Instructions for Use

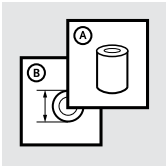


ÖSSUR®
LIFE WITHOUT LIMITATIONS

Philadelphia®

Tracheotomy Collar

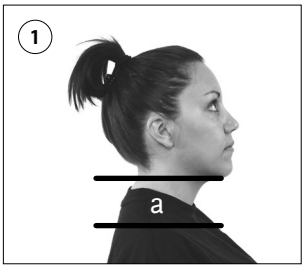
颈部固定器

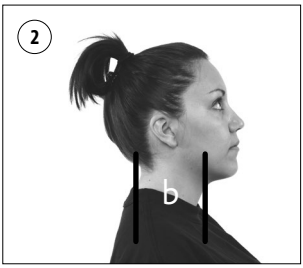


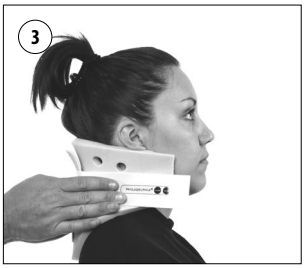
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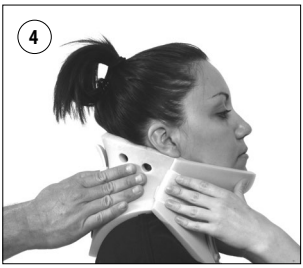
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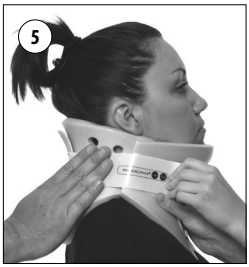
ZH | 中文说明书 6


1
a


2
b


3


4


5

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.

Ensure that correct spinal protocol is followed.

Height: Measure the vertical distance from the top of the patient's shoulder to the tip of the chin **(Fig. 1-a)**. The measurement corresponds to the height of the device. If the patient's measurement falls between two consecutive sizes, apply the smaller size first.

Circumference: Measure around the patient's neck **(Fig. 2-b)**. The measurement corresponds to the size circumference of the device.

Measurement A - Neck Height				
Infant	1.25" (3.2 cm)			
Pediatric	1.75" (4.4 cm)			
Adult	2.25" (5.7 cm)	3.25" (8.3 cm)	4.25" (10.8 cm)	5.25" (13.3 cm)

Measurement B - Neck Circumference	
Size	**Circumference**
Infant	6" - 8" (15.2 - 20.3 cm)
Pediatric	8" - 11" (20.3 - 27.9 cm)
Adult Small	10" - 13" (25.4 - 33.0 cm)
Adult Medium	13" - 16" (33.0 - 40.6 cm)
Adult Large	16" - 19" (40.6 - 48.3 cm)
Adult Extra Large	19"+ (48.3 cm+)

Supine Application

- Slide the back piece behind the patient´s neck and center it, noting arrow on panel pointing up **(Fig. 3)**.

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. 4)**. 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. 5)**. 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.

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

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。

确保遵循正确的脊柱保护治疗方案。

高度：测量患者肩部顶端到下颌尖的垂直距离（**图 1-a**）。该测量值对应于器械的高度。

如果患者的测量值介于两个连续尺寸之间，请先应用较小的尺寸。

周长：围绕患者颈部进行测量（**图 2-b**）。该测量值对应于器械的周长尺寸。

测量 A - 颈高				
婴儿款	1.25 英寸 （3.2 厘米）			
儿童款	1.75 英寸 （4.4 厘米）			
成人款	2.25 英寸 （5.7 厘米）	3.25 英寸 （8.3 厘米）	4.25 英寸 （10.8 厘米）	5.25 英寸 （13.3 厘米）

测量 B - 颈围	
尺寸	**周长**
婴儿款	6 - 8 英寸（15.2 - 20.3 厘米）
儿童款	8 - 11 英寸（20.3 - 27.9 厘米）
成人款小号	10 - 13 英寸（25.4 - 33.0 厘米）
成人款中号	13 - 16 英寸（33.0 - 40.6 厘米）
成人款大号	16 - 19 英寸（40.6 - 48.3 厘米）
成人款超大号	19 英寸以上（48.3 厘米以上）

仰卧位佩戴

- 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 3）**。

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 4）**。 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 5）**。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。

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

- 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
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备案人 / 生产企业联系方式 :+354 5151300
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使用期限：产品启用后 3 个月
生产批号：见外包装
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说明书版本号 : 13

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