



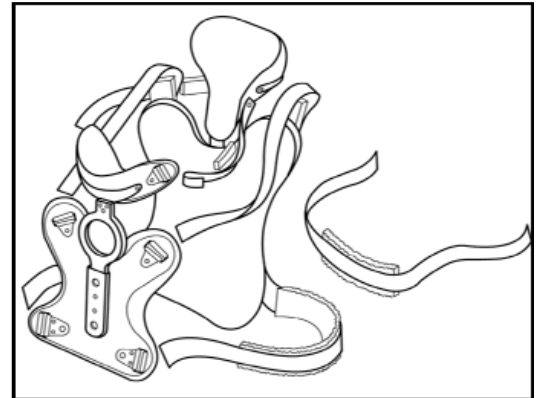
**INTRODUCTION**

The Lerman MINERVA is a cervical orthosis that consists of two shells, anterior and posterior, which are joined by torso and shoulder straps. The posterior segment has an attached occipital support, which may be moved vertically. A sliding mandibular support is attached to the anterior shell. This mandibular support may also be adjusted vertically. A forehead strap is included to provide additional support. The Lerman MINERVA is constructed entirely of non-ferrous materials.

Product Code	Size	Measurement (Chin to Distal Edge of Brace*)
A193REG	Regular	13"-16" (33-41 cm)
A193SM	Small	11"-13" (28-33 cm)
A193PED	Pediatric	9"-11" (23-28 cm)

\*Distal edge of the brace should be positioned at the inferior end of the sternum.

Product Code	Description
A193REG-CHIN-MR	CHIN ASSY REG MINERVA
A193SM-CHIN-MR	CHIN ASSY SM MINERVA
A193PED-CHIN-MR	CHIN ASSY PED MINERVA
A193REG-OCPT-MR	OCCIPITAL ASSY REG MINERVA
A193SM-OCPT-MR	OCCIPITAL ASSY SM MINERVA
A193PED-OCPT-MR	OCCIPITAL ASSY PED MINERVA
O10901	MINERVA PAD SET RG
O10902	MINERVA PAD SET SM
O10927	PAD CHIN RG MINERVA
O10928	PAD OCCIP RG MINERVA
O10931	PAD CHIN SM MINERVA



**INDICATIONS**


The Lerman Minerva is intended to support and stabilize C2-T3 stable fractures, muscular/ligamentous injury, degenerative joint disease, cervical pain, and nerve impingement.

**CONTRAINDICATIONS**

Unstable fractures, type II dens fractures.

**INSTALLATION AND USE**

1. Compare the posterior section with the patient to roughly determine the correct height of the occipital support with respect to the posterior shell.
2. Make height adjustments as necessary to the posterior section by removing the screws and sliding the bar. Replace the screws when adjustments are complete.
3. Contour and adjust the posterior section as needed.
4. With the help of an assistant, log-roll the patient to his/her side to fit the posterior section.

 **Be sure the head and neck are supported during the log-roll process.**

5. When a successful posterior fit is achieved, roll the patient onto his/her back.
6. Make height adjustments as necessary to the anterior section by removing the screws and sliding the bar. Replace the screws when adjustments are complete.
7. Contour and adjust the anterior section as needed.
8. Adjust all hook and pile closures to a snug comfortable position.
9. Attach the optional forehead strap for additional support if needed.





## MAINTENANCE

- Periodically check the Lerman MINERVA fasteners for looseness and tighten as appropriate.
- Qualified assistance should be obtained when cleaning the device. Homecare providers must be trained by the fitting practitioner.
- The shell of the Lerman MINERVA can be cleaned with soap and warm water or rubbing alcohol.
- The hook and loop adhered liners can be removed and washed with a gentle soap and cold water and air-dried away from any heat sources.
- If the Lerman MINERVA 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/repared 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.