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CooperSurgical®

MILEX® RING Folding Pessaries

UK CA 0086 CE 2797

AVAILABLE MODELS

RING without SUPPORT

REF

MXPER

(Pessary Only)

RING with SUPPORT

REF

MXPRS

(Pessary Only)

RING with KNOB without Support

REF

MXPERK

(Pessary Only)

RING with KNOB with SUPPORT

REF

MXPRSK

(Pessary Only)

MD **R_xOnly**

DEVICE DESCRIPTION

Milex® Pessaries are silicone devices that are offered in a range of different configurations and sizes which are inserted into the vagina to function as support for the uterus, bladder and rectum.

WARNINGS

- Ring Folding Pessaries: Sizes 11 through 13 contain a wire coil - remove before X-ray or MRI.
- Do not leave pessaries in place for long periods of time, as serious complications can occur which may require surgical intervention.
- Do not use these pessaries on a patient with a known silicone allergy.
- In pregnant patients, the physician may need to exercise clinical judgment to detect and guard against preterm labor, premature rupture of membranes, and infection.
- In patients who have undergone prior placement of surgical mesh in the vagina, the physician may need to exercise clinical judgment regarding placement of a pessary and if used, consider more frequent clinical evaluations to detect and guard against potential mesh erosion or displacement.
- Chemicals in various vaginal preparations can interact with the pessary material, resulting in discoloration or deterioration of the pessary.
- In cases of acute inflammation, the physician may need to exercise clinical judgment regarding placement of a pessary and if used, consider more frequent clinical evaluations to detect and guard against exacerbated inflammation.
- In cases of bleeding, other than menstrual bleeding,the physician may need to exercise clinical judgment regarding placement of a pessary and if used, consider more frequent clinical evaluations to detect and guard against exacerbated bleeding.

INTENDED USE

To provide support to pelvic organs when inserted in the vagina.

INDICATIONS FOR USE

- RING without SUPPORT pessary is indicated for support in Stage I and Stage II prolapse.
- RING with SUPPORT pessary is indicated for support in Stage I and Stage II prolapse complicated by a mild cystocele.
- RING with KNOB pessary, without SUPPORT is indicated for stress urinary incontinence complicated by Stage I or Stage II uterine prolapse.
- RING with KNOB with SUPPORT pessary is indicated for stress urinary incontinence complicated by Stage I or Stage II uterine prolapse and mild cystocele.

PERFORMANCE CHARACTERISTICS

- Pessaries for pelvic organ prolapse generally have two categories: the support pessaries and the space-occupying pessaries.
- Pessaries are available in a range of sizes and shapes. Milex pessaries can be fitted in the convenience of your office and are easily managed by patients.
- A properly fitted pessary should not be felt by the patient while in place.
- A pessary can provide immediate relief of pelvic organ prolapse, stress urinary incontinence and defecatory problems.
- Pessaries may be used in the assessment of patient symptoms of prolapse reduction and stress urinary incontinence and assist in determining appropriate surgical options.

INTENDER USERS

Adult female population; at the physician's discretion, the patient can be instructed in the proper removal, cleaning and reinsertion techniques for her own pessary.

TARGET PATIENT POPULATION

Adult female population suffering from pelvic organ prolapse or urinary stress incontinence.

CLINICAL BENEFIT

Clinical Benefit	Expected Clinical Outcome
These pessaries are solutions for assessing and relieving symptoms of pelvic organ prolapse, stress incontinence, cystocele, rectocele, and nocturia associated with urinary retention	Diagnosis and relief of symptoms for pelvic organ prolapse, stress incontinence, cystocele, rectocele, and nocturia associated with urinary retention.

CONTRAINDICATIONS

- The presence of cancer, infection, lacerations, or eroded surgical mesh in the internal pelvic region.
- Severe atrophy of the vaginal tissue.
- Patient unable or unwilling to comply with required device care and in-office follow-up.

ADVERSE EFFECTS

The following adverse effects may occur with the use of a Pessary:

- Dysuria
- Pelvic Pain
- Abnormal vaginal discharge or odor
- Vaginal Bleeding or spotting
- Mucosal Ulceration
- Allergic reaction

PLEASE NOTE: If a serious incident is suspected from using the Ring Pessary, report the details of the incident to CooperSurgical via phone number +1 203-601-5200 Ext 3100 or by email at ProductSurveillance@coopersurgical.com and to the local Health Authority in your country. A serious incident may have caused or contributed to: a death, a delay in a procedure which resulted in death or serious injury, or a malfunction.

RECOMMENDED CLEANING INSTRUCTIONS

Prepare a cleaning solution by mixing a mild soap with tap water using the soap manufacturer's recommended concentration. Prepare this solution in a container large enough to fully submerge the device.

1. Soak and Scrub
   a. Soak the device in the container of prepared soap solution for a minimum of 5 minutes.
   b. Following the 5-minute soak period, scrub the device for a minimum of 15 seconds with a soft-bristled brush, such as a tooth brush and/or pipe brush. Scrub device below water line to prevent aerosolization of contaminants.
   c. Following scrub, inspect device for visible soil residue.
2. Rinse
   a. Remove the device from the soap solution and thoroughly rinse under flowing tap water for a minimum of 30 seconds.
   b. Allow the device to dry.

DEVICE LIFETIME

The useful life of a pessary is 5 years. Examine frequently e.g., two to three months for signs of deterioration (such as cracks or breaks in the silicone outer surface). A pessary should be replaced if damaged.

Current clinical data indicates typical continuous use of pessary is from successful fitting up to 13 years. Other durations of continuous use should be at the discretion of the healthcare professional based on the individual patient's condition.

DISPOSAL OF DEVICE

This device must be handled and disposed of as healthcare medical waste in accordance with hospital procedures and applicable regulations.

Any device that has been contaminated with potentially infectious substances of human origin (such as bodily fluids) must be handled according to hospital protocol for infectious medical waste.

PATIENT INSTRUCTIONS FOR PESSARY USE

PRECAUTION

COOPERSURGICAL RECOMMENDS PESSARIES BE INSERTED AND REMOVED BY THE PHYSICIAN OR OTHER HEALTHCARE PROFESSIONAL UNLESS OTHERWISE DIRECTED.

- To ensure the desired correction of your condition, your healthcare professional needs your full cooperation.
- It is essential that your healthcare professional inspect your vagina at frequent intervals for evidence of pressure and or allergic reaction.
- A gradual increase in the interval of inspection may be considered at the discretion of the treating practitioner.

REPORT ANY OF THE FOLLOWING SYMPTOMS TO YOUR PHYSICIAN

- Any difficulty in urinating
- Any discomfort
- Any changes in the color or consistency of vaginal discharge
- Any increase in the amount of vaginal discharge or vaginal bleeding
- Any foul odor associated with vaginal discharge
- Vaginal itching
- If the pessary falls out

For medical emergencies and for all medically related advice, consult your healthcare professional.

FOR THE PHYSICIAN / HEALTHCARE PROFESSIONAL

Review these instructions with the patient to establish use regimen.

INSTRUCTIONS

Figure 1

Figure 2

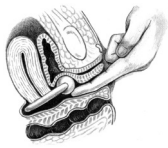

Figure 3

1. Wear dry gloves. When necessary, lubricate only the entering end of the pessary with lubricating vaginal gel. Hold as illustrated in Figure 1.
2. The pessary is folded along the axis of the bigger outer holes(or the inner notches for the Ring without Support) by bringing the small round holes together. The KNOB will be at the top of the arch (see Figure 2). The arch formed points downward as shown with the Ring pessary.
3. Direct the pessary past the cervix into the posterior fornix. Allow the pessary to open again into the ring shape after passing the introitus.
4. The index finger is inserted deep into the vagina to turn the pessary approximately 90° so that the KNOB is resting behind the symphysis pubis (see Figure 3). The RING pessaries in this position cannot be folded and pushed out.
5. Ask the patient to sit, stand and bear down slightly. If there is no leakage, and the patient is comfortable with the pessary in position, have her empty her bladder. A properly fitted pessary takes up slack in redundant tissue, holding the uterus higher in the vagina.
6. If the patient can void without difficulty, and the pessary remains in position upon re-examination, and the patient is comfortable with the pessary in place, this is a good indication that the correct size may have been selected. Patient experience may vary.

   Note: If the patient is unable to urinate with the pessary in position, remove it and fit her with the next smaller size. Repeat as necessary.
7. Examine the patient while she is in the standing position to ensure the pessary has not shifted position. The patient should not feel the pessary once it is in position. The pessary should not be too loose as it may turn or be expelled and it should not be too tight as it may cause discomfort.
8. The healthcare professional should be able to sweep one finger between the pessary and the vaginal walls. If there is not enough space to do this, the next smaller size should be tried. If excessive space exists, the pessary will not be effective and may rotate or even be expelled.
9. It is sometimes necessary to refit the patient with a different size or type of pessary after a period of time. Do not assume that a replacement will always be the same size as the previous one. Check the fitting to ensure continued patient comfort and relief of symptoms.
10. Ulcerations and erosions frequently occur in cases of complete prolapse due to irritation of the exteriorized cervix or vaginal wall. Whenever possible, reducing the mass and treating the irritation are primary steps before using a pessary. Prolapse reduction may resolve cervical vaginal irritation. Verification of cervical cytology (pap) and or biopsy as clinically indicated.
11. During each visit, the vagina should be carefully inspected for evidence of pressure or allergic reaction. The patient should be questioned concerning douching, discharge, disturbance of bowel function or urination. It may be necessary to fit another size or an entirely different type of pessary.
12. At the physician's discretion, the patient can be instructed in the proper removal, cleaning and reinsertion techniques for her own pessary. This process can be performed nightly or even weekly by the patient under ideal circumstances.

TO REMOVE

- Use one finger to depress the perineum. Turn the pessary until the notches face the introitus. Fold the pessary and gently ease it out.

RECOMMENDED FOLLOW-UP

- Have patient return within 24 hours for first examination.
- Have patient return for second examination within 3 days.
- Examine frequently. Have patient return for examination every two to three months for signs of deterioration (such as cracks or breaks in the silicone outer surface).

Note: The above schedule of follow-up examinations may be altered to fit the needs of the individual patient at the discretion of the healthcare provider.

GLOSSARY OF SYMBOLS

Source: IS0 15223-1 and ISO 7000

	Packaging unit
	Consult instructions for use or consult electronic instructions for use
	Caution
	Non-sterile
	Single patient multiple use
REF	Catalogue number
LOT	Batch code
	Use-by date
	Country of manufacture ("CC" shall be replaced by either the two letter or the three letter country code)
	Manufacturer
R_xOnly	**Caution:** U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare professional
	Do not use if package is damaged and consult instructions for use
	Keep dry
MD	Medical device
	Importer
EC REP	Authorized Representative in the European Community/ European Union
CE 2797	Product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations
UK CA 0086	The product conforms to the UK Device Medical Regulation 2002, as amended. The product can be freely marketed in Great Britain (England, Wales and Scotland)

CooperSurgical®

Phone: (800) 243-2974
Fax: (800) 262-0105
International
Phone: +1(203) 601-9818
Fax: +1 (203) 601-4747
www.coopersurgical.com

UK Responsible Person
Research Instruments Ltd
Bickland Industrial Park,
Falmouth, Cornwall TR11 4TA, UK

EC REP 

CooperSurgical Distribution B.V.
Celsiusweg 35, 5928 PR Venlo
The Netherlands

CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611 USA

Made in Costa Rica