

Orthomerica's One Headband Guarantee



Orthomerica's STARband® program promotes the One Headband Guarantee for the treatment of infants with deformational head shapes in collaboration with our STARband clinicians. It is important to understand that the fit and function of each orthosis depends on a thorough evaluation, medical history, design features, modifications requested, and clinical expertise and technique.

Moderate deformities may require up to 2cm of cranial growth for correction, while severe deformities may require 3cm or more of cranial growth for correction. By design, the STARband addresses substantial brain and head growth within the initial modification and the strategic addition of pads and/or removal of the ½" liner material throughout treatment. The standard modification options available with the STARband correct symmetry, proportion, and sloping up to 3cm of growth, with an additional ½-inch foam liner to accommodate strategic adjustments for additional correction if needed.

As a result, our records indicate that over 98%+ of infants yield optimal clinical results with only one STARband. Only the most severe deformities with sufficient remaining growth for continued correction may benefit from a second orthosis.

Patients over 13 months adjusted age or with less than 6mm of asymmetry and a cephalic ratio less than 90% are excluded from the One Headband Guarantee, as well as the postoperative treatment of infants with craniosynostosis.

STARband Clinician Responsibilities

To comply with the One Headband Guarantee program, each clinician must submit the following information:

- Evidence of Correct Fit and Treatment Instructions at the Delivery Appointment**

The clinician must submit documentation (e.g. clinic visit note) of the STARband fitting correctly when delivered to the patient, along with education and instructions to caregivers about care and cleaning of the orthosis, the 23-hour per day wearing schedule, and regular follow-up appointments.
- Evidence of Wearing Schedule Compliance**

Improvement in the overall head shape with minimal growth over bossed or prominent holding areas in the STARband indicates compliance with the orthotic wearing schedule, whereas global circumferential growth and/or minimal change in the head shape is an indication of non-compliance. The clinician must submit documentation that demonstrates patient compliance including a current scan, and basic manual measurements consistently obtained over the course of the STARband treatment program.
- Evidence of Exhaustion of Modification Options**

The clinician must submit documentation demonstrating that additional modifications are no longer possible to maintain optimal fit for continued correction. This includes photos/videos of the current orthosis on the patient with anterior, posterior, lateral and vertex views. Similar photos of the orthosis must be provided along with several views of the inner surface, contours and trim lines. On occasion, the existing STARband may need to be returned for further evaluation by Orthomerica's cranial team.
- Evidence of Concurrent Medical Diagnosis**

The clinician must submit documentation from the physician of a concurrent medical diagnosis or medical treatment that has impacted the use of the current STARband. Cases where the patient is not able to use the orthosis as expected such as an area of skin irritation or common infant fever, are not part of the One Headband Guarantee.

5. **Strategic Plan for 2nd Headband**

If minimal or no correction has been obtained with the current STARband, the clinician must provide appropriate documentation that substantiates why the second orthosis is expected to yield optimal results when the first one did not.

6. **Free 2nd STARband Commitment**

The clinician must provide written confirmation that the parents/caregivers/payers are not being charged for the second orthosis and/or associated clinical services.

7. **Acknowledgment of Only One STARband Needed for Over 98%+ of Patients**

Within their own cranial practice, the clinician acknowledges that using the standard STARband modifications and treatment protocols to regularly monitor compliance with the wearing schedule and fit of the STARband results in fewer than 2% of their patients requiring a second STARband to obtain optimal clinical results. The use of the One Headband Guarantee is for the rare case in which an age-appropriate patient with remaining cranial growth available is not able to obtain optimal treatment results with a single STARband. The One Headband Guarantee is not available for more than 2% of a clinician's STARband orders.