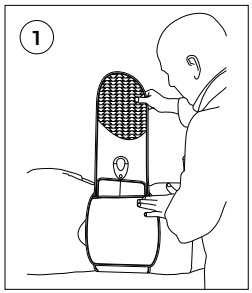

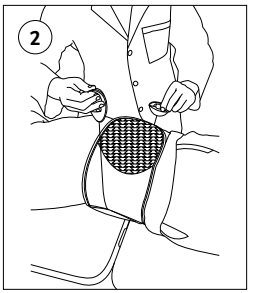

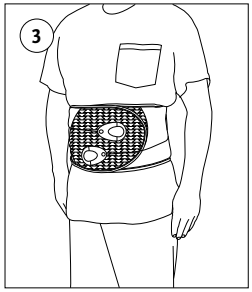

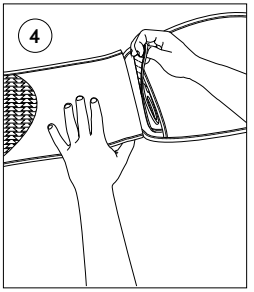

ENGLISH

MD Medical Device

INTENDED USE

The device is intended to provide gross immobilization of the lumbar spine and/or compression
The device must be fitted and adjusted by a healthcare professional.

Indications for use

Indications that require gross immobilization of the lumbar region of the spine, this may include stable, non-displaced spinal fractures (L1-L5), spinal stenosis, herniated discs, degenerative spinal pathologies, spondylolisthesis, spondylolysis.

Contraindications

- Unstable, displaced fractures.

Warnings and Cautions:

- This is a supportive device only and is not intended or guaranteed to prevent spinal injury.
- The patient should be instructed how to tighten and loosen the compression system while at home. Do not overtighten the compression system to the point where it causes discomfort or difficulty breathing.
- For sitting, the patient may find it desirable to slightly loosen the compression system.

GENERAL SAFETY INSTRUCTIONS

The healthcare professional should inform the patient about everything in this document that is required for safe use of this device.

Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities.
The patient should stop using the device and contact a healthcare professional:

- If there is a change or loss in device functionality, or if the device shows signs of damage or wear hindering its normal functions.
- If any pain, skin irritation, or unusual reaction occurs with the use of the device.

The device is for single patient – multiple use.

FITTING INSTRUCTIONS

Device Application

1. Before application, ensure the Belt Compression System is stretched to its full width.
2. If required, secure the Posterior Panel to the inside of the Adjustable Belt using the posterior panel attachments. The attachment straps on the belt should Hook-and-Loop directly into the panels.
3. Log roll the patient onto their side. Position the Posterior Panel centered over the spine, with the bottom of the Posterior Panel at approximately the sacrococcygeal joint **(Fig. 1)**.

Note: Panels can be removed from their fabric sleeve and customized by heat-molding, grinding, or trimming, to achieve correct patient fit.

4. Log roll the patient back into the supine position.
5. If required, the Anterior Panel should be centered on the abdomen with the bottom edge just above the symphysis pubis, while still allowing the patient to sit comfortably. Attach the Anterior Panel to the inside of the adjustable belt using the anterior panel attachments.
6. Wrap both belt arms around and to the front of the patient and secure with the overlapping closures.
7. Slide thumbs through the holes in the two compression system handles and pull until the device is at the appropriate tightness **(Fig. 2)**. Please note that the best placement for the handles on the belt front is within the oval area designated in the middle **(Fig. 3)**.

Device Adjustments

To heat mold the panels, use a heat gun (350 °F/175 °C).
The belt arms can be trimmed by detaching the belt arms from the Hook-and-Loop Strip posteriorly **(Fig. 4)**.
Trimming the belts at an angle can give the opportunity to accommodate different anatomies.

Device Removal

1. Detach compression system handles slowly from the belt to loosen and re-attach them to the sides of the Adjustable Belt.
2. Detach the Overlap Closures and remove the device.
3. To ensure a proper fit, ensure the Belt Compression System is stretched to its full width before re-applying the device.

Accessories and Replacement Parts

Please refer to the Össur catalog for a list of available replacement parts or accessories.

USAGE

Cleaning and care

Washing the device with the soft goods detached allows for more thorough cleaning.

- Hand-wash using mild detergent and rinse thoroughly.
- Air dry.

Note: Do not machine-wash, tumble dry, iron, bleach, or wash with fabric softener.
Note: Avoid contact with salt water or chlorinated water. In case of contact, rinse with fresh water and air dry.

DISPOSAL

The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

LIABILITY

Össur does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device assembled with components from other manufacturers.
- Device used outside of recommended use condition, application, or environment.

中文

MD 医疗器械

预期用途

用于对人体腰部部位的外固定或支撑。

适应症

需要整体固定腰椎区域的适应症，包括稳定型、非移位的腰椎骨折（L1–L5）、椎管狭窄、腰椎间盘突出、腰椎退行性病变、腰椎滑脱、峡部裂。

禁忌症

- 不稳定的移位骨折。

警告和注意事项：

- 本产品仅提供支撑性功能械，不可用于或不能确保防止脊柱损伤。
- 应指导患者如何在家中调整滑轮加压系统。请勿过度拉紧加压系统，以免引起不适或呼吸困难。
- 坐位时，稍微放松加压系统会使患者感到更舒适。

一般安全说明

专业人员应负责告知患者本文档中安全使用本器械所需的所有信息。
任何与本器械相关的严重事故必须向制造商和有关当局报告。

下列情况下，患者应停止使用本器械并联系专业医护人员：

- 如果器械的功能发生变化或丧失，或器械出现损坏或磨损迹象，影响其正常功能。
- 如果在使用器械时出现任何疼痛、皮肤刺激或异常反应。

本器械供单个患者 – 多次使用。

本器械必须由专业人员适配安装和调整。

佩戴说明

器械应用

1. 在佩戴之前，请确保腰围加压系统放松至其全宽。
2. 如有需要，请使用后板连接件将后板固定在可调式腰围内侧。腰围上的连接绑带应直接粘扣在后板上。
3. 整体平移滚动患者的身体来保持侧卧位。将后板置于脊柱正中位置，使后板的底部大约落在骶尾关节处。（图 1）。

注意：可将后板从其衬套中取出，并通过热塑调整、磨销或修剪来进行调整，以实现患者个性化贴合。

4. 整体平移滚动患者使其回到仰卧位。
5. 如有需要，应将前板置于腹部居中位置，其底部边缘处于耻骨联合正上方，同时使患者仍可采取舒适的坐姿。使用前板连接件将前板固定在可调式腰围内侧。
6. 将两端腰围臂缠绕至患者身体前侧并用重叠闭合扣固定。
7. 将两个大拇指插入两个加压系统手握柄上的孔里，拉动手握柄直至腰围的松紧度合适（图 2）。请注意，手握柄在腰围前侧固定的最佳位置为中间指定的椭圆区域内（图 3）。

调整支具

如要热塑调整前后板，请使用热风枪（350°F/175°C）。可通过将腰围臂从魔术贴带上拆下，在后方修剪腰围长度（图 4）。成适当角度修剪腰围可以适应不同的解剖学结构。

移除支具

1. 从腰围上缓慢拆下加压系统手握柄使其腰围放松，然后将其重新连接到可调式腰围侧面。
2. 打开重叠闭合扣，取下腰围。
3. 为确保妥善贴合，在重新佩戴器械之前，请确保腰围加压系统拉伸至其全宽。

配件和替换零件

请参阅 Össur 目录以获取可用更换零件或附件的列表。

使用方法

清洁和保养

在卸下柔软物品的情况下清洗器械可以进行更彻底的清洁。

- 使用温和的清洁剂手洗并彻底冲洗。
- 通风处晾干。

注意：请勿机洗、滚筒烘干、熨烫、漂白或使用织物柔软剂洗涤。

注意：避免接触盐水或氯化水。如果接触，请用淡水冲洗并风干。

最终处置

本器械及其包装必须按照各自的地方或国家环境法规进行处置。

责任

Össur 不承担以下责任：

- 器械未按照使用说明进行维护。
- 器械与其他制造商的零部件组装在一起。
- 器械在推荐的使用条件、应用或环境之外使用。

代理人和生产厂家信息

备案人 / 生产企业 :Össur hf. 奥索股份有限公司

备案人 / 生产企业地址：Grjothals 1–5 Reykjavik 110 Iceland

备案人 / 生产企业联系方式：+354 5151300

代理人及售后服务机构：奥索假肢矫形康复器材（上海）有限公司

代理人及售后服务机构地址：上海市徐汇区虹梅路 1801 号 B 区 201 室

代理人及售后服务机构联系方式：021–6127 1727

生产日期：见外包装

使用期限：产品启用后 6 个月

生产批号：见外包装

医疗器械备案凭证编号 / 技术要求编号：

国械备 20190176

说明书版本号 :7

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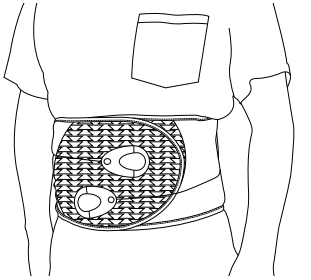

Instructions for Use

OAM RIGID LUMBAR™