to give support to a pelvic organ prolapse as determined by a trained and licensed clinician familiar with the possible side effects, typical finding, limitations, indications or contraindications of fitting a pessary. This device is not intended for use except as indicated.

### CONTRAINDICATIONS

Pessaries are contraindicated in acute genital tract infections, pelvic infections, or non-compliant patients.

### Instructions for Use:

#### A. Size Selection

1. The appropriate Conservative Pelvic Organ Pessary size should be selected after vaginal examination. The clinician may measure the vaginal length using a sterile ruler and select a Conservative Pelvic Organ Pessary that most closely approximates this measurement in the table below. The size of the device will depend on the length and width of the vagina. Fitting the pessary usually requires a trial of various sizes to determine the proper pessary size. A vaginal lubricant may be required for the patient's comfort before insertion of pessary.

Product Code	Length	Width
CPOP-065 (XSmall)	60mm	65mm
CPOP-070 (Small)	65mm	70mm
CPOP-075 (Medium)	70mm	75mm
CPOP-080 (Large)	75mm	80mm
CPOP-085 (XLarge)	80mm	85mm

#### B. Insertion into the vaginal cavity

1. Perform a routine pelvic examination prior to the fitting and introduction of the pessary to determine the appropriate pessary size. The pessary should be large enough for its indication, yet not cause any undue pressure or discomfort.
2. Compress the pessary along the vertical axis so that it is symmetrical when folded and gently insert the pessary through the introitus, leading with the wider end. Once the pessary has passed the introitus, release the compressed pessary so that it resumes its normal shape and the wider end is positioned at the back and the narrower end is closer to the opening.
3. Gently move the pessary to cervix to support the cystocele or rectocele and uterus. When in the correct position, the clinician should be able to insert an examining finger between the outer edge of the pessary and the vaginal wall.
4. Once in place, the pessary should not dislodge or feel uncomfortable when standing, sitting, during physical activity or bearing down.
5. When fitting the pessary, be sure to instruct the patient on its cleaning, insertion and removal. The patient should perform these tasks before the first follow up visit.
6. Instruct the patient to report any discomfort immediately.

#### C. Device removal

1. Gently grasp the lower part of the pessary and with gentle downward traction remove the pessary from the vagina.

2. The pessary should be removed for cleaning every day. The pessary can be cleaned with mild soap and warm water.
3. Sexual intercourse should not occur with the pessary in place. The pessary should be removed before sexual intercourse.
4. Discuss with the patient the importance of following instructions and the expected length of time for pessary usage.

**WARNINGS:** This device should be fitted only by clinicians trained in proper techniques for fitting a vaginal pessary.

**CAUTIONS:** Caution must be used when using energy devices with this device. Any prolonged direct contact may damage devices.

**STORAGE CONDITIONS:** When in the packaged and sterile state, store in a dry, dark place.

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