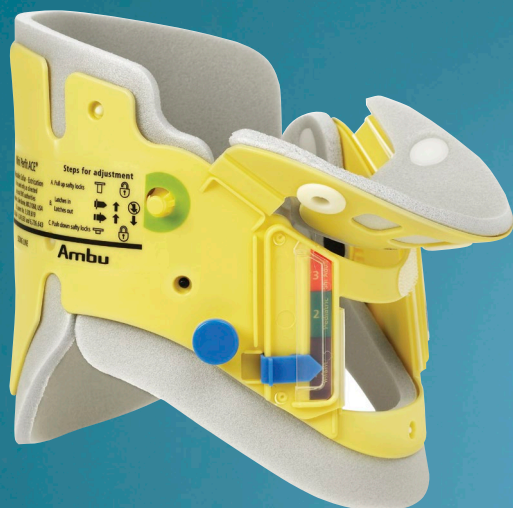
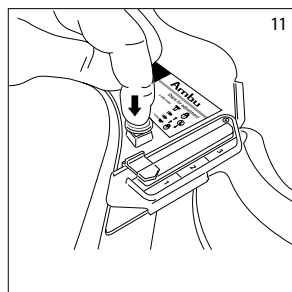
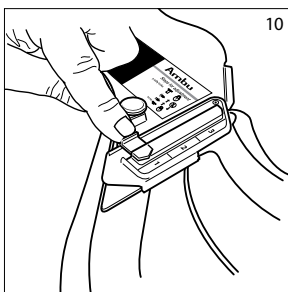
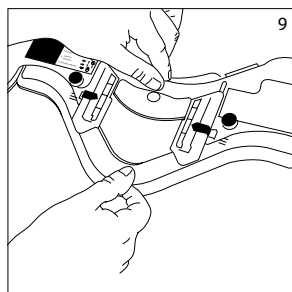
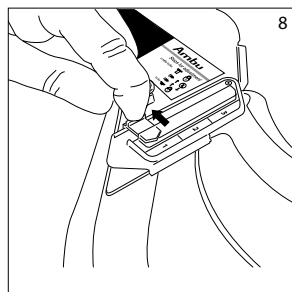
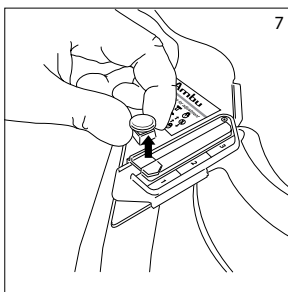
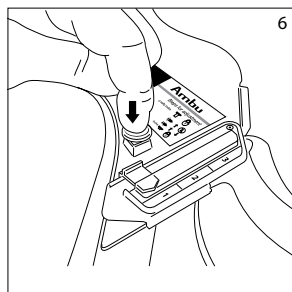
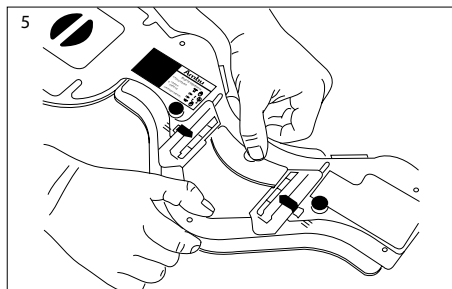
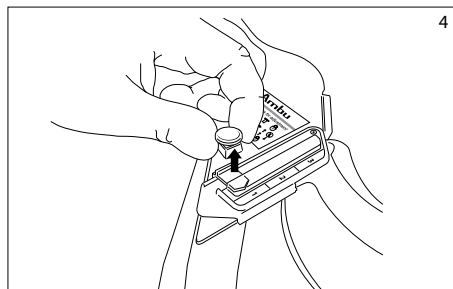
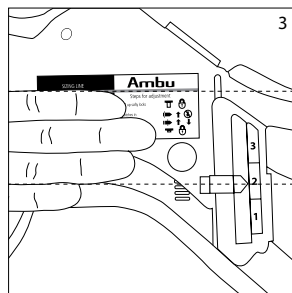
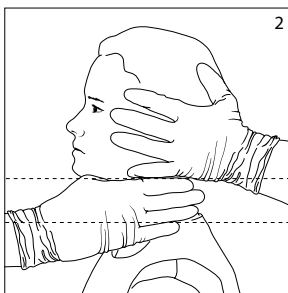
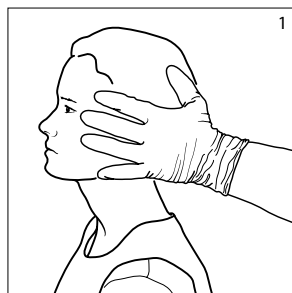


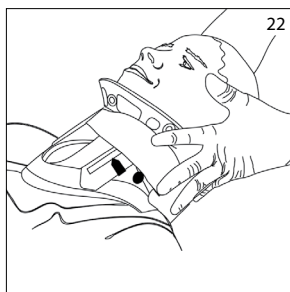
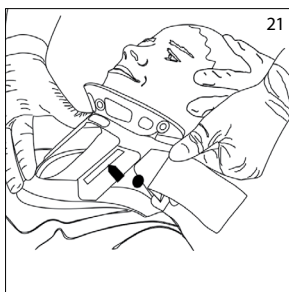
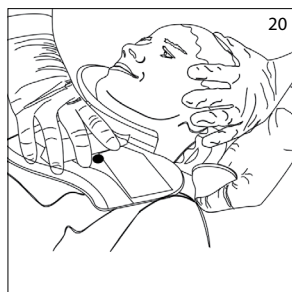
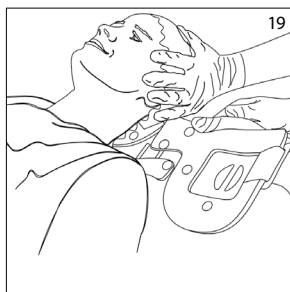
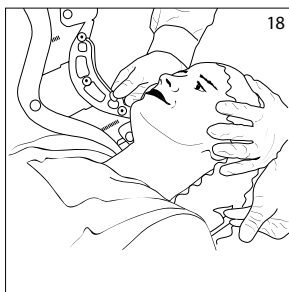
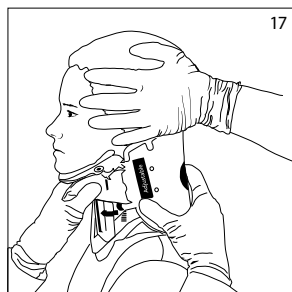
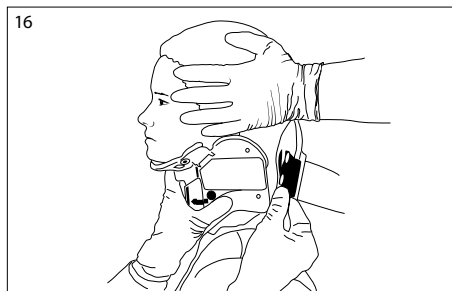
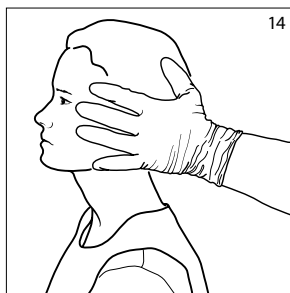
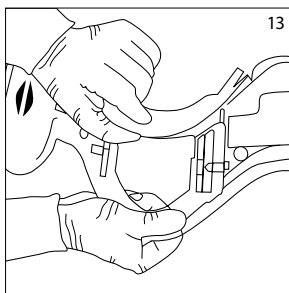
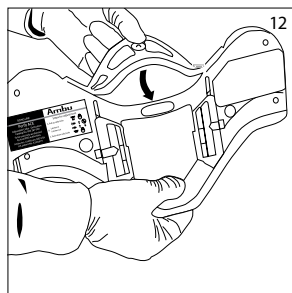
INSTRUCTIONS FOR USE

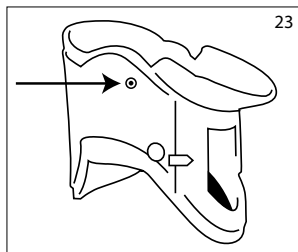
Ambu® Mini Perfit ACE™

Ambu









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en	This product is MR Safe	Single patient multiple use	Country of manufacturer	Medical Device	UK Conformity Assessed	UK Responsible Person	Importer (For products imported into Great Britain only)
cs	Tento výrobek je MR bezpečný	K opakovanému použití u jednoho pacienta	Země výrobce	Zdravotnický prostředek	Posouzení shody s předpisy Velké Británie	Odpovědná osoba ve Velké Británii	Dovozce (Pouze pro produkty dovážené do Velké Británie)
da	Dette produkt er MR-sikkert	Flergangsbrug til enkelt patient	Producentland	Medicinsk udstyr	Den britiske overensstemmelsesvurderingsmærkning	Ansvarshavende i UK	Importør (Kun for produkter importeret til Storbritannien)
de	Dieses Produkt ist MR-sicher	Mehrfachverwendung bei einem Patienten	Produktionsland	Medizinprodukt	Konformität für das Vereinigte Königreich geprüft	Verantwortliche Person im Vereinigten Königreich	Importeur (Nur für nach Großbritannien importierte Produkte)
el	Αυτό το προϊόν είναι ασφαλές για MR	Για πολλαπλές χρήσεις σε έναν ασθενή	Χώρα κατασκευαστή	Ιατροτεχνολογικό προϊόν	Με πιστοποίηση συμμόρφωσης HB	Αρμόδιο πρόσωπο Ηνωμένου Βασιλείου	Εισαγωγέας (Μόνο για προϊόντα που εισάγονται στη Μεγάλη Βρετανία)
es	Este producto es compatible con RM	Varios usos en un único paciente	País de origen del fabricante	Producto sanitario	Conformidad evaluada del Reino Unido	Persona responsable en el Reino Unido	Importador (Únicamente para productos importados a Gran Bretaña)
fi	Tämä tuote on MK-turvallinen	Yhden potilaan käyttöön, monta käyttökertaa	Valmistusmaa	Lääkinnällinen laite	UKCA-merkintä	UK vastuuhenkilö	Maahantuoja (Koskee vain Iso-Britanniaan tuotavia tuotteita)
fr	Ce produit ne présente aucun danger en cas d'IRM	Usage multiple pour un seul patient	Pays du fabricant	Dispositif médical	Marquage UKCA	Responsable Royaume-Uni	Importateur (Pour les produits importés en Grande-Bretagne uniquement)
hu	Ez a termék MR-biztos	Egyetlen pácienshez, több alkalommal használható eszköz	A gyártó országa	Orvostechnikai eszköz	Felmért egyesült királysági megfelelőség	Egyesült királysági felelős személy	Importőr (Csak Nagy-Britanniába importált termékek esetén)
it	Questo prodotto è compatibile con RM	Monopaziente, multiuso	Paese di produzione	Dispositivo medico	Conformità Regno Unito verificata	Persona responsabile nel Regno Unito	Importatore (Solo per prodotti importati in Gran Bretagna)
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	英国適合性評価	英国責任者	輸入業者 (英国に輸入された製品のみ)
nl	Dit product is MR-veilig	Meervoudig gebruik bij één patiënt	Land van fabrikant	Medisch hulpmiddel	Op conformiteit beoordeeld in het VK	Verantwoordelijke voor het VK	Importeur (Alleen voor naar Groot-Brittannië geïmporteerde producten)
no	Dette produktet er MR-sikkert	Til bruk flere ganger for én pasient	Produksjonsland	Medisinsk utstyr	UK Conformity Assessed	Ansvarlig person i Storbritannia	Importer (Kun for produkter importert til Storbritannia)

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 -40 °C (-40 °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 ⑰ ⑱ ⑲ ⑳
- Secure the collar using the velcro. ㉑ ㉒ ㉓
- A nasal airway tubing can be attached to the tube hooks at both sides. ㉔

4.0. Disposal

Used products must be disposed off according to local procedures.