

CAREGIVER INSTRUCTIONS FOR WEAR AND CARE OF THE STARband® CRANIAL ORTHOSES

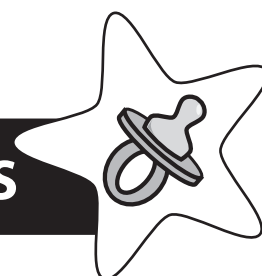
Your Doctor has prescribed a STARband for your baby. The STARband is a lightweight, custom molded head band designed specifically for your baby's head shape. The inside of the STARband has a rounded contour that will allow your baby to sleep and move around without putting weight on the flattened areas of the head. The STARband will not interfere with any of your baby's activities, and most caregivers report that their babies adapt to it quickly. The STARband is an effective treatment for babies between 3 and 18 months of age, and has been successfully used to treat babies with head shape problems since 2001. It is made from materials that are safe to use against the skin. You will be taught how to clean the STARband and check your baby's skin to prevent any problems. The STARband is a lightweight, plastic and foam band made from a casted impression of the baby's head. The flexible plastic outer shell is lined with polyethylene foam that is removed by the practitioner throughout the course of STARband treatment to allow for growth and to provide a pathway for your baby's head to grow into a more normal symmetrical shape. A stop gap foam insert fills the space in the side opening to reduce the likelihood of over-tightening the band. The STARband offers a simple solution for babies with abnormal head shapes. Correction usually occurs within 3-6 months when the baby begins orthotic treatment before 12 months of age. In older babies, a longer treatment program is necessary because the baby's head does not grow as rapidly after 12 months of age. The baby's active growth is a dynamic component of the treatment. Compliance to the twenty-three hour per day wearing schedule is crucial to a successful outcome. The head becomes more symmetrical and normally shaped as the baby's own growth is directed into the normal contours inside the STARband.

ABNORMAL HEAD SHAPES

Many babies are born with either flattened areas on the head or some other unusual head shape. The flattening can be caused by the head being constricted in the cramped space inside the womb or from the pressure of the birth process itself. Twins, triplets, and other multiples have even less space than single babies, so head shape problems are more common with this group. If the deforming forces are removed after birth, and the baby is placed in a variety of positions, it is possible for the head to become more rounded and symmetrical. But for some babies, the flattening does not disappear in the first few months, even with repositioning. When this occurs, the STARband is prescribed to guide the head into a symmetrical and well-proportioned shape. The most common types of abnormal head shapes are deformational plagiocephaly, asymmetrical brachycephaly, symmetrical brachycephaly and deformational scaphocephaly. Your practitioner will provide you with more information about how your baby's head shape will be directed into a more symmetrical and well-proportioned shape during the treatment program.

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TORTICOLLIS AND THE IMPACT OF SUSTAINED POSITIONING ON THE HEAD

It is possible that the flattening present at birth can worsen, especially if the baby's neck muscles are tight, weak, or asymmetrical. This condition is called torticollis, and it contributes to head shape problems by restricting head turning to one side or the other, and restricting the muscles that tip and extend the neck. When the baby has an abnormal head shape and torticollis, the torticollis must be treated along with using the STARband® Cranial Orthosis to correct the head shape.

Torticollis is usually treated by therapy 2-3 times a week for a specific period of time. A home program is also provided to help maintain the length of the neck muscles and promote the normal function of these muscles through normal developmental activities like rolling, sitting, crawling, and generalized play. Besides torticollis, another postnatal cause of deformational plagiocephaly occurs when the back of the baby's head rests for prolonged periods of time against a hard surface like an infant carrier, car seat, swing, or stroller. Before 1992, babies were put to sleep on their tummies, which varied the amount of pressure on the back of the head. However, since the very successful "Back to Sleep" program was initiated in an effort to end Sudden Infant Death Syndrome (SIDS), babies now spend all night on their backs until they are able to roll and reposition themselves. The Back to Sleep program has dramatically reduced the incidence of SIDS and is one of the most effective health programs ever initiated. Unfortunately, the combination of the carriers we use to hold and position our babies during the day and placing babies to sleep on their backs all night has increased the potential for the development of head shape deformities. Practitioners and caregivers should support the American Academy of Pediatrics Back to Sleep Program and encourage tummy time during the day while the baby is awake and supervised in order to minimize the effects of continuous supine positioning on the head.

CRANIOSYNOSTOSIS

The brain is rapidly growing in the first year of life. The bony plates of the skull are joined by fibrous sutures that allow the skull to expand in response to the brain growth. There is a medical condition that is less common than deformational head shape problems called craniosynostosis that causes the baby's head to grow abnormally. This condition appears to be similar to deformational deformities, but in craniosynostosis, the abnormal shape is caused by the premature closure of one or more sutures in the skull. The skull deforms because the restricted suture does not allow growth in that area.

Physicians, especially specialists like pediatric plastic surgeons or neurosurgeons, can usually differentiate the two conditions of deformational plagiocephaly and craniosynostosis by compiling a complete history, and performing a clinical assessment. The physician may order a test like a CT scan or MRI to make a more definite diagnosis if craniosynostosis is suspected. Surgery is the treatment of choice for babies with craniosynostosis. The surgeon removes the prematurely closed suture to allow the head to assume a more normal shape and growth pattern. Sometimes the surgeon orders a STARband after the surgery to either maintain the surgical correction, or to provide further correction of the head shape.

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WEAR AND CARE INSTRUCTIONS

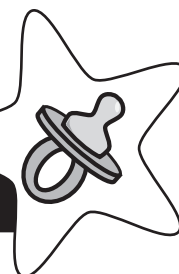
1. Your baby will eventually wear his or her STARband® Cranial Orthosis 23 hours a day, but needs several days to adjust to wearing the STARband. Follow the schedule below to gradually increase the wearing time. Do not accelerate this program, even if your baby is not having any problems. The wearing schedule below was developed to prevent skin problems and to help your baby adjust to the STARband.

DAY	ON	OFF	NAP	NIGHT
1	1 hr	1 hr	no	no
2	2 hrs	1 hr	no	no
3	4 hrs	1 hr	yes	yes
4	8 hrs	1 hr	yes	yes
5	23 hrs	1 hr	yes	yes

2. This wearing schedule provides a safe way to acclimate to the STARband. The fifth day is considered full time wear, and at this point, the STARband should only be removed for one hour per day. The STARband should be removed and cleaned during the baby's bath.
3. Remove the STARband if your baby has a fever or the flu. Return to full time wear as soon as possible. If the baby has not been able to wear the STARband for 48 hours, ramp up the wearing schedule slowly over a few days to help the baby adapt to wearing the STARband again.
4. If your baby has been diagnosed with torticollis, the torticollis must be treated in order to achieve head shape correction. If your therapist or physician has given you neck exercises to perform, remove the STARband for the exercises and replace the band as soon as the exercises are finished.
5. At bath time each day, remove and clean the STARband. Only use unscented rubbing alcohol to clean the inside of the STARband. Other cleaners such as soap, water, bleach, or perfume can cause skin irritation and should not be used inside the STARband. Vigorously rub the inside of the STARband with a clean washcloth containing the rubbing alcohol, or apply rubbing alcohol using a new soft toothbrush. Set the band upside down to dry. A fan, in addition to the rubbing alcohol, may be used to help alleviate odor that sometimes develops inside the band. Drying in the sun can also help to alleviate the odor and speed up the drying process.
6. Shampoo the baby's head daily, and reapply the STARband when both the head and the band are dry. Babies with very sensitive scalps may benefit from a mild, unscented hypoallergenic shampoo. The STARband should not get wet and should be removed for swimming. After swimming, wash your child's head with shampoo to remove chlorine, sunscreen, etc. Reapply the orthosis when both your baby's hair and the STARband are dry.
7. For the first several days, your baby may perspire excessively until his or her body becomes accustomed to the STARband. This is normal, and during this time, the STARband can be removed for a couple minutes throughout the day to dry the baby's head and band with a towel or cool hair dryer. The STARband should be reapplied as soon as the baby's hair and the band are dry. Do not use powders, lotions, or wipes on the baby's head or inside the STARband. These products may contain perfumes and ingredients that can lead to skin irritation. Dress your baby in cooler clothing if the baby perspires excessively.

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WEAR AND CARE INSTRUCTIONS *(continued)*

8. If the baby develops a rash, consult your Doctor immediately. Also keep the baby as cool as possible, and towel or blow dry the baby's hair and the inside of the band throughout the day with a cool hair dryer to prevent moisture buildup. Replace the STARband as soon as the band and hair are dry. Time out of the band should be less than 10 minutes.
9. If you need to cut your baby's hair during STARband® Cranial Orthosis treatment, do not shave the entire head. The contact of the band against the head may cause irritation when the hair starts to grow back in and the baby may develop skin irritation. Try to keep your baby's hair the same length throughout treatment to prevent fitting problems that may result from a decrease or increase in the amount of hair.
10. Skin checks should be performed every time the STARband is removed. Call your practitioner immediately if there is an area of deep redness that does not fade in one hour after removing the band. This may indicate a need for an adjustment. If there is any skin breakdown, remove the band and contact your Doctor. The STARband should not be worn until the skin is healed.
11. Excessive time out of the STARband (more than 48 hours) may create problems with the fit of the STARband since the baby's head is growing continuously. Limit the time out of the STARband, and seek assistance when something prevents your baby from tolerating or wearing the band.
12. Each time you place the STARband on the baby's head, check the chafe, strap, and stop gap foam insert to make sure they are secure. Loose parts can be a choking hazard and can result in asphyxiation if the parts are swallowed.
13. When the STARband is off your baby's head, keep the STARband away from family pets. Dogs have been known to chew the plastic and foam liner.
14. The STARband must be worn as prescribed, 23 hours a day, to constrain further abnormal growth and encourage growth in the correct locations. Even at the end of treatment, the band should be worn 23 hours a day until the physician, practitioner and caregiver agree that treatment is complete.
 - a. Early discontinuation of treatment against medical advice may result in incomplete correction of the head shape.
 - b. Continued use of the STARband against medical advice may restrict skull growth and may impair brain growth and development.
15. Explain the purpose of the STARband to other caregivers, and train them in the proper application, removal, and wearing schedule. Training is important for family, friends, daycare personnel, and any other person taking caring of your baby.
16. If you have questions or concerns about your baby's care, contact your practitioner so that any issues can be resolved quickly. Information and resources are available for caregivers on Orthomerica's website at www.starbandkids.com. Orthomerica wishes you and your baby a most successful STARband experience.

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