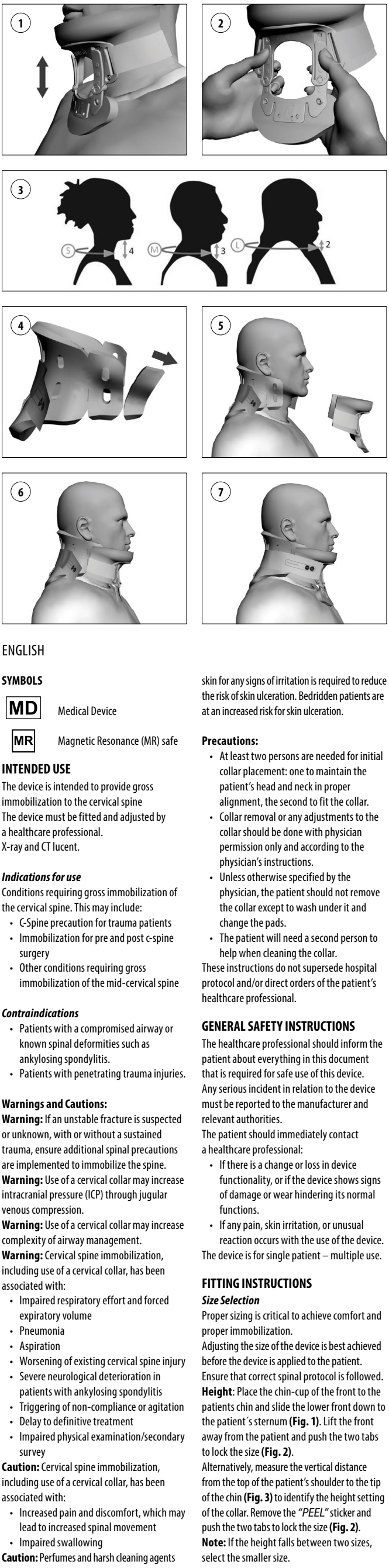


ENGLISH

SYMBOLS

MD Medical Device

MR Magnetic Resonance (MR) safe

INTENDED USE

The device is intended to provide gross immobilization to the cervical spine
The device must be fitted and adjusted by a healthcare professional.
X-ray and CT lucent.

Indications for use

Conditions requiring gross immobilization of the cervical spine. This may include:

- C-Spine precaution for trauma patients
- Immobilization for pre and post c-spine surgery
- Other conditions requiring gross immobilization of the mid-cervical spine

Contraindications

- Patients with a compromised airway or known spinal deformities such as ankylosing spondylitis.
- Patients with penetrating trauma injuries.

Warnings and Cautions:

Warning: If an unstable fracture is suspected or unknown, with or without a sustained trauma, ensure additional spinal precautions are implemented to immobilize the spine.
Warning: Use of a cervical collar may increase intracranial pressure (ICP) through jugular venous compression.
Warning: Use of a cervical collar may increase complexity of airway management.
Warning: Cervical spine immobilization, including use of a cervical collar, has been associated with:

- Impaired respiratory effort and forced expiratory volume
- Pneumonia
- Aspiration
- Worsening of existing cervical spine injury
- Severe neurological deterioration in patients with ankylosing spondylitis
- Triggering of non-compliance or agitation
- Delay to definitive treatment
- Impaired physical examination/secondary survey

Caution: Cervical spine immobilization, including use of a cervical collar, has been associated with:

- Increased pain and discomfort, which may lead to increased spinal movement
- Impaired swallowing

Caution: Perfumes and harsh cleaning agents should not be used on or under the collar, as they may compromise the integrity of materials.
Caution: Use of a cervical collar for cervical spine immobilization is not recommended in situations where patients are awake, alert, not intoxicated, without neck tenderness or pain and without abnormal sensory or motor findings on examination.
Caution: Regular cleaning of the collar, pads and the skin beneath along with inspection of the skin for any signs of irritation is required to reduce the risk of skin ulceration. Bedridden patients are at an increased risk for skin ulceration.

Precautions:

- At least two persons are needed for initial collar placement: one to maintain the patient's head and neck in proper alignment, the second to fit the collar.
- Collar removal or any adjustments to the collar should be done with physician permission only and according to the physician's instructions.
- Unless otherwise specified by the physician, the patient should not remove the collar except to wash under it and change the pads.
- The patient will need a second person to help when cleaning the collar.

These instructions do not supersede hospital protocol and/or direct orders of the patient's healthcare professional.

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 immediately 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

Size Selection

Proper sizing is critical to achieve comfort and proper immobilization.
Adjusting the size of the device is best achieved before the device is applied to the patient.
Ensure that correct spinal protocol is followed.
Height: Place the chin-cup of the front to the patients chin and slide the lower front down to the patient´s sternum **(Fig. 1)**. Lift the front away from the patient and push the two tabs to lock the size **(Fig. 2)**.
Alternatively, measure the vertical distance from the top of the patient's shoulder to the tip of the chin **(Fig. 3)** to identify the height setting of the collar. Remove the *"PEEL"* sticker and push the two tabs to lock the size **(Fig. 2)**.
Note: If the height falls between two sizes, select the smaller size.
Note: This device is designed to be sized and locked into a single position only once; it is not intended to be resized.
Circumference: Identify your patient´s profile type **(Fig. 3)** and refer to the size guide below. Alternatively, measure the patient's neck circumference. Adjust the back piece to the correct circumference by tearing away sections of the foam to change to a smaller circumference **(Fig. 4)**.

Patient Type	Neck Height	Circumference	Circumference Adjustment
Stout	2 (2.25" / 5.7 cm)	Large (16" - 19" / 41 - 48 cm)	No tear off
Average Male	3 (3.25" / 8.3 cm)	Medium (13" - 16" / 33 - 41 cm)	Tear off 1 section on each side
Thin Female	4 (4.25" / 10.8 cm)	Small (10" - 13" / 25 - 33 cm)	Tear off 2 sections on each side

Supine Application

Ensure that correct spinal protocol is followed.

- Slide the back piece behind the patient´s neck and center it, noting arrow on panel pointing up **(Fig. 5)**.

Note: Long hair should be placed outside of the back piece.

- Apply the front piece with the chin secured in the recess and center it to secure neutral alignment. The front piece overlaps the back piece to ensure effective immobilization and comfort **(Fig. 6)**. The front arrow should point upward.
- Apply the Hook and Loop strap on both sides. Tighten straps alternately to an equal length on both sides **(Fig. 7)**. Excess may be trimmed.
- The Plastazote material can be trimmed or heat moulded as necessary depending on the patient's anatomy. Ensure that all edges are rounded off smoothly.

Note: Device application must be secure to ensure proper fit, maintain alignment, and prevent the chin from slipping inside.

Device Removal

Ensure that correct spinal protocol is followed.
Undo the straps, remove the front piece and slide the back piece out from behind the head.

USAGE

Cleaning and care

- Wipe with a damp cloth and mild soap.
- 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

标识

MD 医疗器械

MR 磁共振 (MR) 安全

预期用途

用于对人体头部的外固定或支撑。
本器械必须由专业人员适配安装和调整。
可透 X 射线和 CT。

适应症

需要颈椎整体固定的情况。这可能包括：

- 外伤患者的颈椎预防使用
- 颈椎手术前后固定
- 其他需要整体固定中段颈椎的状况

禁忌症

- 气道受损或已知脊柱畸形（如强直性脊柱炎）的患者。
- 有穿透性创伤的患者。

警告和注意事项：

警告：如果怀疑有不稳定性骨折或未知不稳定性骨折，无论是否有持续性创伤，请确保采取额外的脊柱预防性措施来固定脊柱。
警告：使用颈托可能会因颈静脉受压而导致颅内压 (ICP) 升高。
警告：使用颈托可能会增加气道管理的复杂性。
警告：颈椎固定，包括使用颈托，与下列相关：

- 呼吸力和用力呼气量受损
- 肺炎
- 吸入性肺炎
- 现有颈椎损伤的恶化
- 强直性脊椎炎患者神经功能严重恶化
- 引发患者不配合或产生激越反应
- 延误最终治疗
- 对体检或二次检查造成妨碍

注意：颈椎固定，包括使用颈托，与下列相关：
疼痛和不适感增加，可能导致脊柱运动增加
吞咽障碍
警告：不应在颈托或颈托与颈椎接触面使用香水和刺激性清洁剂，因为它们可能会损害材料的完整性。
警告：在患者清醒、警觉、未醉酒、颈部无压痛或疼痛以及检查时无异常感觉或运动表现的情况下，不建议使用颈托固定颈椎。
警告：需要定期清洁颈托外框、衬垫和皮肤，并检查皮肤是否有任何受刺激迹象，以降低皮肤溃疡的风险。卧床患者使用时，面临的皮肤溃疡风险更高。

预防措施：

- 最少需要两人才能实现颈托初始佩戴：第一个人保持患者的头部和颈部正确对齐，第二个人佩戴颈托。
- 只能在医生准许的情况下，遵照其指导拆除颈托或进行任何颈托调整。
- 除非医生另行指明，请勿拆下颈托——但要清洗颈托下覆部分和更换衬垫时除外。
- 清洁颈托时，患者将需要他人协助。

以下说明不能替代医院的治疗方案和 / 或患者的专业医护人员的直接 医嘱。

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。
患者应立即联系医疗保健专业人员：

- 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。

佩戴说明

尺寸选择

合适的尺寸对于实现舒适与适当固定十分关键。
最佳做法是在为患者佩戴之前先调整好颈托尺寸。
确保遵循正确的脊柱保护治疗方案。
高度：将前片的下颌杯放于患者下颌处，并将前下部向下滑动，至患者胸骨位置（**图 1**）。 将前部向外提，然后推动两个扣片，以锁定尺寸（**图 2**）。
或者，测量从患者肩部顶端到下颌尖的垂直距离（**图 3**），以确定颈托的高度设置。取下“PEEL”贴纸，然后推动两个扣片，以锁定尺寸（**图 2**）。
注意：如果高度介于两个尺寸之间，请选择较小的尺寸。
注意：根据设计，在调好尺寸后只能锁定在单一位置一次；不可再次调整尺寸。
周**长：**确定患者的轮廓类型（**图 3**）并参考下面的尺寸指南。或者，测量患者的颈围。通过撕掉泡沫的某些部分以更改为较小周长，从而将后片调整为正确周长（**图 4**）。

患者类型	颈部高度	周长	周长调整
矮胖	2（2.25 英寸 / 5.7 厘米）	大号（16 - 19 英寸 / 41 - 48 厘米）	无需撕揭
中等身型男性	3（3.25 英寸 / 8.3 厘米）	中号（13 - 16 英寸 / 33 - 41 厘米）	每侧撕下 1 个部分
瘦削身型女性	4（4.25 英寸 / 10.8 厘米）	小号（10 - 13 英寸 / 25 - 33 厘米）	每侧撕下 2 个部分

仰卧位佩戴

确保遵循正确的脊柱保护治疗方案。

- 将后片滑至患者颈后并将其居中放置，注意让面板上的箭头朝上（**图 5**））。

注意：长头发应该放在后片外面。

- 佩戴前片（下颌固定在凹槽中），并将其居中放置以确保中性对齐。 前片与后片重叠，以确保有效固定和舒适度（图 6））。 前部箭头应朝上。
- 在两侧应用钩环带。 在两侧交替收紧固定绑带，使其多余部分的长度相等（图 7））。 多余部分可以修剪。
- 可以根据需要对 Plastazote 材料进行修剪或热成型，具体取决于患者的解剖学结构。 确保所有边缘都平滑地磨圆。

注意：佩戴器械必须牢固，以确保正确贴合，保持对齐，并防止下颌滑入内部。

移除支具

确保遵循正确的脊柱保护治疗方案。
松开颈椎固定绑带，取下前片，并将后片从头后滑出。

使用方法

清洁和保养

- 用湿中性皂液毛巾擦拭。
- 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 3 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 20181375
说明书版本号：7

Össur Americas
200 Spectrum Center Drive, Suite 700
Irvine, CA 92618, USA
Tel: +1 (949) 382 3883
Tel: +1 800 233 6263
ossurusa@ossur.com

UK REP
Össur UK Ltd
Unit No 1, S:Park
Hamilton Road
Stockport SK1 2AE, UK
Tel: +44 (0) 8450 065 065
ossuruk@ossur.com

Össur Europe BV
De Schakel 70
5651 GH Eindhoven
The Netherlands
Tel: +800 3539 3668
Tel: +31 499 462840
info-europe@ossur.com

Össur Deutschland GmbH
Melli-Beese-Str. 11
50829 Köln
Deutschland
Tel: +49 (0) 800 180 8379
info-deutschland@ossur.com

Össur Canada
2150 – 6900 Graybar Road
Richmond, BC
V6W 0A5 , Canada
Tel: +1 604 241 8152

Össur Nordic
Box 7080
106 07 Kista, Sweden
Tel: +46 1818 2200
info@ossur.com

Össur Iberia S.L.U
Calle Caléndula, 93 -
Miniparc III
Edificio E, Despacho M18
28109 El Soto de la Moraleja,
Alcobendas
Madrid – España
Tel: 00 800 3539 3668
orders.spain@ossur.com
orders.portugal@ossur.com

Össur Europe BV – Italy
Via Dante Mezzetti 14
40054 Budrio, Italy
Tel: +39 051 692 0852
orders.italy@ossur.com

Össur APAC
2F, W16 B
No. 1801 Hongmei Road
200233, Shanghai, China
Tel: +86 21 6127 1707
asia@ossur.com

Össur Australia
26 Ross Street,
North Parramatta
NSW 2151 Australia
Tel: +61 2 88382800
infosydney@ossur.com

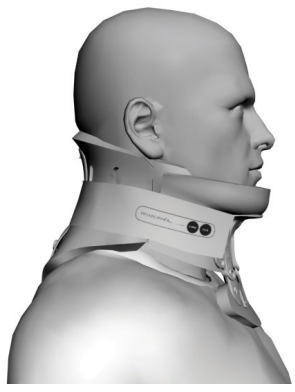
Össur South Africa
Unit 4 & 5
3 on London
Brackengate Business Park
Brackenfell
7560 Cape Town
South Africa
Tel: +27 0860 888 123
infosa@ossur.com

Össur hf.
Grjóthálsi 1-5
110 Reykjavík
Iceland

CE UK CA

WWW.OSSUR.COM ©Copyright Össur 2025-01-02 IFU 1386_003 Rev. 7

Instructions for Use



ÖSSUR®
LIFE WITHOUT LIMITATIONS

Philadelphia®

Adjustable Tracheotomy Collar
颈部固定器