**0800502, 0800504**
**Sterno Occipital Mandibular Immobilizer (SOMI) Brace**
**Practitioner Instructions and User Guide**
25483-001 REV F

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## INTRODUCTION

The SOMI is a cervical orthosis that limits cervical flexion and rotation and to a lesser extent, cervical extension and lateral flexion. Since both the occipital and mandibular components attach anteriorly to the single torso plate, it is particularly suited for supine application where disturbance to the cervical spine must be kept to a minimum.

| Model no. | Size | Chin to distal end of brace |
|---|---|---|
| 0800502 | Small | 8” - 12” (20 - 31 cm) |
| 0800504 | Regular | 11” - 15” (28 - 38 cm) |

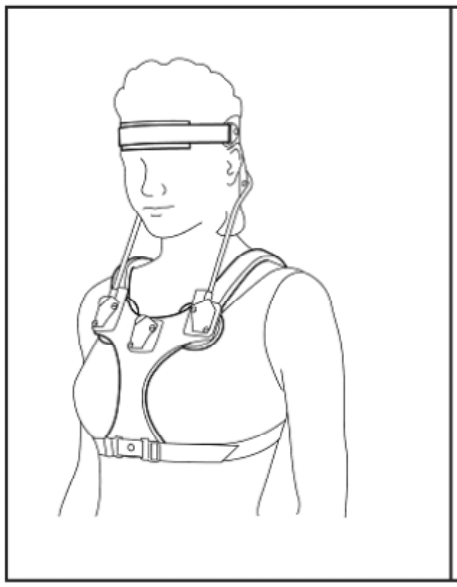

**FIGURE 1:** SOMI Brace w/o Mandibular Component

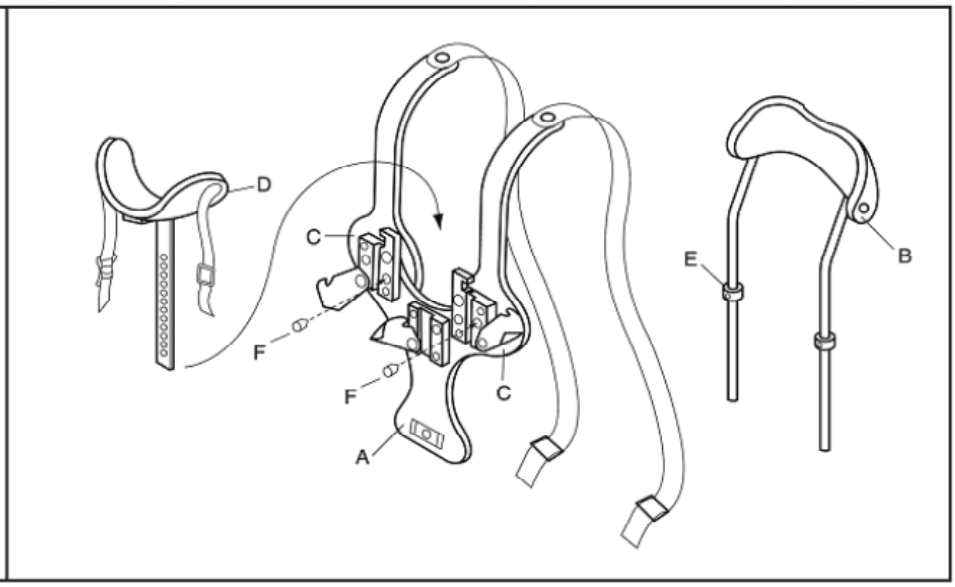


**FIGURE 2:** SOMI Brace Assembly

**FITTING INSTRUCTIONS** (refer to FIGURE 2)

1. Fit chest plate A. Modify shape if necessary after first removing occipital component B, discs C, and mandibular component D. Bend horizontally to follow chest contour and vertically to conform to the sternum.
2. Reassemble discs C to chest plate using the two inner threaded holes for small patients or the two outer holes for larger patients.
3. Adjust angle of both shoulder supports so that each passes over the shoulder comfortably between the insertion of the trapezius and the acromion.
4. Tighten screws to lock shoulder supports. Insert pointed setscrews F into the open threaded holes and tighten to prevent shoulder supports from rotating.
5. Fit occipital component B by adjusting and fixing stops E for proper elevation. Insert rod stops into the slots on the chest plate, close fasteners and bend posteriorly to position the occipital pad under the occiput.
6. Fit mandibular component D by positioning chin pad under chin at correct elevation. Fix in position by setting proper hole over pin. Mark selected hole by etching so that component can be replaced in proper position if it is removed. Close fastener.



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A separate headband is included for use as an auxiliary support when the mandibular component is removed for eating, shaving, etc. The headband attaches to the two snaps on the occipital component. The strap encircles the cranium and is maintained in position with a hook and pile closure.

**Warning: Failure to follow the installation and use procedures set forth above may lead to structural failure of the components subjecting the user to a risk of serious personal injury.**

**QUESTIONS**

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Trulife has appointed Medical Device Safety Service (MDSS) of Hannover, Germany to act as our EU authorized representative. They may be contacted at:

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**LIMITED WARRANTY**

Trulife warrants that the Sterno Occipital Mandibular Immobilizer (SOMI) Brace will be free from defects in material and workmanship for the Sterno Occipital Mandibular Immobilizer (SOMI) Brace from the date of installation.

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 a Sterno Occipital Mandibular Immobilizer (SOMI) Brace 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 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.