

Michigan Cranial Reshaping Orthosis

GENERAL INFORMATION

The physician always evaluates the infant and makes the determination as to the appropriateness of the Michigan Cranial Reshaping Orthosis. Pediatricians, pediatric neurosurgeons and plastic surgeons are then usually consulted by the families when they first notice the baby's abnormal head symmetry. Using this transdisciplinary approach, an accurate diagnosis can be reached. Babies from 3 to 14 months of age can usually be successfully treated with this type of orthosis therapy.

After the prescription is issued, by the doctor, the clinician fills out the work order which specifies the size of the orthosis needed. The work order must be filled out completely. This gives the manufacturer of the orthosis the exact instructions on materials and the necessary fabrication techniques to meet the baby's individual needs.

The size and shape of the baby's head determines whether or not our standardized size will be used, or if a full custom mold needs to be taken. If a custom orthosis is required, a cast of the baby's head will be made using established casting procedures or scanning methods, being sure to show the landmark locations. (centerline, nose, ears, eyes, and trim lines) The cast can be sent to Danmar as is, (*See Packing Instructions*) and our technicians will mold the positive plaster cast and do the modifications to round out the shape. The orthotist can also mold the positive cast, make the modifications and send that finished cast to Danmar. We can also return the orthosis untrimmed if the orthotist decides to do the final trimming at the time of the fitting.

The color choices available are light blue, light pink, royal blue, black, purple, red or white. We also offer some designs to enhance the cosmetic appearance of the orthosis if that is desirable. The family or primary caregivers must thoroughly review the Use and Care Instructions and Frequently Asked Questions provided at the first fitting appointment. It explains the importance of monitoring the baby's progress and head growth. Head circumference measurements and evaluations of neurological development will be done at regular

intervals to reduce the potential of any impairment of regular growth and development.

Also for the first 5 days, a log should be kept by the parents noting such items as the position of the orthosis (i.e. stationary or did it shift) and red marks on the skull.

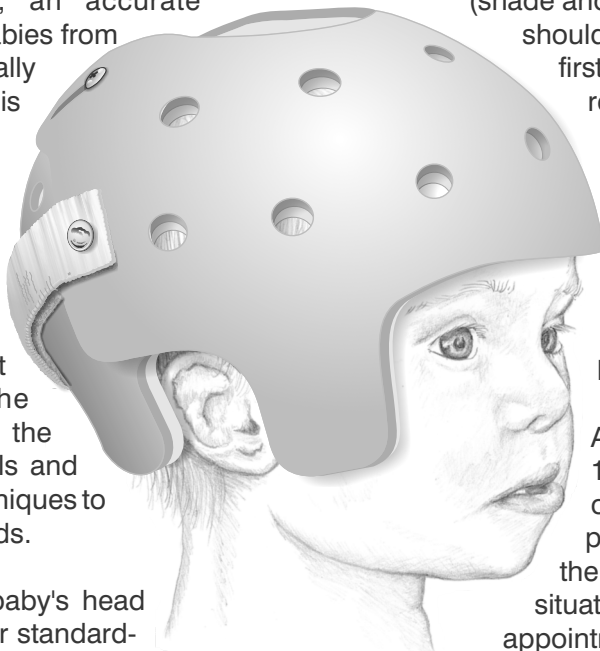
(shade and severity). **WARNING:** Skin conditions should be evaluated every 3-4 hours for the first 3 or 4 days. If there is skin irritation or redness, do not wait until it forms a blister. Call the Orthotist immediately. If any skin breakdown (chaffing, peeling, bleeding etc.) is noted, remove the orthosis and call the Orthotist immediately. This type of skin evaluation should be done at frequent intervals, after every few hours of wear.

Any red spots that last for more than 3 1/2 hours could indicate that the orthosis needs to be adjusted. The primary care giver should be told to call the orthotist and tell them what the situation is, rather than waiting for their next appointment. A regular appointment schedule is set between the family and the Orthotist to ensure periodic checks by a professional.

The baby's head will perspire due to wearing the orthosis. This is normal and the baby should be kept as comfortable as possible by dressing in lighter clothing and by wiping the baby's head. Occasionally a thin stocking cap is useful.

DANMAR PRODUCTS, INC. has trained technicians with many years of experience in making orthosis and headgear, and a system which insures on time deliveries. We have been in business since 1968, concentrating our energies into creating unique and innovative products to meet the needs of our customers.

CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDERS OF A PHYSICIAN. THE SALE, DISTRIBUTION AND USE OF THIS DEVICE ARE RESTRICTED TO PRESCRIPTION USE IN ACCORDANCE WITH 21 CFR 801.109. FREQUENTLY ASKED QUESTIONS



FREQUENTLY ASKED QUESTIONS

WHERE CAN I GO FOR INFORMATION ON CRANIAL SHAPING THERAPY?

Your pediatrician can explain the basics of positional plagiocephaly. The doctor probably will offer referrals to one of the many type of specialists in this field including plastic surgeons or pediatric neurosurgeons.

There are many resources available for further research. At our website, <http://www.danmarproducts.com>, under Cranial Shaping there are links to informational sites.

There are web sites which have links to Preferred Physicians Listing, Specialists in this field, Parents Support Groups, and recent articles from various publications.

WHAT IS THE BEST AGE FOR THIS ORTHOSIS TREATMENT?

While this is the recommended therapy from the age of three months up to eighteen months of age, the best results are achieved when treatment is started early. As a child gets older, the skull becomes thicker and the molding becomes more difficult.

HOW WILL THE ORTHOSIS BE FITTED?

A circumference measurement will be taken of the baby's head and the clinician will adjust the sizing of the orthosis, then secure it by means of the side fasteners. In the event that a custom orthosis is needed, a stockingnette will be put on the baby's head and a cast will be taken using plaster bandages, which set in just a couple of minutes. Standard casting procedures are used, and while the baby will not be very happy about having this done, it does not hurt. There is some water that drips off during the process but this is not harmful. Then the cast is removed and the orthotist marks the cast showing where the eyes,

nose, ears and centerline are located. At the next appointment, a custom lightweight plastic orthosis with an inner soft foam layer will be fitted to the baby's head.

HOW LONG WILL THE BABY HAVE TO WEAR THIS ORTHOSIS?

There are many variables, as each baby is unique and is evaluated periodically during the appointments at the orthotist's office. For example, the timeline is dependent on the age of the baby when the treatment starts, and the degree of reshaping that is necessary. Usually, it is just a matter of months before the desired results are obtained. The mean treatment time based on our studies is 9.6 months.

DOES OUR INSURANCE COVER THE COSTS OF THIS THERAPY?

With so many types of insurance available, the best answer we can give is to call your insurance carrier after you have the prescription from your doctor. Some insurance companies classify deformational plagiocephaly as cosmetic rather than a medical necessity. Be persistent, as some parents have reported after first being turned down they were later approved for payment.

WHAT ARE CONTRAINDICATIONS AND PRECAUTIONS?

Contraindications: Contraindication for this orthosis include craniosynostosis, hydrocephalus and unstable skin.

Precautions: If positional plagiocephaly is associated with torticollis, there may be some additional types of therapy needed as well.

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have been innovating
special needs products
for over forty years.*



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