

kinder  **BAND**™
CRANIAL ORTHOSIS HELMET

Practitioner & Caregiver
Labeling Information

Special Controls
WARNINGS AND CONTRAINDICATIONS
(for Practitioners)

INDICATIONS FOR USE: The kinderBAND™ Cranial Orthosis Helmet is intended for use on infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape.

Sale, distribution and use of this device is restricted to prescription use in accordance with 21 CFR 801.109.

CONTRAINDICATIONS: This device is not for use on infants with craniostynosis or hydrocephalus.

WARNINGS: Evaluate head circumference measurements and neurological status at intervals to appropriate to the infants age and rate of head growth. A clinician or caregiver must evaluate the patients' skin at frequent intervals. For complete instructions follow the described in the *Skin Check and Trouble Shooting for Wear and Care of Cranial remolding helmet* labeling sheets

PRECAUTIONS: If the positional plagiocephaly is associated with torticollis, the torticollis must also be treated. Evaluate the device's structural integrity and fit carefully. Use the following information provided in *Directions for fitting, Tips for Trimlines, strategies for improving fit and Adjustment of cranial remolding helmet* to help reduce the potential for the device to slip out of place and cause asphyxiation or trauma to the infant's eyes and skin.

ADVERSE EFFECTS: This device may cause skin irritation or breakdown.

INSTRUCTIONS: Use the enclosed labeling sheets, entitled Practitioner's Instructions, for proper scanning, measuring, ordering, fitting, troubleshooting, adjusting and care of the device.

The materials used in construction of the helmet have been assessed for biocompatibility with testing appropriate for long term direct skin contact.

The Interview and Questionnaire

Parents are understandably concerned about the skills, credentials, and attitudes of the professionals who treat their children. It is best to involve the parents immediately in the treatment program because it engages them in the process and promotes cooperation and compliance. Parents play an active role in implementing any cranial orthosis helmet program and without their full support, the treatment may be ineffective. Find an atmosphere that is comfortable and informal and start by inquiring about what steps brought the parents and child to your office.

Guiding parents through the *Patient Information Sheet* is often a useful tool for establishing contact with the parents. Try to get a sense of what the parents expect and answer any questions they have about the treatment protocols. Enlisting the parent as an assistant will initiate the team approach that will be crucial to the success of the orthosis. The shape acquisition process is discussed on the following pages. It is helpful to reassure the parents that the process is not dangerous. Their child may fuss and get upset, but it is time-limited and a very important part of the process. Describe the procedure to the parent, talk reassuringly to the child, and ask the parent to assist you. If the parent is uncomfortable with this, you can enlist the help of another adult.

Clinical Photographs

Photographs are an excellent way to document pre- and post-treatment results. They are effective tools to use with insurance companies to quantify positive clinical outcomes. In addition, they provide the referring physician, practitioner and parents with visual feedback. If you plan on using these pictures for case studies, research, or promotional purposes make sure that you have the permission of the parents and have a signed consent form on file. When taking pictures, the infant's head should fill as much of the frame as possible.

Two photographs are particularly helpful as a point of reference:

Photograph 1: Take a close-up of the child looking straight into the camera.

Photograph 2: Have the parent suspend the child horizontally in space at about the parent's waist level. Take the picture from above, trying to include the entire top of the child's head, and position of the ears.

Repeat these pictures at the end of treatment, or more often as necessary for documentation. Note where the flat spots are located; describe the ear position, eyes, forehead, and any other pertinent features. The Orthometry form can be used to document these areas.

Patient Information Sheet

Please answer the following questions so that we may treat your child effectively.

Date: _____

1. Child's Name: _____ Date of Birth: _____
2. Child's Gender: M F
3. Birth Weight: _____ Birth Length: _____ Number of weeks at birth: _____
4. Did you notice anything unusual about the way the baby was positioned in utero?
 Yes No
 If yes, please explain: _____
5. What type of birth (*check all that apply*): Single Multiple Vaginal
 C-Section Head-down Breech Forcep Suction
6. Were there problems during delivery?
 If yes, please explain:

7. When did you notice your child's head shape was different? _____
8. Did your child have to spend long periods of time in one position for the first weeks or months of life? Yes No
 If yes, why? _____
9. Do you have other children? Yes No
 Number of male _____ Number of female _____
10. Did any of your other children have differently shaped heads? Yes No
 If yes, please explain:

11. Does your baby have any neck tightness? Yes No
12. Have you or a physical therapist used exercises to stretch your baby's neck before beginning treatment for a cranial helmet? Yes No
13. Does your child participate in an early intervention program? Yes No
 If yes, give details of the program _____

Patient Information Sheet

- 14. During the day my child lies on the left or right side of the head. R L
- 15. When you walk in to my child’s room the crib is on which wall?
 Left of door as you enter Right of door Straight
- 16. As you face the crib, which end of the crib is the infant’s head? R L
- 17. What position does your baby like to sleep in? _____
- 18. Can your child can hold their head up and look around? Yes No
- 19. Does your child respond to voices both the left and right side and they are able to turn and look? Yes No
- 20. My child is in daycare or with a sitter _____ days a week.

I give my permission for this data/photos to be used for clinical studies or presentations. All data/photos will be HIPAA Compliant to safeguard the patient’s privacy.

Signature of Parent/Guardian _____ Date _____

Signature of Orthotist/OT _____ Date _____

*Thank you for taking the time to answer these questions.
It will help us to better serve your child*

Practitioner's Instructions: Shape Acquisition Process – Scanning

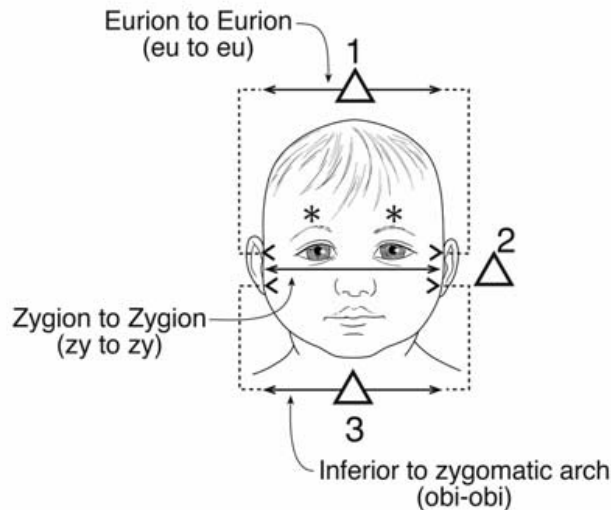
(see kinderBAND™ Scanning PowerPoint)

1. Take the caregiver and infant to the exam room and make sure the lights are low and there is some sort of white noise to help both relax.
2. Review patient information sheet with the caregiver.
3. Ask the caregiver to undress the infant down to the diaper. Drape the infant with a white shirt.
4. The infant is to be seated on the caregiver's knee(s) facing the caregiver.
5. Explain to the caregiver how the shape is acquired and show the speed and accuracy of scanning by scanning your own hand.
6. To get the maximum exposure of the neck, ask the caregiver to give gentle distraction downward to the infant's shoulders by gently pulling the infant's upper arms down perpendicular to the floor.
7. Once the caregiver is comfortable and the infant is positioned, cover the head with the scanning hood. Give the infant a toy to focus on – something with lights and perhaps music that will provide distraction.
8. Attach the transmitter to the top of the scanning hood.
9. Begin scanning, starting on the posterior aspect of the head. Scan down to the shoulder level and continue around using superior to inferior sweeps with the scanner.
10. When you get to the face, you **must** shield the infant's eyes with your hands. Shielding of the eyes is mandatory.
11. Start at the level of the brow and work superiorly to the top of the head. Then start at the cheeks and scan inferior to the level of the clavicle.
12. Working quickly and precisely, scan the entire head. When complete, the total number of sweeps should be between 5 and 7.
13. Once the scanning process is complete, take digital photos. Complete the Order form and all Key (Secondary) Measurements.
14. Allow the caregiver time to dress the infant. Schedule an appointment for fitting the orthosis in the next 10 days.

Key Measurements: Explanation

Key (Secondary) measurements are crucial for qualifying data is accurate, complete and pertinent to the fabrication and clinical protocol.

We ask for four spanned dimensions and a circumference at the equator. All dimensions are to be given in millimeters. Equipment needed for this task are outside calipers with smooth rounded point, a good quality woven non-stretch tape, 300 mm steel ruler and our Orthometry form. Topographical landmarks and description are below.



eu (eurion): the most lateral point on the head (identified in opposition, see below)

1. **eu-eu (1)** (maximum cranial breadth), measured by spreading calipers: slide both tips of caliper down lateral sides of parietal bones, then move caliper tips forward and back until maximum width (eurions) is reached.

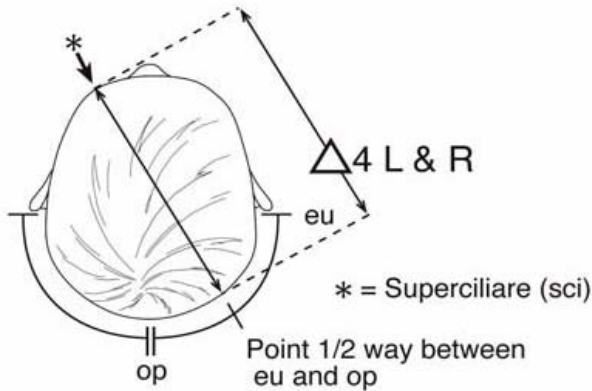
zy (zygion): the most lateral point on the zygomatic arch.

2. **zy-zy (2)** (maximum facial breadth), measured by spreading caliper: by palpation, locate the most lateral point of the zygomatic arch with the tips of index fingers and place the caliper tips on the arches with enough pressure to feel the bone. Move the caliper back and forth, up and down to identify maximum diameter.

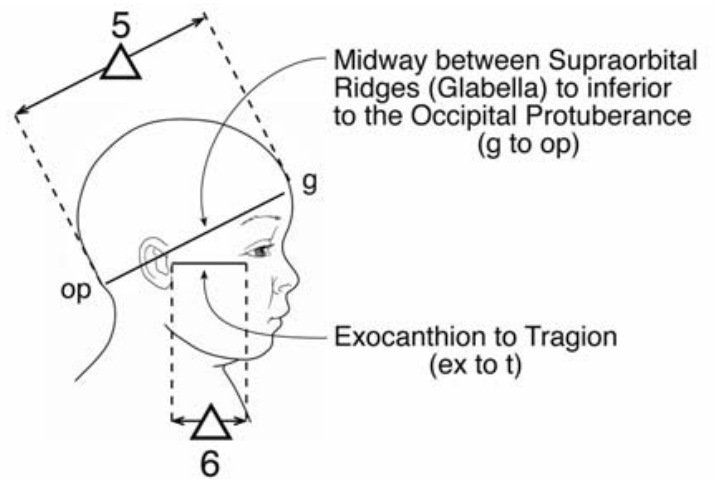
Obi (otobasion inferius): the lowest point of attachment of the external ear to the head.

3. **obi -obi (3)** (otobasion inferius): (external ear to the head breadth), measured by spreading calipers: slide both tips of caliper down lateral sides of parietal bones, then move caliper tips forward and back until maximum width (eurions) is reached.

Key Measurements: Explanation (continued)



4. **Maximum and minimum diagonal diameter (4):** a point ½ between eu and op to the frontal boss on L and R side. Measured on the left and right sides of the head using spreading calipers: hold the anterior tip of caliper to superciliare, touch posterior tip lightly to a point ½ between eu and op. Reverse for other side of head.



g (glabella): the most prominent point in the median sagittal plane between the supraorbital ridges.

op (opisthocranium): the most prominent posterior point on the occiput.

5. AP **g-opb (5)** measured on the midline of the head calipers: hold the anterior tip of caliper lightly to glabella and posterior tip to opisthocranium.
6. ex-t (6) (orbito-tragial distance, also referred to as upper cheek depth), measured on the left and right sides of the face using spreading calipers: hold the anterior tip of caliper to exocanthion, touch posterior tip lightly to tragus. Reverse for other side of face.

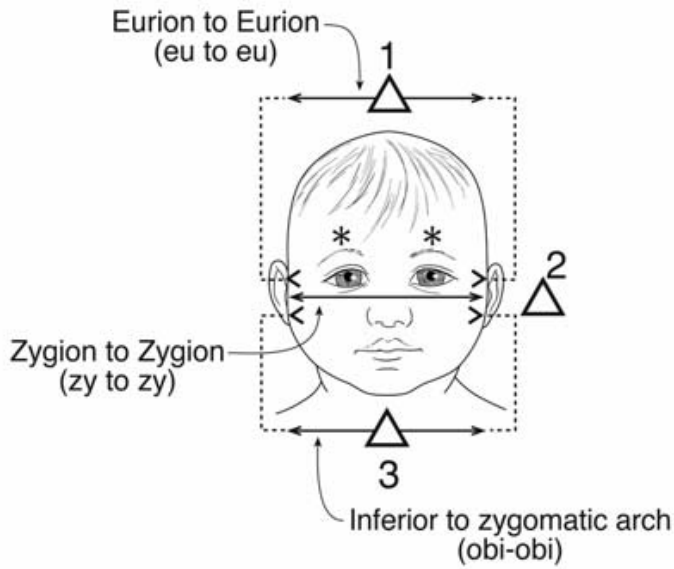
ex (exocanthion): the outer corner of the eye fissure where the eyelids meet.

t (tragon): at the notch above the tragus of the ear where the upper edge of the cartilage disappears into the skin of the face.

7. **Head circumference**, measured by tape: encircle the tape around the head covering glabella and opisthocranium, do not stretch tape too tightly.

Key Measurements: Guide

Key Measurements: Please take all of the measurements indicated below and enter them at the bottom of Key Measurement Form - Page 2.



1. Eurion to Eurion



2. Zygion to Zygion

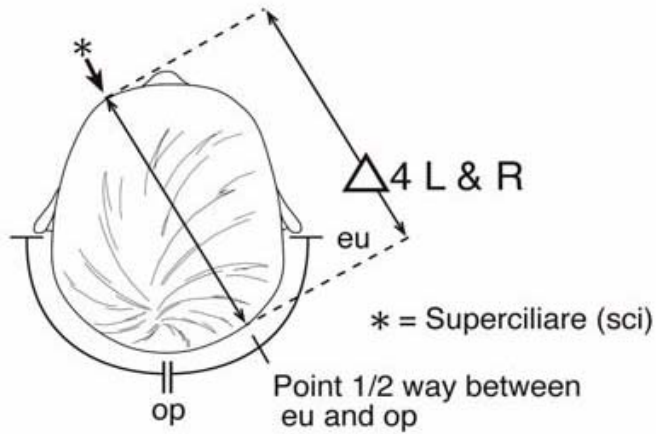


3. Inferior to Zygomatic Arch

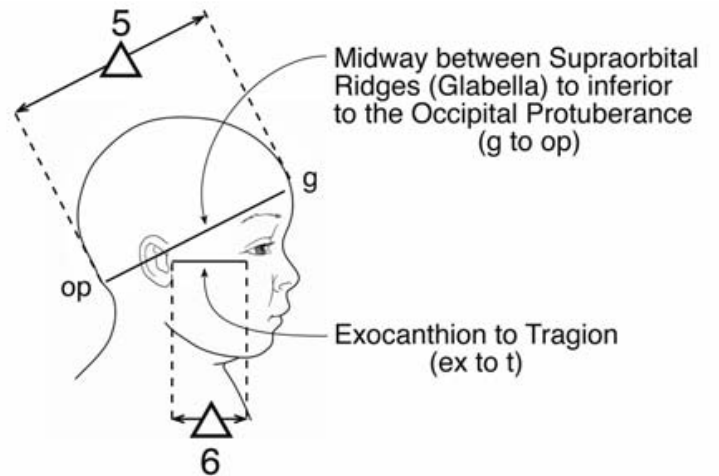


Key Measurements: Guide (continued)

4. Diagonal Diameter



5. Glabella to Occipital Protuberance



Key Measurements

6. Exocanthion to Tragon



- OPTIONAL 1. _____
- OPTIONAL 2. _____
- OPTIONAL 3. _____
- MANDATORY** 4L. _____ 4R. _____
- OPTIONAL 5. _____
- OPTIONAL 6. _____
- MANDATORY** 7. _____

kinderBAND™ Order Form

Cranial helmets must be fit within 14 days of being scanned or cast

Infant's Name: _____ Date Needed: _____
 Date of Birth: _____ Diagnosis: _____
 Corrected Age in Months: _____ Practitioner: _____
 Gender: Female Male Facility Name: _____
 Physician: _____ Shipping Address: _____
 Date of Scanning/Casting: _____
 Billing Address: _____
 _____ Telephone: _____ Fax: _____
 P.O #: _____ Shipping: UPS Next Day 2nd Day Ground

Type of Model: Scan - Modified Negative Impression – Modified* Positive Mold - Modified
 Scan - Unmodified Negative Impression – Unmodified*
Send All Clinical Photos: Front/Back Left/Right Top

**Attach Anterior & Posterior photos of infant in the cast. Casts must meet BioSculptor Quality Control standards. Please contact us if you would like to view our casting protocol.*

IMPORTANT: See Key Measurement Form for instructions (Please complete MANDATORY measurements for manufacturing purposes. Optional measurements are for reporting purposes)

Eurion to Eurion 1. _____
 Zygion to Zygion 2. _____
 Inferior to Zygomatic arch 3. _____
 Max. & Min. Diagonal Diameter 4L. _____ 4R. _____ **MANDATORY**
 Glabella to inf. to Occipital Protuberance 5. _____
 Exocanthion to Tragion 6. _____
 Head Circumference (above eyebrows) 7. _____ **MANDATORY**

Head Shape (check all boxes that apply) *Deformation must be of nonsynostotic origin or post surgical correction*

Occipital Area: Flattening bilaterally R>L L>R
 Parietal Area: Flattening right Flattening left Biparietal narrowing
 Ears: Right anterior ear shift Left anterior ear shift
 Head Height: Increased right Increased left Increased posterior
 Frontal Area: Flattening right Flattening left Frontal bossing
 R>L L>R
 Other: Right orbit anterior Left orbit anterior Narrowed fissure
 Right malar eminence Left malar eminence R L

Modification: (check one)

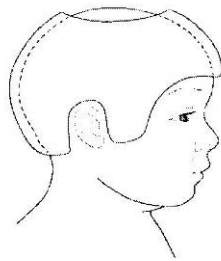
Correct asymmetry; Correct proportion to projected circumferential head growth
 Full Correction of asymmetry and cranial vault height asymmetry
 Correct asymmetry only

Primary Asymmetry Modification: Posterior Anterior
Neck Modification: Defined Sub-Occipital Groove Neck Smoothed and Left "As Is"

kinderBAND™ Order Form

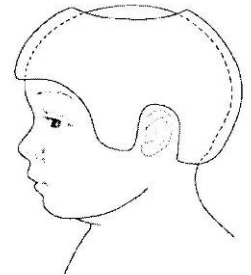
Check the appropriate box below. Defaults are in ***BOLD ITALICS***

- Trimlines: ***As illustrated below:***
- Side Opening: ***Side opposite of posterior flattening*** Same side of posterior flattening Other
- Top Opening: ***Oval*** D-Trim BioSculptor to determine by head shape
- Optional Holding Caps: Anterior Right Anterior Left Posterior Right Posterior Right



Right Lateral

Default trimlines will be used unless indicated on surrounding diagrams. Please also indicate any special instructions below:



Left Lateral

Material: ***Standard Helmet: 3/16" white copolymer - 1/2" layer white polyethylene foam - 1 1/2" Dacron strap***

Transfer design: ***None*** Yes: Transfer # _____ (Designs and #s shown on Order Form - Pg 3)

- Finish: ***Trimmed & Finished*** Blank on Mold and Split
- Chafe Attachment: ***Anterior to slot opening*** Posterior to slot opening Do not attach

Head Shape (modifications specified by Practitioner)

- | | | | | | | | |
|-----------------|--------|-------------------------------|-------------------------------|---------------------------------|--------------------------------|--|--|
| Occipital Area: | Bilat: | <input type="checkbox"/> <2mm | <input type="checkbox"/> <4mm | <input type="checkbox"/> <6mm | <input type="checkbox"/> <8mm | <input type="checkbox"/> <10mm | <input type="checkbox"/> <12mm |
| | R: | <input type="checkbox"/> <2mm | <input type="checkbox"/> <4mm | <input type="checkbox"/> <6mm | <input type="checkbox"/> <8mm | <input type="checkbox"/> <10mm | <input type="checkbox"/> <12mm |
| | L: | <input type="checkbox"/> <2mm | <input type="checkbox"/> <4mm | <input type="checkbox"/> <6mm | <input type="checkbox"/> <8mm | <input type="checkbox"/> <10mm | <input type="checkbox"/> <12mm |
| Parietal Area: | R: | <input type="checkbox"/> <2mm | <input type="checkbox"/> <4mm | <input type="checkbox"/> <6mm | | | |
| | L: | <input type="checkbox"/> <2mm | <input type="checkbox"/> <4mm | <input type="checkbox"/> <6mm | | | |
| Frontal Area: | R: | <input type="checkbox"/> <2mm | <input type="checkbox"/> <4mm | <input type="checkbox"/> <6mm | | | |
| | L: | <input type="checkbox"/> <2mm | <input type="checkbox"/> <4mm | <input type="checkbox"/> <6mm | | | |
| Par. widening: | R: | <input type="checkbox"/> <2mm | <input type="checkbox"/> <4mm | <input type="checkbox"/> <6mm | | | |
| | L: | <input type="checkbox"/> <2mm | <input type="checkbox"/> <4mm | <input type="checkbox"/> <6mm | | | |
| | | | | | Torticollis: | <input type="checkbox"/> Right | <input type="checkbox"/> Left |
| | | | | | | <input type="checkbox"/> Constant radius (U shape) | <input type="checkbox"/> Smooth as presented |
| Head Height: | | <input type="checkbox"/> +R | <input type="checkbox"/> +L | <input type="checkbox"/> + Post | <input type="checkbox"/> + Ant | | |
| | | <input type="checkbox"/> <2mm | <input type="checkbox"/> <4mm | <input type="checkbox"/> <6mm | <input type="checkbox"/> <8mm | <input type="checkbox"/> <10mm | <input type="checkbox"/> <12mm |

Send Instructions

- Checklist - Items to Send**
- Order Form
 - Scan or Cast
 - All Photos – Clinical & Cast

Electronic: www.noplaster.com

Mail: BioSculptor
2480 West 82nd Street, 1A
Hialeah, Florida 33016

Contact:
T 877.246.2884
F 305.823.8304

Transfer Paper: *NOTE – Due to heat and plastic, transfer patterns may appear slightly different on helmet.*



Ocean
CL-1



Butterflies
CL-2



Butterfly, Purple
CL-3



Butterfly, Blue
CL-4



Camouflage
CL-5



Jumbo
CL-6



Jungle Animals
CL-7



Martians
CL-8



Dark Sky
CL-9



Fly & Drive White
CL-10



Fly & Drive Blue
CL-11



Little Bear, White
CL-12



Little Bear, Orange
CL-13



Light Pink
CL-14



Military 2 Camouflage
CL-15



Ice Age 2
CL-16

Measurement Progression Form (optional)

Use this form to track progress of treatment using the kinderBAND™.

Week 1: Starting Measurements

Max. & Min. Diagonal Diameter L. _____ R. _____

Head Circumference (above eyebrows) _____

Week 2-3:

Max. & Min. Diagonal Diameter L. _____ R. _____

Head Circumference (above eyebrows) _____

Week 3-4:

Max. & Min. Diagonal Diameter L. _____ R. _____

Head Circumference (above eyebrows) _____

Week 4-5:

Max. & Min. Diagonal Diameter L. _____ R. _____

Head Circumference (above eyebrows) _____

Week 5-6:

Max. & Min. Diagonal Diameter L. _____ R. _____

Head Circumference (above eyebrows) _____

Week 6-7:

Max. & Min. Diagonal Diameter L. _____ R. _____

Head Circumference (above eyebrows) _____

Week 7-8:

Max. & Min. Diagonal Diameter L. _____ R. _____

Head Circumference (above eyebrows) _____

Week 8-9:

Max. & Min. Diagonal Diameter L. _____ R. _____

Head Circumference (above eyebrows) _____

Week 9-10:

Max. & Min. Diagonal Diameter L. _____ R. _____

Head Circumference (above eyebrows) _____

Week 10-11:

Max. & Min. Diagonal Diameter L. _____ R. _____

Head Circumference (above eyebrows) _____

Practitioner's Instructions: Fitting Instructions

- Care should be taken when fitting cranial helmets.
- Have the caregiver hold the child on their lap.
- The practitioner will spread the helmet slightly, position the posterior inferior border distal to the occipital equator and with a firm quick motion pull it down to encompass the head. This is best accomplished with speed and precision.
- Look at the quality of the fit. Is the distal anterior margin parallel with the distal edge of the brow or glabella? It is extremely important to keep as much coverage as possible to prevent localized areas of pressure.
- The more frontal coverage the quicker good molding results can be achieved.
- The posterior aspect should cover the mastoid foramen.
- The fit laterally should be close with only 1mm clearance between the top of the ears and the helmet.
- Side extensions should be parallel with the ramus of the mandible.
- Areas to avoid pressure include the Zygomatic arch and the orbit. These are covered with thin skin and are prone to breakdown.
- Helmets work on a 4 point control system - 2 points stabilize diagonally across coronal and sagittal plane with anterior posterior stability maintained by being distal to the mastoid foramen and maintaining a long, broad trim line from the glabella covering the frontal boss. There should be no pressure over the lesser developed frontal boss as this is an area that we would like to have a correction in. Diagonally in the coronal sagittal plane in the opposite direction of stability, there are 2 non contact areas. This allows the head to grow with control in to the voids.
- When initially fit, it may look like the helmet is too big. As the child's head grows both in length and circumference the helmet will be less of a focal point as material is being removed from the inside of the helmet.
- It is extremely important to keep as much coverage as possible to prevent localized areas of pressure. The posterior aspect should cover the mastoid foramen. In some cases this may initially limit head extension. As growth occurs this will become less of a factor.

Practitioner Instructions: Strategies for Improving Fit

Problem: The helmet is sliding over both eyes

The anterior trimline at the forehead must be right above the eyebrows or it will not provide appropriate purchase on the head. If it is not catching the forehead the trimline is probably too low.

The anterior trimline should not be lower than the eyebrows. Trim this just barely above the brow.

If the first two scenarios are fine, consider adding an occipital pad. Test the likelihood of this working by placing a finger inside the posterior occipital section of the orthosis. If this prevents the orthosis from slipping down over the eyes, add the occipital pad, being careful to avoid adding pressure over the occiput that could lead to flattening.

If all of the above possibilities are fine, the slippage may be due to the infant having a very flat occiput. Often adding an occipital pad on a brachycephalic head will not correct the problem at all and it will only make the orthosis dig in to the occipital area as it rides up on the head.

Problem: The helmet slides or twists sideways

Try adding an occipital pad.

This may happen if you are modifying the orthosis too much in the parietal region and not enough in the occipital midline.

You may be losing contact in the temporal region when material is removed there. If this is allowing the orthosis to lose contact with the head, replace part of the thickness there.

Orthoses that are on asymmetrical heads sometimes rotate slightly. This should resolve as a more symmetrical head is modeled.

Problem: Facial correction is not occurring

This is sometimes a problem if there is neck muscle asymmetry. Check to see if there is tightness on one side that was not noticed before.

Check to see how the parents have been doing with the neck exercises. They may have decreased the frequency or the time.

Make sure that the neck tightness is addressed or facial correction will not be optimal.

If there is no improvement in facial correction and/or no orthosis correction, despite exercises being done, have health care team reassess the treatment program.

It is more difficult to achieve skull base changes in older children.

Facial correction, especially to the molar eminence, may not be as dramatic as corrections to the cranial vault. Ear asymmetry may not correct completely.

Practitioner Instructions: Follow-Up Visits

A series of follow-up appointments is needed to monitor the child's progress and make modifications to the helmet. These scheduled visits should be two or three weeks apart to optimize treatment. If the family is having any problems with the helmet between visits, the child should be seen as soon as possible to ensure that the orthosis is fitting properly. More frequent appointments may be needed with some patients at times of rapid growth, to correct problems, or to ensure compliance. Begin each visit by asking the parents how the helmet treatment has been processing. Ask specifically about the number of hours the child has been wearing the orthosis, and discuss the importance of wearing the helmet 23 hours per day if this has not been happening. The following items should be assessed at each visit:

1. **SKIN INTEGRITY:** Remove the helmet and inspect the child's skin. Make adjustments necessary to correct any problems. This may involve grinding away liner if it is determined that there is too great a pressure in a certain area.
2. **FLAT AREAS:** Each time the child comes in for an adjustment, assess the symmetry of the child's head. Make sure that there is space built in to the helmet for the flattened areas to expand. Continue to remove the foam inside the helmet so that the head can continue to grow in the desired direction. Place ventilation holes over the void (flat spot) and using a probe make sure there is no contact.
3. **HIGH SPOTS:** As the flattened areas begin to fill in, it may be necessary to add a pad over the "high spots" to maintain contact and to continue directing the growth of the head in the desired direction.
4. **AIR HOLES:** 3/8" air holes may be drilled in the helmet for heat dissipation, as well as to check areas of contact and relief.
5. **OVERALL FIT:** Make sure the helmet is well seated on the head. As the head circumference increases as a function of normal growth, adjust the inside liner to accommodate the growth. Make sure that the child's pediatrician or referring physician is assessing head growth at every visit to monitor normal development.
6. **END OF TREATMENT:** When the child outgrows the helmet, or the helmet is discontinued for any reason, contact the referring physician. To document the changes that occurred during the helmet treatment, repeat the same photographs that were taken at the beginning of treatment and place a copy in your files. If the family wants to pursue an additional helmet to get more correction, refer them back to their physician for a reevaluation and a new prescription.

Practitioner Instructions: Skin Check and Troubleshooting

1. For the first two days an infant wears the helmet a caregiver should do skin checks every one to two hours and at frequent intervals thereafter.
2. If the skin is bright red in a specific area (and does not disappear in 15 to 30 minutes), the helmet should be relieved by either grinding or removing about 1/16" to 1/8" of foam liner in that spot only or relieving the plastic with a heat gun.
3. Most pressure problems are usually seen in the first week, and then towards the end of treatment when the child begins to outgrow the helmet. If there are pressure problems at times other than these, check the caregiver's application procedure. If that is correct, make adjustments as in #2 above.
4. Infants often perspire excessively for the first few days in the helmet until the child's body accommodates to the orthosis and some children develop skin irritation due to perspiration. The irritation usually looks like a large area of redness in the area of total contact such as the forehead or occiput. If either perspiration or irritation is a problem ask the caregiver to remove the helmet for a few minutes throughout the day to clean and dry the infants head and before replacing it try using A&D ointment for relief, or consult your physician. If the irritation continues, a textile cranial interface may be worn between the patients head and the orthosis.
5. Infants sometime develop white flaking over large areas of skin without redness. This is acceptable and no modification is needed.
6. Use only reagent grade isopropyl alcohol inside the helmet. Other products using perfumes, Clorox, etc. can leave residue and cause irritation.
7. Infants who have a shunt need very close monitoring in any cranial molding orthosis. The first time a helmet is fit, observe the child over a 30 to 45 minute time period. At that time check the shunt for any pinkness or redness. If any pinkness or redness does occur, remove the orthosis and modify the foam or re-contour the plastic to relieve that area. Caregivers should be instructed to remove the helmet if they see any sign of pinkness or redness over the shunt and contact their Orthotist for an immediate adjustment.
8. The orthosis must be worn 23 hours a day to constrain any undesirable growth and encourage growth in the correct locations. Even at the end of treatment the helmet should be worn 23 hours a day until treatment is stopped. There are a few times when it is acceptable to remove the helmet. These are: when the child has a high fever (104°F), flu, day surgery, bath time, and when swimming. Rescanning/recasting may be necessary if the helmet is not worn for an extended period of time.

Practitioner Instructions: Adjustment Instructions

Modifications should be made to the area of the orthosis where you want volume to fill in the void. Check for no contact with a probe through the ventilation holes.

Space has been built into the orthosis, so for the first week or two, adjustments may not be required. The child should still be assessed by the Orthotist during this time.

1. Modifications will be necessary as the flat areas begin to increase in volume and fill the void.
2. Approximately 1mm of liner should be removed at each visit. The modification should be fairly symmetrical, i.e., if you remove material from one area, it's likely you will need to remove the same amount from another area that also needs room for volume to fill in.
3. An orthosis is outgrown if any of the following conditions exist
 - a. It digs into the parietal region where the orthosis opens. This should not happen before all liners are removed.
 - b. The orthosis does not rest properly on the child's head and is circumferentially outgrown.
 - c. The orthosis leaves excessive redness – usually in the forehead area.
4. Length time the orthosis is effective:

Age At Beginning of Treatment	Average Time for the Orthosis to be Effective
3 month old child	Two months
5 month old child	Three months
7 month old child	Four months

5. The orthosis becomes ineffective between 3 and 4 months of use because it is no longer able to exert corrective forces on the head. This is true even if the orthosis still fits after wearing it for four months. When the child outgrows the orthosis or the orthosis fails to provide corrective forces, reassess whether to fabricate a new cranial molding helmet to get further correction or stop treatment if the results are satisfactory.



For Parents/Caregivers

Special Controls WARNINGS AND CONTRAINDICATIONS

- **INDICATIONS FOR USE:** The kinderBAND™ Cranial Orthosis Helmet is intended for use on infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape.
- Sale, distribution and use of this device is restricted to prescription use in accordance with 21 CFR 801.109.
- **CONTRAINDICATIONS:** This device is not for use on infants with untreated craniosynostosis or unshunted hydrocephalus.
- **ADVERSE EFFECTS:** This device may cause skin irritation or breakdown.
- **INSTRUCTIONS:** Follow the enclosed labeling sheets for proper usage and care of the device.
- The materials used in this orthosis have been assessed for biocompatibility with testing appropriate for long term direct skin contact.

Caregivers Guide to the kinderBAND™ and Positional Plagiocephaly

Plagiocephaly is an asymmetrical molding of the head caused by external forces. It can be caused by a number of factors involving positions such as extended time in a neonatal unit, the birth process, the position in the womb and often the infants preferred sleeping position. It can also be caused by a condition called torticollis. In this case there is asymmetry in the muscles on either side of the neck that flex the head, tip it and turn it to the opposite side. When one of these muscles is tight it causes the baby to sleep primarily on one side and the back of the head tends to flatten there. The entire side including the ear moves forward as the head assumes a parallelogram shape. In many cases, there is bulging of the forehead on the same side.

There is another condition called Craniosynostosis that creates a head shape deformation that can resemble positional plagiocephaly. However, this condition is caused by premature fusion of the sutures of the skull. The skull can assume a very unusual shape if one or more of these sutures close before the child's brain achieves full growth. Neurosurgeons or plastic surgeons can often differentiate these two conditions based on observations, but more definitive tests like CAT scans or MRI can clarify the diagnosis. If the child has Craniosynostosis, surgery may be necessary to realign the plates of the skull and allow normal growth to occur. Infants with Craniosynostosis should be seen by a specialist for this condition.

Positional plagiocephaly does not affect the brain, and is not the cause of mental retardation, cerebral palsy or seizures if not treated. If the baby is quite young (say, less than 3-4 months), if the deformity is mild, and if the baby can be persuaded to sleep with his/her head to the other side, this may be all that is required. Turning the crib around the other way may help. Your pediatrician may also recommend stretching exercises for the torticollis as well. Otherwise, a custom fitted cranial molding helmet may be recommended.

Purpose

The cranial molding helmet is a custom made orthosis available by prescription only. It is used to treat children between three and 18 months of age for abnormal head shapes such as positional plagiocephaly and brachycephaly. Properly used, the molding helmet promotes facial and skull symmetry through passive constraints during the period of rapid growth of the infant's cranium. Cranial molding helmets have been successfully fitted when used under the prescription of a pediatric neurosurgeon or craniofacial surgeons. The cranial molding helmet encourages growth into the concavity formed in the helmet. Furthermore the helmet can easily be adapted to the growing skull size and shape by removing layers of its lining. The orthotic is made from a three dimensional (3D) digital model of the infant's cranium acquired with BioScanner™ orthotic and prosthetic digitizing system. The BioScanner was specifically developed for use in the orthotic and prosthetic fields. It is a two camera laser measurement system with repeatable accuracy of 0.005 inch. Data is sent in an encrypted HIPAA compliant manor to our ftp server. A corrected positive model is machined from the scan; this is used as a tool to form the device. The positive mold is then used to form a foam and plastic shell. Each orthosis is made of an outer shell of plastic and an inner shell of foam, a strap and buckle are used for securing the orthosis and an optional removable spacer is supplied as a safety mechanism. The treating clinician modifies the orthosis for precise fit and monitors to ensure that no severe or adverse reaction occurs.

The Second Appointment

At the time of the second appointment the helmet will be fit and guidelines and instructions will be given to all caregivers. Your practitioner will also guide you through the procedures for applying and removing the helmet with guidelines for taking care of the helmet and recognizing possible trouble signs.

Follow-up Appointments

Regular follow up appointments will be scheduled every two to four weeks. If you have any questions or concerns, do not wait for the follow up appointment. As your child grows, the helmet may be difficult to get on and leave red spots for more than one hour when removed. If you have concern regarding a matter such as this, please do not wait for your scheduled appointment.

Care of the Helmet

Once a day, wipe the inside and outside of the helmet thoroughly with reagent grade isopropyl alcohol (wintergreen is preferable due to its pleasant scent) to destroy bacteria and remove residues that may cause irritations. Use only reagent grade isopropyl alcohol. Allow the helmet to dry well. When the helmet is completely dry, put the helmet back on the child for the rest of the evening and night.

Usage Time for the First Week

The first week is critical. This schedule allows the baby to become accustomed to the helmet. Ultimately the baby will be in the helmet most of the time so that he or she becomes used to it. The recommended schedule for the first four days is:

<u>Helmet is</u>	<u>on</u>	<u>off</u>	<u>on for nap</u>	<u>on for the night</u>
Day 1	1 hour	1 hour	no	no
Day 2	2 hour	1 hour	no	no
Day 3	4 hour	1 hour	yes	yes
Day 4	8 hour	1 hour	yes	yes
Day 5 & beyond	23 hours	1 hour	yes	yes

This cycle is repeated through the day, giving slight breaks for hot weather or messy foods that may discolor the foam or mark skin with food stain. The fifth day is considered full time wear. The helmet should not be worn for baths or in the pool. The liner should be patted dry with a clean dry towel. We do not recommend using talcum powder as this dries in the liner and may be abrasive to the skin. Continuous wearing time through the time of treatment is important. If the helmet is tight before your appointment with the Orthotist, or if you notice red pressure points on the skin, call and make appointment as soon as possible with the Orthotist who made the helmet.

Other Tips

- 1) Keep away from pets
- 2) Hydrocortizone for red areas
- 3) Try to loosen the helmet and see if the red areas subside
- 4) Call your Orthotist for further directions and any questions you may have
- 5) Make sure everyone that helps apply and remove the helmet knows the appropriate technique for doing so and the proper way to clean it