LAGIS®

# TRANSANAL ACCESS PORT

English

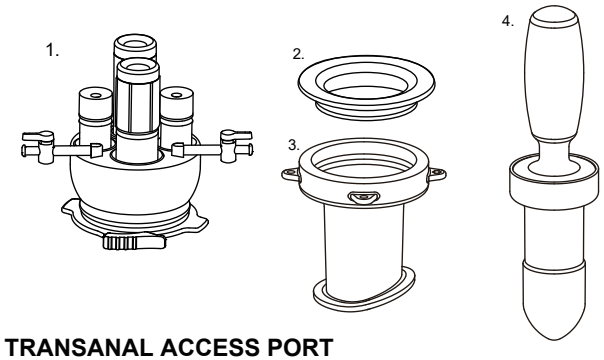
30°C 13°C LATEX Rx only STERILE R 2 STERILIZE CE 2797

www.lagis.com.tw/eifu_en.php

**BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.**

## ◆ DEVICE DESCRIPTION：

The Transanal Access Port consists of top housing, attachment ring, access channel, and introducer. The top housing consists of combinations of different number of 5mm, 5-12mm, and 15mm ports. The stopcock valves on the top housing are compatible with luer lock to provide gas insufflation and desufflation. The top housing can be removed during the procedure, allowing for the extraction of large specimens. The access channel allows connection to the attachment ring and top housing to provide circumferential anal retraction. The introducer may be inserted to aid in placing the access channel into position.
For the device CRS-A01M without top housing, it is designed for use with the cap for wound retractor and trocars to maintain pneumoperitoneum.




*1.Top housing*

*2.Attachment ring*

*3.*Access channel

*4.*Introducer

**TRANSANAL ACCESS PORT**

| Models | Top Housing | Attachment Ring | Access Channel | Introducer |
|---|---|---|---|---|
| CRS-60-0220M | O | O | O | O |
| CRS-A01M | X | O | O | O |

## ◆ INDICATIONS/INTENDED PURPOSE：

- The Transanal Access Port is designed for use during transanal natural orifice transluminal endoscopic surgery for maintaining pneumoperitoneum while allowing for insertion of multiple surgical instruments through the anus into the body cavity.
- Expected clinical benefits: less postoperative pain, complications, wound infections, and hernia formation; improved cosmesis; lower short-term cost; and optimal midterm and long-term surgical and oncologic outcomes.
- Patient target group: the Transanal Access Port is intended for adults who need transanal minimally invasive surgery procedures.

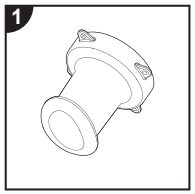
## ◆ CONTRAINDICATIONS：

The Transanal Access Port is not intended for use when minimally invasive surgery techniques are contraindicated.

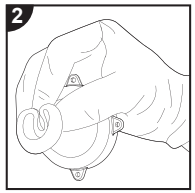
## ◆ INSTRUCTIONS FOR USE：

Prior to use, inspect the contents of the packaging and the packaging itself to ensure the integrity is not compromised.

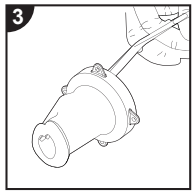
**INSTALLATION AND ASSEMBLY**



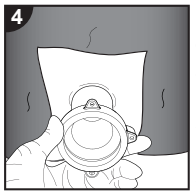

Apply sterile lubrication to the distal end of the access channel.



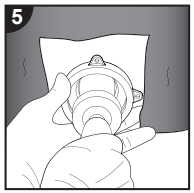

Manually compress the distal end of the access channel in a folded form.



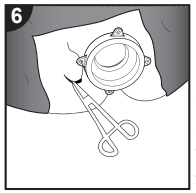

Use the forceps to clip the folded end of the access channel and place it into anus.



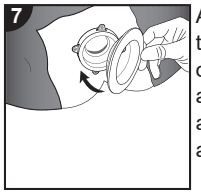

Make sure the distal end of the access channel is securely seated behind levator sling.



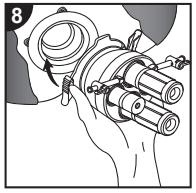

Apply the lubrication to the introducer to aid in placing the access channel into position.



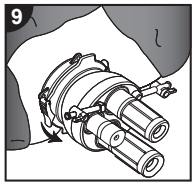

Remove the introducer. Hold the access channel and suture the suture ports to secure.



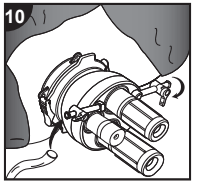

Apply lubrication to the indentation of attachment ring and the access channel, and connect them.



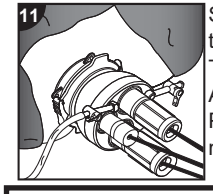

Attach the top housing to the attachment ring.




Make sure the 2 lever locks are locked.

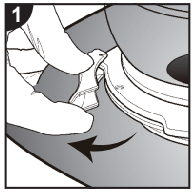



Attach insufflation tubing to one of the two stopcocks. Make sure the other stopcock valve is closed.

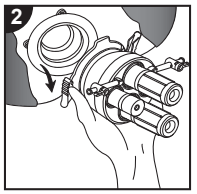



Start insufflation and the Transanal Access Platform is ready for use.

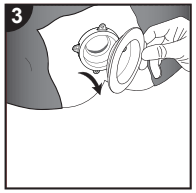
**DISASSEMBLY**



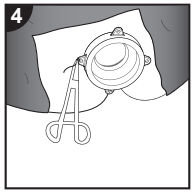

Disassemble the lever lock.



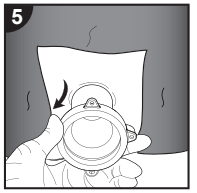

Disassemble the top housing from the attachment ring.




Disassemble the attachment ring from the access channel.

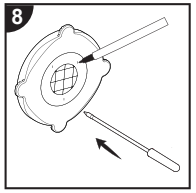



Remove sutures.

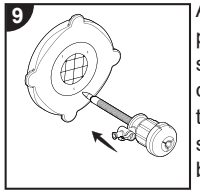



Gently pull out the access channel until it is removed from the anus.

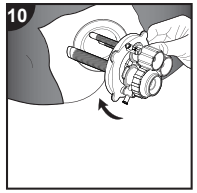
**CAP FOR WOUND RETRACTOR SERIES REPEAT STEP 1 TO 7**



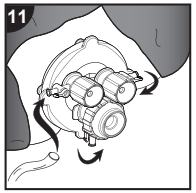

Use a needle like conical tip to create the first insertion within the boundary line.



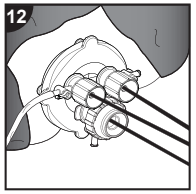

According to the procedure, surgeons can insert other trocars by the same steps within the boundary line.




Attach the trocar-inserted Cap on the white ring.

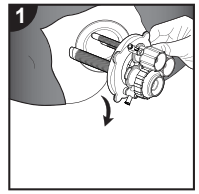



Attach insufflation tubing to one of the two stopcocks. Make sure the other stopcock valve is closed.



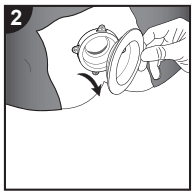

Start the procedure.

**DISASSEMBLY**

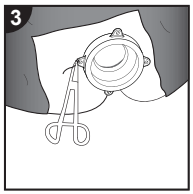



Disassemble the trocar-inserted Cap from the attachment ring.

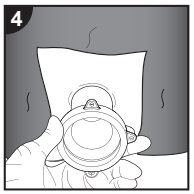
## DISASSEMBLY




Disassemble the attachment ring from the access channel.




Remove sutures.




Gently pull out the access channel until it is removed from the anus.

## ◆ WARNINGS AND PRECAUTIONS :

- Do not use if the device or the sterile packaging is open or damaged, as this may cause an increase in the incidence of wound infections.
- If endoscopic instruments or accessories from different manufacturers are used together in a procedure, verify compatibility prior to performing the procedure.
- This device is packaged and sterilized for single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocess, or resterilization may create contamination, infection, cross-infection, or even compromise the integrity of the device and lead to device failure which in turn may result in patient injury, illness or death.
- This device should be operated only by surgeons with adequate training and familiarity with surgical techniques. Consult medical literature for further information regarding techniques, hazards, contra-indications, and complications prior to performing the procedures.
- Do not pierce the access channel with a needle or install a suture into or through the device to facilitate removal of the access channel. Piercing the access channel will result in damage and potential loss of pneumoperitoneum during the procedure.
- Please remove the top housing while introducing the gauze. Do not introduce the gauze into the cavity from the 5 mm or 12 mm ports to prevent damage of valves of the ports.
- Return the device and packaging to the distributor or implement safe disposal handling by the healthcare professionals if the sterile packaging is damaged or unintentionally opened before use.
- The used device which comes into contact with bodily fluids should be considered as biomedical waste and safely disposed of by healthcare professionals in compliance with the national waste management regulation to prevent patients, users, and other persons from biological contamination or infection.
- In the event of malfunction of the device, changes in performance that they may affect safety, or even any serious incident, please report to the manufacturer, the competent authority of the Member State and the authorized representative immediately according to the contact information provided on the label or in this instructions for use.
- Improper assembly or operation of the device may result in prolong surgical time, patient allergy, and tissue or organ injuries from mechanical damage to the patient or operator.

## ◆ ENVIRONMENTAL CONDITIONS FOR STORAGE :

Appropriate storage environment is a clean and dry area away from sunlight with a temperature range of 13~30°C (55.4~86°F).

## ◆ EXPLANATION OF SYMBOLS :

| | | | | | |
|---|---|---|---|---|---|
| | Temperature limit | | Caution | EU REP | Authorized representative in the European Community/European Union |
| | Do not resterilize | | Manufacturer | | Not made with natural rubber latex |
| | Do not re-use | | Consult instructions for use or consult electronic instructions for use | | Do not use if package is damaged and consult instructions for use |
| | Date of manufacture | | Single sterile barrier system | STERILE R | Sterilized using irradiation |
| MD | Medical device | ℞ only | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. | CE 2797 | CE Marking according to MDR 2017/745 |

ITL-0105 Ver.M 2025

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LAGIS®

# PUERTO DE ACCESO TRANSANAL

Español

13°C 30°C LATEX Rx only STERILE R STERILIZE 2797

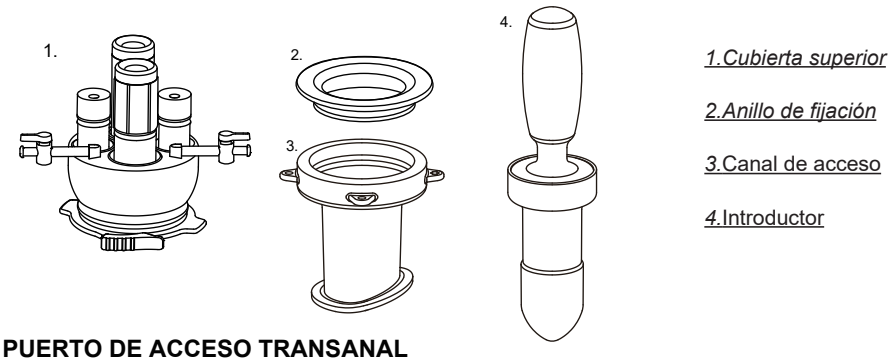
www.lagis.com.tw/eifu_en.php

**ANTES DE UTILIZAR EL PRODUCTO, LEA ATENTAMENTE LA SIGUIENTE INFORMACIÓN.**

## ◆ DESCRIPCIÓN DEL DISPOSITIVO：

El puerto de acceso transanal incluye una cubierta superior, un anillo de fijación, un canal de acceso y un introductor. La cubierta superior está compuesta por varios puertos de 5 mm, entre 5-12 mm, y 15 mm. Las válvulas de la llave de cierre de la cubierta son compatibles con Luer Lock para inyectar o extraer gas. La cubierta superior se puede quitar durante el procedimiento, lo que permite la extracción de muestras grandes. El canal de acceso se puede unir al anillo de fijación y a la cubierta superior para que formar una circunferencia en la separación anal. El introductor puede insertarse para ayudar a colocar el canal de acceso en su posición.

Para el dispositivo CRS-A01M, que no cuenta con cubierta superior, está diseñado para usarse con la Tapa para Retractor de Incisión y los trócares para mantener el neumoperitoneo.




*1.Cubierta superior*

*2.Anillo de fijación*

*3.*Canal de acceso

*4.*Introductor

### PUERTO DE ACCESO TRANSANAL

| Modelos | Cubierta superior | Anillo de fijación | Canal de acceso | Introductor |
|---|---|---|---|---|
| CRS-60-0220M | O | O | O | O |
| CRS-A01M | X | O | O | O |

## ◆ INDICACIONES/PROPÓSITO PREVISTO：

- El puerto de acceso transanal está diseñada para su uso durante la cirugía endoscópica transluminal a través de un orificio natural transanal para mantener el neumoperitoneo y, a la misma vez, permitir la inserción de varios instrumentos quirúrgicos en la cavidad corporal a través del ano.
- Beneficios clínicos esperados: menor dolor posoperatorio, complicaciones, infecciones de heridas y formación de hernias, estética mejorada, menor coste a corto plazo y resultados quirúrgicos y oncológicos óptimos a medio y largo plazo.
- Grupo objetivo de pacientes: el puerto de acceso transanal está diseñado para adultos que requieren procedimientos de cirugía transanal mínimamente invasiva.

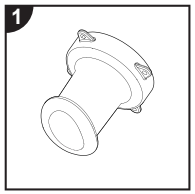
## ◆ CONTRAINDICACIONES:

El puerto de acceso transanal no está diseñado para su uso cuando las técnicas de cirugía mínimamente invasivas están contraindicadas.

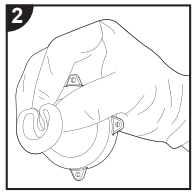
## ◆ INSTRUCCIONES DE USO：

Antes de su uso, inspeccione el contenido del envase y del embalaje en sí para asegurarse de que no se haya visto comprometida la integridad de este.

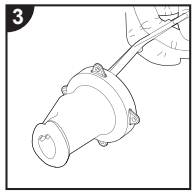
### INSTALACIÓN Y MONTAJE



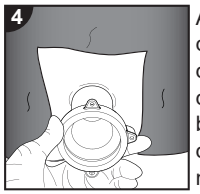

Aplique lubricante estéril en el extremo distal del canal de acceso.



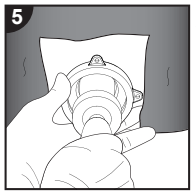

Comprima manualmente el extremo distal del canal de acceso hasta que quede doblado.



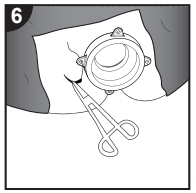

Utilice las pinzas para sujetar el extremo doblado del canal de acceso y colóquelo en el ano.



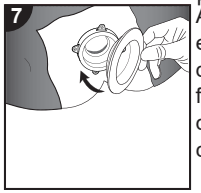

Asegúrese de que el extremo distal del canal de acceso esté bien colocado detrás del músculo puborrectal.



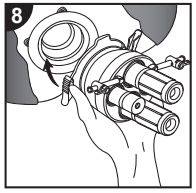

Aplique lubricante en el introductor para ayudar a colocar el canal de acceso en su posición.



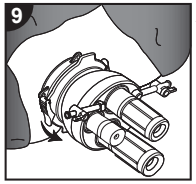

Retire el introductor. Sujete el canal acceso y suture los puertos de sutura para que quede sujeto.



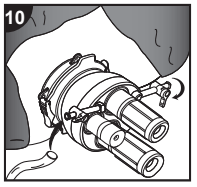

Aplique lubricante en la hendidura del anillo de fijación y el canal de acceso, y conéctelos.



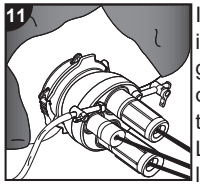

Fije la cubierta superior al anillo de fijación.




Asegúrese de que los dos cierres de palanca estén bloqueados.

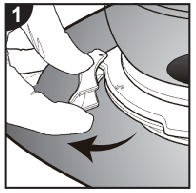



Conecte el tubo de insuflación a una de las dos llaves de cierre. Asegúrese de que la válvula de la otra llave esté cerrada.

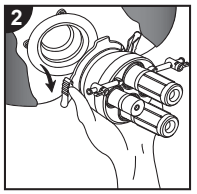



Inicie la inyección de gas. El puerto de acceso transanal de LAGIS está listo para su uso.

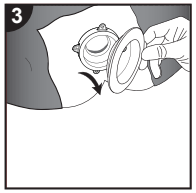
### DESMONTAJE



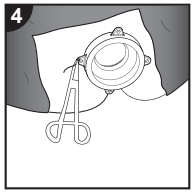

Desacople la palanca de bloqueo.



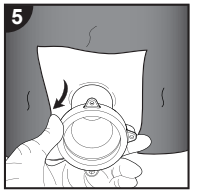

Separe la cubierta superior del anillo de fijación.




Separe el anillo de fijación del canal de acceso.

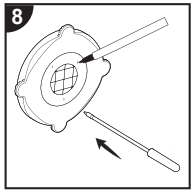



Retire las suturas.

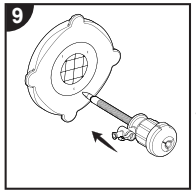



Tire con cuidado del canal de acceso hasta que salga del ano.

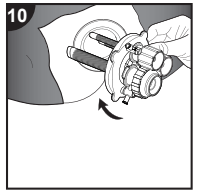
### TAPA PARA RETRACTOR DE INCISIÓN SERIE REPETIR PASOS DEL 1 A 7



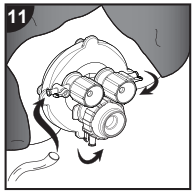

Utilice una aguja de tipo cónico para crear la primera inserción dentro de la línea delimitadora.



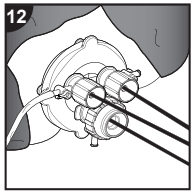

De acuerdo con el procedimiento, los cirujanos pueden insertar otros trócares siguiendo los mismos pasos dentro de la línea delimitadora.




Coloque la tapa insertada con el trócar en el anillo blanco.

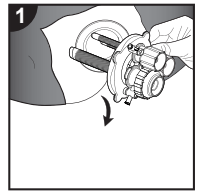



Conecte el tubo de insuflación a una de las dos llaves de cierre. Asegúrese de que la válvula de la otra llave esté cerrada.



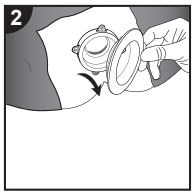

Inicie el procedimiento.

### DESMONTAJE

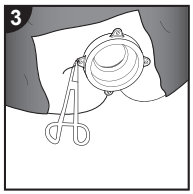



Separe la tapa insertada con el trocar del anillo de fijación.

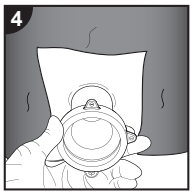
## DESMONTAJE




Separe el anillo de fijación del canal de acceso.




Retire las suturas.




Tire con cuidado del canal de acceso hasta que salga del ano.

## ◆ ADVERTENCIAS Y PRECAUCIONES:

- No utilizar si el dispositivo o el envase estéril están abiertos o dañados, ya que hacerlo podría causar un aumento en la incidencia de las infecciones en las heridas.
- Si se utiliza instrumental o accesorios endoscópicos de otros fabricantes juntos en alguna intervención, compruebe la compatibilidad antes de realizarla.
- Este dispositivo está empaquetado y esterilizado para su uso con un solo paciente. No reutilizar, reprocesar ni reesterilizar. La reutilización, el reprocesamiento o la reesterilización pueden generar contaminación, infección, infección cruzada o incluso comprometer la integridad del dispositivo y provocar fallos en el mismo que, a su vez, pueden ocasionar lesiones, enfermedades o la muerte del paciente.
- Este dispositivo debe ser utilizado únicamente por cirujanos con la capacitación adecuada y familiarizados con las técnicas quirúrgicas. Consulte publicaciones médicas para obtener más información sobre técnicas, riesgos, contraindicaciones y complicaciones antes de realizar las intervenciones.
- No perfore el canal de acceso con una aguja ni haga una sutura dentro o a través del dispositivo para facilitar la extracción del canal de acceso. La perforación del canal de acceso provoca daños y la posible pérdida del neumoperitoneo durante el procedimiento.
- Retire la cubierta superior mientras introduce la gasa. No introduzca la gasa en la cavidad a través de las cánulas de 5 mm o 12 mm para evitar daños en las válvulas de las cánulas.
- Devuelva el dispositivo y el embalaje al distribuidor o indique a un profesional sanitario que manipule y deseche de forma segura el producto si el empaque estéril está dañado o se abrió accidentalmente antes de su uso.
- El dispositivo usado que entre en contacto con fluidos corporales debe considerarse desecho biomédico y debe desecharse de forma segura por profesionales sanitarios, de conformidad con la regulación nacional de gestión de desechos para evitar que los pacientes, los usuarios y otras personas sufran contaminación o infección biológica.
- En caso de que el producto no funcione correctamente, se observen modificaciones en su rendimiento que puedan afectar a la seguridad o incluso causar cualquier incidente grave, informe inmediatamente al fabricante, a la autoridad competente del Estado miembro y al representante autorizado, según la información de contacto proporcionada en la etiqueta o en estas instrucciones de uso.
- El montaje o el manejo incorrectos del dispositivo pueden dar como resultado una prolongación de la duración de la cirugía, alergias al paciente y lesiones tejidos u órganos por daños mecánicos al paciente u operario.

## ◆ CONDICIONES AMBIENTALES PARA EL ALMACENAMIENTO:

El entorno adecuado de almacenamiento es una zona limpia y seca lejos de la luz del sol con un rango de temperatura de 13~30°C (55.4~86°F).

## ◆ EXPLICACIÓN DE LOS SÍMBOLOS：

| | | | | | |
|---|---|---|---|---|---|
| | Límite de temperatura | | Precaución | EU REP | Representante autorizado en la Comunidad Europea/Unión Europea |
| 2 STERILIZE | No reesterilizar | | Fabricante | LATEX | Este producto no está fabricado con goma de látex natural |
| 2 | No reutilizar | | Consulte las instrucciones de uso o las instrucciones electrónicas de uso | | No utilizar si el envase está dañado y consultar las instrucciones de uso |
| | Fecha de fabricación | | Indica un único sistema de barrera estéril | STERILE R | Esterilizado mediante radiación |
| MD | Producto sanitario | Rx only | PRECAUCIÓN: las leyes federales de los Estados Unidos solo permiten la venta de este dispositivo por parte un médico o por prescripción facultativa. | CE 2797 | Marcado CE según MDR 2017/745 |

ITL-0205 Ver.M 2025

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E-Mail: mail@obelis.net

LAGIS®

# PORTA DI ACCESSO TRANSANALE

Italiano

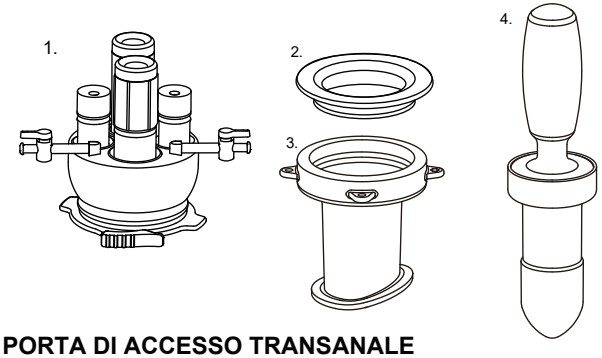
13°C 30°C LATEX Rx only STERILE R 2 STERILIZE CE 2797

www.lagis.com.tw/eifu_en.php

**PRIMA DI UTILIZZARE IL PRODOTTO, LEGGERE CON ATTENZIONE LE INFORMAZIONI QUI DI SEGUITO INDICATE.**

## ◆ DESCRIZIONE DEL DISPOSITIVO:

La Porta di accesso transanale è composta da un alloggiamento superiore, un anello di fissaggio, un canale di accesso e un introduttore. L'alloggiamento superiore è costituito da combinazioni di diversi numeri di porte che misurano 5 mm, 5-12 mm e 15 mm. Le valvole di arresto sull'alloggiamento superiore sono compatibili con il luer lock per consentire l'insufflazione e la desufflazione del gas. L'alloggiamento superiore può essere rimosso durante la procedura, consentendo così l'estrazione di campioni di grandi dimensioni. Il canale di accesso consente il collegamento all'anello di fissaggio e all'alloggiamento superiore per fornire una retrazione anale circonferenziale. L'introduttore può essere inserito per facilitare l'operazione di posizionamento del canale di accesso.
Per il dispositivo CRS-A01M senza alloggiamento superiore, è progettato per l'uso con il cappuccio per divaricatore di ferite e con i trocar per mantenere il pneumoperitoneo.




*1.Alloggiamento superiore*

*2.Anello di fissaggio*

*3.*Canale di accesso

*4.*Introduttore

### PORTA DI ACCESSO TRANSANALE

| Modelli | Alloggiamento superiore | Anello di fissaggio | Canale di accesso | Introduttore |
|---|---|---|---|---|
| CRS-60-0220M | O | O | O | O |
| CRS-A01M | X | O | O | O |

## ◆ INDICAZIONI/DESTINAZIONE D'USO:

- La Porta di accesso transanale è progettata per l'uso durante la chirurgia endoscopica transluminale a orifizio naturale transanale per mantenere lo pneumoperitoneo e consentire l'inserimento di più strumenti chirurgici attraverso l'ano nella cavità corporea.
- Benefici clinici attesi: meno dolore post-operatorio, complicazioni, infezioni della ferita e formazione di ernie; migliore cosmesi; costi inferiori a breve termine e risultati chirurgici e oncologici ottimali a medio e lungo termine.
- Gruppo target di pazienti: La Porta di accesso transanale è rivolta agli adulti che necessitano di interventi di chirurgia mini-invasiva transanale.

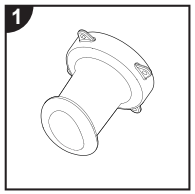
## ◆ CONTROINDICAZIONI:

La Porta di accesso transanale non è stata pensata per essere usata nei casi in cui le tecniche di chirurgia mini-invasiva sono controindicate.

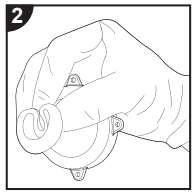
## ◆ ISTRUZIONI PER L'USO:

Prima dell'uso, ispezionare il contenuto della confezione e la confezione stessa per assicurarsi che tutti gli elementi siano integri.

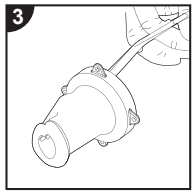
### INSTALLAZIONE E MONTAGGIO



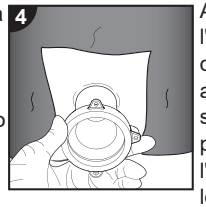

Applicare una lubrificazione sterile all'estremità distale del canale di accesso.



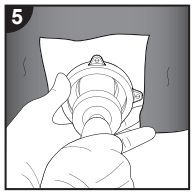

Comprimere manualmente l'estremità distale distale del canale di accesso in forma ripiegata.



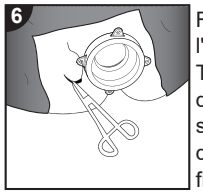

Utilizzare la pinza per bloccare l'estremità ripiegata del canale di accesso e posizionarla nell'ano.



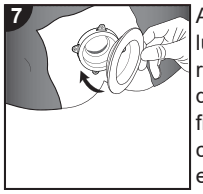

Accertarsi che l'estremità distale del canale di accesso sia saldamente posizionata dietro l'imbracatura dei levatori.



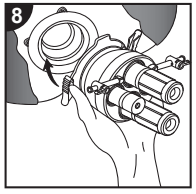

Applicare la lubrificazione sull'introduttore per facilitare il posizionamento del canale di accesso.



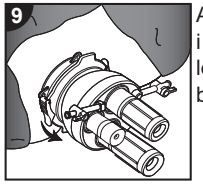

Rimuovere l'introduttore. Tenere il canale di accesso e suturare le porte di sutura per fissarle.



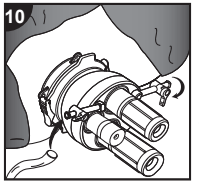

Applicare la lubrificazione alla rientranza dell'anello di fissaggio e al canale di accesso e collegarli.



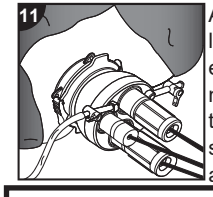

Collegare l'alloggiamento superiore all'anello di fissaggio.




Accertarsi che i 2 blocchi a leva siano bloccati.

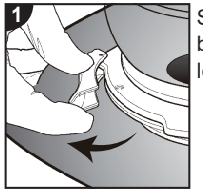



Collegare il tubo di insufflazione a uno dei due rubinetti di arresto.

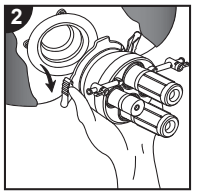



Avviare l'insufflazione e la piattaforma di accesso transanale sarà pronta all'uso.

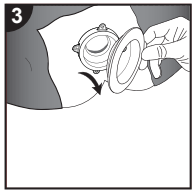
### SMONTAGGIO



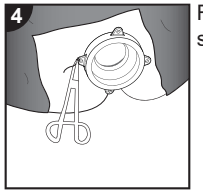

Smontare il blocco della leva.



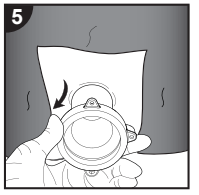

Smontare l'alloggiamento superiore dall'anello di fissaggio.




Smontare l'anello di fissaggio dal canale di accesso.

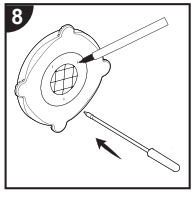



Rimuovere le suture.

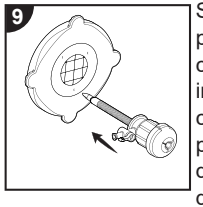



Estrarre delicatamente il canale di accesso fino a rimuoverlo dall'ano.

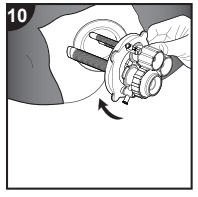
### CAPPUCCIO PER LA SERIE DEL DIVARICATORE DI FERITE - RIPETERE I PASSAGGI DA 1 A 7



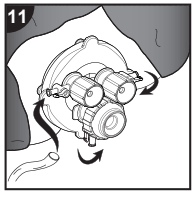

Utilizzare un ago con punta conica per creare il primo inserimento all'interno della linea di demarcazione.



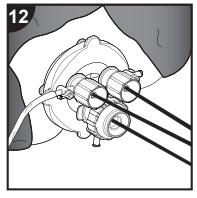

Secondo la procedura, i chirurghi possono inserire altri trocar con gli stessi passaggi all'interno della linea di demarcazione.




Fissare il tappo inserito con il trocar sull'anello bianco.

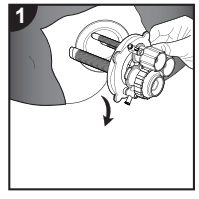



Collegare il tubo di insufflazione a uno dei due rubinetti di arresto.
Accertarsi che la valvola dell'altro rubinetto di arresto sia chiusa.



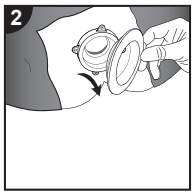

Avviare la procedura.

### SMONTAGGIO

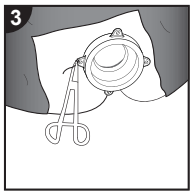



Smontare il tappo inserito con il trocar dall'anello di fissaggio.

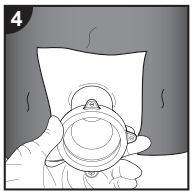
## SMONTAGGIO




Smontare l'anello di fissaggio dal canale di accesso.




Rimuovere suture.




Estrarre delicatamente il canale di accesso fino a rimuoverlo dall'ano.

## ◆ AVVERTENZE E PRECAUZIONI:

- Non utilizzare se il dispositivo o la confezione sterile sono aperti o danneggiati, dato che ciò potrebbe causare un aumento dell'incidenza delle infezioni delle ferite.
- Qualora nel contesto di una procedura vengano utilizzati insieme strumenti endoscopici o accessori di produttori diversi, sarà opportuno verificare la compatibilità degli stessi prima di eseguire la procedura.
- Questo dispositivo è confezionato e sterilizzato solo per uso singolo. Non riutilizzare, ritrattare o risterilizzare. Il riutilizzo, il ritrattamento o la risterilizzazione possono creare contaminazioni, infezioni, infezioni incrociate o addirittura compromettere l'integrità del dispositivo e provocare un guasto che a sua volta può causare lesioni, malattie o morte del paziente.
- Questo dispositivo deve essere utilizzato solo da chirurghi con un'adeguata formazione e familiarità con le tecniche chirurgiche. Consultare la letteratura medica per ulteriori informazioni in merito a tecniche, rischi, controindicazioni e complicazioni prima di eseguire le procedure.
- Non forare il canale di accesso con un ago né installare una sutura all'interno o attraverso il dispositivo per facilitare la rimozione del canale di accesso. La perforazione del canale di accesso provoca danni e la potenziale perdita di pneumoperitoneo durante la procedura.
- Rimuovere l'alloggiamento superiore mentre si introduce la garza. Non introdurre la garza nella cavità dalle porte da 5 mm o 12 mm per evitare di danneggiare le valvole delle porte.
- Restituire il dispositivo e la confezione al distributore o attuare una gestione sicura dello smaltimento da parte degli operatori sanitari se la confezione sterile viene danneggiata o aperta involontariamente prima dell'uso.
- Il dispositivo usato che entra in contatto con i fluidi corporei deve essere considerato un rifiuto biomedico e smaltito in modo sicuro dall'operatore sanitario in conformità con le norme nazionali sulla gestione dei rifiuti, per evitare che i pazienti, gli utenti e le altre persone possano subire contaminazioni o infezioni biologiche.
- In caso di anomalia di funzionamento del dispositivo, di variazioni delle prestazioni che possono influire sulla sicurezza o di incidenti gravi, si prega di segnalare immediatamente al produttore, all'autorità competente dello Stato membro e al rappresentante autorizzato usando le informazioni di contatto fornite sull'etichetta o nelle presenti istruzioni per l'uso.
- L'assemblaggio o l'uso improprio del dispositivo possono causare un prolungamento dei tempi chirurgici, allergia al paziente e lesioni ai tessuti o agli organi dovute a danni meccanici al paziente o all'operatore.

## ◆ CONDIZIONI AMBIENTALI DI CONSERVAZIONE:

L'ambiente di conservazione appropriato è un'area pulita e asciutta, lontana dalla luce del sole, con una temperatura compresa tra 13 e 30 °C (55,4 e 86 °F).

## ◆ SPIEGAZIONE DEI SIMBOLI：

| | | | | | |
|---|---|---|---|---|---|
| | Limiti temperatura | | Attenzione | EU REP | Rappresentante autorizzato nella Comunità Europea/Unione Europea |
| | Non risterilizzare | | Produttore | | Non prodotto con lattice di gomma naturale |
| | Non riutilizzare | | Consultare le istruzioni per l'uso o consultare le istruzioni per l'uso elettroniche | | Non utilizzare se la confezione è danneggiata e consultare le istruzioni per l'uso |
| | Data di produzione | | Sistema di barriera sterile singola | STERILE R | Sterilizzato tramite irraggiamento |
| MD | Dispositivo medico | ℞ only | ATTENZIONE: La legge federale statunitense limita la vendita di questo dispositivo a medici o su prescrizione medica. | CE 2797 | Marcatura CE in conformità con MDR 2017/745 |

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E-Mail: mail@obelis.net

LAGIS®

# TRANSANALER ZUGANGSPORT

Deutsch

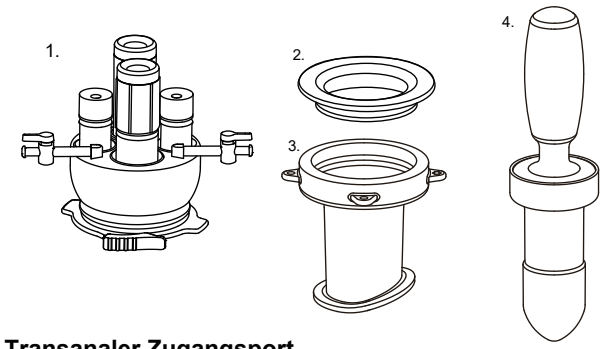
13°C 30°C | LATEX | Rx only STERILE R | 2 STERILIZE | CE 2797

www.lagis.com.tw/eifu_en.php

**VOR DEM GEBRAUCH DES PRODUKTS MÜSSEN SIE DIE FOLGENDEN INFORMATIONEN SORGFÄLTIG LESEN.**

## ◆ GERÄTEBESCHREIBUNG:

Der Transanaler Zugangsport besteht aus dem oberen Gehäuse, dem Befestigungsring, dem Zugangskanal und der Einführhilfe. Das obere Gehäuse besteht aus Kombinationen verschiedener Anzahlen von 5 mm, 5-12 mm, und 15 mm Ports. Die Absperrventile am oberen Gehäuse sind mit Luer-Lock kompatibel und ermöglichen die Gasinsufflation und desufflation. Das obere Gehäuse kann während des Eingriffs abgenommen werden, so dass auch große Proben entnommen werden können. Der Zugangskanal ermöglicht den Anschluss an den Befestigungsring und das obere Gehäuse, um eine anale Retraktion in Umfangsrichtung zu ermöglichen. Die Einführhilfe kann eingeführt werden, um den Zugangskanal in Position zu bringen. Das Gerät CRS-A01M ohne oberes Gehäuse ist für die Verwendung mit der Kappe für Wundretraktor und Trokaren zur Aufrechterhaltung des Pneumoperitoneums.




*1.Oberes Gehäuse*

*2.Befestigungsring*

*3.*Zugangskanal

*4.*Einführhilfe

**Transanaler Zugangsport**

| Modelle | Oberes Gehäuse | Befestigungsring | Zugangskanal | Einführhilfe |
|---|---|---|---|---|
| CRS-60-0220M | O | O | O | O |
| CRS-A01M | X | O | O | O |

## ◆ INDIKATIONEN/ZWECK:

- Der Transanaler Zugangsport ist für den Einsatz bei der transanalen transluminalen endoskopischen Chirurgie mit natürlicher Öffnung konzipiert, um das Pneumoperitoneum aufrechtzuerhalten und gleichzeitig das Einführen mehrerer chirurgischer Instrumente durch den Anus in die Körperhöhle zu ermöglichen.
- Erwarteter klinischer Nutzen: weniger postoperative Schmerzen, Komplikationen, Wundinfektionen und Hernienbildung; verbesserte Kosmese; geringere kurzfristige Kosten; optimale mittel- und langfristige chirurgische und onkologische Ergebnisse.
- Patientenzielgruppe: Der Transanaler Zugangsport ist für Erwachsene bestimmt, die transanale minimalinvasive chirurgische Eingriffe benötigen.

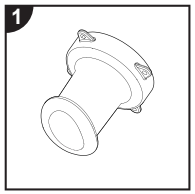
## ◆ GEGENANZEIGEN:

Der Transanaler Zugangsport ist nicht zur Verwendung vorgesehen, wenn minimal-invasive Operationstechniken kontraindiziert sind.

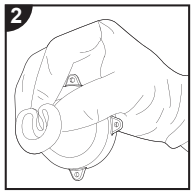
## ◆ GEBRAUCHSANWEISUNG:

Prüfen Sie vor dem Gebrauch den Inhalt der Verpackung und die Verpackung selbst, um sicherzustellen, dass die Unversehrtheit nicht beeinträchtigt ist.

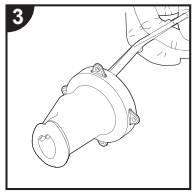
### INSTALLATION UND MONTAGE



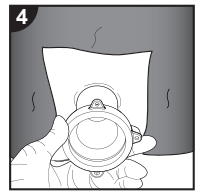

Tragen Sie steriles Gleitmittel auf das untere Ende des Zugangskanals auf.



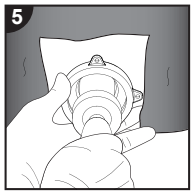

Drücken Sie das untere Ende des Zugangskanals von Hand in gefalteter Form zusammen.



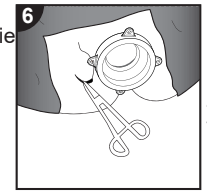

Klemmen Sie das gefaltete Ende des Zugangskanals mit der Zange ab und führen Sie ihn in den Anus ein.



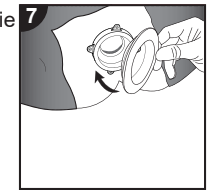

Stellen Sie sicher, dass das untere Ende des Zugangskanals sicher hinter der Levatorschlinge sitzt



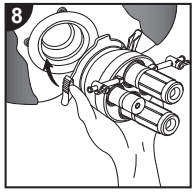

Tragen Sie das Gleitmittel auf die Einführhilfe auf, um den Zugangskanal leichter in Position zu bringen.



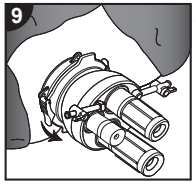

Entfernen Sie die Einführhilfe. Halten Sie den Zugangskanal fest und nähen Sie die Nahtöffnungen zu, um diese zu sichern.



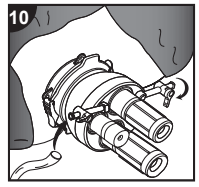

Verteilen Sie Gleitmittel auf der Vertiefung des Befestigungsrings und dem Zugangskanal und verbinden Sie sie.



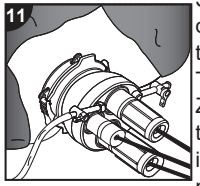

Befestigen Sie das obere Gehäuse am Befestigungsring.




Vergewissern Sie sich, dass die 2 Hebelverschlüsse verriegelt sind.

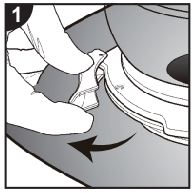



Schließen Sie den Insufflationsschlauch an eines der beiden Ventile an. Vergewissern Sie sich, dass das andere Ventil geschlossen ist.

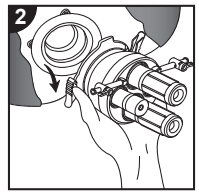



Starten Sie die Insufflation und der Transanale Zugangsplattform ist einsatzbereit.

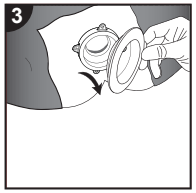
### DEMONTAGE



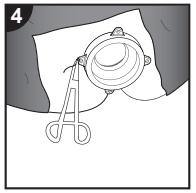

Demontieren Sie das Hebelschloss.



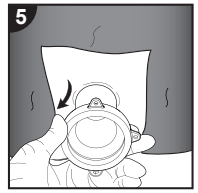

Nehmen Sie das obere Gehäuse vom Befestigungsring ab.




Nehmen Sie den Befestigungsring vom Zugangskanal.

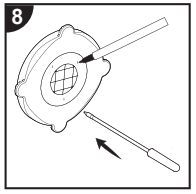



Fäden ziehen.

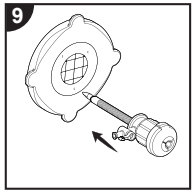



Ziehen Sie den Zugangskanal vorsichtig heraus, bis er aus dem After entfernt ist.

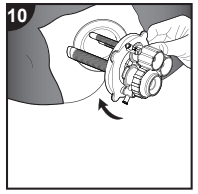
**KAPPE FÜR WUNDRETRAKTOR-SERIE WIEDERHOLEN SIE SCHRITT 1 BIS 7**



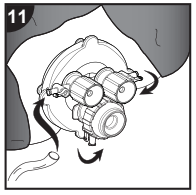

Verwenden Sie eine Nadel mit einer konischen Spitze, um die Einführungsstelle innerhalb der Begrenzungslinie zu erstellen.



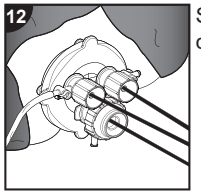

Entsprechend dem Verfahren können Chirurgen andere Trokare durch die gleichen Schritte innerhalb der Grenzlinie einführen.




Befestigen Sie die mit dem Trokar eingesetzte Kappe am weißen Ring.

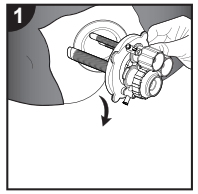



Schließen Sie den Insufflationsschlauch an eines der beiden Ventile an. Achten Sie darauf, dass das andere Ventil geschlossen ist.



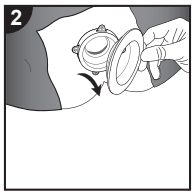

Starten Sie den Eingriff.

### DEMONTAGE

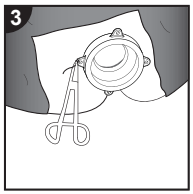



Nehmen Sie die mit einem Trokar versehene Kappe vom Befestigungsring ab.

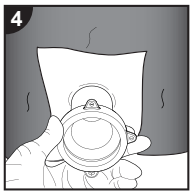
## DEMONTAGE




Entfernen Sie den Befestigungsring vom Zugangskanal.




Fäden ziehen.




Ziehen Sie den Zugangskanal vorsichtig heraus, bis er aus dem After entfernt ist.

## ◆ WARNHINWEISE UND VORSICHTSMASSNAHMEN:

- Nicht verwenden, wenn das Gerät oder die Sterilverpackung geöffnet oder beschädigt ist, da dies zu einer erhöhten Inzidenz von Wundinfektionen führen kann.
- Wenn endoskopische Instrumente oder Zubehör verschiedener Hersteller zusammen in einem Verfahren verwendet werden, ist die Kompatibilität vor der Durchführung des Verfahrens zu überprüfen.
- Dieses Produkt ist nur für den einmaligen Gebrauch bei einem Patienten verpackt und sterilisiert. Das Produkt darf nicht wiederverwendet, wiederaufbereitet oder resterilisiert werden. Die Wiederverwendung, Wiederaufbereitung oder Resterilisation kann zu Kontaminationen, Infektionen, Kreuzinfektionen oder sogar zur Beeinträchtigung der Integrität des Geräts führen und zum Ausfall des Geräts führen was wiederum Verletzungen, Erkrankungen oder den Tod des Patienten zur Folge haben kann.
- Dieses Produkt sollte nur von Chirurgen verwendet werden, die über eine angemessene Ausbildung verfügen und mit den chirurgischen Techniken vertraut sind. Konsultieren Sie die medizinische Fachliteratur, um weitere Informationen über Techniken, Gefahren, Kontraindikationen und Komplikationen zu erhalten, bevor Sie die Eingriffe durchführen.
- Stechen Sie nicht mit einer Nadel in den Zugangskanal und bringen Sie keine Naht in oder durch das Gerät ein, um das Entfernen des Zugangskanals zu erleichtern. Das Durchstechen des Zugangskanals führt zu einer Beschädigung und einem möglichen Verlust des Pneumoperitoneums während des Eingriffs.
- Bitte entfernen Sie das obere Gehäuse, während Sie die Gaze einführen. Führen Sie die Gaze nicht über die 5-mm- oder 12-mm-Ports in den Hohlraum ein, um eine Beschädigung der Ventile der Ports zu vermeiden.
- Geben Sie das Produkt und die Verpackung an den Händler zurück oder sorgen Sie für eine sichere Entsorgung durch das medizinische Fachpersonal, wenn die Sterilverpackung vor der Verwendung beschädigt oder unbeabsichtigt geöffnet wurde.
- Das verwendete Produkt, das mit Körperflüssigkeiten in Berührung gekommen ist, sollte als biomedizinischer Abfall betrachtet und vom medizinischen Fachpersonal gemäß den nationalen Abfallentsorgungsvorschriften sicher entsorgt werden, um Patienten, Anwender und andere Personen vor biologischen Kontamination oder Infektion zu schützen.
- Im Falle einer Funktionsstörung des Geräts, einer Veränderung der Leistung, die die Sicherheit beeinträchtigen könnte, oder sogar eines schwerwiegenden Vorfalls informieren Sie bitte unverzüglich den Hersteller, die zuständige Behörde des Mitgliedstaats und den Bevollmächtigten gemäß den auf dem Etikett oder in dieser Gebrauchsanweisung angegebenen Kontaktinformationen.
- Eine unsachgemäße Montage oder Bedienung des Geräts kann zu einer verlängerten Operationszeit, Allergien beim Patienten und Gewebe- oder Organverletzungen durch mechanische Beschädigung des Patienten oder des Bedieners führen.

## ◆ UMWELTBEDINGUNGEN FÜR DIE LAGERUNG:

Die geeignete Lagerung sollte in einem sauberen, trockenen und vor Sonnenlicht geschützten Raum bei einer Temperatur von 13~30°C (55.4~86°F) erfolgen.

## ◆ ERKLÄRUNG DER SYMBOLE:

| | | | | | |
|---|---|---|---|---|---|
| | Temperaturbegrenzung | | Vorsicht | EU REP | Bevollmächtigter Vertreter in der Europäischen Gemeinschaft/Europäischen Union |
| 2 STERILIZE | Nicht resterilisieren | | Hersteller | LATEX | Ohne Naturkautschuk hergestellt |
| 2 | Nicht wiederverwenden | | Gebrauchsanweisung oder elektronische Gebrauchsanweisung beachten | | Bei beschädigter Verpackung nicht verwenden und Gebrauchsanweisung beachten |
| | Herstellungsdatum | | System mit nur einer Sterilbarriere | STERILE R | Mit Strahlung sterilisiert |
| MD | Medizinprodukt | ℞ only | VORSICHT: US-Bundesgesetz beschränkt den Verkauf dieses Produkts an einen Arzt oder auf dessen Anordnung. | CE 2797 | CE-Kennzeichnung gemäß MDR 2017/745 |

ITL-0405 Ver.F 2025

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LAGIS®

# PORT D'ACCÈS TRANSANAL

Français

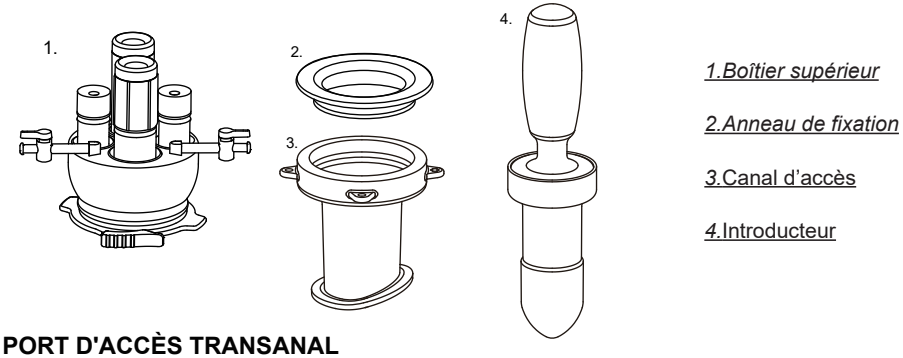
13°C 30°C LATEX Rx only STERILE R STERILIZE 2 2797

www.lagis.com.tw/eifu_en.php

**LISEZ ATTENTIVEMENT LES INFORMATIONS SUIVANTES AVANT D'UTILISER CE PRODUIT.**

## ◆ DESCRIPTION DU DISPOSITIF:

Le port d'accès transanal se compose d'un boîtier supérieur, un anneau de fixation, un canal d'accès et un introducteur. Le boîtier supérieur est constitué de combinaisons de différents nombres de ports de 5 mm, de 5 à 12 mm et de 15 mm. Les robinets du boîtier supérieur sont compatibles avec les embouts Luer-Lok afin de permettre l'insufflation et l'exsufflation. Le boîtier supérieur peut être retiré pendant la procédure, ce qui permet d'extraire des échantillons volumineux. Le canal d'accès permet le raccordement à l'anneau de fixation et au boîtier supérieur afin d'obtenir un écartement anal circulaire. L'introducteur peut être inséré pour aider à mettre en place le canal d'accès.
Quant au dispositif CRS-A01M sans boîtier supérieur, il est conçu pour être utilisé avec le couvercle pour écarteur de plaie et les trocarts, afin de maintenir le pneumopéritoine.




*1.Boîtier supérieur*

*2.Anneau de fixation*

*3.*Canal d'accès

*4.*Introducteur

### PORT D'ACCÈS TRANSANAL

| Modèles | Boîtier supérieur | Anneau de fixation | Canal d'accès | Introducteur |
|---|---|---|---|---|
| CRS-60-0220M | O | O | O | O |
| CRS-A01M | X | O | O | O |

## ◆ INDICATIONS / UTILISATION PRÉVUE:

- Le port d'accès transanal est conçu pour être utilisé dans des interventions endoscopiques transluminalesà travers l'orifice anal naturel, afin de maintenir un pneumopéritoine tout en permettent l'insertion par l'anus, et dans la cavité corporelle, de plusieurs instruments chirurgicaux.
- Avantages cliniques attendus: réduction de la douleur postopératoire, des complications, des infections de la plaie et de la formation d'hernies ; meilleurs résultats cosmétiques ; réduction des coûts à court terme ; et meilleurs résultats chirurgicaux et oncologiques à moyen et long terme.
- Groupe de patients cibles: le port d'accès transanal est conçu pour les adultes nécessitant de procédures chirurgicales transanales mini-invasives.

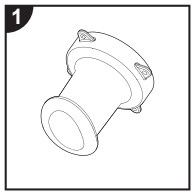
## ◆ CONTRE-INDICATIONS:

Le port d'accès transanal n'est pas conçu pour être utilisé dans les cas où les techniques chirurgicales mini-invasives sont contre-indiquées.

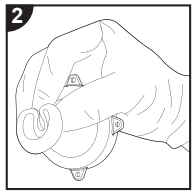
## ◆ INSTRUCTIONS D'UTILISATION:

Avant l'utilisation, examinez le contenu de l'emballage et l'emballage lui-même pour vérifier que leur intégrité n'est pas compromise.

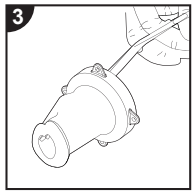
### INSTALLATION ET MONTAGE



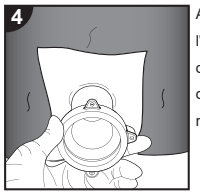

Appliquez une lubrification stérile à l'extrémité distale du canal d'accès.



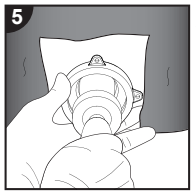

Comprimez manuellement l'extrémité distale du canal d'accès sous une forme pliée.



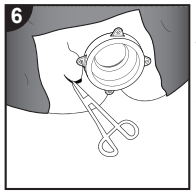

Utilisez la pince pour clipser l'extrémité pliée du canal d'accès et placez-la dans l'anus.



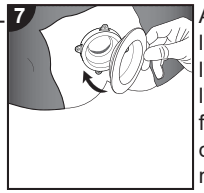

Assurez-vous que l'extrémité distale du canal d'accès est bien en place derrière la sangle du releveur.



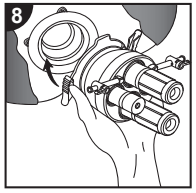

Appliquez la lubrification à l'introducteur pour faciliter la mise en place du canal d'accès en position.



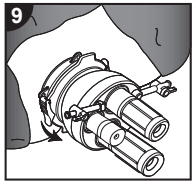

Retirez l'introducteur. Maintenez le canal d'accès et suturez les ports de suture pour la fixation.



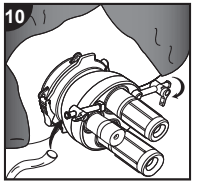

Appliquez de la lubrification sur l'indentation de l'anneau de fixation et du canal d'accès, puis raccordez-les.



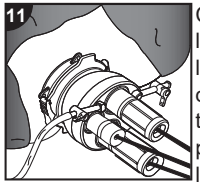

Fixez le boîtier supérieur à l'anneau de fixation.




Vérifiez que les 2 verrous à levier sont verrouillés.

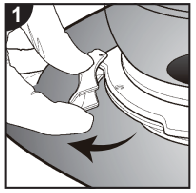



Raccordez le tube d'insufflation à l'un des deux robinets d'arrêt. Assurez-vous que l'autre robinet est fermé.

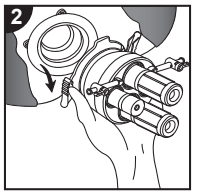



Commencez l'insufflation et la plateforme d'accès transanale est prête à l'emploi.

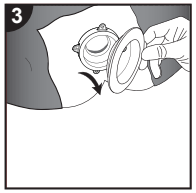
### DÉMONTAGE



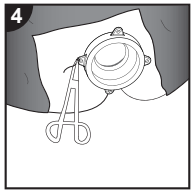

Démontez le verrou à levier.



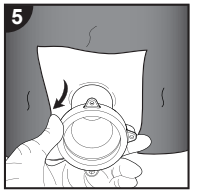

Détachez le boîtier supérieur de l'anneau de fixation.




Détachez l'anneau de fixation du canal d'accès.

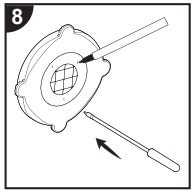



Retirez les sutures.

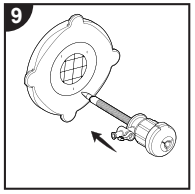



Tirez doucement le canal d'accès jusqu'à ce qu'il soit retiré de l'anus.

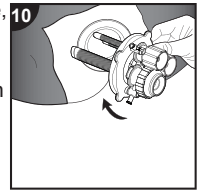
### CAPUCHON POUR SÉRIE D'ÉCARTEURS DE PLAIE RÉPÉTEZ LES ÉTAPES 1 À 7



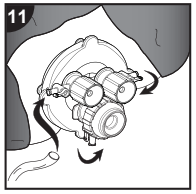

Utilisez une pointe conique en forme d'aiguille pour créer la première insertion à l'intérieur de la ligne de démarcation.



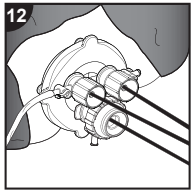

Selon la procédure, les chirurgiens peuvent insérer d'autres trocarts en suivant les mêmes étapes à l'intérieur de la ligne de démarcation.




Fixez le capuchon inséré par le trocart sur l'anneau blanc.

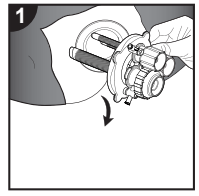



Raccordez le tube d'insufflation à l'un des deux robinets d'arrêt. Assurez-vous que l'autre robinet est fermé.



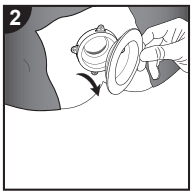

Lancez la procédure.

### DÉMONTAGE

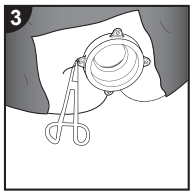



Détachez le capuchon inséré par le trocart de l'anneau de fixation.

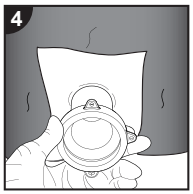
## DÉMONTAGE




Désassemblez l'anneau de fixation du canal d'accès.




Retirez les sutures.




Tirez doucement le canal d'accès jusqu'à ce qu'il soit retiré de l'anus.

## ◆ AVERTISSEMENTS ET PRÉCAUTIONS:

- N'utilisez pas ce dispositif si celui-ci ou son emballage stérile sont ouverts ou endommagés. Cela pourrait augmenter l'incidence des infections des plaies.
- Si des instruments ou des accessoires endoscopiques de différents fabricants sont utilisés en même temps dans une intervention, vérifiez leur compatibilité avant d'exécuter la procédure.
- Ce dispositif est emballé et stérilisé en vue d'une utilisation sur un seul patient. Il ne faut pas le réutiliser, ni le re-traiter, ni le restériliser. La réutilisation, le re-traitement ou la restérilisation peuvent être cause de contamination, d'infection ou d'infection croisée, ou même compromettre l'intégrité du dispositif et entraîner sa défaillance, ce qui peut à son tour blesser, rendre malade ou tuer le patient.
- Ce dispositif ne doit être utilisé que par des chirurgiens dûment formés et familiarisés avec les techniques chirurgicales. Avant d'exécuter les procédures, consultez de la documentation médicale pour vous informer plus à fond sur les techniques, les risques, les contre-indications et les éventuelles complications.
- Ne percez pas le canal d'accès avec une aiguille et n'installez pas une suture dans ou à travers le dispositif pour faciliter le retrait du canal d'accès. La perforation du canal d'accès provoquerait des dommages, et probablement la perte du pneumopéritoine pendant la procédure.
- Retirez le boîtier supérieur lors de l'introduction de la gaze. N'introduisez pas la gaze dans la cavité depuis les ports de 5 ou de 12 mm, pour éviter d'endommager les vannes de ces ports.
- Les professionnels de santé doivent retourner le dispositif et son emballage au distributeur, ou le mettre au rebut de manière sécurisée, si l'emballage stérile est endommagé ou involontairement ouvert avant le moment de l'utiliser.
- Les dispositifs usagés ayant été en contact avec des fluides corporels doivent être considérés comme des déchets biomédicaux. Ils doivent être mis au rebut de manière sécurisée par des professionnels de santé, conformément à la réglementation nationale sur la gestion des déchets, afin de protéger les patients, les utilisateurs et toutes autres personnes de toute contamination ou infection biologique.
- En cas de mauvais fonctionnement du dispositif ou de modifications de ses prestations susceptibles d'affecter la sécurité ou de provoquer un incident grave, veuillez en informer au plus vite le fabricant, l'autorité compétente de l'État membre et le représentant agréé en utilisant les coordonnées de contact figurant sur l'étiquette ou dans les présentes instructions d'utilisation.
- Un montage ou une utilisation incorrects de ce dispositif pourrait prolonger la durée de l'intervention chirurgicale, déclencher une allergie chez le patient, ou causer à des organes ou à des tissus de celui-ci ou de l'opérateur des lésions dues à des dommages mécaniques.

## ◆ CONDITIONS ENVIRONNEMENTALES POUR L'ENTREPOSAGE:

L'environnement de rangement approprié est un lieu propre et sec, à l'abri du soleil, et où la température est comprise entre 13 et 30 °C (55,4 et 86 °F).

## ◆ EXPLICATION DES SYMBOLES :

| | | | | | |
|---|---|---|---|---|---|
| | Limite de température | | Avertissement | EU REP | Représentant agrée dans la Communauté européenne / Union européenne |
| 2 STERILIZE | Ne pas restériliser | | Fabricant | LATEX | Non fabriqué avec du latex de caoutchouc naturel |
| 2 | Ne pas réutiliser | | Consultez le mode d'emploi ou les instructions d'utilisation électroniques | | Ne pas utiliser si l'emballage est endommagé et consulter le mode d'emploi |
| | Date de fabrication | | Indique un système à barrière unique stérile | STERILE R | Stérilisé par irradiation |
| MD | Dispositif médical | ℞ only | Avertissement : la loi fédérale américaine stipule que la vente de ce dispositif est réservée aux médecins ou sur prescription médicale. | CE 2797 | Marquage CE selon MDR 2017/745 |

ITL-0505 Ver.F 2025

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E-Mail: mail@obelis.net

LAGIS®

# PORTA DE ACESSO TRANSANAL

Português

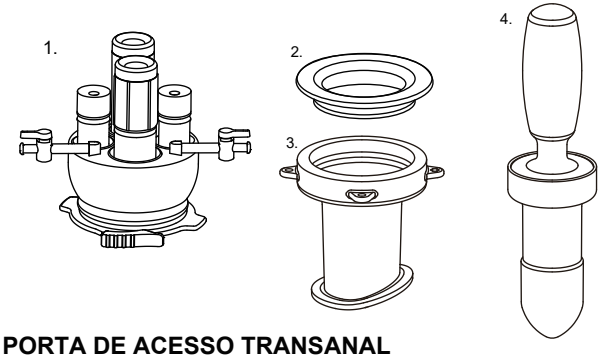
13°C 30°C LATEX Rx only STERILE R STERILIZE 2797

www.lagis.com.tw/eifu_en.php

**ANTES DE UTILIZAR O PRODUTO, LEIA ATENTAMENTE AS SEGUINTES INFORMAÇÕES.**

## ◆ DESCRIÇÃO DO DISPOSITIVO:

A Porta de Acesso Transanal é composta do compartimento superior, anel de fixação, canal de acesso, e introdutor. O compartimento superior consiste dem combinações de diferentes números de portas de 5 mm, 5-12 mm, e 15 mm. As válvulas da torneira no compartimento superior são compatíveis com luer lock para fornecer insuflação e desinsuflação de gás. O compartimento superior pode ser removido durante o procedimento, permitindo a extração de amostras grandes. O canal de acesso permite a ligação ao anel de fixação e ao compartimento superior para fornecer retração anal circunferencial. O introdutor pode ser inserido para auxiliar a colocação do canal de acesso em posição.
Para o dispositivo CRS-A01M sem compartimento superior, foi concebido para ser utilizado com a tampa para retrator de incisão e trocartes para manter o pneumoperitoneu.




*1.Compartimento superior*

*2.Anel de fixação*

*3.*Canal de acesso

*4.*Introdutor

**PORTA DE ACESSO TRANSANAL**

| Modelos | Compartimento superior | Anel de Fixação | Canal de Acesso | Introdutor |
|---|---|---|---|---|
| CRS-60-0220M | O | O | O | O |
| CRS-A01M | X | O | O | O |

## ◆ INDICAÇÕES/FINALIDADE PREVISTA:

- A Porta de Acesso Transanal foi concebida para utilização durante a cirurgia endoscópica transluminal do orifício natural transanal para manter o pneumoperitónio, permitindo ao mesmo tempo a inserção de múltiplos instrumentos cirúrgicos através do ânus na cavidade corporal.
- Benefícios clínicos esperados: menos dor pós-operatória, complicações, infeções de incisões, e formação de hérnias; melhor cosmese; menor custo a curto prazo; e resultados cirúrgicos e oncológicos ideais a médio e longo prazo.
- Grupo alvo de pacientes: A Porta de Acesso Transanal é destinada a adultos que precisam de procedimentos cirúrgicos transanais minimamente invasivos.

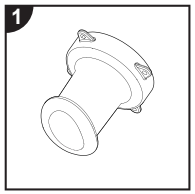
## ◆ CONTRAINDICAÇÕES:

A Porta de Acesso Transanal não se destina a ser utilizada quando as técnicas cirúrgicas minimamente invasivas são contraindicadas.

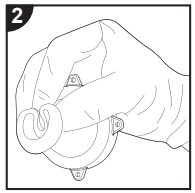
## ◆ INSTRUÇÕES DE UTILIZAÇÃO:

Antes da utilização, inspecione o conteúdo da embalagem e a própria embalagem para se assegurar de que a integridade não está comprometida.

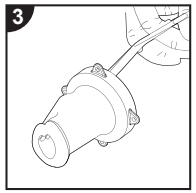
**INSTALAÇÃO E MONTAGEM**



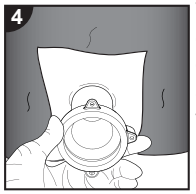

Aplique lubrificante estéril na extremidade distal do canal de acesso.



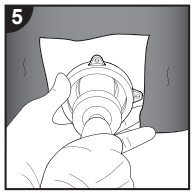

Comprimir manualmente a extremidade distal do canal de acesso em uma forma dobrada.



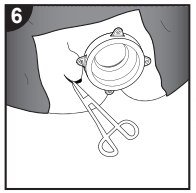

Use a pinça para prender a extremidade dobrada do canal de acesso e insira-a no ânus.



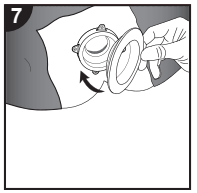

Verifique se a extremidade distal do canal de acesso está firmemente posicionada atrás do levantador do ânus.



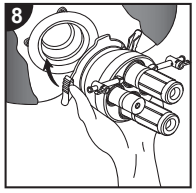

Aplique lubrificante no introdutor para facilitar o posicionamento do canal de acesso.



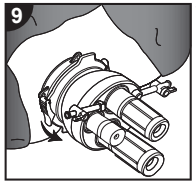

Remova o introdutor. Segure o canal de acesso e costure os pontos de sutura para fixá-lo.



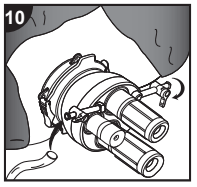

Aplique lubrificante na ranhura do anel de fixação e no canal de acesso, e conecte-os.



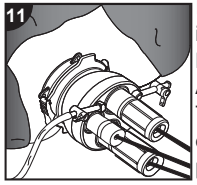

Conecte o compartimento superior ao anel de fixação.




Verifique se as 2 travas de alavanca estão bloqueadas.

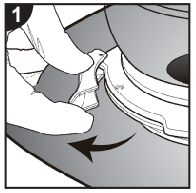



Conecte o tubo de insuflação a uma das duas torneiras de controle. Verifique se a válvula da outra torneira de controle está fechada.

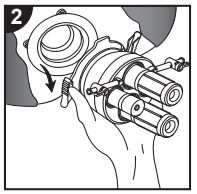



Inicie a insuflação e a Plataforma de Acesso Transanal estará pronta para uso.

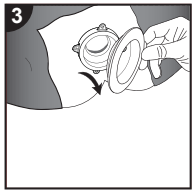
**DESMONTAGEM**



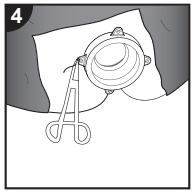

Desmonte o bloqueio da alavanca.



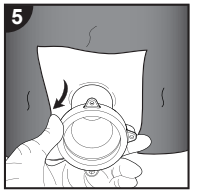

Desmonte o compartimento superior do anel de fixação.




Remova do canal de acesso o anel de fixação.

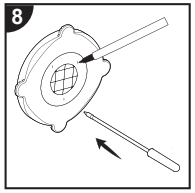



Remova os pontos.

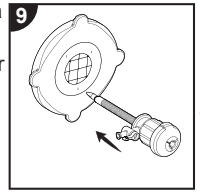



Puxe suavemente o canal de acesso até que ele seja removido do ânus.

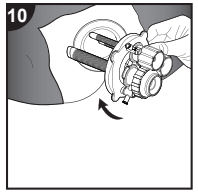
**TAMPA PARA SÉRIE RETRATOR DE INCISÃO: REPITA OS PASSOS 1 A 7**



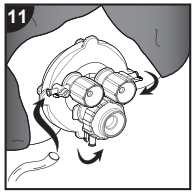

Use uma agulha com ponta cônica para criar a primeira inserção dentro da linha de limite.



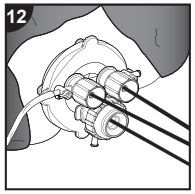

De acordo com o procedimento, os cirurgiões podem inserir outros trocartes seguindo os mesmos passos dentro da linha de limite.




Prenda a Tampa do trocarte inserido no anel branco.

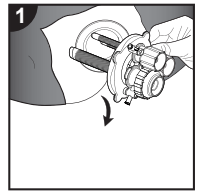



Conecte a tubulação de insuflação a uma das duas torneiras de controle. Verifique se a válvula da outra torneira de controle está fechada.



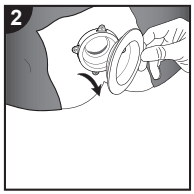

Inicie o procedimento.

**DESMONTAGEM**

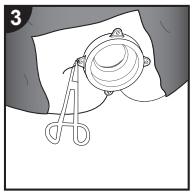



Desmonte a Tampa inserida do trocarte do anel de fixação.

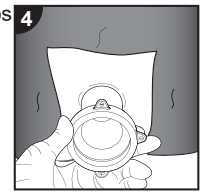
## DESMONTAGEM




Remova do canal de acesso o anel de fixação.




Remova os pontos.




Puxe suavemente o canal de acesso até que ele seja removido do ânus.

## ◆ ADVERTÊNCIAS E PRECAUÇÕES:

- Não utilize se o dispositivo ou a embalagem esterilizada abertos ou danificados, visto que isto pode causar um aumento na incidência de infeções da incisão.
- Se os instrumentos endoscópicos ou acessórios de diferentes fabricantes forem utilizados em conjunto num procedimento, verificar a compatibilidade antes de realizar o procedimento.
- Este dispositivo é embalado e esterilizado apenas para utilização num único paciente. Não reutilize, reprocesse ou reesterilize. A reutilização, reprocessamento ou reesterilização podem causar contaminação, infeção, infeção cruzada ou até comprometer a integridade do dispositivo e levar à falha do dispositivo, o que, por sua vez, pode resultar em lesões no paciente, doença ou morte.
- Esse dispositivo deve ser operado apenas por cirurgiões com formação adequada e familiarizados com técnicas cirúrgicas. Consulte a literatura médica para obter mais informações sobre técnicas, perigos, contraindicações e complicações antes de realizar os procedimentos.
- Não perfurar o canal de acesso com uma agulha ou instalar uma sutura dentro, ou através, do dispositivo para facilitar a remoção do canal de acesso. A perfuração do canal de acesso resultará em danos e potencial perda de pneumoperitónio durante o procedimento.
- Remover o compartimento superior enquanto se introduz a gaze. Não introduzir a gaze na cavidade a partir das portas de 5 mm ou 12 mm para evitar danos nas válvulas das portas.
- Devolva o dispositivo e a embalagem ao distribuidor ou implemente um manuseamento seguro de eliminação por parte dos profissionais de saúde se a embalagem estéril estiver danificada ou tiver sido involuntariamente aberta antes da utilização.
- O dispositivo utilizado que entra em contacto com fluidos corporais deve ser considerado como resíduo biomédico e eliminado com segurança pelo profissional de saúde em conformidade com o regulamento nacional de gestão de resíduos para evitar que pacientes, utilizadores e outras pessoas sejam contaminados ou infetados de forma biológica.
- Em caso de funcionamento irregular do dispositivo, alterações no desempenho que possam afetar a segurança, ou mesmo qualquer incidente grave, é necessário comunicar imediatamente ao fabricante, à autoridade competente do Estado-membro e ao representante autorizado, de acordo com as informações de contacto fornecidas no rótulo ou nas presentes instruções de utilização.
- A montagem ou o funcionamento incorretos do dispositivo podem resultar num prolongamento do tempo cirúrgico, alergia do doente e lesões de tecidos ou órgãos oriundas de danos mecânicos para o doente ou para o operador.

## ◆ CONDIÇÕES AMBIENTAIS PARA ARMAZENAGEM:

O ambiente de armazenamento adequado é uma área limpa e seca, afastada da luz solar, com um intervalo de temperaturas de 13 a 30 ºC (55,4 a 86 ºF).

## ◆ EXPLICAÇÃO DOS SÍMBOLOS:

| | | | | | |
|---|---|---|---|---|---|
| | Limitação de temperatura | | Cuidado | EU REP | Representante autorizado na Comunidade Europeia/União Europeia |
| | Não reesterilize | | Fabricante | | Sem látex de borracha natural |
| | Não reutilize | | Consultar instruções de utilização ou consultar instruções eletrónicas de utilização | | Não utilize se a embalagem estiver danificada e consulte as instruções de utilização |
| | Data de fabrico | | Sistema de barreira única estéril | STERILE R | Esterilizado com irradiação |
| MD | Dispositivo médico | ℞ only | Cuidado: o direito federal dos E.U.A. restringe a venda deste dispositivo por ou em nome de um médico. | CE 2797 | Marcação CE de acordo com o MDR 2017/745 |

ITL-0905 Ver.F 2025

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LAGIS®

# TRANSANALE TOEGANGSPOORT

Nederlands

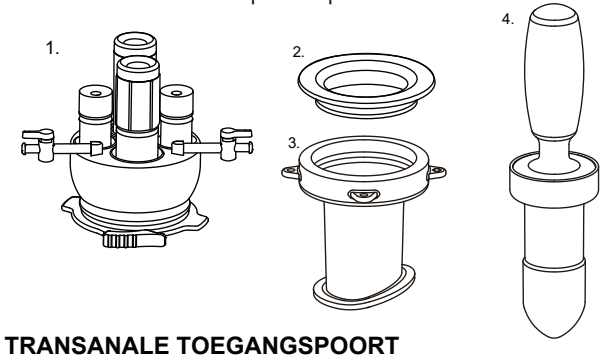
13°C 30°C LATEX Rx only STERILE R STERILIZE 2797

www.lagis.com.tw/eifu_en.php

**LEES DE VOLGENDE INFORMATIE ZORGVULDIG DOOR VOORDAT U HET PRODUCT GEBRUIKT.**

## ◆ BESCHRIJVING HULPMIDDEL:

De transanale toegangspoort bestaat uit een bovenste behuizing, bevestigingsring, toegangskanaal en introducer. De bovenste behuizing bestaat uit combinaties van verschillende aantallen 5 mm, 5-12 mm en 15 mm poorten. De afsluiters op de bovenste behuizing zijn compatibel met luer-lock voor het insuffleren en desuffleren van gas. De bovenste behuizing kan tijdens de ingreep worden verwijderd, zodat grote preparaten kunnen worden geëxtraheerd. Het toegangskanaal maakt verbinding met de bevestigingsring en de bovenste behuizing mogelijk om te zorgen voor circumferentiële anale retractie. De introducer kan worden ingebracht om het toegangskanaal in positie te brengen.
Het hulpmiddel CRS-A01M zonder bovenste behuizing is ontworpen voor gebruik met de kap voor wondretractor en trocars om een pneumoperitoneum te behouden.




*1.Bovenste behuizing*

*2.Bevestigingsring*

*3.*Toegangskanaal

*4.*Introducer

**TRANSANALE TOEGANGSPOORT**

| Modellen | Bovenste behuizing | Bevestigingsring | Toegangskanaal | Introducer |
|---|---|---|---|---|
| CRS-60-0220M | O | O | O | O |
| CRS-A01M | X | O | O | O |

## ◆ INDICATIES/BEOOGD GEBRUIK:

- De transanale toegangspoort is ontworpen voor gebruik tijdens transanale transluminale endoscopische chirurgie met natuurlijke opening voor het handhaven van pneumoperitoneum, terwijl meerdere chirurgische instrumenten via de anus in de lichaamsholte kunnen worden ingebracht.
- Verwachte klinische voordelen: minder postoperatieve pijn, complicaties, wondinfecties en herniavorming; betere cosmesis; lagere kosten op korte termijn; en optimale chirurgische en oncologische resultaten op middellange en lange termijn.
- Patiëntendoelgroep: de transanale toegangspoort is bedoeld voor volwassenen die een transanale mimimaal invasieve chirurgische ingreep moeten ondergaan.

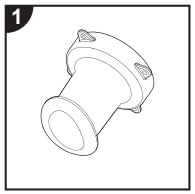
## ◆ CONTRA-INDICATIES:

De transanale toegangspoort is niet bedoeld voor gebruik wanneer minimaal invasieve chirurgische technieken gecontra-indiceerd zijn.

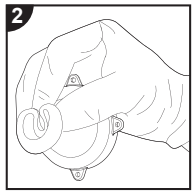
## ◆ GEBRUIKSAANWIJZINGEN:

Controleer vóór gebruik de inhoud van de verpakking en de verpakking zelf om er zeker van te zijn dat de integriteit niet is aangetast.

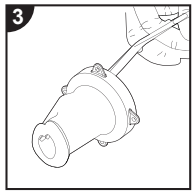
**INSTALLATIE EN MONTAGE**



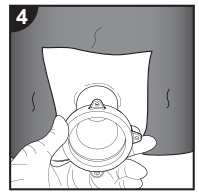

Breng steriele smering aan op het distale uiteinde van het toegangskanaal.



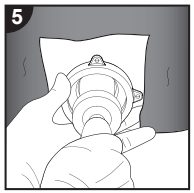

Druk het distale uiteinde van het toegangskanaal handmatig in een gevouwen vorm.



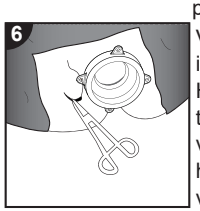

Gebruik de pincet om het gevouwen uiteinde van het toegangskanaal vast te klemmen en in de anus te plaatsen.



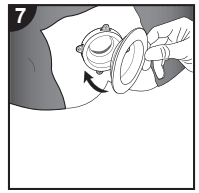

Zorg ervoor dat het distale uiteinde van het toegangskanaal goed achter de levatorband zit.



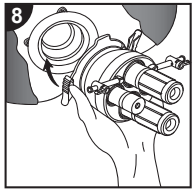

Breng de smering aan op de introducer om te helpen bij het in positie brengen van het toegangskanaal.



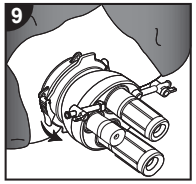

Verwijder de introducer. Houd het toegangskanaal vast en hecht de hechtpoorten vast om deze vast te maken.



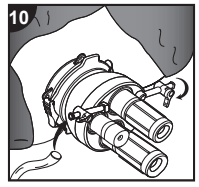

Bren smering aan op de inkeping van de bevestigingsring en het toegangskanaal en verbind ze.



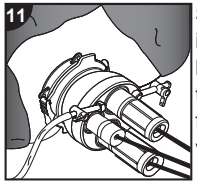

Bevestig de bovenste behuizing aan de bevestigingsring.




Zorg ervoor dat de 2 hendelvergendelingen vergrendeld zijn.

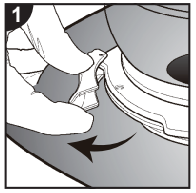



Sluit de insufflatieslang aan op één van de twee stopkranen. Zorg ervoor dat het ventiel van de andere stopkraan gesloten is.

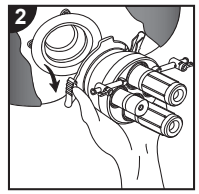



Start de insufflatie en het transanale toegangsplatform is klaar voor gebruik.

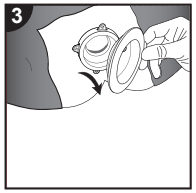
**DEMONTAGE**



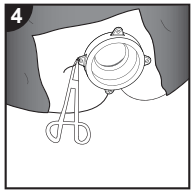

Demonteer de hendelvergrendeling.



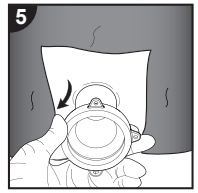

Demonteer de bovenste behuizing van de bevestigingsring.




Demonteeer de bevestigingsring uit het toegangskanaal.

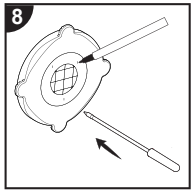



Verwjder hechtingen.

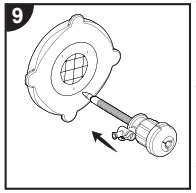



Trek de toegangskanaal het toegangskanaal voorzichtig uit de anus.

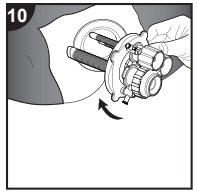
**KAP VOOR WONDRETRACTOR SERIE HERHAAL STAP 1 T/M 7**



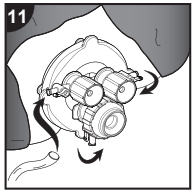

Gebruik een naal als conische punt voor de eerste inbreng binnen de grenslijn te maken.



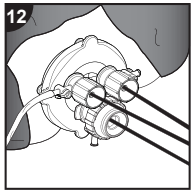

Volgens de procedure kunnen chirurgen andere trocars inbrengen door dezelfde stappen uit te voeren binnen de grenslijn.




Bevestig de in de trocar geplaatste kap op de witte ring.

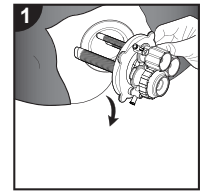



Sluit de insufflatieslang aan op één van de twee stopkranen. Zorg ervoor dat het ventiel van de andere stopkraan gesloten is.



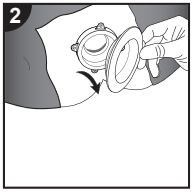

Start de procedure.

**DEMONTAGE**

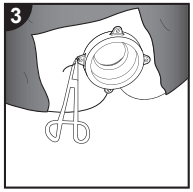



Demonteer de in de trocar geplaatste kap van de bevestigingsring.

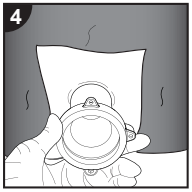
## DEMONTAGE




Demonteer de bevestigingsring van het toegangskanaal.




Verwijder de hechtingen.




Trek het toegangskanaal voorzichtig uit de anus.

## ◆ WAARSCHUWINGEN EN VOORZORGSMAATREGELEN:

- Niet gebruiken als het hulpmiddel of de steriele verpakking geopend of beschadigd, aangezien dit een toename van het aantal wondinfecties kan veroorzaken.
- Als endoscopische instrumenten of accessoires van verschillende fabrikanten samen worden gebruikt, moet u de compatibiliteit controleren vóór het uitvoeren van de ingreep.
- Dit hulpmiddel is verpakt en gesteriliseerd voor eenmalig gebruik bij een patiënt. Niet hergebruiken, opnieuw verwerken of opnieuw steriliseren. Het hergebruiken, opnieuw verwerken of opnieuw steriliseren kan leiden tot besmetting, infectie, kruisbesmetting of zelfs tot aantasting van de integriteit van het hulpmiddel en tot falen van het hulpmiddel, wat weer kan leiden tot letsel, ziekte of overlijden van de patiënt.
- Dit hulpmiddel mag alleen worden gebruikt door chirurgen die voldoende zijn getraind en vertrouwd zijn met chirurgische technieken. Raadpleeg de medische literatuur voor nadere informatie over technieken, risico's, contra-indicaties en complicaties voordat de procedures uit te voeren.
- Doorboor het toegangskanaal niet met een naald en breng geen hechtdraad aan in of door het hulpmiddel om het verwijderen van het toegangskanaal te vergemakkelijken. Het doorboren van het toegangskanaal leidt tot schade en mogelijk verlies van pneumoperitoneum tijdens de ingreep.
- Verwijder de bovenste behuizing terwijl u het gaas inbrengt. Breng het gaas niet in in de holte van de 5 mm of 12 mm poorten om beschadiging van de afsluiters van de poorten te voorkomen.
- Stuur het hulpmiddel en de verpakking terug naar de distributeur of zorg voor een veilige afvalverwijdering door medische professionals indien de steriele verpakking vóór gebruik is beschadigd of onbedoeld is geopend.
- Het gebruikte hulpmiddel dat in contact komt met lichaamsvloeistoffen moet worden beschouwd als biomedisch afval en veilig worden verwijderd door gezondheidszorgprofessionals, overeenkomstig de nationale regelgeving inzake afvalbeheer, om te voorkomen dat patiënten, gebruikers en andere personen biologisch worden besmet of geïnfecteerd.
- In geval van storingen van het hulpmiddel, wijzigingen in de prestaties die van invloed kunnen zijn op de veiligheid of zelfs ernstige incidenten, moet u dit onmiddellijk melden aan de fabrikant, de bevoegde autoriteit van de lidstaat en de gemachtigde volgens de contactinformatie op het label of in deze gebruiksaanwijzing.
- Onjuiste montage of bediening van het hulpmiddel kan leiden tot langere operatietijden, allergie voor de patiënt en weefsel- of orgaanletsel door mechanische schade aan de patiënt of de gebruiker.

## ◆ OMGEVINGSCONDITIES VOOR OPSLAG:

De juiste opslaglocatie is een schone en droge ruimte, buiten het bereik van zonlicht, met een temperatuur van 13~30 °C (55.4~86 °F).

## ◆ UITLEG VAN DE SYMBOLEN:

| | | | | | |
|---|---|---|---|---|---|
| | Beperking temperatuur | | Let op | EU REP | Gemachtigd vertegenwoordiger in de Europese Gemeenschap/Europese Unie |
| | Niet opnieuw steriliseren | | Fabrikant | LATEX | Niet vervaardigd met natuurlijk rubberlatex |
| | Niet hergebruiken | | Raadpleeg de gebruiksaanwijzing of raadpleeg de elektronische gebruiksaanwijzing | | Niet gebruiken als de verpakking beschadigd is en raadpleeg de gebruiksaanwijzing |
| | Productiedatum | | Enkel steriel barrièresysteem | STERILE R | Gesteriliseerd met straling |
| MD | Medisch hulpmiddel | ℞ only | Let op: Krachtens de federale wetgeving van de VS mag dit hulpmiddel alleen door of in opdracht van een arts worden gekocht. | CE 2797 | CE-markering volgens MDR 2017/745 |

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LAGIS®

# TRANSANAL GİRİŞ PORTU

Türkçe

13°C 30°C LATEX Rx only STERILE R 2 STERILIZE CE 2797

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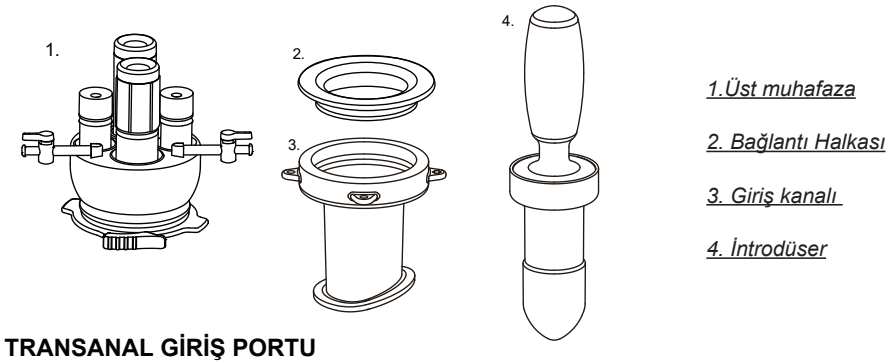
**ÜRÜNÜ KULLANMADAN ÖNCE AŞAĞIDAKİ BİLGİLERİ TAMAMEN OKUYUN.**

## ◆ CİHAZ AÇIKLAMASI :

Transanal Giriş Portu üst muhafaza, bağlantı halkası, giriş kanalı ve introdüserden oluşur. Üst muhafaza, farklı sayıda 5 mm, 5-12 mm ve 15 mm port kombinasyonlarından oluşur. Üst yuvadaki musluk valfleri, gaz insüflasyonu ve desüflasyonu sağlamak için luer kilit ile uyumludur. Üst muhafaza işlem sırasında çıkarılabilir ve büyük numunelerin çıkarılmasına olanak sağlar. Giriş kanalı çevresel anal retraksiyonu sağlamak için bağlantı halkasına ve üst muhafazaya bağlantı sağlar. İntrodüser, giriş kanalının yerine yerleştirilmesine yardımcı olmak için yerleştirilebilir.

Üst muhafazası olmayan CRS-A01M cihazı için, pnömoperitonyumu korumak üzere yara retraktörü kapağı ve trokarlar ile birlikte kullanılmak üzere tasarlanmıştır.




*1.Üst muhafaza*

*2. Bağlantı Halkası*

*3. Giriş kanalı*

*4. İntrodüser*

**TRANSANAL GİRİŞ PORTU**

| Modeller | Üst Muhafaza | Bağlantı Halkası | Giriş Kanalı | İntrodüser |
|---|---|---|---|---|
| CRS-60-0220M | O | O | O | O |
| CRS-A01M | X | O | O | O |

## ◆ ENDİKASYONLAR/KULLANIM AMACI :

- Transanal Giriş Portu, bir yandan anüsten vücut boşluğuna birden fazla cerrahi aletin yerleştirilmesine imkan sağlarken pnömoperitoneumu korumak için transanal doğal açıklıklı transluminal endoskopik cerrahi sırasında kullanılmak üzere tasarlanmıştır.
- Beklenen klinik faydalar: ameliyat sonrası daha az ağrı, daha az komplikasyon, daha az yara enfeksiyonu ve daha az fıtık oluşumu; gelişmiş kozmetik; daha düşük kısa vadeli maliyet; ve optimum orta ve uzun vadeli cerrahi ve onkolojik sonuç.
- Hedef hasta grubu: Transanal Giriş Portu minimal transanal invaziv cerrahi prosedürlere ihtiyaç duyan yetişkinler için tasarlanmıştır.

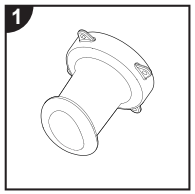
## ◆ KONTRENDİKASYONLAR :

Transanal Giriş Portu, minimal invaziv cerrahi tekniklerin kontrendike olduğu durumlarda kullanılmak üzere tasarlanmamıştır.

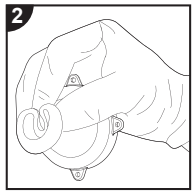
## ◆ KULLANIM TALİMATLARI :

Kullanmadan önce, bütünlüğün tehlikeye atılmadığından emin olmak için ambalajın içeriğini ve ambalajın kendisini inceleyin.

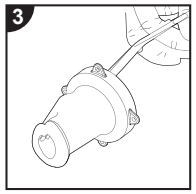
**KURULUM VE MONTAJ**



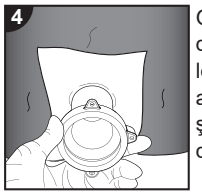

Giriş kanalının distal ucunu steril bir şekilde yağlayın.



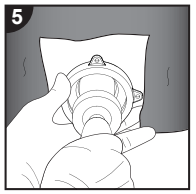

Giriş kanalının distal ucunu katlanmış bir biçimde elle sıkıştırın.



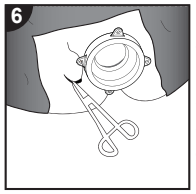

Giriş kanalının katlanmış ucunu klipslemek için forseps kullanın ve anüs içine yerleştirin.



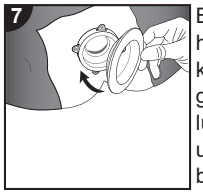

Giriş kanalının distal ucunun levatör askısının arkasında güvenli şekilde oturduğundan emin olun.



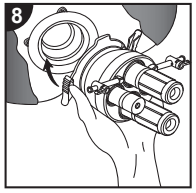

Giriş kanalının yerine yerleştirilmesine yardımcı olması için introdüsere lubrikasyon uygulayın.



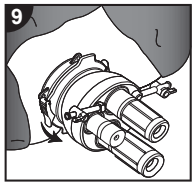

İntrodüseri çıkarın. Giriş kanalını tutun ve sabitlemek için sütür portlarını dikin.



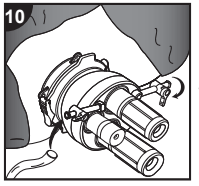

Bağlantı halkasının ve giriş kanalının girintisine lubrikasyon uygulayın ve bunları bağlayın.



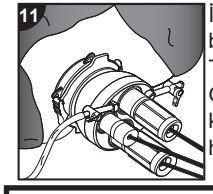

Üst muhafazayı bağlantı halkasına takın.




2 kol kilidinin kilitli olduğundan emin olun.

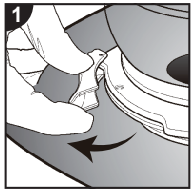



İnsüflatör hortumunu iki musluktan birine takın. Diğer musluk vanasının kapalı olduğundan emin olun.

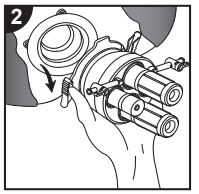



İnsüflasyonu başlatın; Transanal Giriş Platformu kullanıma hazırdır.

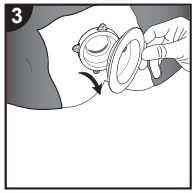
**SÖKME**



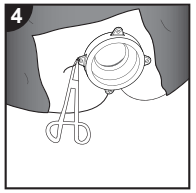

Kol kilidini sökün.



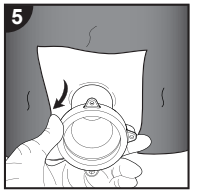

Üst muhafazayı bağlantı halkasından sökün.




Bağlantı halkasını giriş kanalından sökün.

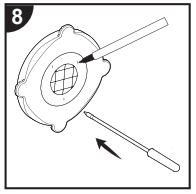



Dikişleri alın.

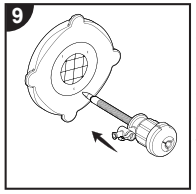



Giriş kanalını anüsten çıkana kadar yavaşça dışarı çekin.

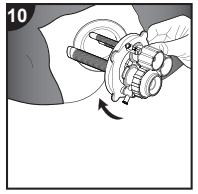
**YARA RETRAKTÖRÜ KAPAĞI SERİSİ - 1. İLA 7. ADIMLARI TEKRARLAYIN**



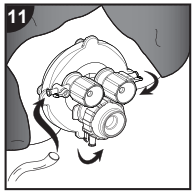

Sınır çizgisi içinde ilk yerleştirmeyi oluşturmak için iğne benzeri konik bir uç kullanın.



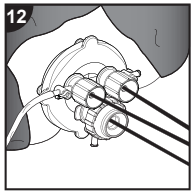

Prosedüre göre, cerrahlar sınır çizgisi içinde aynı adımı izleyerek diğer trokarları yerleştirebilir.




Trokar yerleştirilmiş Kapağı beyaz halkaya takın.

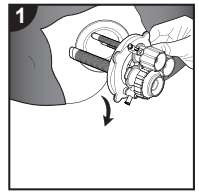



İnsüflasyon hortumunu iki musluktan birine takın. Diğer musluk valfinin kapalı olduğundan emin olun.



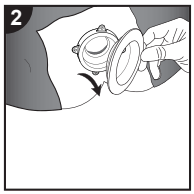

Prosedürü başlatın.

**SÖKME**

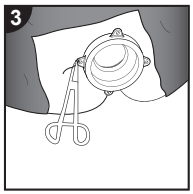



Trokar yerleştirilmiş Kapağı bağlantı halkasından sökün.

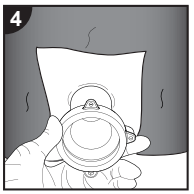
## SÖKME




Bağlantı halkasını giriş kanalından sökün.




Dikişleri alın.




Giriş kanalını anüsten çıkana kadar yavaşça dışarı çekin.

## ◆ UYARILAR VE ÖNLEMLER :

- Yara enfeksiyonu insidansında artışa neden olabileceğinden, cihaz veya steril ambalaj açılmışsa veya hasar görmüşse kullanmayın.
- Bir prosedürde farklı üreticilerin endoskopik aletleri veya aksesuarları birlikte kullanılıyorsa prosedürü gerçekleştirmeden önce uyumluluğu doğrulayın.
- Bu cihaz yalnızca tek hastada kullanım için paketlenmiş ve sterilize edilmiştir. Tekrar kullanmayın, yeniden işlemeyin veya yeniden sterilize etmeyin. Yeniden kullanım, işleme veya sterilizasyon kontaminasyon, enfeksiyon, çapraz enfeksiyon oluşturabilir, hatta cihazın bütünlüğünü tehlikeye atabilir ve cihaz arızasına yol açarak hastanın yaralanmasına, hastalanmasına veya ölümüne neden olabilir.
- Bu cihaz yalnızca yeterli eğitim almış ve cerrahi tekniklere aşina olan cerrahlar tarafından kullanılmalıdır. Prosedürleri gerçekleştirmeden önce teknikler, tehlikeler, kontrendikasyonlar ve komplikasyonlar hakkında daha fazla bilgi edinmek için tıbbi literatüre başvurun.
- Giriş kanalını iğne ile delmeyin veya giriş kanalının çıkarılmasını kolaylaştırmak için cihazın içine veya içinden bir sütür yerleştirmeyin. Giriş kanalının delinmesi, prosedür sırasında hasara ve potansiyel pnömoperitoneum kaybına neden olur.
- Gazlı bezi sokarken lütfen üst muhafazayı çıkarın. Portların valflerinin hasar görmesini önlemek için gazlı bezi 5 mm veya 12 mm portlardan boşluğa sokmayın.
- Steril ambalajın hasarlı olması veya kullanımdan önce istemeden açılması durumunda cihazı ve ambalajı distribütöre iade edin veya sağlık uzmanları tarafından güvenli bir şekilde imha işlemini uygulayın.
- Vücut sıvılarıyla temas eden kullanılmış cihaz biyomedikal atık olarak değerlendirilmeli ve hastaları, kullanıcıları ve diğer kişileri biyolojik kontaminasyon veya enfeksiyondan korumak için sağlık uzmanları tarafından ulusal atık yönetimi yönetmeliğine uygun olarak güvenli bir şekilde imha edilmelidir.
- Cihazın arızalanması, performansında güvenliği etkileyebilecek değişiklikler veya herhangi bir ciddi olay meydana gelmesi durumunda, lütfen etikette veya bu kullanım talimatında belirtilen iletişim bilgilerini kullanarak derhal üreticiye, Üye Ülkenin yetkili makamına ve yetkili temsilciye bildirin.
- Cihazın yanlış montajı veya kullanımı ameliyat süresinin uzamasına, hasta alerjisine ve hastada veya kullanıcıda mekanik hasar nedeniyle doku veya organ yaralanmalarına neden olabilir.

## ◆ SAKLAMA İÇİN ÇEVRESEL KOŞULLAR :

Uygun depolama ortamı, 13~30°C (55,4~86°F) sıcaklık aralığında, güneş ışığından uzak, temiz ve kuru bir alandır.

## ◆ SEMBOLLERİN AÇIKLAMASI :

| | | | | | |
|---|---|---|---|---|---|
| | Sıcaklık sınırı | | Dikkat | EU REP | Avrupa Topluluğu/Avrupa Birliği'nde yetkili temsilci |
| | Yeniden sterilize etmeyin | | Üretici | | Doğal kauçuk lateks ile üretilmemiştir |
| | Tekrar kullanmayın | | Kullanım talimatlarına bakın veya elektronik kullanım talimatlarına bakın | | Ambalaj hasarlıysa kullanmayın ve kullanım talimatlarına bakın |
| | Üretim tarihi | | Tekli steril bariyer sistemi | STERILE R | Işınım kullanılarak sterilize edilmiştir |
| MD | Tıbbi cihaz | ℞ only | Dikkat: Federal (ABD) yasalar bu cihazın satışını bir doktor tarafından veya bir doktorun siparişi üzerine yapılacak şekilde kısıtlar. | CE 2797 | MDR 2017/745'e göre CE İşareti |

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