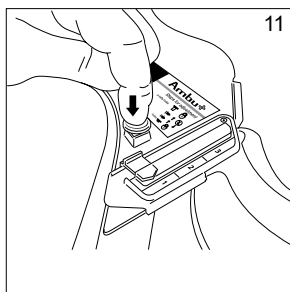
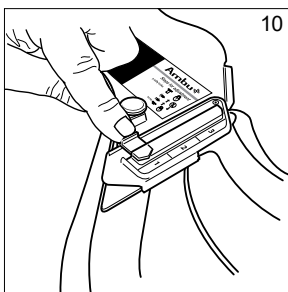
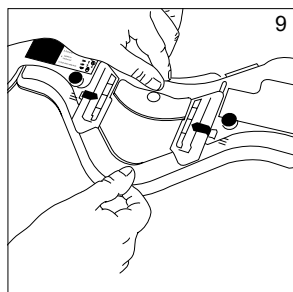
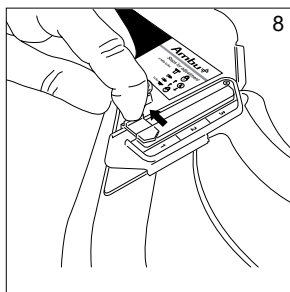
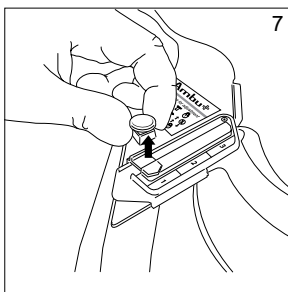
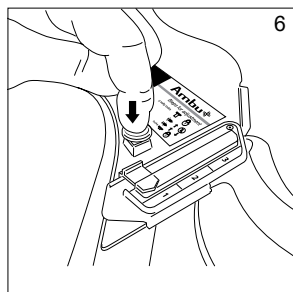
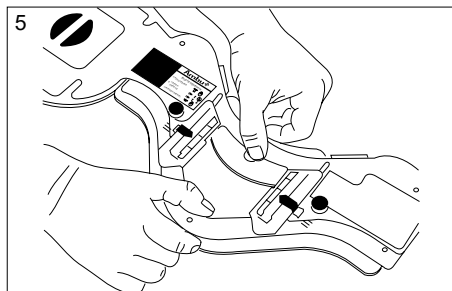
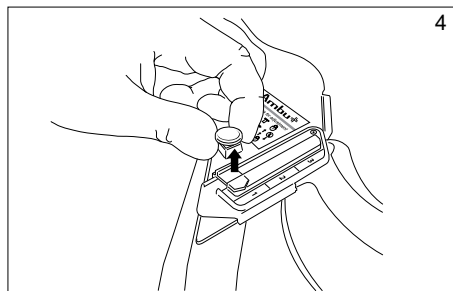
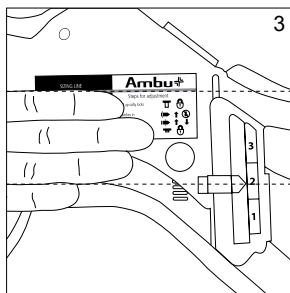
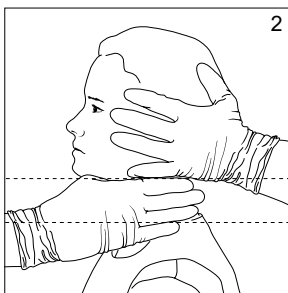
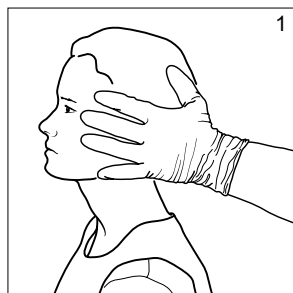
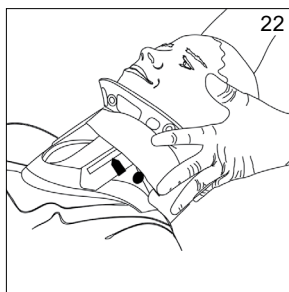
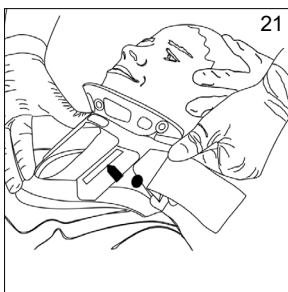
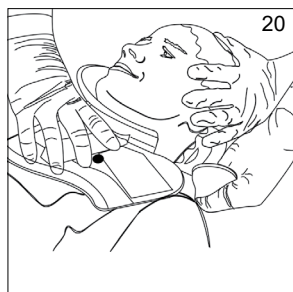
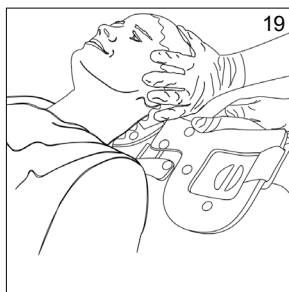
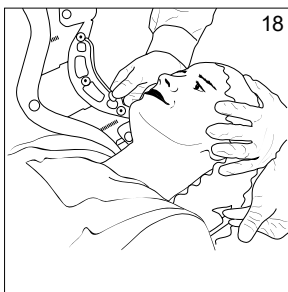
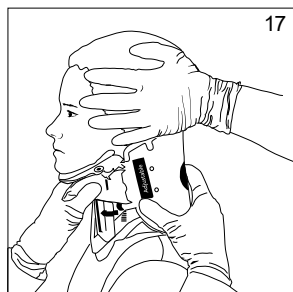
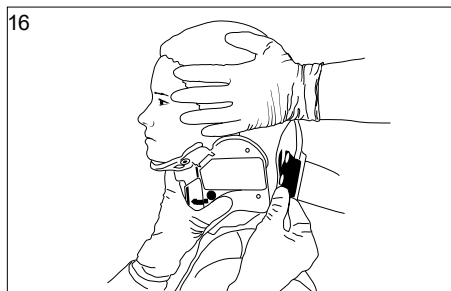
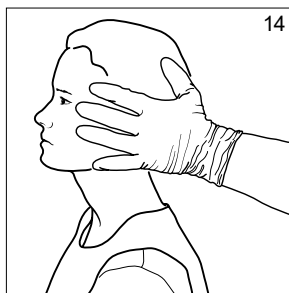
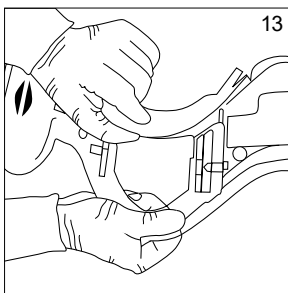
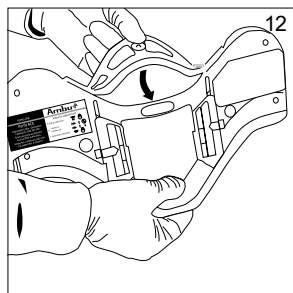


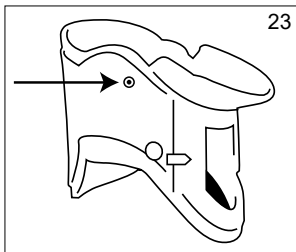
Instructions for use

Ambu[®] Mini Perfit ACE™









	MR			MD
EN	This product is MR Safe.	Single patient multiple use	Country of manufacturer	Medical Device
BG	Този продукт е безопасен при МР.	За многократна употреба от един пациент	Държава на производителя	Медицинско изделие
CS	Tento výrobek je MR bezpečný.	K opakovanému použití u jednoho pacienta	Země výrobce	Zdravotnický prostředek
DA	Dette produkt er MR-sikkert.	Flergangsbrug til enkelt patient	Producentland	Medicinsk udstyr
DE	Dieses Produkt ist MR-sicher.	Mehrfachverwendung bei einem Patienten	Produktionsland	Medizinprodukt
EL	Αυτό το προϊόν είναι ασφαλές για ΜΡ.	Για πολλαπλές χρήσεις σε έναν ασθενή	Χώρα κατασκευαστή	Ιατροτεχνολογικό προϊόν
ES	Este producto es compatible con RM.	Varios usos en un único paciente	País de origen del fabricante	Producto sanitario
ET	Toode on MR-kindel.	Korduskasutuseks ühe patsiendiga	Tootja riik	Meditsiiniseade
FI	Tämä tuote on MK-turvallinen.	Yhden potilaan käyttöön, monta käyttökertaa	Valmistusmaa	Lääkinnällinen laite
FR	Ce produit ne présente aucun danger en cas d'IRM.	Usage multiple pour un seul patient	Pays du fabricant	Dispositif médical
HR	Ovaj proizvod siguran je za upotrebu uz MR.	Za višekratnu upotrebu na jednom pacijentu	Zemlja proizvođnje	Medicinski uređaj
HU	Ez a termék MR-biztos.	Egyetlen pácienshez, több alkalommal használható eszköz	A gyártó országa	Orvostechnikai eszköz
IT	Questo prodotto è compatibile con RM.	Monopaziente, multiuso	Paese di produzione	Dispositivo medico
JA	本製品はMRでは安全です。	1人の患者が複数回使用できる	製造業者の国	医療装置
LT	Šis gaminy s yra saugus naudoti su magnetinio rezonanso (MR) įranga.	Naudoti vienam pacientui daug kartų	Gamintojo šalis	Medicinos prietaisas
LV	Šis ir MR vidē lietošanai drošs produkts.	Atkārtotai lietošanai vienam pacientam	Ražotājvalsts	Medicīniskā ierīce
NL	Dit product is MR-veilig.	Meervoudig gebruik bij één patiënt	Land van fabrikant	Medisch hulpmiddel
NO	Dette produktet er MR-sikkert.	Til bruk flere ganger for én pasient	Produksjonsland	Medisinsk utstyr
PL	Ten produkt można stosować bezpiecznie w badaniach rezonansu magnetycznego.	Produkt wielokrotnego użytku, dla jednego pacjenta	Kraj producenta	Wyrób medyczny
PT	Este produto é seguro para utilização em IRM.	Utilização múltipla num único paciente	País do fabricante	Dispositivo médico
RO	Acest produs este sigur pentru utilizare în IRM.	Utilizare multiplă pentru un singur pacient	Țara producătorului	Dispozitiv medical
RU	Данное изделие безопасно для использования с МРТ.	Для индивидуального многократного использования	Страна-изготовитель	Медицинское устройство
SK	Tento produkt je bezpečný na použitie pri MR.	Na opakované použitie u jedného pacienta	Krajina výrobcu	Zdravotnícka pomôcka
SL	Ta izdelek je varen za uporabo z magnetno resonanco.	Za večkratno uporabo pri enem bolniku	Država proizvajalca	Medicinski pripomoček
SV	Denna produkt är MR-säker.	För flergångsbruk på en patient	Tillverkningsland	Medicinteknisk produkt
TR	Bu ürün MR güvenlidir.	Tek hasta için, tekrar kullanılabilir	Üretildiği ülke	Tıbbi Cihazdır
ZH	本产品可在 MR 中安全使用。	可供单个患者多次使用	制造商所属国家/地区	医疗设备



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1.0. Important Information – Read Before Use

All instructions must be read and understood prior to application of the collar. All directions are to be considered as guidelines and not an attempt to define medical practice.

1.1. Intended Use

The Ambu® Mini Perfit ACE collar is a one-piece rigid cervical spine immobilization device designed to assist the rescuer with the maintenance of neutral alignment, prevention of lateral (side-to-side) sway and anterior-posterior (forward and backward) flexion and extension of the cervical spine during patient transport or movement.

1.2. Contra Indications

Immobilization with a collar is not recommended in trauma patients with penetrating injuries or with ankylosing spondylitis.

1.3. Warnings and Cautions

WARNINGS

1. The collar is intended for application by licensed health care practitioners as directed by a physician or other medical authority. Permanent injury may result from use other than as directed by a physician or other medical authority.
2. Do not re-use collar on another patient. The collar is for single patient use. Re-use can cause contamination leading to infections.
3. Do not use the collar on a patient for more than 24 hours. Prolonged stay in a collar has been associated with the development of pressure ulcers.

CAUTIONS

1. Ensure the chin piece is in correct position and that the size is fixed at all time during use as detachment of collar during use can lead to severe neck injury.

1.4. Potential Adverse Events

Diagnostic disturbance, skin abrasion or pressure ulcers and impaired ventilation.

1.5. General Notes

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

2.0. Specifications

Storage temperature: Tested at -30 °C (-22 °F) and +70 °C (158 °F) according to EN 1789.

Operational Temperature: -10 °C ~ +40 °C (14 °F~104 °F).

3.0. Use of the Ambu® Mini Perfit ACE™

- Have one rescuer manually stabilize the head and neck, gently holding the head and neck in the neutral alignment position. (1)
- Measure the distance between an imaginary plane drawn horizontally and immediately below the patient's chin and second horizontal plane drawn immediately on top of the patient's shoulder. (2)
- Compare this distance with the distance from the collar sizing line to the lower aspect of the plastic collar body (not the foam). (3)
- To adjust the collar, disengage the locking buttons by pulling up. (4)

- Adjust the collar to the appropriate size by pulling collar apart until the distance between the sizing line and the collar body equals your finger measurement. (5)
- Engage the locking buttons by pushing down. (6)
- If the collar needs to be resized, disengage the locking buttons by pulling up. (7)
- Pull the ratchet latches out. (8)
- The collar may now be adjusted to the appropriate size. (9)
- Push the ratchet latches in and engage the locking buttons by pushing down. (10,11)
- Before placing the collar on the patient, ensure that the chin piece is flipped to front. (12, 13)
- Wrap the collar around the patients neck. (14, 15, 16, 18, 19, 20)
- Secure the collar using the velcro. (17, 21, 22)
- A nasal airway tubing can be attached to the tube hooks at both sides. (23)

4.0. Disposal

Used products must be disposed off according to local procedures.



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