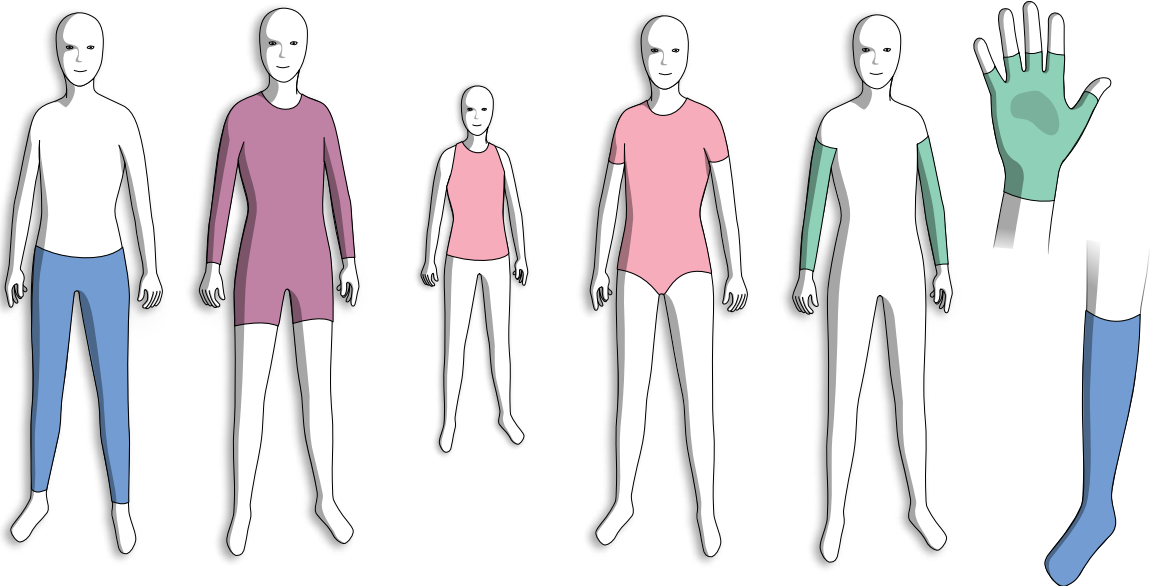


# Instructions For Use

## Professional Instructions





### Product Description

Elements Body is a dynamic textile orthosis, made to measure to meet patient clinical needs.

### Intended Use

Elements Body is an orthosis that provides a versatile intervention that can be effective in the management of both high and low tone across a spectrum of neurological conditions. The orthosis can enhance sensory and proprioceptive feedback, fine motor skills and postural control. This is a made-to-measure product for adults and children that will meet the clinical needs identified by the healthcare professional.

Single patient, multiple use.

### Indications

Elements Body is suitable for the following neurological diagnoses presenting with specific symptoms.

- Cerebral Palsy: Hypotonia, Spasticity, Ataxia
- Multiple Sclerosis, Stroke & Acquired Brain Injury: Spasticity, Ataxia
- Muscular Dystrophy, Acquired Spinal Cord Injury and Downs Syndrome: Hypotonia
- Athetosis: Spastic Athetosis

### Contraindications

- Osteoporosis
- Osteogenesis imperfecta

### Limitations

Use the orthosis initially for short periods of time e.g. 1-2 hours to allow your body to get

used to the product. Increase wearing time gradually until 6-8 hours continually wear is achieved.

Note, if the product is worn for more, you may feel over-stimulated and fatigued. The orthosis should not be worn at night while sleeping.

Redness/skin marks can show, usually in the armpit or in the area of an opening or under a zipper. If redness/skin marks are noted, gently massage the area to improve blood circulation. Redness or skin marks should normally disappear after 40 minutes.

If any red skin marks or irritation last more than 8 hours with the product removed, please discontinue use and consult with the prescriber.

It is important to ensure that the integrity of the skin and the garment are intact before application of the orthosis, to prevent damage to the skin.

Limitations may arise when providing Elements Body Orthoses to patients with complex needs. Challenges related to donning and doffing, as well as caregiver comprehension, may affect compliance.

### Warnings

If you have a skin condition, circulation disorder, poor temperature regulation, oedema and/or compromised respiratory function, it is important to secure medical clearance before provision. The orthosis must be dry before fitting. Avoid using skin care products immediately prior to application of the orthosis.

## Material Specification

Shell fabric: 51% polyamide 32% elastane 17% cotton

Reinforcement fabric: 81% polyamide 19% elastane

Depending on model other materials may be included.

## Washing Instruction

Elements Body is made from elasticated material that will benefit from regular washing. We recommend washing every third day to allow material restitution to ensure that it retains its technical properties.

Close zippers before washing and use a laundry bag to protect zippers, fasteners etc. Please use a mild, non-biological (free from enzymes) detergent. Do not use fabric softener. It is important that the product is completely dry before use.

## Information

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## Disposal

Disposal in accordance with local legislation (combustible waste).

## Patient Assessment & Product Fitting

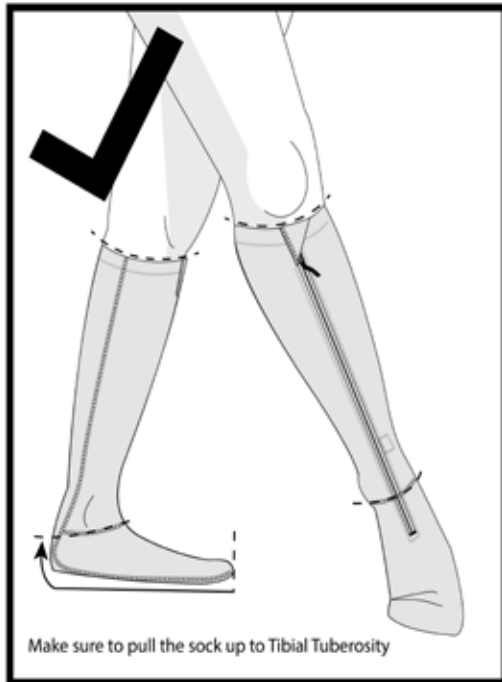
Prior to measuring for an Elements Body, ensure the Patient is suitable for the Orthosis. As part of the assessment process ensure you have selected the most appropriate reinforcement panels to meet the patient needs. Extra care should be taken for patients with impaired vision, cognitive disabilities and/or reduced sensitivity.

**When fitting the Elements Body, the following procedure is recommended:**

1. Open all zippers and closures before donning.
2. When the orthosis is on, check that all seams are in alignment with the arms, legs and side of body.
3. Close zippers one at the time, start with body closure (suit/body) and then move distally. Make sure the facing behind the closure is protecting the skin.
4. Check that the Elements Body orthosis has a snug and comfortable fit.
5. If the Elements Body has an opening for a gastro tube/peg feed, check that this is in the correct position.

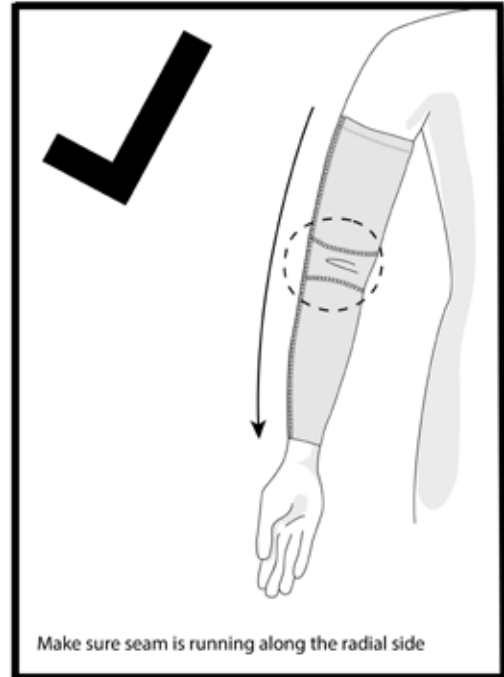
Special recommendations for Elements Body with legs (trousers/suit):

1. Pull each leg of the garment above the knee gently, one at a time.
2. Check that the seams at the knee section are above and below the knee joint and they allow the knee to flex.
3. Pull the suit/waist over buttocks and hips.



Special recommendations for Elements Body with sleeves (vest/suit):

1. Gently insert one arm at a time and pull the garment over the shoulders.
2. Check that the seams at the elbow section are above and below the joint and they allow the elbow to flex.
3. Make sure the fit at the armpit is snug but not uncomfortable.



## EN Elements Body -Dynamic textile orthosis

### Adjustments & Alterations

This product may only be altered by medical professionals or by staff at Camp Scandinavia.

If it is the first time your patient is fitted with Elements Body and adjustments are needed, a first free of charge alteration is provided given that it is requested within 8 weeks from delivery and fulfills our requirements.

Camp Scandinavia can perform alteration under other conditions as well, but these services will be charged for. Please contact your local customer support to learn more about options and possibilities.

If you prefer to do alterations in-house a selection of materials and components are available. Please contact your local customer support for ordering. N.B. Some alterations may bring the orthosis outside of its intended use. Make sure internal protocols for custom made devices are used.

Please contact your local Customer Support or visit our website for guidance documents and alteration forms.

### Wear & Care

Make sure the Patient/Care Giver receives and understands the Patient Instructions. If the Elements Body Orthosis is prescribed as a Custom-Made Device, please explain clinical reasoning to the Patient/Care Giver.

Inform the Patient/Care Giver on how to handle any potential redness/skin marks. If redness/skin marks are found it is usually in the armpit, at an opening or under a zipper. If

this does occur gently massage the area to improve blood circulation. Redness or skin marks should normally disappear after 40 minutes, if they do not, instruct the Patient/Care Giver to consult their treating clinician. Do not use skin care products during use of the garment, apply any skin care product after removing the Elements Body Orthosis.

It is also important to inspect the Orthosis daily before use to make sure it is free from damages.

### Follow Up

The garment should be monitored frequently to ensure the garment remains fit for purpose and clinically effective.

Elements body Orthoses must have a close and snug fit to be functional. This means that it is important to monitor any physical changes in patients using Elements Body. Inform Patients/Care Givers to report weight changes, both loss and gain, as well as any other health condition or medication that may result in oedema.

We recommend that children must be reviewed at a maximum interval of 6 months. Inform Parents/Care Giver to report growth changes in between follow-up sessions.





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