Description

• Plastazote padded, tempered wire frame makes for a well-tolerated and comfortable cervical orthosis.
• Molded polyethylene occipital pad with aluminum stay allows easy contouring of posterior component.
• Lined with a cloth covered foam material for added comfort. Liner can be ordered separately.
• Hook and loop closure allows easy application by the patient.

Function

• Serves as a reminder to restrict head motion.
• Mechanically limits head nodding (flexion) and tends to reduce activity of the neck contours.
• Caution should be taken when unstable cervical fractures are present. The wire frame cervical orthosis may not provide adequate stability of these conditions.

Product Number	Product Description	Neck Circumference	Collar Height
JS-4040-S	L.A. Wire Frame Cervical Orthosis, Short	30-39 cm • 12-15.5 in	8-13.5 cm • 3-5.3 in
JS-4040-R	L.A. Wire Frame Cervical Orthosis, Regular	39-45 cm • 15.5-18 in	8-13.5 cm • 3-5.3 in

Indications

C3-C6 ligament/muscular injuries, degenerative joint disease, rheumatoid arthritis.

Fitting

• Assess patient and determine size.
• Head should be positioned according to doctor's direction.
• Collar comes to you in a neutral position (figure 1).
• Chin should fit into chin piece.
• Contour for maximum contact with chin, chest and posterior cervical arch. This can be achieved by bending the wire within the Plastazote padding and in the front portion of the brace.
• To increase flexion, bring the chin and chest portions together (figure 2).
• Extension can be achieved by spreading the two sections apart to the desired height or amount of extension desired. (Figure 3).
• Width can be adjusted by bending the sides together.
• The occipital pad with the aluminum stay allows easy contouring of posterior component to cervical arch. Contour orthoses so that there is no undue pressure on any bony prominence such as the prominent clavicle and/or sternum.
• If patient can stand or sit, finalize adjustments in these positions.

Figure 1

Figure 2

Figure 3

Notes:

• Clean surface of foam tube with rubbing alcohol when replacing moleskin chin pad.
• For best results, shape the wire frame collar over a rounded surface such as a bed frame of the back of a chair.

Fitting Problems

• Unusually short neck.
• Bony prominences
• Fixed abnormal position of the head.

Cleaning Frame

- Clean by hand with mild detergent or alcohol.
- Rinse with water.
- Wipe dry before reapplication.

Fabric Liners

- Remove liners and place in laundry bag.
- Machine wash with mild detergent, gentle cycle, cold water and tumble dry cool temperature.

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.