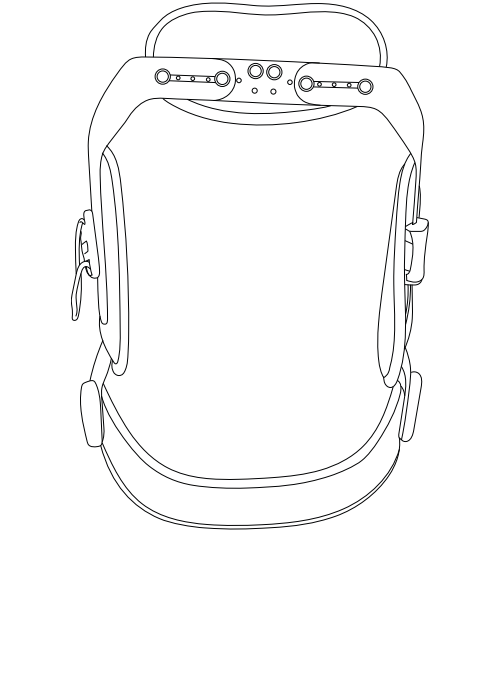




SIERRA... HYPEREXTENSION TLSO

**HYPEREXTENSION BRACE
HYPEREXTENSIONSORTHESE
SOPORTE DE HIPEREXTENSIÓN
TUTORE IPER ESTENDIBILE
ORTHÈSE D'HYPEREXTENSION
BRACE TEGEN OVERSTREKKING
PODPĚRA NA HYPEREXTENZI TRUPU
HYPEREXTENSION BØJLE
ΝΑΡΟΗΚΑΣ ΥΠΕΡΕΚΤΑΣΗΣ
HYPEREXTENSIONSSJONSTØTTE
ORTEZA PRZEPROSTOWA
LAAJENNUSTUKI
HYPERFÖRLÄNGNINGSSTÖD
ГИПЕРЭКСТЕНЗИОННЫЙ КОРСЕТ
CINTA DE HIPEREXTENSAO
过度伸展矫正器**

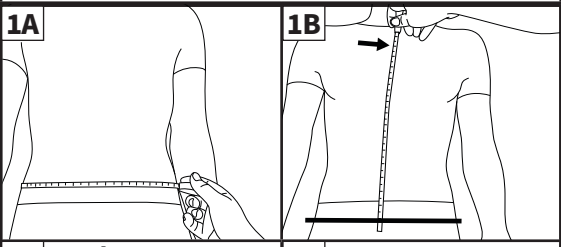


MD MEDICAL DEVICE

SINGLE PATIENT- MULTIPLE USE

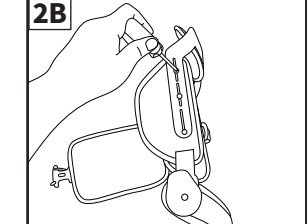
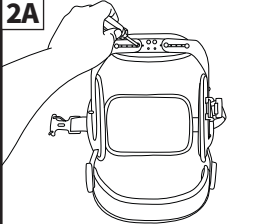
CAUTION

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

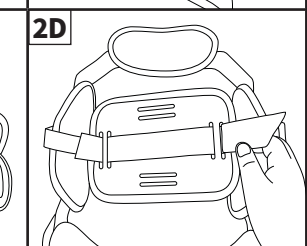
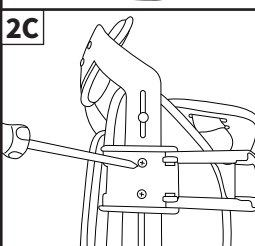


1. SIZING
A. To identify the appropriate size brace, measure the patient around the widest part of the pelvis.
B. Measure from the pelvis to just below the sternal notch.

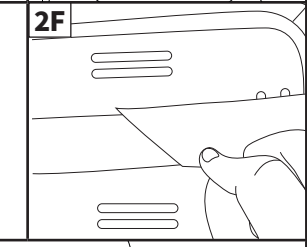
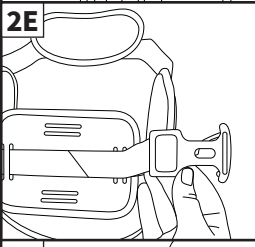
	S	M	L	XL
PELVIC	23.5-29.5 in 60-75 cm	29.5 - 35.5 in 75-90 cm	35.5-41.5 90-105 cm	41.5-45.5 105-115 cm
LENGTH	15.5-18 in 39-46 cm	16.5-19 in 42-49 cm	17.5-20.5 in 45-52 cm	19.5-22 in 49-56 cm



2. ADJUSTMENT
Width Adjustment
A. To adjust the width, remove the screws located at the top of the brace, adjust to the appropriate width and replace the screws. Tighten securely.
Height Adjustment
B. To adjust the height, remove the screws on both sides of the brace.
C. Note that the screws on the lever latch will also need to be loosened or removed.
Posterior Strap Adjustment
D. To adjust the posterior strap, remove the hook from the loop.
E. Shorten or lengthen the strap at the buckle.
F. Place the hook back onto the loop and press to secure.
G. Ensure the posterior pad is centered on the back.



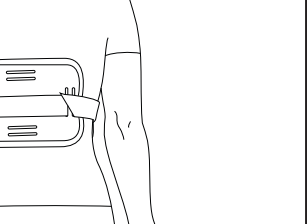
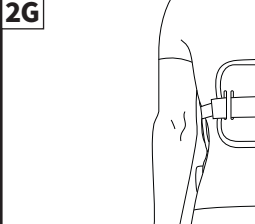
3. APPLICATION
A. To apply the brace, detach the clip from the frame.
B. Ensure the lever latch is in the open position.
C. Position the brace over the torso.
D. The top of the brace should be located about two finger widths down from the sternal notch.
E. Wrap the attachment strap around the torso ensuring the posterior pad is centered on the back.
F. Pull the attachment clip over the post on the right side and secure.
G. Once the brace and strap are in place, close the lever latch on the left side to tighten the brace to the patient. Only when appropriate, remove the brace by opening the lever latch and detach the attachment clip from the post.



INTENDED USE
To provide motion restriction and stability of the Thoracic-lumbar-sacral spine.

INDICATIONS
Postoperative support, Degenerative disc disease, Bulging or herniated disc, Fracture management, Kyphosis, Spondylolysis (Osteoarthritis/Degenerative Joint Disease).

CONTRAINDICATIONS
Hypersensitivity or allergies to any of the materials from which the brace is made. Swelling of the lymphatic tissue caused by circulatory disorders. Patients who are not allowed to wear a brace according to medical instructions.



PRECAUTIONS
READ INSTRUCTIONS BEFORE USE. Proper training in the use of this device should take place before it is applied. These directions are guidelines only and are not offered as medical recommendations. If you suffer from a serious medical condition, we strongly suggest that you consult with a licensed health care professional before using this product. Proper fitting is required for this product to be effective. Under some circumstances, this product may be prescribed by a physician. Please see the limited warranty for further information.

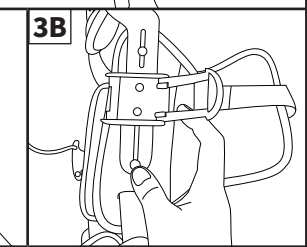
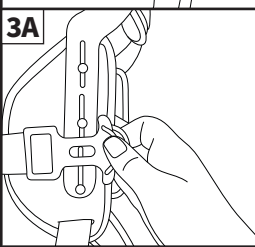
CARE INSTRUCTIONS
Hand wash only at 30° C. Wash with mild detergent; Air dry; Do not use bleach or other chemicals.

MATERIALS
Aluminum, Steel, Polypropylene, Nylon, Polyurethane, Brass.

NOT MADE WITH NATURAL RUBBER LATEX.

DISPOSAL
Product may be safely disposed in accordance with local laws.

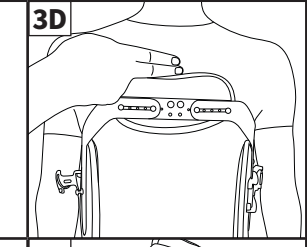
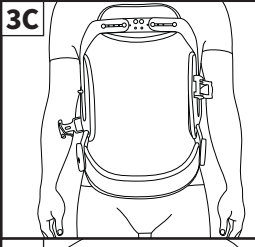
REPORTING
Please report any serious incident involving the use of this device to both the Competent Authority in your state and to the manufacturer (listed on this document).



LIMITED WARRANTY
Aspen Medical Products, LLC, Irvine, CA 92618, warrants to the user who originally purchases this product that it is free from defects in material and workmanship. The sole obligation of Aspen Medical Products, LLC in the event of breach of warranty shall be to repair or replace the defective product (or parts).

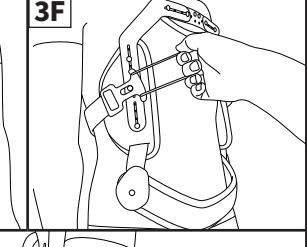
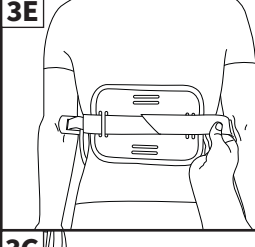
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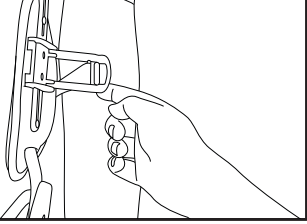
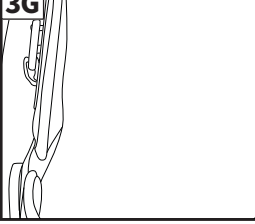
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ENGLISH

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DEUTSCH
ASPEN MEDICAL PRODUCTS GmbH Im Leuschnerpark 4, 64347 Griesheim
aspemmp.de • +49 (0) 6155 89291-0 Pat. aspemmp.de/patents

1. GRÖSSENBESTIMMUNG
A. Um die richtige Größe der Stütze zu bestimmen, messen Sie den Patienten um den breitesten Bereich des Beckens herum.
B. Messen Sie vom Becken bis nach gerade unterhalb der sternalen Kerbe.

	SMALL	MEDIUM	LARGE	X-LARGE
BECKEN	23.5-29.5 in 60-75 cm	29.5 - 35.5 in 75-90 cm	35.5-41.5 90-105 cm	41.5-45.5 105-115 cm
LÄNGE	15.5-18 in 39-46 cm	16.5-19 in 42-49 cm	17.5-20.5 in 45-52 cm	19.5-22 in 49-56 cm

2. EINSTELLUNG
Breiteinstellung
A. Zum Anpassen der Breite entfernen Sie die Schrauben an der Oberseite der Stütze, um auf die entsprechende Breite zu stellen, und setzen Sie die Schrauben wieder ein. Ziehen Sie sie fest.
Höheinstellung
B. Zum Anpassen der Höhe entfernen Sie die Schrauben an den beiden Seiten der Stütze.
C. Beachten Sie, dass die Schrauben an der Hebelverriegelung ebenfalls gelöst oder entfernt werden müssen.
Einstellung des hinteren Gurts
D. Stellen Sie den hinteren Gurt ein. Entfernen Sie hierzu den Haken von der Schlaufe.
E. Verkürzen oder verlängern Sie den Gurt an der Schnalle.
F. Bringen Sie den Haken wieder an der Schlaufe an und drücken Sie zum Befestigen.
G. Stellen Sie sicher, dass das hintere Polster auf der Rückseite zentriert ist.

3. ANWENDUNG
A. Um die Stütze anzubringen, trennen Sie die Klammer vom Rahmen.
B. Stellen Sie sicher, dass die Hebelverriegelung in der offenen Position ist.
C. Legen Sie die Stütze über den Oberkörper an.
D. Die Oberseite der Stütze sollte sich etwa zwei Fingerbreiten unter der sternalen Kerbe befinden.
E. Wickeln Sie den Befestigungsgurt um den Oberkörper und stellen Sie dabei sicher, dass das hintere Polster auf dem Rücken zentriert ist.
F. Ziehen Sie die Befestigungsklammer über den Pfosten auf der rechten Seite und befestigen Sie.
G. Sobald die Stütze und der Gurt in Position sind, schließen Sie die Hebelverriegelung auf der linken Seite, um die Stütze am Patienten zu befestigen. Entfernen Sie bei Bedarf die Stütze, indem Sie die Hebelverriegelung öffnen und die Befestigungsklammer vom Pfosten lösen.

VERWENDUNGSZWECK
Um Bewegungs einschränkung und Stabilität der thorakal-lumbal-sakralen Wirbelsäule zu ermöglichen.

INDIKATIONEN
Postoperative Unterstützung, degenerative Bandscheibenerkrankung, Bandscheibenverfall oder -hernie, Kyphose, Spondylolyse (Osteoarthritis/degenerative Gelenkerkrankung).

INDIKATIONEN
Postoperative Unterstützung, degenerative Bandscheibenerkrankung, Bandscheibenverfall oder -hernie, Kyphose, Spondylolyse (Osteoarthritis/degenerative Gelenkerkrankung).

CONTRAINDICATIONS
Hypersensibilidad o alergía a cualquiera de los materiales de fabricación del soporte. Inflamación del tejido linfático causado por trastornos circulatorios. Pacientes que, de acuerdo a instrucciones médicas, no están autorizados a usar un soporte.

PRECAUCIONES
LEER LAS INSTRUCCIONES ANTES DE UTILIZAR EL PRODUCTO. Se necesita una capacitación adecuada acerca del uso de este dispositivo antes de colocarlo. Estas instrucciones son solo pautas y no se ofrecen como recomendaciones médicas. Si padece una afección médica leve, le recomendamos muy especialmente que consulte con un profesional de la salud con licencia antes de usar este producto. Se requiere un ajuste adecuado para que este producto sea eficaz. En algunas circunstancias, este producto puede ser recetado por un médico. Consulte la garantía limitada para obtener más información.

INSTRUCCIONES DE CUIDADO
Lave a mano solamente y a 30° C. Lave con detergente suave. Deje secar al aire. No use blanqueador ni otros productos químicos.

MATERIALES
Aluminio, acero, polipropileno, nailon, poliuretano, latón.

NO ESTÁ HECHO CON LÁTEX DE GOMA NATURAL.

ELIMINACIÓN
El producto se puede eliminar de forma segura de acuerdo a las normas locales.

INFORME
Informe de cualquier incidente grave relacionado con el uso de este dispositivo tanto a la autoridad competente de su estado como al fabricante (mencionado en este documento).

GARANTÍA LIMITADA
Aspen Medical Products, LLC, Irvine, CA 92618, garantiza al comprador original y al usuario que este producto está libre de defectos de material y mano de obra. La única obligación de Aspen Medical Products, LLC en el caso de violación de la garantía, será la de reparar o reemplazar el producto o las piezas con fallas.

Aspen Medical Products, LLC no tendrá obligación alguna respecto de esta garantía limitada en los siguientes casos:
(a) El producto no fue comprado a Aspen Medical Products, LLC ni a través de sus canales de distribución autorizados.
(b) El producto fue modificado.
(c) Cualquier repuesto no suministrado por Aspen Medical Products, LLC fue insertado en el producto.
(d) El producto no se utilizó de acuerdo con las Instrucciones de Uso de Aspen Medical Products, LLC.

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ESPAÑOL

1. TALLAS
A. Para identificar la talla apropiada para el soporte, mida la parte más ancha de la pelvis del paciente.
B. Mida desde la pelvis hasta justo debajo de la horquilla esternal.

	PEQUEÑO(S)	MEDIANO(M)	GRANDE (L)	EXTRAGRANDE(XL)
PÉLVICO	23.5-29.5 pulgadas 60-75 cm	29.5 - 35.5 pulgadas 75-90 cm	35.5-41.5 90-105 cm	41.5-45.5 105-115 cm
LARGO	15.5-18 pulgadas 39-46 cm	16.5-19 pulgadas 42-49 cm	17.5-20.5 pulgadas 45-52 cm	19.5-22 pulgadas 49-56 cm

2. AJUSTE
Ajuste del ancho
A. Para ajustar el ancho, quite los tornillos ubicados en la parte superior del soporte, ajuste al ancho apropiado y reemplace los tornillos.
Ajuste de altura
B. Para ajustar la altura, quite los tornillos a ambos lados del soporte.
C. Tenga en cuenta que los tornillos del enganche de la palanca también deberán ser aflojados o quitados.
Ajuste de la correa posterior
D. Para ajustar la correa posterior, retire el gancho de la presilla.
E. Acorte o alargue la correa en la hebilla.
F. Coloque nuevamente el gancho en la presilla y presione para asegurarlo.
G. Asegúrese de que la almoladilla posterior está centrada en la espalda.

3. USO
A. Para aplicar el soporte, separe el clip de la carcasa.
B. Asegúrese de que el enganche de la palanca esté en la posición abierta.
C. Coloque el soporte sobre el torso.
D. La parte superior del soporte debe ubicarse aproximadamente a dos dedos por debajo de la horquilla esternal.
E. Envuelva la correa de sujeción en torno al torso, asegurándose de que la almoladilla posterior se encuentre centrada en la espalda.
F. Tire del clip de fijación sobre el poste en el lado derecho y asegúrelo.
G. Una vez que el soporte y la correa estén en su lugar, cierre el enganche de la palanca en el lado izquierdo para ajustar el soporte al paciente. Solo cuando sea apropiado, retire el soporte abriendo el enganche de la palanca y separe el clip de fijación del poste.

USO PREVISTO
Garantir la limitazione del movimento e la stabilità della colonna vertebrale toraco-lombo-sacrale.

INDICAZIONI
Supporto postoperatorio, malattia degenerativa del disco, gonfiore del disco o ernia del disco, gestione delle fratture, cifosi, spondilosi (osteoartrosi/malattia degenerativa delle articolazioni).

CONTROINDICAZIONI
Ipersensibilità o allergia ai materiali con i quali è composto il prodotto. Gonfiore del tessuto linfatico causato da disturbi circolatori. Pazienti che non possono indossare un tutore secondo le istruzioni mediche.

CONTRAINDICACIONES
Hipersensibilidad o alergía a cualquiera de los materiales de fabricación del soporte. Inflamación del tejido linfático causado por trastornos circulatorios. Pacientes que, de acuerdo a instrucciones médicas, no están autorizados a usar un soporte.

PRECAUCIONES
LEER LAS INSTRUCCIONES ANTES DE UTILIZAR EL PRODUCTO. Se necesita una capacitación adecuada acerca del uso de este dispositivo antes de colocarlo. Estas instrucciones son solo pautas y no se ofrecen como recomendaciones médicas. Si padece una afección médica leve, le recomendamos muy especialmente que consulte con un profesional de la salud con licencia antes de usar este producto. Se requiere un ajuste adecuado para que este producto sea eficaz. En algunas circunstancias, este producto puede ser recetado por un médico. Consulte la garantía limitada para obtener más información.

INSTRUCCIONES DE MANUTENCIÓN
Lave a mano solo a 30° C; lavar con un detergente delicado; asciugare all'aria; non usare candeggina o altri prodotti chimici.

MATERIALI
Alluminio, acciaio, polipropilene, nylon, poliuretano, ottone.

NON REALIZZATO CON LATTICE DI GOMMA NATURALE.

SMALTIMENTO
Smaltire il prodotto in sicurezza ai sensi delle norme locali.

INFORME
Informe de cualquier incidente grave relacionado con el uso de este dispositivo tanto a la autoridad competente de su estado como al fabricante (mencionado en este documento).

GARANTÍA LIMITADA
Aspen Medical Products, LLC, Irvine, CA 92618, garantiza al usuario que este producto está libre de defectos de material y mano de obra. La única obligación de Aspen Medical Products, LLC en el caso de violación de la garantía, será la de reparar o reemplazar el producto o las piezas con fallas.

Aspen Medical Products, LLC no tendrá obligación alguna respecto de esta garantía limitada en los siguientes casos:
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(b) El producto fue modificado.
(c) Cualquier repuesto no suministrado por Aspen Medical Products, LLC fue insertado en el producto.
(d) El producto no se utilizó de acuerdo con las Instrucciones de Uso de Aspen Medical Products, LLC.

Aspen Medical Products, LLC shall have no obligation under this limited warranty in the event:
(a) The product was not purchased from Aspen Medical Products, LLC or through its authorized channels of distribution;
(b) The product is altered;
(c) Any parts not supplied by Aspen Medical Products, LLC are inserted into the product; or
(d) The product is not used in accordance with the Aspen Medical Products, LLC Instructions for Use.

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ITALIANO

1. TAGLIE
A. Per identificare la misura adeguata del tutore, misurare il paziente intorno alla parte più larga del bacino.
B. Misurare dal bacino fino a poco sotto la tacca sternale.

	PICCOLA (S)	MEDIA (M)	GRANDE (L)	MOLTOGRANDE(XL)
BACINO	23.5-29.5"	29.5 - 35.5"	35.5-41.5 90-105 cm	41.5-45.5 105-115 cm
LUNGHEZZA	15.5-18 po 39-46 cm	16.5-19" 42-49 cm	17.5-20.5" 45-52 cm	19.5-22" 49-56 cm

2. REGOLAZIONE
Regolazione della larghezza
A. Per regolare la larghezza, rimuovere le viti situate nella parte alta del tutore, regolare alla larghezza appropriata e riposizionare le viti. Stringere in modo sicuro.
Regolazione dell'altezza
B. Per regolare l'altezza, rimuovere le viti su entrambi i lati del tutore.
C. Si noti che anche le viti sul sistema della leva devono essere allentate o rimosse.
Regolazione della cinghia posteriore
D. Per regolare la cinghia posteriore, aprire il velcro.
E. Accorcere o allungare la cinghia alla fibbia.
F. Richiudere il velcro e premere bene.
G. Accertarsi che il cuscinetto posteriore sia centrato sulla schiena.

3. APPLICAZIONE
A. Per applicare il tutore, staccare il gancio dalla struttura.
B. Accertarsi che il laccio della leva sia in posizione aperta.
C. Posizionare il tutore sul torso.
D. La parte superiore del tutore si deve trovare a circa due dita dalla tacca sternale.
E. Avvolgere la cinghia intorno al torso accertandosi che il cuscinetto posteriore sia centrato sulla schiena.
F. Tirare la clip di fissaggio sul supporto sul lato destro e fissare.
G. Una volta che tutore e cinghia sono in posizione, chiudere il sistema a leva sulla sinistra per stringere il tutore al paziente. Solo ove appropriato, rimuovere il tutore aprendo sistema a leva e staccando la clip di fissaggio dal supporto.

USO PREVISTO
Garantire la limitazione del movimento e la stabilità della colonna vertebrale toraco-lombo-sacrale.

INDICAZIONI
Supporto postoperatorio, malattia degenerativa del disco, gonfiore del disco o ernia del disco, gestione delle fratture, cifosi, spondilosi (osteoartrosi/malattia degenerativa delle articolazioni).

CONTROINDICAZIONI
Ipersensibilità o allergia ai materiali con i quali è composto il tutore. Gonfiore del tessuto linfatico causato da disturbi circolatori. Pazienti che non possono indossare un tutore secondo le istruzioni mediche.

CONTRAINDICAZIONI
Ipersensibilità o allergia ai materiali con i quali è composto il tutore. Gonfiore del tessuto linfatico causato da disturbi circolatori. Pazienti che non possono indossare un tutore secondo le istruzioni mediche.

PRECAUCIIONES
LEERRE LE ISTRUZIONI PRIMA DELL'USO. Prima dell'applicazione di questo dispositivo è necessario effettuare una formazione adeguata sull'utilizzo. Queste indicazioni sono solo linee guida e non sono offerte come raccomandazioni mediche. Se si soffre di un grave condizione medica, si consiglia vivamente di consultare un professionista sanitario autorizzato prima di utilizzare questo prodotto. Un réglage adéquat est nécessaire pour que ce produit soit efficace. Dans certaines circonstances, ce produit peut être prescrit par un médecin. Veuillez consulter la garantie limitée pour de plus amples informations.

INSTRUCCIONES DE MANUTENCIÓN
Lave a mano solo a 30° C;

