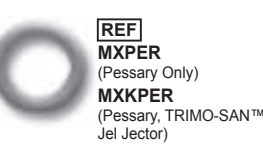
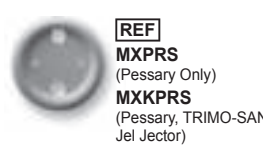
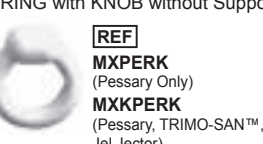





EN

<div>MILEX[®] a CooperSurgical Brand</div>
<h2>RING Folding Pessaries</h2>
For uterine prolapse (Stage I and Stage II) R_xOnly
<div> <p>AVAILABLE MODELS</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>RING without SUPPORT</p>  <p>[REF] MXPER (Pessary Only) MXKPER (Pessary, TRIMO-SAN™, Jel Jector)</p> </div> <div style="width: 45%;"> <p>RING with SUPPORT</p>  <p>[REF] MXPRS (Pessary Only) MXKPRS (Pessary, TRIMO-SAN™, Jel Jector)</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <p>RING with KNOB without Support</p>  <p>[REF] MXPERK (Pessary Only) MXKPERK (Pessary, TRIMO-SAN™, Jel Jector)</p> </div> <div style="width: 45%;"> <p>RING with KNOB with SUPPORT</p>  <p>[REF] MXPRSK (Pessary Only) MXKPRSK (Pessary, TRIMO-SAN™, Jel Jector)</p> </div> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p>Single-Patient Use</p> <p>Wash pessary with mild soap and thoroughly rinse prior to initial use.</p> </div> <div style="margin-top: 10px;"> <p>DESCRIPTION</p> <p>The Milex® RING 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.</p> <p>WARNINGS</p> <ul style="list-style-type: none"> 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. </div> <div style="text-align: center; margin-top: 10px;">  </div>

ES

<div>MILEX[®] a CooperSurgical Brand</div>
<h2>Pesarios plegables de ANILLO</h2>
Para prolapsos uterinos (de estadio I o II) R_xOnly
<div> <p>MODELOS DISPONIBLES</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>ANILLO sin SOPORTE</p>  <p>[REF] MXPER (solo pesario) MXKPER (pesario, TRIMO-SAN™, Jel Jector)</p> </div> <div style="width: 45%;"> <p>ANILLO con SOPORTE</p>  <p>[REF] MXPRS (solo pesario) MXKPRS (pesario, TRIMO-SAN™, Jel Jector)</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <p>ANILLO con BOTÓN y sin SOPORTE</p>  <p>[REF] MXPERK (solo pesario) MXKPERK (pesario, TRIMO-SAN™, Jel Jector)</p> </div> <div style="width: 45%;"> <p>ANILLO con BOTÓN y con SOPORTE</p>  <p>[REF] MXPRSK (solo pesario) MXKPRSK (pesario, TRIMO-SAN™, Jel Jector)</p> </div> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p>Useo con una sola paciente</p> <p>Lave el pesario con un jabón suave y enjuáguelo bien antes de utilizarlo por primera vez.</p> </div> <div style="margin-top: 10px;"> <p>DESCRIPCIÓN</p> <p>El pesario de ANILLO 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.</p> <p>ADVERTENCIAS</p> <ul style="list-style-type: none"> Los tamaños 11 a 13 contienen una bobina metálica que debe retirarse antes de realizar una radiografía o una resonancia magnética. 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. </div> <div style="text-align: center; margin-top: 10px;">  </div>

NL

<div>MILEX[®] a CooperSurgical Brand</div>
<h2>Opvouwbare RING-pessaria</h2>
Voor baarmoederprolaps (Graad I en Graad II) R_xOnly
<div> <p>BESCHIKBARE MODELLEN</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>RING zonder STEUN</p>  <p>[REF] MXPER (Alleen pessarium) MXKPER (Pessarium, TRIMO-SAN™, Jel Jector)</p> </div> <div style="width: 45%;"> <p>RING met STEUN</p>  <p>[REF] MXPRS (Alleen pessarium) MXKPRS (Pessarium, TRIMO-SAN™, Jel Jector)</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <p>RING met KNOP met zonder STEUN</p>  <p>[REF] MXPERK (Alleen pessarium) MXKPERK (Pessarium, TRIMO-SAN™, Jel Jector)</p> </div> <div style="width: 45%;"> <p>RING met KNOP met STEUN</p>  <p>[REF] MXPRSK (Alleen pessarium) MXKPRSK (Pessarium, TRIMO-SAN™, Jel Jector)</p> </div> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p>Gebruik voor één patiënt</p> <p>Was het pessarium met milde zeep en spoel grondig vóór het eerste gebruik.</p> </div> <div style="margin-top: 10px;"> <p>BESCHRIJVING</p> <p>Het Milex® RING-pessarium is een medisch hulpmiddel van siliconen dat in de vagina wordt ingebracht om te fungeren als steun voor de baarmoeder, blaas en/of rectum.</p> <p>WAARSCHUWINGEN</p> <ul style="list-style-type: none"> Maten 11 t/m 13 bevatten een draadspool - verwijder deze vóór röntgenopnamen of MRI. 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. </div> <div style="text-align: center; margin-top: 10px;">  </div>

- Chemicals in various vaginal preparations can interact with the pessary 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

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

CONTRAINDICATIONS

- The presence of pelvic infections 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.
 - 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. When necessary, lubricate only the entering end of the pessary with TRIMO-SAN. Hold as illustrated in Figure 1.
- 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.

INSTRUCCIONES DE USO PARA LA PACIENTE

PRECAUCIÓN

A MENOS QUE SE INDIQUE DE OTRO MODO, COOPERSURGICAL RECOMIENDA QUE LAS OPERACIONES DE INSERCIÓN Y RETIRADA DEL PESSARIO CORRIAN A CARGO DE UN MÉDICO O DE OTRO PROFESIONAL SANITARIO.

- Para garantizar que su problema se soluciona adecuadamente, el profesional sanitario necesita su plena colaboración.
- Asimismo, es crucial que el profesional sanitario realice revisiones periódicas de su vagina para ver si existen indicios de presión o de reacciones alérgicas.
- El médico encargado del tratamiento puede considerar apropiado alargar gradualmente la frecuencia con la que se realizan tales revisiones.
- Es importante evaluar los efectos del gel vaginal TRIMO-SAN

SI EXPERIMENTA CUALQUIERA DE LOS SIGUIENTES SÍNTOMAS, INFORME A SU MÉDICO:

- Dificultad para orinar
- Malestar o molestias de cualquier tipo
- Cambios en el color o la consistencia del flujo vaginal
- Aumento de la cantidad de flujo o de sangrado vaginal
- Olor desagradable asociado al flujo vaginal
- Prurito vaginal
- Salida del pesario

Para urgencias médicas y cualquier consejo de tipo médico, consulte a su profesional sanitario.

INFORMACIÓN PARA EL MÉDICO / PROFESIONAL SANITARIO

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

INSTRUCCIONES

- Lleve guantes secos. En caso necesario, lubrique únicamente el extremo de inserción del pesario con TRIMO-SAN. Sostenga el dispositivo tal como se muestra en la figura 1.
- Plegue el pesario a lo largo del eje de los orificios externos más grandes (o de las muescas internas del pesario de ANILLO sin SOPORTE) haciendo coincidir los orificios redondos pequeños. El BOTÓN se encuentra en la parte superior del arco (consulte la figura 2).

PATIËNTINSTRUCTIES VOOR GEBRUIK VAN PESSARIUM

OPGREET

COOPERSURGICAL BEVEELT AAN DAT DE PESSARIA WORDEN INGBRACHT EN VERWIJDERD DOOR DE ARTS OF ANDERE PROFESSIONELE ZORGVERLENERS, TENIJZ ANDERS AANGEGEVEN.

- Om de gewenste correctie van uw toestand te verzekeren, heeft de professionele zorgverlener uw volle medewerking nodig.
- Het is essentieel dat de professionele zorgverlener uw vagina met frequente intervallen inspecteert op sporen van druk en/of allergische reactie.
- Een geleidelijke toename van het inspectie-interval kan naar goeddunken van de behandelende arts worden overwogen.
- Het is belangrijk om de effecten van de vaginale gel TRIMO-SAN te evalueren.

MELD DE VOLGENDE SYMPTOMEN AAN UW ARTS

- Moelite bij het urineren
- Ongemak
- Veranderingen in de kleur of consistentie van vaginale afscheiding
- Toename van de hoeveelheid vaginale afscheiding of vaginale bloeding
- Onaangename geur geassocieerd met vaginale afscheiding
- Vaginale jeuk
- Als het pessarium uitvalt




Raadpleeg uw professionele zorgverlener voor medische noodgevallen en alle medisch gerelateerde adviezen.

VOOR DE ARTS / PROFESSIONELE ZORGVRELENER

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

INSTRUCTIES

- Draag droge handschoenen. Smeer, wanneer nodig, alleen het ingaande uiteinde van het pessarium met TRIMO-SAN in. Houd vast zoals weergegeven in Figuur 1.
- Het pessarium wordt gevouwen langs de as van de grotere buitenste gaten (of de binnenste uitsparingen bij de RING zonder STEUN) door de kleine ronde gaten bij elkaar te brengen. De KNOP zal zich aan de

		
Figure 1	Figure 2	Figure 3
<ol style="list-style-type: none">Direct the pessary past the cervix into the posterior fornix. Allow the pessary to open again into the ring shape after passing the introitus. 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. Ask the patient to sit, stand and bear down slightly. If there is no leakage, 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. 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. <p>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.</p> 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. 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. 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.		

	EXPLANATION OF SYMBOLS
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