



Wear and Care Guide
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The Surestep Sprout3D Cranial Remolding Orthosis (CRO) is designed to gently help correct your baby's head shape. These instructions are intended to help you learn how to use and care for the orthosis while your baby is in treatment. If you have specific questions about your baby's care plan, please contact your clinician.

➤ What to Expect

Your clinician will ensure an appropriate fit of the helmet that causes no discomfort. Your baby's head will grow into the device while it gently corrects the cranial asymmetry and returns the head shape to a healthy range.

Your clinician will set a schedule to review the progress that your child makes over the coming weeks and months.

✔ Applying and Removing the Sprout3D CRO

Your clinician will show you how to correctly apply and remove the cranial band which opens and closes on the side. The brim of the cranial band should sit just above your child's eyebrows at the front.

✦✦ Cleaning the Sprout3D CRO

You can expect your baby's head to sweat, especially during the first few weeks, even in cool weather. When you remove the helmet for bathing, you should thoroughly clean and disinfect it, along with washing your baby's hair.

In the first few weeks, you may need to clean the helmet twice a day. Use a soft brush or toothbrush and a soapy solution to gently scrub the inside. Alternatively, you may use 70% isopropyl alcohol in a spray bottle and wipe with a damp paper towel and clean water. Allow the helmet to dry before placing it back on your child's head.



Wearing Schedule

It is recommended that your baby wear the helmet 23 hours a day, after a break-in period. This will minimize the total treatment time it will need to be worn and maximize the corrections. It should be removed only for bathing.

Your clinician will provide a schedule to gradually increase the hours per day the helmet is worn. You'll reach the recommended 23 hours per day after about a week. A typical wearing schedule may look like this:

DAY	ON/OFF TIME	NAPS	NIGHT	SKIN CHECK
Day 1	1 hour on/1 hour off (repeat until bedtime)	No	No	Each time removed
Day 2	2 hours on/1 hour off (repeat until bedtime)	No	No	Each time removed
Day 3	4 hours on/1 hour off (repeat until bedtime)	Yes	No	Each time removed
Day 4	6 hours on/1 hour off (repeat until bedtime)	Yes	No	Each time removed
Day 5	6-8 hours on/1 hour off (repeat until bedtime)	Yes	No	Each time removed
Day 6	8 hours on/1 hour off	Yes	Yes	Each time removed
Day 7	23 hour on/1 hour off	Yes	Yes	Each time removed



✓ Intended Use

The sale, distribution, and use of the Surestep Sprout3D CRO is restricted to prescription use in accordance with 21 CFR 801.109.

Sprout3D is intended for medical purposes to:

- Apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape.
- Treat infants from 3-18 months with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads.

Sprout3D is contraindicated in infants with pre-surgical craniosynostosis or hydrocephalus.

✓ Warnings and Precautions

1. Evaluate head circumference and neurological status at intervals appropriate to the infant's age and rate of head growth.
2. Adverse events (e.g. skin irritation, skin breakdown) have occurred with this device type. Evaluate the skin at frequent intervals.
3. If the positional plagiocephaly is associated with torticollis, the torticollis must be additionally treated.
4. Evaluate the device fit at appropriate intervals to reduce the potential for restriction of cranial growth, possible impairment of brain growth and development, and skin irritation and/or breakdown.
5. Evaluate the structural integrity of the device at appropriate intervals to reduce the potential for the device to slip out of place and cause asphyxiation or trauma to the eyes or skin.



17530 Dugdale Drive, South Bend, IN 46635
877.462.0711 | surestep.net

