

Ballert Cranial Molding Helmet

Practitioner & Caregiver Labeling Information

Ballert Orthopedic



SPECIAL CONTROLS
Ballert Orthopedic
Ballert Cranial Molding Helmet
WARNINGS AND CONTRAINDICATIONS
(For Practitioners)

1. The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.
2. **CONTRAINDICATIONS:** This device is not for use on infants with craniosynostosis or hydrocephalus.
3. **WARNINGS:** Evaluate head circumference measurements and neurological status at intervals appropriate to the infant's age and rate of head growth. A clinician or caregiver must evaluate the infant's skin at frequent intervals. For complete instructions follow the steps described in the *Skin Check and Troubleshooting, Directions for Fitting Ballert's Cranial Molding Helmet*, and the "Cranial Molding Helmet Instruction Sheet" labeling sheets.
4. **PRECAUTIONS:** If the positional plagiocephaly is associated with torticollis, the torticollis must also be treated. Evaluate the device's structural integrity and fit it carefully. Use the following information provided in *Directions for Fitting Ballert's Cranial Molding Helmet, Strategies for Improving Fit*, and *Adjustment of Ballert's Cranial Molding Helmet* to reduce the potential for the device to slip out of place and cause asphyxiation or trauma to the infant's eyes or skin.
5. **ADVERSE EFFECTS:** This device may cause skin irritation or breakdown.
6. **INSTRUCTIONS:** Follow the enclosed labeling sheets *Ballert Cranial Molding Helmet Casting Procedure, Directions for Fitting Ballert's Cranial Molding Helmet, Skin Check and Troubleshooting*, and the *Cranial Molding Helmet Instruction Sheet* for proper casting, fitting and care and use of the device.
7. The materials used in Ballert's Cranial Molding Helmet have been assessed for biocompatibility with testing appropriate for long-term direct skin contact.

These Warnings and contraindications comply with the special controls established for the predicate device. They are to be used with Ballert's Cranial Molding Helmet.



SPECIAL CONTROLS
Ballert Orthopedic
Ballert Cranial Molding Helmet
WARNINGS AND CONTRAINDICATIONS
(For Parents/Caregivers)

1. The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.
2. This device is not for use on infants with craniosynostosis, scaphocephaly or hydrocephalus.
3. **ADVERSE EFFECTS:** This device may cause skin irritation or breakdown.
4. **INSTRUCTIONS:** Follow the enclosed *Cranial Molding Helmet Instruction Sheet* for proper care and use of the device.
5. The materials used in Ballert's Cranial Molding Helmet have been assessed for biocompatibility with testing appropriate for long-term direct skin contact.

These Warnings and contraindications comply with the special controls established for the predicate device. They are to be used with Ballert's Cranial Molding Helmet. This information to be contained in the instruction sheet.



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 Ballert's orthotic 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 Ballert's treatment protocols. Enlisting the parent as an assistant will initiate the team approach that will be crucial to the success of the orthosis.

The casting procedure 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 picture 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. Some may find it easier to lay the baby on the exam table.

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 can treat your child effectively.

Date: _____

Patient's Name: _____ Date of Birth: _____ M F

Birth Weight: _____ Birth Length: _____ Number of weeks at birth: _____

What type of birth (*check all that apply*):

One child Multiple Head-down Forceps Breech Suction
Cæsarean Vaginal

Were there problems during delivery: _____

Did you notice anything unusual about the way the baby was positioned in utero? Y N

If yes, please explain: _____

Does your baby have any neck tightness? Y N

Have you or a physical therapist used exercises to stretch your baby's neck before beginning treatment for a cranial helmet? Y N

What position does your baby like to sleep in (before orthotic treatment)? _____

Did your child have to spend long periods of time in one position for the first weeks or months of life? Y N

If yes, why? _____

Did your child's head appear to be normally shaped at birth? Y N

At what age did you first notice your child's head was abnormally shaped? _____

Do you have other children? Y N Number of male _____ Number of female _____

Did any of your other children have abnormally shaped heads? Y N

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



PRACTITIONER INSTRUCTIONS

CASTING PROCEDURE

HAVE THE FOLLOWING SUPPLIES READY BEFORE CASTING THE PATIENT:

1. One 6 layer stock of 4" wide extra fast setting plaster splints, 7" long
2. Four 6 layer stacks of 6" wide extra fast setting plaster splints, 6" long
3. 1 ply BK sock with a small hole cut out for the child's face
4. 2 pairs of gloves for the practitioner and the parent
5. 14" stockinette with the sides cut open and a hole cut in the middle to sue as a poncho
6. Bandage scissors
7. Indelible pencil
8. Soap to use as a separating agent
9. Container of lukewarm water
10. Clean towels and a sink to wash up.

Set Up: Ask the parent to undress the child down to the diaper. Place the 14" stockinette with the hole cutout over the child's head like a poncho so it provides protection from the plaster. Have the child sit on the parent's (or caregiver's) lap. Drape the parent to prevent plaster from soiling his or her clothes.

Place the BK sock over the child's head with the face open. Make sure the stockinette covers the entire eyebrow, ears, and the outside part of the cheeks.

With the indelible pencil, mark the midline at the top of each ear and trace the anterior aspect of each ear. Mark the midline and lateral aspect of each eyebrow.

Splint 1: Dip the 4" x 7" plaster splints into the water. Four to six layers seem to work best, applied two at a time. Smooth the plaster throughout the gauze and get most of the water out of it. Lay the splint lengthwise from the entire forehead including the eyebrows to the back of the head. Smooth to get total contact.

Splints 2 and 3: Prepare one of the 6" stacks of plaster splints for the right side, and position it so that it overlaps the forehead splint. Extend the splint down towards the jaw, incorporating the side of the cheek and ear. Work the plaster in well, making sure to delineate the ear. Place one hand on top of the head and the other hand over the right ear and hold while the plaster cures. Repeat this procedure for the left side.

Splint 4: Prepare another 6" stack of splints and lay them over the top of the head.

Splint 5: Prepare the last 6" stack, add liquid soap or Vaseline to the edges to act as a separator, and lay the stack across the back of the head to neck level.

Use one hand to lock in the base of the occiput, and the other to provide counter stability at the forehead. Hold until the plaster is cured. Use the indelible pencil to cross hatch the back panel where it overlaps the other sections.



Carefully remove the back panel. Cut the stockinette under the child's chin and at the back of the head, and carefully lift off the plaster mold. Remove the stockinette from the inside of the impression. The inside of the impressions should be smooth with no gaps in the plaster. Lay the impression on its back to dry. Provide the parent with an area and supplies to clean up the child, including a soft cloth, mild baby soap, and a clean towel. The parent can then dress the child, and schedule an appointment for the fitting. The child should be fit with Ballert's Cranial Molding Helmet within two weeks of the casting.



PRACTITIONER INSTRUCTIONS FOR FITTING THE BALLERT CRANIAL MOLDING HELMET

1. The orthosis has been designed for the practitioner to finalize the trimlines at the time of the fitting. The definitive orthosis will be designed and trimmed to provide the best corrective position based on the type and severity of the child's plagiocephaly.
2. The helmet can be safely spread open without compromising the plastic. The plastic will return to the original shape once it is in place.
3. Fasten the Velcro[®] strap through the chafe and close the Velcro[®] so that the helmet closes completely. There is correction built in to the Ballert Cranial Molding Helmet, and it does not need the Velcro[®] pulled over-tight to work effectively.
4. Use the following guidelines to determine the correct fit and trimlines:
 - a. **EYES:** Trim so that the eyebrows are barely visible. It is important that this trimline be as inferior as possible to help keep the helmet in the correct position on the head. Trim around the eyes to allow growth in the frontal area. Laterally, the temporal portion should be extended to the edge of the eye orbit without disrupting peripheral vision. The plastic should be trimmed away or a void created if there is a flat area there.
 - b. **EARS:** Keep the trimline close to the ears, especially on brachycephalic infants to provide as much total contact as possible in this area. If the plastic is too narrow here, the brachycephalic head tends to bulge at the ears. Asymmetrical heads need maximum plastic through this area to prevent "twisting" of the orthosis. Pressure directly over the ears should be avoided. You may maintain a more open trimline at the ear in the direction you would like the ear to move.
 - c. **FLAT SIDE OF THE FACE:** Make sure the temporal piece is not digging in on the flat side. Recontour this extension if it is pressing into the temporal region. Be cautious about trimming this extension because reducing its length may cause the helmet to rotate.
 - d. **SUPERIOR OCCIPITAL REGION:** If this is trimmed down too low and the head protrudes through the top, the orthosis may create undesirable head height. If the plastic is too high, the helmet will not get good purchase on the head.
 - e. **SUBOCCIPITAL REGION:** Sometimes the helmet rides up if the child is young and still has poor head control. Trim the inferior posterior edge long enough to get good purchase and still allow sufficient head extension. Suboccipital padding may be added to help control rotation..
 - f. **PARIETAL REGION:** The side opening should not have a gap where it fastens.
5. **WOBBLE:** Some wobble is to be expected, especially in the first few weeks on very asymmetrical heads. The helmet will tend to move in the direction of the deformity. If the helmet is too wobbly, a 1/8" or 3/16" suboccipital pad can be applied. Test this by placing a finger under the posterior distal edge of the helmet. If this increases the helmet stability, an suboccipital pad will probably be helpful.



6. OCCIPITAL PAD: Determine the midpoint of the area just below the occipital protruberance and shape a polyethylene foam wedge to conform to it. This should promote better purchase and provide an anchoring point for fixation. Avoid placing the pad more too high (wedge should not be at or superior to the occipital protuberance) so you do not impinge on the occipital area and create flattening there.
7. SKIN: Check the skin after 20 minutes. The skin should show signs of total contact (i.e., pinkness) in the areas providing the corrective forces. Extremely white or dark red areas are not acceptable levels of pressure and indicate that the internal pressure may be too high within the helmet. As a first strategy, remove 1/8" of the foam liner material from the specific area of pressure.
8. DIRECTIONS: Give the parents written and verbal directions for care of the helmet. Be available to answer their questions by phone or in person during an office visit.



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. In all cases, the occipital pad should be inferior to the occipital protuberance, and in this instance a lower pad even to the upper cervical area may keep the helmet in place. If none of this works, the helmet may have to be tightened laterally in the parietal and temporal areas because often this is a result of over-correction in modifications.

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 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, if exercises are being done and there is no orthosis correction, have the 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 progressing. 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. Moleskin may be added in areas where persistent rash develops.
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. We find that a pedilan foam sanding cone works best. 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 helmet treatment, repeat the same photographs that were taken at the beginning of treatment and place a copy in your files. If the

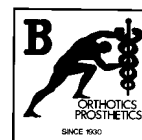


family wants to pursue an additional helmet to get more correction, refer them back to their physician for a reevaluation and a new prescription.



PRACTITIONER INSTRUCTIONS SKIN CHECK AND TROUBLESHOOTING

1. For the first two days an infant wears the helmet, the caretakers should do skin checks every 1-2 hours and at frequent intervals thereafter.
2. If the skin is bright red in a specific area (and it does not disappear within 15 to 30 minutes), the helmet should be relieved by either grinding or removing about 1/16" to 1/8" of the 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 parent's application procedure. If that is correct, make the adjustment 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 an area of total contact such as the forehead or occiput. If either perspiration or irritation is a problem, ask the parent to remove the helmet for a few minutes throughout the day to clean and dry the infant's head and helmet before replacing it. Hydrocortisone cream may help improve the skin condition quickly and can be applied to the head after bath time. If hydrocortisone is used, it should be applied very sparingly and if redness or rash grows worse, discontinue the hydrocortisone (the child may be allergic to it) and consult the patient's pediatrician. Aveeno makes a shampoo that is soothing to itchy skin and often provides relief.
5. Infants sometimes develop white flaking over large areas of the skin without redness. This is acceptable, and no modification is needed.
6. Use only rubbing alcohol inside the helmet. Other products containing perfume, Clorox, etc. can cause irritation.
7. Infants who have a shunt need very close monitoring in any cranial molding orthosis. The first time the helmet is fit, observe the child over a 30-45 minute time period. After that time, check the skin and shunt for any sign of pinkness or redness. If any pinkness or redness does occur, remove the orthosis and modify the foam or recontour the plastic to relieve that area. Parents 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 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 degrees), flu, day surgery, bath time, and when swimming. Recasting may be necessary if the helmet is not worn for an extended period of time.



PRACTITIONER INSTRUCTIONS

ADJUSTMENT OF THE CRANIAL MOLDING HELMET

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

4. Length of time the orthosis is effective:

AGE AT BEGINNING OF TREATMENT	AVERAGE TIME ORTHOSIS IS EFFECTIVE
3 month old child	Two months
5 month old child	Three months
7 month old child	Four months

5. The orthosis becomes ineffective after between 3 and 4 months 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.



CAREGIVER GUIDE TO POSITIONAL PLAGIOCEPHALY AND THE BALLERT CRANIAL MOLDING HELMET

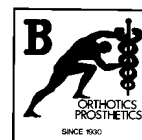
Plagiocephaly is an asymmetrical molding of the head caused by external forces. It can be caused by a number of factors involving position such as extended time spent in a neonatal unit, the birth process, position in the womb, and often the infant's preferred sleeping position. It can also be caused by a condition called torticollis. In this case, there is an 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 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 observation, but more definitive tests like CAT scan or MRI can clarify the diagnosis. If a 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. Many ancient people including the Egyptians, Peruvian Indians, and Pacific Northwest Indian tribes used various methods to shape their baby's skulls. The infant skull is thin and malleable, and if babies spend extended time in one position the head can become deformed and asymmetrical. If the baby is less than 3-4 months of age and the asymmetry is mild, alternative positioning is recommended to get the baby to sleep with his/her head to the other side. Ways to achieve this include having the infant respond to toys and stimulation toward the opposite direction and "tummy time" during the day. Your doctor may also recommend stretching exercises if your child has torticollis. If repositioning and exercises are not effective, your physician may recommend a cranial orthosis such as Ballert's Cranial Molding Helmet. **If the plagiocephaly is accompanied by torticollis, the torticollis must be treated as well.**

Ballert's Cranial Molding Helmet

Ballert's cranial molding helmet is a lightweight, plastic and foam orthosis made from a cast impression of your child's head. It is made of a plastic flexible shell lined



with polyethylene foam. The foam can be modified over time to allow for growth and will provide a pathway for your child's head to grow into a more symmetrical shape. Ballert's cranial molding helmet allows your baby to sleep in any position he/she finds comfortable, yet keeps pressure off the flat spots and constrains head growth along the axis of the prominent parts. It offers a simple and direct solution to the problem of deformational or positioning plagiocephaly. Correction usually occurs within 2 to 3 months with patients beginning helmet treatment between 4 and 7 months of age. In older patients, longer treatment time is usually needed.



Ballert Cranial Molding Helmet

Frequently Asked Questions by Caregiver

DOES MY INSURANCE PAY FOR CRANIAL HELMETS?

Each insurance company has different coverage and medical policy guidelines. It is best to contact your insurance company and employer benefits coordinator to determine the type and level of coverage for durable medical equipment (DME) and orthotics and prosthetics (O&P). It is not uncommon for insurance companies to require a letter of medical necessity from your referring physician stating that a cranial molding orthosis is medically necessary and is not being prescribed for cosmetic reasons. If untreated, problems that may be associated with positional plagiocephaly include vision and hearing problems, temporomandibular joint disorder (TMJ), etc. Ask your orthotist and referring physician to provide you with the necessary information (e.g., prescription, letter of medical necessity, photos) to assist you in obtaining the coverage and reimbursement. Additional information can be found at PLAGIOCEPHALY.ORG. Under the files section, select INSURANCE HELP for a listing of files that include clinical studies, appeals letters, etc. Be persistent – many patients have successfully gone through the appeals process and have gotten paid after their first claim was originally denied.

HOW SOON WILL WE SEE IMPROVEMENT?

This varies, but some parents have seen improvement after only 2 weeks of helmet use. Correction continues over time, and requires complete compliance to achieve the greatest degree of symmetry.

WILL MY CHILD EXPERIENCE ANY DISCOMFORT WEARING BALLERT'S HELMET?

In most cases, children adapt quite easily to the orthosis. If you have any concerns about the amount of discomfort your child is experiencing, contact your orthotist for more information.

DO WE NEED FOLLOW UP?

Yes. In most cases, your child will need a helmet adjustment by the orthotist every two to three weeks. Contact your orthotist sooner if the helmet seems tight or you notice any problems. The referring physician may wish to see the child after 6-8 weeks of helmet treatment to evaluate progress.

WHO TELLS US WHEN TO STOP WEARING IT?

The decision to discontinue wearing the helmet should be made by the physician in conjunction with the orthotist. The orthosis has done its job when the child's head rounds into the symmetrical shape of the helmet, or when the head shape has changed to an acceptable degree of symmetry and the child has outgrown the helmet.

WILL WE NEED MORE THAN ONE HELMET FOR TREATMENT?

In cases of moderate to severe positional plagiocephaly, it is possible for the child to outgrow the first helmet before all possible correction may be achieved. If this happens, the physician, orthotist and parents plan an active role in determining if another orthosis is appropriate for the child. Any additional orthosis will require new insurance billing and prior approval is recommended before proceeding.

WILL THE CHILD'S HEAD REVERT BACK TO THE FLAT SHAPE WITH THE HELMET IS DISCONTINUED?



It is not common for the child's head shape to revert back to its original shape. As children get older, they spend more time sitting, crawling and walking which minimizes the amount of time they spend on their backs. Further skull shape improvement may occur over time.

WHERE CAN I GET MORE INFORMATION?

There is a wonderful discussion group that is primarily composed of parents at a website called **www.plagiocephaly.org**. To sign up for this free support group, go to egroups.com and enter the word plagiocephaly in the search box to register. You can also get information on cranial molding helmets at Ballerts website: **www.ballert-op.com**

