



## INTRODUCTION

Your doctor has prescribed the SOMI brace to position and restrict motion of your cervical spine (neck) during your recovery process. It is important that all directions given to you by hospital personnel, including, but not limited to; your physician, nurse, physical therapist, occupational therapist, and Orthotist, are strictly adhered to. This brace is designed to immobilize your head and neck while your injury heals.

Model	Size	Chin to distal end of brace	Accessories	Description
0800502	Small	8" - 12" (20 - 31 cm)	1400027R00	SOMI CHIN BAR ASSEMBLY RG
0800504	Regular	11" - 15" (28 - 38 cm)	1400027S00	SOMI CHIN BAR ASSEMBLY SM
			1400028R00	NECK BAR ASSEMBLY RG
			1400028S00	NECK BAR ASSEMBLY SM
			140-CHAN	KIT-SOMI CHANNEL OCCIPITAL/CHIN

## INDICATIONS

C4/5-T3/4 stable fractures, post operative stabilization.

## INSTRUCTIONS AND USE



**Do not remove your brace unless directed by your physician. Removal of the brace may jeopardize your recovery or lead to a more serious injury.**

### Bathing

- Bathing should be done with the brace on.
- Avoid unnecessary bending or twisting. Showering should be done while sitting on a hard chair.
- Bathe using a mild soap.

**Note: Do not use scented talc powders or scented soaps to wash under the padding of the brace as they may irritate your skin.**

- Thoroughly dry the pads after bathing by running a towel under the brace.
- Run alcohol swabs under the pads to eliminate perspiration and/or bacteria that accumulates during the day.
- Obtain bathing assistance from a second person if necessary.

### Eating

Eating with your brace on will be a challenge. Because of the nature of the headpiece, you will not be able to bend your neck or open your mouth very wide. Remember to take small bites and use a straw for drinking liquids whenever possible.



**Do not pull on the head or chin piece. Interference with the fit of the brace may jeopardize your recovery or lead to a more serious injury.**

### Getting out of bed

When getting out of bed, lie on your side. Use your elbow and your opposite arm to push yourself to a sitting position. Be careful not to bend or twist your neck or back.

### Clothing

Clothing is to be worn over your brace. A button down shirt is recommended for ease of dressing.

## WHEN TO CONTACT YOUR HEALTH CARE PROVIDER


### Contact your Physician if:

- You are experiencing severe or abnormal pain.
- You are experiencing numbness.
- You are having difficulty caring for your own needs, including cooking, toileting, bathing, or eating.

### Contact your Orthotist or Therapist if:

- Something on the brace is malfunctioning.
- You are having a problem with the fit.
- You cannot sit down, eat, or toilet properly because the brace is too restrictive.
- The brace is causing you pain or is causing a sore or abrasion.



 **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.**


#### 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

 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.