

CUBE Flexible Pessary

a CooperSurgical Brand

Support for Stage III prolapse/procedentia

AVAILABLE MODELS

CUBE	CUBE WITH DRAINAGE HOLES
REF MXPEC (Pessary Only)	REF MXPECH (Pessary Only)
MXKPEC (Pessary, TRIMO-SAN™, Jel Jector)	MXKPECH (Pessary, TRIMO-SAN™, Jel Jector)



Single-Patient Use

Rx Only

Wash pessary with mild soap and thoroughly rinse prior to initial use.

DESCRIPTION

The Milex® 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

- 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

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ES

Pesario flexible de CUBO

a CooperSurgical Brand

Sostén para prolapsos de estadio III

MODELOS DISPONIBLES

CUBO	CUBO CON ORIFICIOS DE DRENAJE
REF MXPEC (solo pesario)	REF MXPECH (solo pesario)
MXKPEC (pesario, TRIMO-SAN™, Jel Jector)	MXKPECH (pesario, TRIMO-SAN™, Jel Jector)



Uso con una sola paciente

Rx Only

Lave el pesario con un jabón suave y enjuáguelo bien antes de utilizarlo por primera vez.

DESCRIPCIÓN

El pesario de CUBO de Milex® es un producto sanitario fabricado en silicona que se inserta en la vagina como sostén para el útero, la vejiga o el recto.

ADVERTENCIAS

- No deje los pesarios colocados durante un período 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

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NL

Flexibel CUBE-pessarium

a CooperSurgical Brand

Steun voor Graad III prolaps/procedentia

BESCHIKBARE MODELLEN

CUBE	CUBE MET AFVOERGAATJES
REF MXPEC (Alleen pessarium)	REF MXPECH (Alleen pessarium)
MXKPEC (Pessarium, TRIMO-SAN™, Jel Jector)	MXKPECH (Pessarium, TRIMO-SAN™, Jel Jector)



Gebruik voor één patiënt

Rx Only

Was het pessarium met milde zeep en spoel grondig voor het eerste gebruik.

BESCHRIJVING

Het Milex® CUBE-pessarium is een medisch hulpmiddel van siliconen dat in de vagina wordt ingebrengt om te fungeren als steun voor de baarmoeder, blaas en/of rectum.

WAARSCHUWINGEN

- 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.

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material, resulting in decoloration 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 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.
 - 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.

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.

TRIMO-SAN is available at the prescription counter of your pharmacy. A prescription is required.

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 should not be too tight as it may cause discomfort.



Figure 1



Figure 2

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 meet the needs of the individual patient at the discretion of the healthcare provider.

EXPLANATION OF SYMBOLS

REF Reorder number

LOT Batch code

Date of manufacture

Use-by date

Consult instructions for use

Not made with natural rubber latex

Manufacturer

TRIMO-SAN™ is a trademark of CooperSurgical, Inc.
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Made in Costa Rica

- Pida a la paciente que regrese para una segunda revisión transcurridos 3 días.
- Pida a la paciente que acuda a la consulta a intervalos de unos meses para someterse a revisiones sucesivas.

Nota: En función de lo que considere oportuno el profesional sanitario, la pauta de revisiones de seguimiento mencionada puede cambiarse para adaptarse a las necesidades individuales de cada paciente.

EXPLICACIÓN DE SÍMBOLOS

REF Número para nuevo pedido

LOT Código de lote

Fecha de fabricación

Fecha de caducidad

Consultar las instrucciones de uso

No está fabricado con látex de caucho natural

Rx Only PRECAUCIÓN: Las leyes federales de EE. UU. limitan la venta de este dispositivo a médicos o por prescripción médica.

Fabricante

TRIMO-SAN™

es una marca comercial de CooperSurgical, Inc. Milex® y CooperSurgical son marcas comerciales registradas de CooperSurgical, Inc.

INFORMACIÓN PARA EL MÉDICO / PROFESIONAL SANITARIO

Repare estas instrucciones con la paciente para establecer la pauta de uso.

INSTRUCCIONES

- Lleve guantes secos. Comprima el pessario entre el pulgar y el dedo índice (consulte la figura 1). En caso necesario, puede recubrir el borde de inserción TRIMO-SAN.
- Utilice los dedos de la otra mano para separar los labios e introducir el pessario en la vagina. Asegúrese de que el ajuste es el correcto (consulte la figura 2).
- Pídale a la paciente que se siente, se ponga de pie para asegurarse de que el pessario no ha cambiado de posición. La paciente no debe sentir el pessario una vez que este se encuentre en su posición correcta.
- Pídale a la paciente (o a su cuidador) que inserte y retire el pessario de CUBO varias veces antes de que la paciente abandone la consulta.



Figura 1



Figura 2

noodgevallen en alle medisch gerelateerde adviezen.

VOOR DE ARTS / PROFESSIONELE ZORGVERLENER

Neem deze instructies met de patiënt door om het gebruiksschema te bepalen.

INSTRUCTIES

- Draag droge handschoenen. Druk



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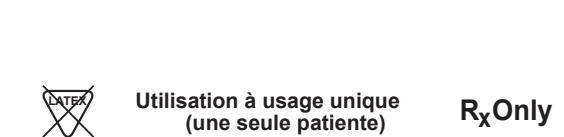
Pessaire CUBE souple

Soutien des prolapsus/procidences de stade III



MODELES DISPONIBLES

CUBE	CUBE AVEC ORIFICES DE DRAINAGE
REF MXPEC (Pessaire uniquement)	REF MXPECH (Pessaire uniquement)
MXPKEC (Pessaire, TRIMO-SAN™, Jel Jector)	MXPKECH (Pessaire, TRIMO-SAN™, Jel Jector)



Utilisation à usage unique (une seule patiente) RxOnly

Avant sa première utilisation, laver le pessaire avec un savon doux et le rincer abondamment.

DESCRIPTION

Le Pessaire CUBE Milex® est un dispositif médical en silicium à insérer dans le vagin pour soutenir l'utérus, la vessie et/ou le rectum.

MISES EN GARDE

- Ne pas laisser en place les pessaires pendant de longues périodes, car il existe un risque de complications graves pouvant nécessiter une intervention chirurgicale.
- Ne pas utiliser ces pessaires sur une patiente allergique au silicium.
- Les substances chimiques présentes dans diverses préparations vaginales peuvent interagir avec le matériau du pessaire et entraîner sa décoloration ou sa détérioration. Le TRIMO-SAN™ n'interagit pas avec le matériau du pessaire. Utiliser exclusivement du TRIMO-SAN. La compatibilité des autres matériaux n'a pas été testée.

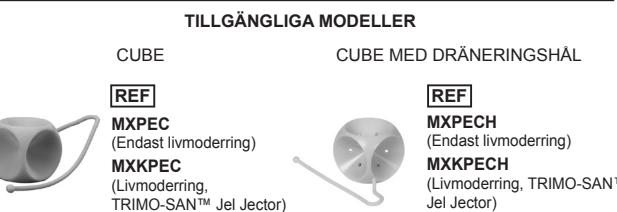
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CUBE flexibel livmoderring

Stöd för tredje gradens framfall/procidencia



Ska endast användas av en och samma patient RxOnly

Rengör livmoderringen med mild tvål och skölj noga innan den används för första gången.

BESKRIVNING

Milex® CUBE livmoderring är en medicinteknisk produkt tillverkad i silikon som förs i den sida som stöd åt livmodern, urinblåsan och ändtarmen.

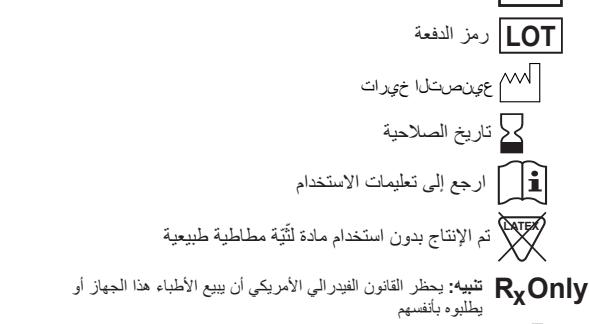
VARNINGAR

- Använd inte en livmoderring under en längre tid, då det kan uppstå allvarliga komplikationer som kan kräva kirurgiskt ingrepp.
- Patienter som har en känd allergi mot silikon ska inte använda denna livmoderring.

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لا تُسحب الجلب إلى الفرج

يُنصح بالرجوع إلى تعليمات الاستخدام

CooperSurgical, Inc. هي علامة تجارية لشركة TRIMO-SAN™ CooperSurgical, Inc. ميلكس® CooperSurgical, Inc.

الشركة المصنعة

الشركة المصنعة