

## INTRODUCTION

The Malibu Cervical Collar consists of two independently height adjustable shells, anterior and posterior, made of heat-moldable Kydex. The anterior opening allows for a tracheotomy tube and the soft closed-cell foam liner offers patient comfort. The CV100 Malibu Cervical Collar comes in one size that fits most adults and the CV101 is the pediatric version. There is also an optional Thoracic Extension available if more stabilization is required.

The Malibu Cervical Collar is MRI Safe. The Thoracic Extension is constructed entirely of non-ferrous materials.

Product Number	Product Description	Neck Circumference
CV100	Malibu Cervical Orthosis, Adult	30 - 43 cm • 12 - 17 in
CV101	Malibu Cervical Orthosis, Pediatric	20-28 cm • 8 - 11 in

Product Number	Product Description	Distance from Sternal Notch to Xyphoid Process
CV102	Thoracic Extension, Adult	26.7 cm • 10.5 in
CV103	Thoracic Extension, Pediatric	20.3 cm • 8.0 in

## INDICATIONS

The Malibu is designed for cervical spine precaution for trauma patients, immobilization for pre and post cervical spine surgery, degenerative disorders, Spinal Stenosis, Spondylolisthesis, ligament/muscular injuries, Rheumatoid Arthritis, degenerative joint disease, and nerve impingements.


### Important Note

- These instructions are only general guidelines and may be altered by the certified practitioner according to each individual's needs or the specifications of the prescribing physician.
- Treatment protocol may vary from institution to institution and the adherence of these requirements is the responsibility of the certified practitioner or prescribing physician.

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

### Important Reminders for Patients

- Follow physician's and the certified practitioner's instructions for length of wear.
- Follow physician's and the certified practitioner's instructions for activities that are acceptable while wearing the orthosis
- Physician's orders should supersede all protocol.

 **Due to restricted movement, patient should not operate motor vehicles or large equipment where full visibility is required.**

## INSTALLATION AND USE

### Malibu Cervical Collar

1. Detach straps to separate the anterior and posterior sections.
2. Compare the posterior section to the patient to roughly determine the correct height with respect to the posterior shell (measured from the base of the neck to the occiput). Loosen the thumb screws and make height adjustments as necessary.
3. Contour and adjust the posterior shell as needed using a heat gun. Hold shape until Kydex has thoroughly cooled.
4. Replace and tighten the thumb screws.
5. Determine placement of the mandibular pad on the anterior section and, using the self-adhesive hook dots on the interior of the liner, apply the mandibular pad.
6. Place the posterior and anterior sections on the patient and attach/adjust the straps to a snug tolerable position.

### Malibu Thoracic Extension (optional)

1. Fit the Malibu Cervical Collar as stated above.
2. Contour and adjust the anterior and posterior uprights as needed, lightly using a heat gun to avoid delaminating the composite. Hold shape until the composite upright has thoroughly cooled.
3. Replace the ½" nylon thumb screws on the Malibu Cervical Collar with the ¾" nylon thumb screws supplied with the Malibu Thoracic Extension on the anterior and posterior collar upright, attach the appropriate Malibu Thoracic Extension at the screw locations. Replace and tighten the thumb screws.
4. Place the posterior and anterior sections on the patient and attach/adjust the straps to a snug comfortable position.
5. Attach/adjust the side straps on the sides of the Malibu Thoracic Extension to a snug tolerable position.

### Liner (optional)

1. Place the self-adhesive hook dots on the edges of the interior of the collar to attach the anterior and posterior liners.

### MAINTENANCE

- Periodically check the fasteners on the Malibu Cervical Collar and Thoracic Extension, if used, for looseness.
- The shell of the Malibu Cervical Collar and Thoracic Extension can be cleaned with soap and warm water or rubbing alcohol.
- The optional hook and loop adhered liners can be removed and washed with a gentle soap and water and air-dried.
- If the Malibu Cervical Orthosis 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.



### Trulife

3225 Woburn St. Suite 160  
Bellingham, WA 98226  
USA

Phone (+1) 360 697 5656

Email [supportop@trulife.com](mailto:supportop@trulife.com)



### MDSS GmbH

Schiffgraben 41  
30175 Hannover  
Germany

## 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.