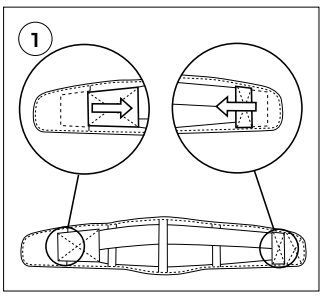

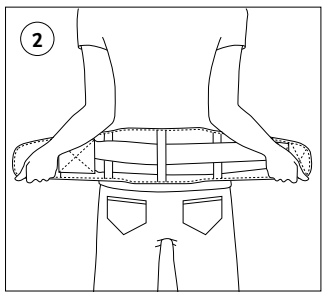

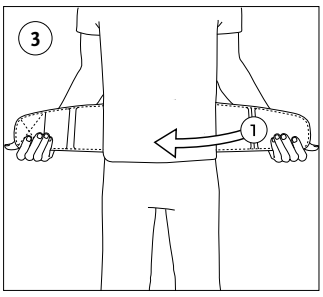

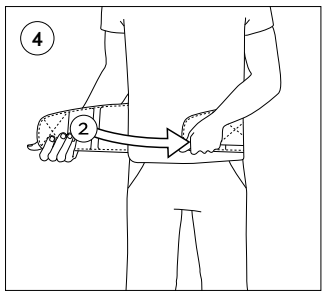

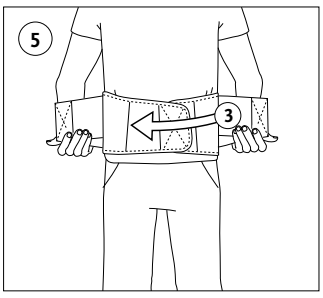

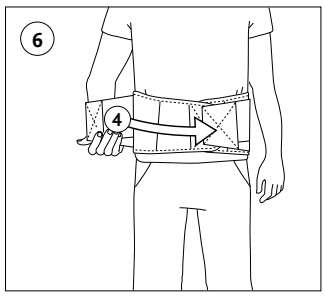

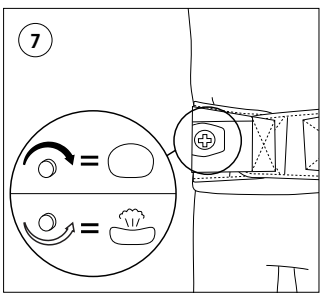

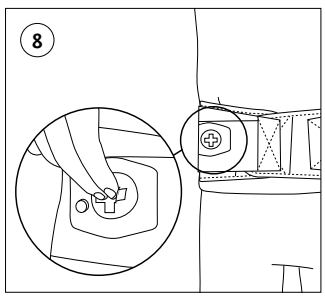

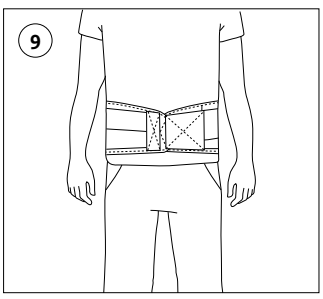

ENGLISH

SYMBOLS

MD Medical Device

LATEX **Caution:** This device contains natural rubber **latex** which may cause allergic reactions.

INTENDED USE

The device is intended to provide gross immobilization of the lumbar spine and/or compression

Indications for use

Lower back conditions that may benefit from gross motion restriction, such as:

- Muscular low back pain
- Lumbosacral Strains
- Chronic low back pain
- Sciatica

Contraindications

- Conditions requiring more rigid or higher immobilization (> D12) or a surgical procedure, unless medically indicated.
- Pelvic floor dysfunction.

Warnings and Cautions:

- Do not use the device if your skin is prone to skin lesions from pressure or rubbing. Compression from the device can cause a skin lesion.
- Do not use the device if you have a skin lesion in the lower back region where the device is worn. Compression from the device can make a skin lesion worse.
- The device should not be used for extended periods of time and removed during long periods of rest, e.g., sleep.

GENERAL SAFETY INSTRUCTIONS

Read these instructions carefully before use. Keep them for future reference.
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.

USAGE

Device Application

1. Unfasten the elastic outer straps and secure them to the device so that there is no tension on the outer straps **(Fig. 1)**.
2. Align the device behind the patient with the lumbar pad centered on the lower back **(Fig. 2)**.
3. Wrap the arms around the waist in the order shown **(Fig. 3, 4)**
4. Pull the ends of the outer straps forward equally and fasten the two ends onto the ends of the inner belt **(Fig. 5, 6)**
5. Air version only: Turn the valve clockwise until the inflate icon is on top and press the air pump until the desired inflation is achieved **(Fig. 7, 8)**. Do not over-turn the valve.

Device Removal

Unfasten the outer straps and then unfasten the belt arms to remove the device.
Air version only: Turn the valve counterclockwise until the deflate icon is on top and press the air pump to deflate the bladder.

Accessories and Replacement Parts

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

Cleaning and care

- Hand-wash using mild detergent and rinse thoroughly.
- Air dry, do not expose to direct heat.

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.
Note: Bleach can cause the device to discolor and decrease elasticity. If elasticity is decreased, the device will not work as intended.

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

标识

MD 医疗器械

LATEX 警告：本器械含可能引发过敏反应的天然乳胶成分。

预期用途

用于对人体腰部部位的外固定或支撑。

适应症

适用于受益于腰背部总体运动限制的下背部疾病，例如：

- 腰肌劳损性下背部腰痛（腰肌酸痛）
- 腰骶劳损
- 慢性腰痛
- 坐骨神经痛

禁忌症

- 除非有医学提示，否则需要更强或更高支撑固定（> D12）或外科手术的情况。
- 盆底功能障碍。

警告和注意事项：

- 如果您的皮肤容易因压力或摩擦而导致皮肤损伤，请勿使用器械。来自器械的压迫会导致皮肤损伤。
- 如果佩戴器械的腰背区域有皮肤病变，请勿使用器械。来自器械的压迫会使皮肤病变恶化。
- 本器械不应长时间使用，请务必在长时间休息（例如睡觉）时取下。

一般安全说明

使用之前，请仔细阅读这些说明。 保留这些说明，以备将来参考。
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。

使用方法

支具佩戴

1. 松开弹性外绑带并固定在器械上，让外绑带无张力（图 1）。
2. 确保器械腰背中间同腰椎中线对齐（图 2）。
3. 按所示顺序，依次粘贴腰围前部魔术贴（图 3、4）
4. 将外绑带的末端均匀地向前拉，并将两端固定在内绑带的末端（图 5、6）
5. 仅应用于充气款：顺时针转动阀门，直到充气图标位于顶部，按下气泵充气至所需的充气量（图 7、8）。请勿过度转动阀门。

移除支具

解开外绑带，再解开腰围以移除器械。
仅应用于充气款：逆时针转动阀门，直到放气图标位于顶部，然后加压气囊放气。

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。

清洁和保养

- 使用温和的清洁剂手洗并彻底冲洗。
- 通风处晾干，请勿直接暴露于高温。

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。
注意：漂白剂会导致腰围褪色，弹性降低。如果弹性降低，器械将无法按预期提供固定效果。

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
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使用期限：产品启用后 6 个月
生产批号：见外包装
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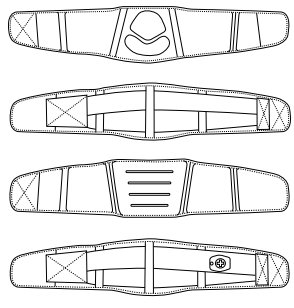

Instructions for Use

腰部固定器
FORMFIT® BACK SUPPORT
FORMFIT® BACK SUPPORT AIR