Caregiver´s Guide

DEFINING COMFORT

DEAR CAREGIVERS,

This simple guide is filled with valuable information on how to care for your little one while wearing their cranial remolding orthosis. It will cover the different types, and provide helpful suggestions for use during daily activities. Included are examples of positioning to help prevent or stop the worsening of any deformity.

We hope you find this information helpful and practical on your child‘s individual journey for successful treatment.

CONTENTS

1

SUMMARY OF TREATMENT WITH THE USE OF AN ORTHOSIS

1.1 Cranial Remolding Orthosis

FOR CHILDREN AGED BETWEEN 3 AND 18 MONTHS

Head shape deformities became more frequent after the Back to Sleep Program focused on preventing SIDS*. Nowadays, more than 3% of newborn babies** have a severe or very severe head shape deformity. Up to 50% have a mild or medium deformity.

Talee Cranial Remolding Orthosis is lightweight and patient-specific. The inner part of the orthosis is round-shaped, allowing the child to sleep and move without any pressure on the flattened area of the head. The orthosis does not interfere with any children's activities and most parents say that their child adapted quickly.

Research*** shows that orthotic treatment using a helmet is the most effective solution for a severe head shape deformity. The cranial orthosis offers a simple solution for children with an abnormal head shape. The head becomes more symmetrical when its growth is guided in the right direction by the orthosis.

*SIDS - Sudden Infant Death Syndrome. It seemed to occur most often when babies slept on their bellies.

**Deformational plagiocephaly: a follow-up of head shape, parental concern and neurodevelopment at ages 3 and 4 years; B L Hutchison, A W Stewart and E A Mitchell; Archives of Disease in Childhood September 2010.

***Effectiveness of Conservative Therapy and Helmet Therapy for Positional Cranial Deformation. Steinberg et al; Plastic and Reconstructive Surgery; March 2015

1.2 Indication

The Talee and the Talee PostOp are the Cranial Remolding Orthoses intended for medical purposes for infants from 3 to 18 months of age with moderate-to-severe cranial deformities.

The Talee is used for infants from 3 to 18 months with moderate-to-severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic- shaped heads and a combination of these defects.

The Talee PostOp is used for infants from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

1.3 Talee and Talee PostOp

Remolding principle

The Cranial Remolding Orthosis (Talee/Talee PostOp) has contact with the head in the prominent regions and a precisely pre-defined internal space in the areas where flattening occurs. When wearing the orthosis, the head is only allowed to physiologically grow in the predefined space of the Cranial Orthosis, which improves the cranial symmetry and/or physiological shape.

During treatment, the Cranial Orthosis is checked regularly by a physician/clinician to ensure proper treatment at all times. At the regular check-ups, a clinician monitors the growth and makes sure that a precise fit is maintained. Adjustments are made to the device as needed to accommodate growth and/or optimize the function of the Cranial Orthosis.

1.4 Treatment Duration

Treatment Duration - Talee

The duration of treatment varies. It depends on how old the child was when the treatment began and how quickly he/she is growing. Children younger than 12 months often complete the treatment within 4–6 months. Older children usually need longer treatment since their skull is only growing slower and becoming stronger, therefore, more resistant to change.

Treatment Duration - Talee PostOp

The treatment usually takes 12 months and requires 3 different remolding orthoses.

A cranial remolding orthosis is not indicated in children younger than 3 months. Rather, children younger than 3 months respond well to positioning. After three months, the baby starts turning and changing positions independently, and therefore, positioning loses its meaning. In this period, physicians reassess the shape of the baby's head to determine whether the baby needs treatment with a cranial remolding orthosis. Once a baby is 12 months old, their brain and skull are no longer growing as fast as in that first year. The latest that treatment can start is at 14 months old and must finish by the time the baby is 18 months old.

1.5 Wearing Schedule

A 23-HOUR WEARING SCHEDULE IS CRUCIAL TO ACHIEVING SUCCESSFUL RESULTS

The orthosis is worn 23 hours a day to prevent any further abnormal skull growth. Wearing the orthosis for less than 23 hours a day could prevent optimal results, or even cause problems with the skull shape. The orthosis is worn 23 hours a day even towards the end of the treatment.

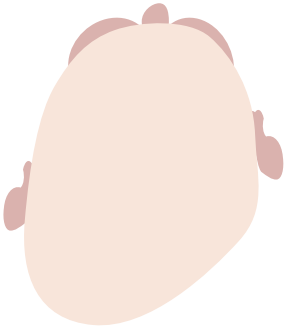
There are several cases when the orthosis is not worn: with a fever or flu, during a bath, or when he/she receives daily treatment. The orthosis can also be taken off during physiotherapy. Failure to follow the wearing schedule may result in rescanning and manufacturing a whole new orthosis.

Day	Orthosis put on	Orthosis taken off	Wearing for sleep/nap	Note
1.	1 hour	1 hour	No	Repeat the cycle throughout the day
2.	2 hours	1 hour	No	Repeat the cycle throughout the day
3.	4 hours	1 hour	No	Repeat the cycle throughout the day
4.	8 hours	1 hour	Yes	Repeat the cycle throughout the day
5.	23 hours	1 hour	Yes	Begin the complete wearing schedule

After Day 5, the orthosis should be worn throughout the day with two half-hour breaks, the first in the morning and the second in the evening.

1.6 Common Head Deformities in Children

Plagiocephaly (pic. 1) is a simple skull deformity. This shape is often associated with Torticollis or other cervical spine impairments which prevent full range of motion in the cervical spine. This results in the baby keeping his/her head in one position for a long time, causing flattening. Deformational Plagiocephaly usually poses a serious problem which should be treated in children with a moderate to very severe degree of head flattening.

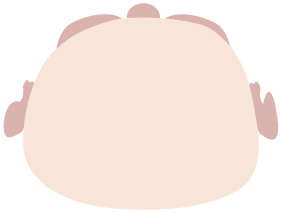


Pic. 1 Plagiocephaly

The head has the following characteristics

- In the back of the head, there is (posterior) flattening on one side, and a prominent area on the other side.
- The ear is noticeably shifted forward on the side of posterior flattening.
- The forehead is shifted forward on the same side as posterior flattening.
- The eye and face may also be shifted forward on the side of posterior flattening, resulting in facial asymmetry.

Symmetrical Brachycephaly (pic. 2) is a deformity relating to the proportionality of the child's head. This shape is most common for children that tend to lie supine for majority of the time without turning their head to the sides. It's a serious problem which should be treated in children with moderate to very severe head flattening.



Pic. 2 Symmetrical Brachycephaly

The head has the following characteristics

- Flattening is centered in the back of the head.
- The head is unusually wide with parietal prominence on both sides.
- Seen in profile, the head is higher and more flattened than usual.
- The forehead is prominent and may be shifted forward on both sides.

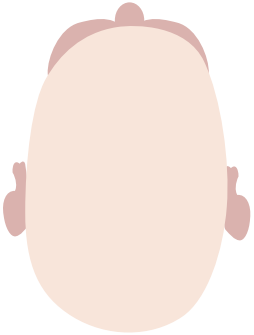
In children with Asymmetrical Brachycephaly (Pic. 3), the unusual head shape is caused by a combination of Plagiocephaly and Brachycephaly. This shape is often associated with Torticollis, which prevents free movement in the cervical spine. In moderate to very severe cases, this deformity is a serious problem and should be treated with an orthosis.

Pic. 3 Asymmetrical Brachycephaly

The head shows the following characteristics

- Both rear sides of the head are flattened (posterior flattening), but one side is flatter than the other.
- The head is unusually wide.
- The head may be higher than usual, and, possibly even higher on one side than on the other.
- The ear may be shifted forward on the side of greater posterior flattening.
- The forehead on the side with greater posterior flattening may also be shifted forward.
- The eye and face on the side of greater posterior flattening may also be shifted forward, resulting in facial asymmetry.

In children with Scaphocephaly (Pic. 4) the head is long and narrow. This cranial deformity is caused by a premature closure of sagittal cranial suture also called sagittal craniosynostosis. Scaphocephaly is the most common type of craniosynostosis. We see a similar head shape in the positional deformity, non-synostotic scaphocephaly. This condition most often occurs as a result of the baby spending most of their time on his/her side. Lying on the side is especially common in premature babies at a neonatal intensive-care unit. In moderate to very severe cases, this deformity is a serious problem and should be treated with a remolding orthosis.



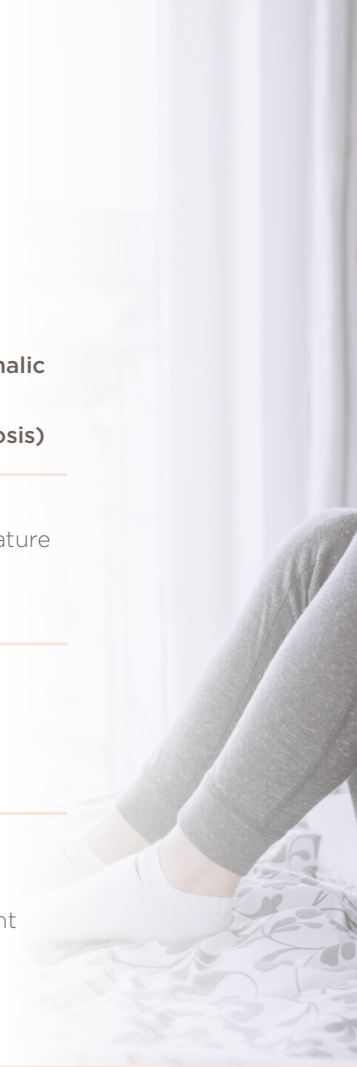
The head shows the following characteristics

- The head is unusually long and narrow
- Asymmetry may occur at the right and left diagonal dimension.

Pic. 4 Scaphocephaly

The head shapes of synostotic and non-synostotic scaphocephaly are very similar but follow different treatment steps. Therefore it is important for physicians to carry out the appropriate examinations to distinguish between these two conditions.

Non-synostotic Scaphocephalic head shape	**Synostotic Scaphocephalic head shape (Sagittal Craniosynostosis)**
Case history of premature birth	No case history of premature birth
No border along the sagittal suture	Visible border along the sagittal suture
The head shape is not worsening	The head shape is worsening in the course of development



1.6.1 Torticollis and Effects of Positioning

Flattening might worsen after birth, especially if the neck muscles are in tension, weakened, or asymmetrical. This condition is known as Torticollis and contributes to problems with the head shape by preventing the head from turning to one side. Torticollis must be treated, along with the use of a cranial remolding orthosis.

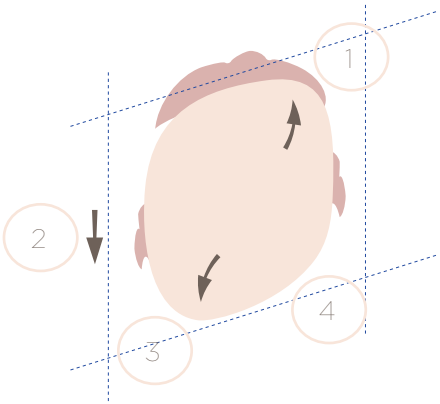
Torticollis treatment is usually done 2–3 times per week. A home exercise program is also important. It helps maintain proper length of the neck muscles and supports the function of these muscles in common activities such as turning, sitting, crawling, and playing. In addition to Torticollis, another possible cause of postnatal deformational Plagiocephaly, could be lying on their back for extensive periods of time against a hard surface – e.g. child seats, car seats, swings, strollers. Before 1992, children used to be put to bed on their bellies which kept the weight off the rear of their head. The "Back to Sleep" campaign had great success in significantly reducing the incidences of the Sudden Infant Death Syndrome (SIDS). On the other hand, using child seats and putting children to sleep on their back throughout the night gave rise to the development of head deformities.

1.6.2 Craniosynostosis

One of the less frequent causes of an unusual head shape is a condition known as Craniosynostosis. Some types of Craniosynostosis manifest themselves, like Plagiocephaly. Craniosynostosis, and the unusual shape of the skull‘s growth, is caused by one or more cranial sutures sealing prematurely. Physicians distinguish between the two conditions through medical examinations. If Craniosynostosis is suspected, the specialist will order more intensive tests, such as CT or MR, to confirm the diagnosis. If a child indeed has Craniosynostosis, surgery is required to correct the bones so that both the brain and skull can continue to grow normally.

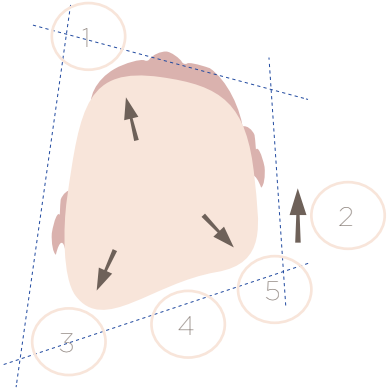
The head shape of children with Craniosynostosis varies depending on which suture is impaired and to what extent. Only physicians can diagnose Craniosynostosis. Children experiencing any symptoms described below should see a physician to diagnose or exclude Craniosynostosis:

- Children with an unusual head shape and a palpable or visible seam along the cranial suture.
- Children with a head shape that is worsening despite positioning.
- Children with diagnosed Plagiocephaly whose condition is not improving or is worsening, despite therapy using a cranial orthosis, in compliance with the treatment program.



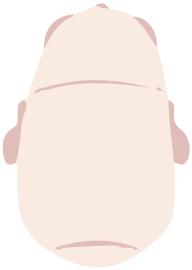
Pic. 5 Right-sided Plagiocephaly

1. Frontal bossing
2. Posterior ear shift
3. Contralateral occipital bossing
4. Occipito-parietal flattening

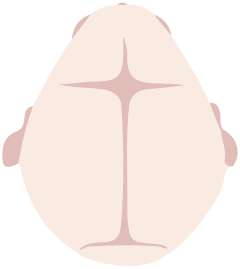


Pic. 6 Right-sided lambdoid Craniosynostosis

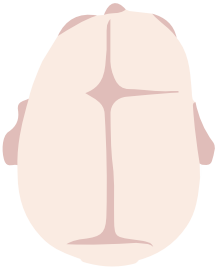
1. Contralateral frontal bossing
2. Anterior ear shift
3. Contralateral parietal bossing
4. Occipito-parietal flattening
5. Occipitomastoid bossing



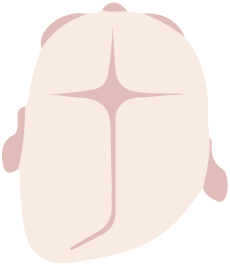
Pic. 7 Saggital synostosis



Pic. 8 Metopic synostosis



Pic. 9 Unicoronal synostosis



Pic. 10 Lambdoid synostosis

Craniosynostosis without surgical correction is a contraindication for the cranial remolding orthosis therapy.

The Cranial Remolding Orthosis can be used for infants between 3 to 18 months of age whose synostosis has been surgically corrected, but who still have cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

(For illustrative purposes only)

2. Talee is Unique

We combined our clinical experience with technical strengths to create a revolutionary, patent-pending, bio-responsive technology.

BREATHABLE
The perforation makes the orthosis breathable and reduces sweating.

LIGHT
We leverage the full potential of 3D printing to make Talee as light as possible.

THIN
Talee is so thin, that babies shortly forget they are even wearing a helmet!

3

INSTRUCTIONS FOR WEARING AND CARE

1. Your child should wear the cranial remolding orthosis 23 hours a day, but the first week will be different so that he/she may gently adapt to the process. Follow the schedule of gradually increasing the wearing period. For your child's safety, do not rush the schedule even if your child experiences no inconvenience. The wearing schedule was developed to both help your child adjust to the orthosis, as well as prevent skin irritations. The fifth day begins the full 23 hour wearing period.
2. Do not use the orthosis when your child is feverish (temperature over 38°C / 100.4 °F). If he/she is running a temperature (up to 38°C / 100.4 °F), he/she can wear the orthosis, but you should check his/her temperature regularly. If it rises, stop wearing the orthosis. Resume the normal schedule as soon as possible.
3. During physiotherapy, the orthosis can be removed. Always consult your physiotherapist. Put the orthosis back on as soon as possible after rehab.
4. Take the orthosis off, clean it, and disinfect it every day. The 1-hour break, in which the Orthosis is not worn during the day, should be divided into two 30-minute breaks for morning and evening hygiene. Use only a non-perfumed, alcohol-based disinfectant to clean the inner surface of the orthosis (other agents may be harmful for your child's skin). Wipe the inner surface of the orthosis properly, either with a clean cloth or a new, soft brush, using an alcohol-based agent. Wipe the orthosis dry. You can use a low-temperature hairdryer to dry the orthosis out – this also helps reduce any odor that might ensue.
5. Wash your child's head every day using shampoo. Put the orthosis back on once both the head and orthosis are dry. Children with very sensitive head skin may want to use hypoallergenic or natural shampoo. The orthosis should not get wet and should be taken off while bathing. Put the orthosis back on after bathing once both the head and orthosis are dry.
6. Your child may sweat excessively the first few days until his/her body adapts to the orthosis. During this early period, it's typical to take the orthosis off for a few minutes and dry both the head and orthosis with

a towel or a low temperature hairdryer when needed. The orthosis should be put back on after having been dried out. Do not use any baby powder, creams, or towels on your child's head beneath the orthosis. These products may contain perfumes or substances which may lead to skin irritation. Dress your child in appropriate clothes to prevent excessive sweating.

7. If your child needs a haircut during the treatment, do not shave his/her head entirely. The contact of the head with the orthosis may lead to irritation when the hair begins to grow. Try to keep the same hair length throughout the treatment to prevent any problems with the shape that may result from greater or lesser volume.
8. Always check the skin after taking the orthosis off. If there is any redness that does not disappear within one hour of taking the orthosis off, contact your orthotist immediately. This may indicate that the orthosis needs to be adjusted. If there is any skin damage, take the orthosis off and contact your orthotist. The orthosis should not be used until the head heals over.
9. If the orthosis is off for more than 48 hours, there may be some difficulty putting the orthosis back on due to skull growth. Limit the time without the orthosis and contact your orthotist if you cannot put the orthosis on.
10. When putting the orthosis on, always check the straps and apertures to make sure they are safely fastened. Loose parts could be dangerous if inhaled or swallowed.
11. While the orthosis is removed, ensure that it is kept away from direct sunlight, excessive heat, pets, and children. Never let children play with the orthosis or fastening strap.
12. Explain the purpose of the orthosis to other caregivers and teach them how to use, care for, and remove the orthosis properly. Practice is important for family, friends, and any other caregivers for your child.
13. If you have any questions or concerns about the care for your child, contact your orthotist. Any issues should be addressed quickly.

4

FREQUENTLY ASKED QUESTIONS

How do I know if the orthosis is fitted correctly or needs to be adjusted?

After taking the orthosis off, if you do not see any red spots on your baby‘s head, or if these spots disappear within the 1-hour daily treatment break, the orthosis is fitting correctly and suitable for wearing.

How can we treat the head’s skin?

Treat the skin with your usual daily routine. Wait for the cream to absorb. Make sure to wait until both the head and orthosis are dry before putting it back on. In the case of prickly heat or contact dermatitis, use creams to soothe and dry out the skin, not petrolatum-based ointments. If unsure, contact your orthotist.

How do I tell pressure sores from contact dermatitis?

If there is a red spot that does not disappear within 1 hour of taking the orthosis off, it is likely contact dermatitis or a pressure sore. First, treat the spot with the cream you are accustomed to using (any protective cream or sensitive skin lotion).

Line the contact point inside the orthosis with a thin cotton plaster and put the orthosis back on. After two to three hours, check the skin to see if there is any improvement. If the skin is soothed, with no signs of irritation, or it‘s noticeably getting better, repeat the process. It is contact dermatitis. Some children may have more sensitive skin, so it will need to be treated like this several times a day. If you have followed the instructions to treat the skin, but see no improvement,

leave the orthosis off for about 3–4 hours. It is a pressure sore and the orthosis might need to be adjusted. Contact your orthotist. Until you can get in to have your orthosis adjusted, treat the spot on the head with cream, and line the spot in the orthosis with a thin cotton plaster.

What do I do if my child hasn't been wearing the orthosis for several days?

If your child hasn't been wearing the orthosis for several days, check for pressure sores on his/her head. Put the orthosis on for about 2–3 hours and then take a break (take the orthosis off). Treat the orthosis and head as usual and wait for any potential pressure sores to disappear. If they disappear within 1 hour, put the orthosis back on, make the application time longer, and then take a pause again. Repeat this procedure until you resume the 23 hour a day wearing schedule. This procedure may take up to 2–3 days. If the pressure sores do not disappear within 1 hour and you fail to resume the wearing schedule, contact your orthotist as soon as possible.

How long until we can see some improvement?

It depends, but usually there is already very apparent improvement after only two weeks of wearing (First Checkup). The greatest skull growth occurs in the first months of wearing the orthosis.

5

POSITIONING OPTIONS

An asymmetrical head shape may be partly improved through thorough and repeated positioning of the child while sleeping and during other activities. It depends on the child's age and the degree of deformity. The goal of positioning is to take the pressure off the impaired area.

5.1 Sleep

Pic. 11 Example of positioning for sleep

- Your baby should always be on his/her back while sleeping.
- Change the position of lights in the room to encourage your child's tendency to turn his/her head. Infants turn their head towards light.
- After your baby falls asleep, turn his/her head to the unaffected side.

5.2 Playing

Pic. 12 Example of positioning while playing

- When the baby is awake, turn them onto their belly and use toys for stimulation.
- Parents often say their children don't like lying on their belly. This may be a result of weak back muscles. Use a rolled towel under your child's chest to lift their shoulders.
- Cross your legs and put your child on them so that they are lying on their belly. Support your child from below at their buttocks by your hands. You can stimulate your child in this position using toys.
- Lying on their belly not only eliminates the pressure exerted on the affected side of the head, but allows your baby to exercise their neck, back, and shoulder muscles.

5.3 Feeding

- Alternate which side you hold your baby for feeding.
- Support your child's head on the unaffected side.

Pic. 13 Example of positioning for feeding

5.4 Traveling

- Limit the time that the baby spends on a hard surface – e.g. in a child seat.
- Use a folded towel or something soft in the car seat to make your baby turn their head onto the unaffected side.

Pic. 14 Example of positioning while traveling

6

WARNINGS

Warning: The infant's skin must be evaluated by the practitioner and caregiver at frequent intervals (e.g. every 3 to 4 hours) for skin irritation or breakdown.

Adverse event/effect: This device may cause skin irritation or breakdown. Discontinuing treatment against medical advice can result in less head shape correction. Extending treatment against medical advice may restrict head growth and impair brain growth and development.
Not following the recommended wearing schedule may result in significant difficulties fitting the orthosis. Any treatment interruption must be consulted with your practitioner.

Warning: Carefully evaluate the device for structural integrity and fit to reduce the potential of the device slipping out of place or parts of the device becoming loose and causing asphyxiation or trauma to the infant‘s eyes or skin.
Warning: Never try to modify the cranial orthosis at home. If any adjustments are needed, please contact your clinician immediately.

Should you have any questions regarding treatment using your cranial remolding orthosis, please contact your medical professional.

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℞only This device is for prescription use only