A cranial molding helmet has been prescribed for your child. This information sheet is provided to give you basic instructions on the purpose, casting and fitting procedure, wear and care for the helmet.

PURPOSE

The cranial molding helmet is a custom-made orthosis, available by prescription only, that is used to treat children between three and eighteen 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.

Working in conjunction with noted pediatric neurosurgeons and craniofacial surgeons, Ballert has created a unique design that encourages skull growth into a concavity formed in the helmet. Furthermore, the helmet can easily be adapted to growing skull size and shape by removing layers of its lining.
Over the years Ballert has created, fitted, and successfully applied literally hundreds of helmets to treat positional plagiocephaly and related conditions. And the parents of our patients have been gratified and relieved by the efficacy and ease of use of these non-invasive devices. By following our guidelines for wearing and caring for the helmet, you will help to ensure that your baby receives the maximum benefit from the Ballert Molding Helmet.

You have taken an important first step in choosing Ballert Orthopedic for your child’s molding helmet, because Ballert uses only **certified orthotists** for the casting and fitting of the helmet, and for follow-up care. To receive certification, orthotists are required to complete a postgraduate course in orthotics and a year-long residency program prior to being allowed to sit for certification exams and becoming certified.

**WHAT TO EXPECT ON YOUR VISITS TO BALLERT**

At your **first appointment**, you will complete a patient information sheet and your child will be casted for the helmet. Here are a few things to remember about the first visit.

- Bring toys, pacifier, bottle, grandparents, or something familiar to the child to provide a distraction.
- Expect your child’s outfit to get soiled (nontoxic plaster material used in the casting is easily removable by washing) and dress him or her accordingly.
- Remember to bring your insurance information.

You and your baby will proceed to an examination room, where a certified orthotist will take a cast of your baby’s head. First, a protective hood is placed on the baby’s head, over which plaster is applied. When the plaster hardens eight to ten minutes later, the cast is removed. The entire appointment lasts approximately 30 minutes from beginning to end.

The procedure is not painful to the infant and requires no sedative at all. In fact, babies sometimes fall asleep during the process. Often the procedure causes more distress to anxious parents than to the child. At the end of the appointment, he will schedule you and your child to return for a second appointment about a week later and answer any questions you may have.

At the **second appointment**, your certified orthotist will answer any questions, evaluate the fit of the helmet and make any necessary adjustments. Your practitioner will also guide you through the procedures for applying and removing the helmet, together with guidelines for taking care of the helmet and recognizing possible trouble signs. For your convenience, these are described on the next page in this brochure.

**Follow-up appointments.** Regular follow-up appointments are scheduled every two to four weeks. If you have a question or concern, 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 30 minutes when removed. If this happens, call us at (773) 878-2445.

If for some reason you cannot make your appointment or are running late, please call us at (773) 878-2445.
**SCHEDULE**

During the first weekend, you will evaluate the helmet fit and get yourself and your baby accustomed to helmet wear. The following schedule is recommended. It is important to observe this schedule as closely as possible.

**Day 1:** Wear the helmet two hours on and two hours off. The helmet is not to be applied at night. Apply the helmet for naps. When the helmet is removed, check your baby’s head for areas of redness which do not go away after 30 minutes.

**Days 2 – 7:** Increase the amount of time in the helmet to three hours on and one hour off. Begin applying the helmet at night so that your baby wears the helmet throughout the night every other night during this period.

**Week 1 on:** At the end of the first week, your baby should be wearing the helmet full time. This means that the helmet is removed only two times daily. Once to inspect for persistent redness when your baby wakes up, and once at bath time to inspect for persistent redness and to wash your baby’s head.

**CARE OF THE HELMET**

Once a day, wash the helmet with mild soap or shampoo (such as Johnson & Johnson baby shampoo). Rinse thoroughly with water two or three times. Wipe the interior surfaces of the helmet with 70% alcohol to destroy bacteria and to remove soap residues that may cause irritation. Allow to dry well. When the baby and the helmet are thoroughly dry, put the helmet back on for the rest of the evening and night.

**IMPORTANT!**

If at any time you are experiencing problems or THINK you may have a problem, please call our office at (773) 878-2445. Someone is available 24 hours a day, 7 days a week to address your concerns.

Expect your baby to perspire in the helmet. Your baby may fuss when the helmet is being put on or taken off. Red spots on the baby’s head typically appear when the helmet is first removed and should go away in 30 minutes or less.

**Trouble signs include:**

- Redness that lasts longer than 30 minutes after the helmet is removed.
- Localized rashes at the back of the skull near the bottom of the helmet are usually nothing to worry about. A rash covering the entire area that the helmet covers may indicate the presence of contact dermatitis, and should be brought to your certified orthotist’s attention. It may also require that you see your pediatrician.
- Looseness or slipping of the helmet, especially when the baby lies down.
HOW TO PUT ON AND TAKE OFF THE HELMET
(DONNING & DOFFING)

The helmet is positioned properly when the front of the helmet lies at or above the eyebrows and the ears are free from hitting any plastic. The helmet is tight enough when it does not move on the baby's head. Your certified orthotist will demonstrate the correct procedure for applying and removing the helmet. The procedure is described below:

To apply strapless helmets, grip the sides, position the helmet above the baby's head, and pull it down over the head with a back-to-front rotating motion so that the ear openings are properly aligned and the lower front border fits symmetrically across the baby's brow. To remove the helmet, simply reverse the process.

To apply helmets with Velcro straps, first disengage the strap. Then stretch the helmet open and bring it straight down over the baby's head, taking care that the ear openings are properly aligned and that the lower front border fits symmetrically across the baby's brow. Reconnect the Velcro strap so that the helmet is completely closed.

ABOUT BALLERT

Ballert is an ABC certified facility. ABC certification means that Ballert meets all of the professional and quality standards set by the American Board for Certification in Orthotics and Prosthetics, Inc. These standards provide you with the finest orthotic and prosthetic devices. Whether your doctor prescribed an off the shelf or custom designed and manufactured device you are assured that Ballert will stand behind its products and will work with you and your doctor to assure the proper balance between function and comfort.
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.
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&Ps). 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
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 that 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.