



Restorative Posture Device (RPD) Cervicothoracic Spine Orthosis



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Indications:

The Restorative Posture Device (RPD) is indicated for patients that present with poor positioning including forward head and neck posture resulting in decreased range of motion (ROM) and increased dysphagia risk as a result of posture as determined on an instrumental exam.



Patient Population:

The intended patient population is adult and youth patients that present poor positioning including forward head and neck posture resulting in decreased range of motion (ROM). This patient may be flaccid (can be passively ranged to an upright position but cannot sustain the position), may present with shortened adaptive tissue (unable to be passively or actively ranged to upright position), or may present with neurological tone with or without shortened adaptive tissue.

Intended Users:

Trained healthcare professionals or patients under the direction of a licensed medical professional.

Precautions:

- Single patient use only.
- Not for prolonged use.
- Replace RPD if any fractures are seen on the frame.
- To ensure safety while remolding, wear heavy gloves; plastic may be hot after heat molding.
- In case of serious injury, report to manufacturer and competent authority.

Intended Uses:

Patients with impaired ability to swallow and lost cervical range of motion - with or without neurological tone – can improve function and gradually increase flexibility by reeducating muscles in the submandibular region to promote the ideal head positioning for anatomical alignment that allows for optimal hyolaryngeal excursion. Patients may also benefit from:

1. Enhanced swallowing treatment when used in conjunction with Ampcare's Effective Swallowing Protocol (ESP™); assists with proper position of head and neck, maintains placement and improves electrical conduction of E Series Electrodes, and provides a resistive exercise protocol.
2. Improved respiratory function, coordination of respiration and swallowing and increased O₂ and CO₂ exchange.
3. Improved pharyngeal space for adequate laryngeal movement and passage of the bolus through the pharyngeal phase.
4. Increased ability to orally accept food taken by mouth (PO) and improve oral ROM, manipulation of the bolus for improved safety of the swallow.
5. Increased healing of any skin breakdown related to pressure, skin-on-skin contact, and lack of air to involved tissue.
6. Decreased neck pain and discomfort; be able to improve the ability to take in nutrition and hydration.
7. Improved ability to receive the stimuli of their environment which could increase their quality of life as they are able to take part in activities which may also improve their degree of orientation/cognition and PO intake.

Potential adverse event / side effect:

If any red areas appear on the skin under the padding and do not resolve within 30 minutes, consider modifying the frame, shortening the wearing period, or adding more padding to resolve the issue.

Specifications:

- Height: 22.23 cm; width: 20.32 cm
- Material: Kydex (thermoplastic acrylic-polyvinyl chloride composite material frame); nylon; polyurethane foam

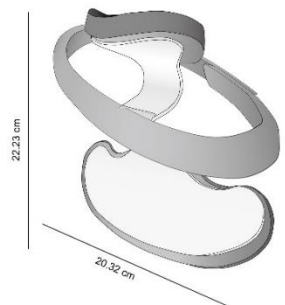
Cleaning:

Remove padding. Hand wash, lay flat and blot with a towel, then air dry. Wipe plastic clean with mild cleanser, protecting the hook-and-loop fasteners. Rinse with water, and allow to dry thoroughly while protecting the hook-and-loop fasteners. Replace padding, making sure all plastic edges where patient's skin might touch is covered.

Warranty:

Ampcare agrees that if any defect in materials or workmanship appears in this product within six months after the original date of consumer purchase, it will replace the product in question free of charge. This applies only if the product has been used as directed and has not been damaged through misuse, accident, or neglect.

If a defect appears, please check that the product is being used in accordance with instructions. If so, return it with this warranty and proof of purchase to your nearest Ampcare Dealer.

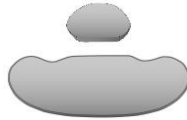


Restorative Posture Device (RPD)

Components:



RPD frame



chin and chest pads



neck strap

Recommended:



heat gun

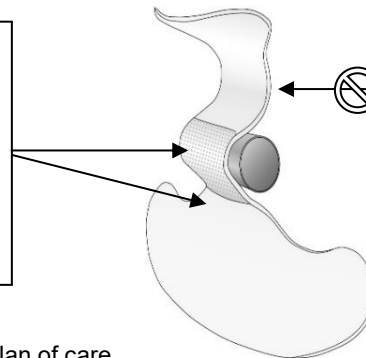
Customizing the Restorative Posture Device:

1. Place the chin plate under the patient's chin to see where modifications are needed. Patient's chin should remain slightly behind the end of the chin plate.
2. Remove chin and chest padding, strap, and hook-and-loop fastener on S-curve.
3. Using a heat gun, spot mold the device only at the middle or bottom of the S curve, limited to 10-15 degrees of stretch. Caution: To ensure safety while remolding, wear heavy gloves; plastic may be hot after heat molding.
4. Move the heat gun in a small circular motion approximately 3" away from the plastic for approximately 30 seconds on each side, only to the area to be remolded. Heat the middle of the S-curve to adjust the height and the bottom of the S curve to adjust the depth of the chest plate. Allow frame to cool.
5. Replace hook-and-loop fastener, padding, and strap to appropriate areas after plastic cools.
6. Place the brace on the patient to ensure that desired modifications are complete.

You may change the curve angle, but keep the S-curve to facilitate a cushioning effect.

Spot mold only at the middle of the S-curve to adjust the height or the bottom of the S-curve to adjust the chest plate.

Avoid heating the top of the S-curve as the angle is set to the appropriate amount of resistance.



NO heat to the upper S-curve.

The use of a small can or PVC is recommended to form the curve.

Application:

1. Apply and remove per physician's order and patient's overall plan of care.
2. Explain to patient in understandable terms what you are about to do.
3. Determine the degree of comfortable range of motion of head/neck. Try to keep the cervical spine in good alignment (erect) for more appropriate vallecular space with a mild dorsal glide (chin retraction) to allow for better epiglottic closure and airway protection.
4. If needed this device can be remolded. Refer to the "Customizing the Restorative Posture Device" section.
5. Adjust the blue strap around patient's neck and secure with hook-and-loop fasteners to form the most comfortable and therapeutic angle. Assure moldable chin cup is comfortable and no plastic is touching the patient's throat.
6. Begin wearing schedule with short duration according to the patient's tolerance levels and their individual conditions. Gradually buildup 30 minutes per day to typically no more than 6 hours per 8-hour shift (6 hours on 2 hours off). Attempt to build muscle strength and prevent weakening. Consider initiating use during ESP dysphagia treatment and/or liquid PO trials.
7. Check all areas of skin where the device touched each time it is removed
8. Chart all pertinent information.

Ordering Information:

The Ampcare Restorative Posture Device (RPD) may be used in conjunction with the Ampcare ESP Therapy System, a neuromuscular electrical stimulation protocol FDA-cleared for the treatment of dysphagia. Contact Ampcare for details about ordering in your area.

Product Number	Product Description
50707	Ampcare Restorative Posture Device (RPD)
50708	RPD Replacement Pad Set, 3 pieces

Disposal: Dispose of components in accordance with local, regional, national, or international regulations.

Explanation of Symbols:



If you are not a certified user of ESP, contact Ampcare to receive video instructions on how to perform ESP exercises.