

EN	
CUBE Flexible Pessary	
TANDEM-CUBE FlexiblePessary	
Support for Stage III prolapse/procidentia	
R_xOnly	
AVAILABLE MODELS	
CUBE	CUBE WITH DRAINAGE HOLES
REF	REF
MXPEC (Pessary Only)	MXPECH (Pessary Only)
MXKPEC (Pessary, TRIMO-SAN™, Jel Jector)	MXKPECH (Pessary, TRIMO-SAN™, Jel Jector)
TANDEM-CUBE	
REF	REF
MXPECT (Pessary Only)	MXKPECT (Pessary, TRIMO-SAN™, Jel Jector)
MXKPECH (Pessary, TRIMO-SAN™, Jel Jector)	
CE 0086	
Single-Patient Use	
Wash pessary with mild soap and thoroughly rinse prior to initial use.	
DESCRIPTION	
The Millex® CUBE Pessary is a medical device made from silicone that is inserted into the vagina to function as a supportive structure of the uterus, bladder and/or rectum.	
WARNINGS	
<ul style="list-style-type: none">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. Chemicals in various vaginal preparations can interact with the pessary	
CooperSurgical	

ES	
Pesario flexible de CUBO	
Pesario flexible de CUBO TÁNDEM	
Sostén para prolapsos de estadio III	
R_xOnly	
MODELOS DISPONIBLES	
CUBO	CUBO CON ORIFICIOS DE DRENAJE
REF	REF
MXPEC (solo pesario)	MXPECH (solo pesario)
MXKPEC (pesario, TRIMO-SAN™, Jel Jector)	MXKPECH (pesario, TRIMO-SAN™, Jel Jector)
CUBO TÁNDEM	
REF	REF
MXPECT (solo pesario)	MXKPECT (pesario, TRIMO-SAN™, Jel Jector)
MXKPECH (pesario, TRIMO-SAN™, Jel Jector)	
CE 0086	
Uso con una sola paciente	
Lave el pesario con un jabón suave y enjuáguelo bien antes de utilizarlo por primera vez.	
DESCRIPCIÓN	
El pesario de CUBO de Millex® es un producto sanitario fabricado en silicona que se inserta en la vagina como sostén para el útero, la vejiga o el recto.	
ADVERTENCIAS	
<ul style="list-style-type: none">No deje los pesarios colocados durante un periodo de tiempo prolongado, pues existe riesgo de complicaciones graves que pueden necesitar una intervención quirúrgica. No utilice estos pesarios con pacientes que presenten una alergia conocida a la silicona. Las sustancias químicas contenidas en diferentes preparados vaginales pueden interactuar con el material del pesario y provocar una decoloración	
CooperSurgical	

NL	
Flexibel CUBE-pessarrium	
Flexibel TANDEM-CUBE-pessarrium	
Steun voor Graad III prolaps/procidentia	
R_xOnly	
BESCHIKBARE MODELLEN	
CUBE	CUBE MET AFVOERGAATJES
REF	REF
MXPEC (Alleen pessarium)	MXPECH (Alleen pessarium)
MXKPEC (Pessarrium, TRIMO-SAN™, Jel Jector)	MXKPECH (Pessarrium, TRIMO-SAN™, Jel Jector)
TANDEM-CUBE	
REF	REF
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CE 0086	
Gebruik voor één patiënt	
Was het pessarium met milde zeep en spoel grondig vóór het eerste gebruik.	
BESCHRIJVING	
Het Millex® CUBE-pessarrium is een medisch hulpmiddel van siliconen dat in de vagina wordt ingebracht om te fungeren als steun voor de baarmoeder, blaas en/of rectum.	
WAARSCHUWINGEN	
<ul style="list-style-type: none">Laat pessaria niet langere tijd op hun plaats, aangezien er ernstige complicaties kunnen ontstaan die chirurgische ingrepen kunnen vereisen. Gebruik deze pessaria niet bij patiënten met een gekende allergie voor siliconen.	
CooperSurgical	

material, resulting in discoloration or deterioration of the pessary. TRIMO-SAN™ does not interact with the pessary material. Use only TRIMO-SAN. Other materials have not been tested for compatibility.

INDICATIONS FOR USE-CUBE

- The CUBE pessary is effective in the support of Stage III prolapse. The CUBE pessary will give additional support in those cases associated with complete lack of vaginal tonicity. The CUBE pessary is also effective in patients having procidentia combined with rectocele and/or cystocele.
- The CUBE pessary is also indicated in vaginal wall prolapse. The unique support is due to the suction action of the six concavities, which, by a slight negative pressure, supports the prolapse and the vaginal walls.
- If only bulk is sufficient to support the prolapse, the CUBE with holes is indicated. The CUBE pessary should be removed nightly and washed with mild soap and water, then thoroughly rinsed. If possible, leave out overnight.

INDICATIONS FOR USE-TANDEM CUBE

- For effective support in Stage III prolapse. The TANDEM-CUBE pessary will give additional support in those cases associated with complete lack of vaginal tonicity, where the patient is unable to retain even the largest size single CUBE pessary. The unique support is due to the suction action of the ten concavities, which, by a slight negative pressure, supports the prolapse and the vaginal walls. The TANDEM-CUBE pessary should be removed nightly and washed with mild soap and water, then thoroughly rinsed. If possible, leave out overnight.

CONTRAINDICATIONS

- The presence of pelvic infections and/or lacerations
- A noncompliant patient
- Endometriosis
- Pregnant patient

RECOMMENDED CLEANING INSTRUCTIONS*

- Prepare a cleaning solution by mixing a mild soap (such as Dawn® or equivalent) with tap water using the soap manufacturer’s recommended concentration. Prepare this solution in a container large enough to fully submerge the device.
- Soak and Scrub
 - Soak the device in the container of prepared soap solution for a minimum of 5 minutes.

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CooperSurgical	

- 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.
 - Following scrub, inspect device for visible soil residue.
- Rinse
 - Remove the device from the soap solution and thoroughly rinse under flowing tap water for a minimum of 30 seconds.
 - Allow the device to dry.

*New pessaries are powdered with food-grade powder.

PATIENT INSTRUCTIONS FOR PESSARY USE

CAUTION

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.
- It is important to evaluate the effects of the vaginal gel TRIMO-SAN.

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

- Wear dry gloves. The pessary is compressed between the thumb and forefingers (see Figure 1). If necessary, the entering edge can be coated with TRIMO-SAN.
- Use the fingers of the other hand to spread the labia and guide the pessary into the vagina. Check the fit (see Figure 2).
- Have the patient sit, stand and bear down. Examine the patient while she is in the standing position to ensure pessary has not shifted position. The patient should not feel the pessary once it is in position.
- Have the patient (or caregiver) insert and remove the CUBE pessary several times before the patient leaves your office.
- 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. The useful life of a pessary is limited. Examine frequently for signs of deterioration (such as cracks or breaks in silicone outer surface). A pessary should be replaced if damaged. 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.

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.

- 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.
- 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.
- 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.

- 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 cytology vaginal irritation. Verification of cervical (pap) and/or biopsy as clinically indicated.
- Evaluation of the endometrium for post-menopausal bleeding should be undertaken as clinically indicated.
- 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.
- 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

DO NOT PULL ON CORD TO REMOVE PESSARY!

The cord is to help locate the CUBE pessary. Pulling on the cord to remove the CUBE can damage vaginal mucosa. To remove the pessary, the suction with the vaginal walls must be broken. Work the finger tips between the vaginal mucosa and the pessary, compress the CUBE between the thumb and forefinger and remove (see Figure 1).

RECOMMENDED FOLLOW-UP

- Have patient return within 24 hours for first examination.
- Have patient return for second examination within 3 days.
- Have patient return for examination every few months.

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.
