CE

INTRODUCTION

This orthosis is meant for patients requiring external cervical spine immobilization for neurologically intact nondisplaced or minimally displaced fractures. Use should not exceed 6 months.

The Lerman Non-Invasive Halo is constructed entirely of non-ferrous materials.

- Incorporates a double upright frame that supports an open ring halo type forehead band and floating chin support which provides immobilization similar to that of the traditional halo without the complications of pins and ring loosening or possible skull and dural penetration from falls.
- A key component of the immobilization is a non-allergenic material incorporated into areas of skin contact that adheres to the skin providing trans-migratory control and prevention of skin ulceration.
- The floating posterior occipital support which attaches to the uprights with four hook and pile straps securely holds the head against the forehead band and reduces pressure over the occiput.
- Uses a single piece, anterior-only vest that is secured by simply sliding two crisscrossed posterior shoulder straps and the waist strap under the patient while the patient remains in the supine position. This design allows for ease of application eliminating the need for side-to-side turning or 'log-rolling'. The buckles are color-coded and numbered to promote easy and accurate fitting.
- The anterior vest is easily removed in case of emergency requiring access to the thoracic cavity.
- Double rods which engage a pair of adjustable serrated rotatable connectors connect the facemask and anterior vest. These connectors allow for height as well as angular adjustments of the facemask with respect to the vest.
- All components of the system that require body contour matching are easily shaped with tools available to the Orthotist.

INDICATIONS

Cervical spine immobilization of stable, non-displaced or minimally displaced fractures.

CONTRAINDICATIONS

Structurally unstable cervical spine immobilization.

⚠ **The silicone bands are not intended for use over irritated or open skin. These areas should be monitored by the healthcare provider.**

⚠ **If the device should fail, immobilize the patient in a supine position and seek emergency help immediately.**

⚠ **Important Notes:**

- These instructions are only general guidelines and may be altered by the fitting specialist according to each individual's needs or the specifications of the prescribing physician.
- Any attempt at moving a patient in an acute and/or post-operative condition should be facilitated with help from support staff and all necessary precautions should be taken.
- Homecare providers must be trained by the prescribing physician or fitting specialist on cleaning and safety procedures.
- Treatment protocol may vary from institution to institution and the adherence of these requirements is the responsibility of the fitting specialist or prescribing physician.

INSTALLATION AND USE

All Lerman Non-Invasive Halo fitting is done with the patient in a supine position. The vest and facemask are fitted as separate components and joined afterwards.

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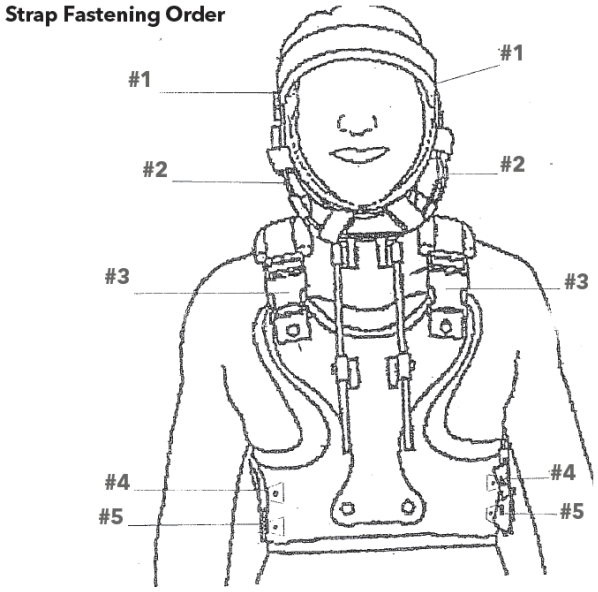

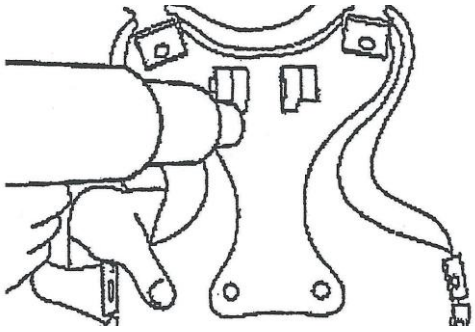

Figure 1: Contouring the vest using a heat gun.

1. Using the wrench provided or a standard 6-point socket driver, loosen the bolts holding the rods to the vest and separate the facemask assembly from the vest.
2. Remove the lower (waist) strap and upper (shoulder) straps from the vest and apply the vest to the patient to determine if the contour is correct. If there is gapping, the vest plate should be contoured by using a heat gun (FIGURE 1). Apply carefully as too much heat may cause delamination of the composite.

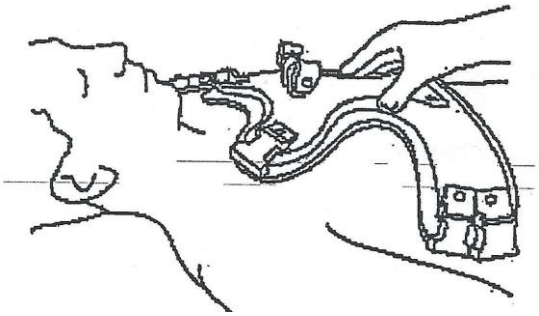

Figure 2: Applying the contoured vest.

3. Apply the contoured vest to the patient (FIGURE 2). Remove the tubular padding from the waist strap and adjust the waist belt length to the approximate length needed for the patient. Slide the waist belt and attach the waist belt to the lower chafe on the vest. Waist buckles are black and numbered “5”. Slide the waist belt under the patient and fasten snugly to the opposite side chafe. Slide the shoulder straps under the back in a crisscross manner and fasten snugly to the upper chafes on the vest. Shoulder straps have matching grey and white colored buckles and are numbered “3” and “4”.
4. To facilitate fitting the facemask, loosen the two bolts on the rotatable connectors. The facemask has a floating chin support which can be adjusted in length by loosening two plastic clips attached to the uprights. The clips are secured by two hook and pile loops (FIGURE 3, labeled A). Remove the loops and undo the plastic clips to allow adjustment to the chin straps. There are also two additional hook and pile loops (FIGURE 3, labeled B) that tether the distal chin strap to the frame. These should also be removed.

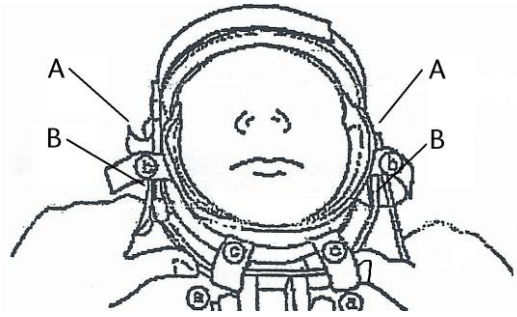

Figure 3: Adjusting the floating chin support.

5. Fit the facemask to the patient. Observe the A/P position of the facemask uprights. They should lie forward of the ears when the forehead band is against the forehead. To adjust the A/P, loosen the forehead band hook and pile (FIGURE 4) to allow for either lengthening or shortening of the forehead band and silicone pad to reposition the uprights.
6. Position the forehead band as low as possible but not more than ½" above the eyebrows. Tighten the chin support by pulling the strap at both ends and fasten them in place with the plastic clips. Be sure the silicone pad on the strap is centered. Reapply the hook and pile loops over the plastic clips.
7. Adjust the chin support tether loops so they are snug. Excess strap should be cut off (FIGURE 5).
8. Remove the bolts from the rotatable serrated connectors attached to the facemask and separate the two parts (FIGURE 6) of the connector. Slide the anterior upright rods into the connectors attached to the vest and reconnect proximal connectors with the bolts. Tighten all four bolts making sure the correct cervical alignment is achieved. Lifting the chin slightly will provide distraction.
9. Apply the occipital support (FIGURE 7) by sliding it under the patient's head and fasten it snugly to the facemask using the four hook and pile straps. The inferior straps are routed through the chafes located on the lower part of the upright to prevent migration of the straps. Raise the patient to sitting position and make fine tuning adjustments as necessary. The facemask should be snug enough to limit teeth separation to not more than 1⁄2" when opening the jaw. A butterfly clip is supplied to keep the shoulder straps from migrating and is applied where the straps are crossed in the back.

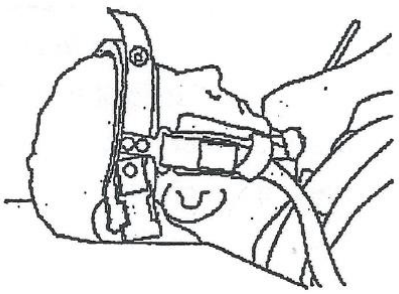

Figure 4: Adjusting the A/P of the forehead band.

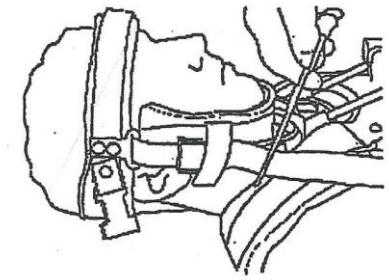

Figure 5: Adjusting the A/P of the forehead band.

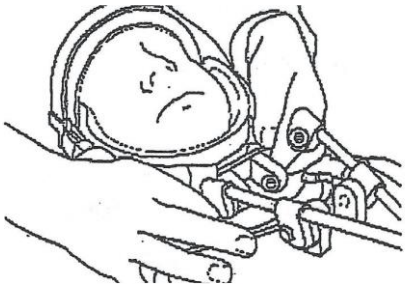

Figure 6: Attaching the facemask assembly to the vest.

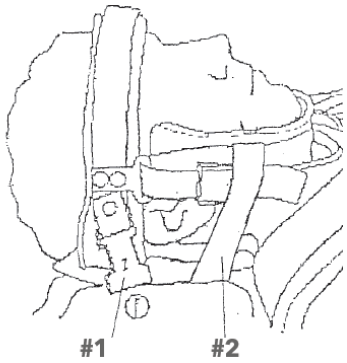

Figure 7: Attaching the occipital support.

MAINTENANCE

- Periodically check the fasteners on the device for looseness.
- Qualified assistance should be obtained when cleaning the device. Homecare providers must be trained by the fitting practitioner.
- The shell of the orthosis can be cleaned with soap and warm water or rubbing alcohol.
- The Velcro adhered liners can be removed and washed with a gentle soap and water and air-dried.
- If the device becomes contaminated with biological fluids, it should be handled as medical waste upon disposal.

STORAGE AND USE

There are no identified restrictions on the temperature of storage and use.

DISPOSAL

There are no hazardous materials in the device. Comply with local and national laws and regulations.

LEGAL INFORMATION

MD The use of this class 1 medical device is subject to the respective national laws of the country of use and may vary accordingly. The user of this device should report any serious incident to Trulife and the competent authority of the country of use.

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LIMITED WARRANTY

Trulife warrants that the PRODUCT will be free from defects in material and workmanship from the date of installation for the warranty period stated on the PRODUCT warranty card.

This warranty will not apply if the PRODUCT has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the PRODUCT has been modified/repaired by persons unauthorized by Trulife.

If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

The application guidelines for this Trulife product are for the use of and by a certified, qualified practitioner only. Patients are not to attempt to apply or adjust the item unless expressly instructed to do so by the practitioner responsible for the prescription and/or initial fitting of the device. All patient questions should be referred to the practitioner and not to the manufacturer. The manufacturer warrants only that the enclosed product has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the medical professional(s) prescribing and/or fitting the device to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed product.

As a condition of the sale of any Trulife product, this product is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in effectivity. Any express or implied warranties are voided if the product is reused or fitted to another patient. Additionally, a license of right to use under any relevant patents pertaining to the product is terminated with the cessation of use by the original patient. As with all Trulife products, this product must be prescribed and applied by a qualified practitioner to determine it meets the needs of the particular patient and accomplishes the desired results.