

ottobock.

MyCRO Band.
Shaped with Care.

Information for Physicians and Specialized Clinicians

Confident patient care.

About Ottobock

For more than 100 years, Ottobock has been developing innovative products that improve the lives of patients around the world. As a global leader in medical technology, our single-minded determination to redefine what's possible in prosthetics and orthotics has earned us a reputation for excellence.

We know how it feels when parents are looking to you for professional expertise and the best treatment options for their children. So, we've engineered a unique, new solution for young patients with cranial deformities that you can recommend with confidence as you guide them through their journey toward desired results.



About MyCRO Band

The Ottobock *MyCRO Band* is a temporary orthosis to aid in the correction of head shape caused by positioning. The orthosis uses contact and growth zones to guide the growth of the head. The contact zones define gentle limits for growth, while the growth zones leave space in areas required for forming the natural head shape.

The unique MySize Closure System™ allows for adjustability as the child grows. The orthosis is made based on a scan, 3D-printed with thermoplastic material and contains a soft, washable lining on the interior.



Improving compliance.

The innovative open-air design of the *MyCRO Band* provides a precision fit and all-day comfort to promote patient acceptance, treatment adherence and better results.

Lighter. Thinner. Better.

MyCRO Band is 20%-40% lighter and 60% thinner than traditional CRO helmets.



Traditional Foam Helmet



Ottobock *MyCRO Band*

| | | |
|-----------|---|--|
| Weight | Small – 6 oz (170 g) Large – 10 oz (283.5 g) | Small – 4.7 oz (135 g) Large – 6 oz (170 g) |
| Thickness | 5/8" (16 mm) | 1/4" (6.5 mm) |

Clinically proven.

Clinical evidence of MyCRO Band

Ottobock conducted the study* "Effectiveness of Ottobock helmet therapy in infants with plagiocephaly, brachycephaly or combination of both and parents' satisfaction."**

The study was composed as a collection of retrospective clinical data from clinicians and a survey for parents. A total of 452 infants were eligible for study enrollment, 41 were excluded as consent of parents was not obtained, 2 were excluded as deformation characteristics were missing. Correction of cranial deformation has been analyzed on 362 infants, and 313 parents have answered the survey.

Effectiveness

The effectiveness was measured comparing the head deformation at the beginning and at the end of the 362 treatments:

Plagiocephaly: CVAI was significantly reduced by 6.1 points ($p < 0.0001$).

Brachycephaly: CI was significantly reduced by 7.6 points ($p < 0.0001$).

Asymmetrical Brachycephaly: CVAI was significantly reduced by 4.8 points ($p < 0.0001$) and CI was significantly reduced by 6.3 points ($p < 0.0001$).

Conclusion

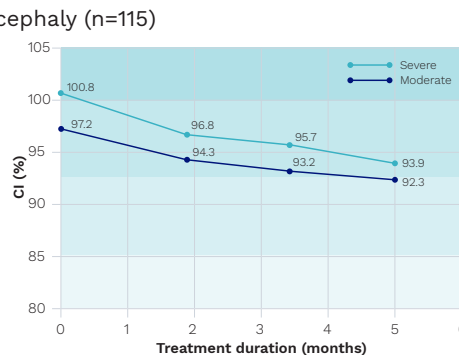
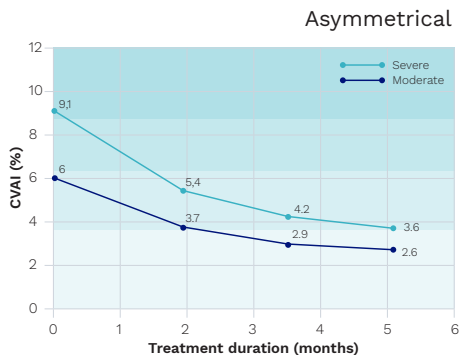
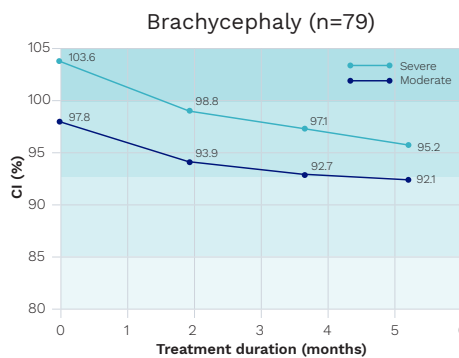
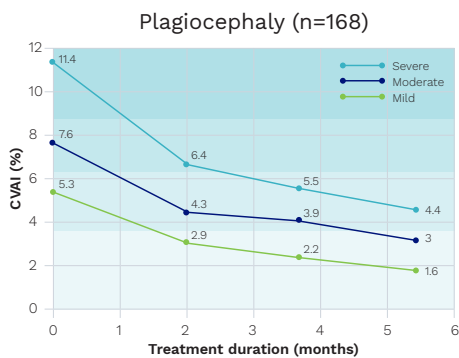
The effectiveness of the helmet therapy was confirmed with a significant ($p < 0.0001$) reduction of cranial deformation reported on the analysis of 362 infants with cranial deformation.

The study confirms that an early onset of helmet treatment is beneficial.

The survey completed by 313 parents confirmed a general high level of satisfaction as 88% were quite satisfied or very satisfied with the treatment.

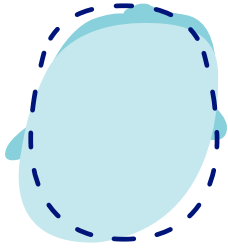
During the helmet treatment, cranial perimeter growth was not limited by the orthosis and the amount and type of side effects are comparable to literature.

The study confirms that Ottobock helmet therapy is effective and safe.

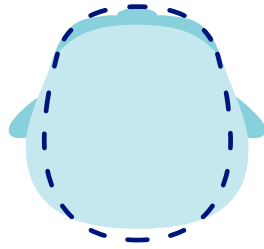


* Find out more about the study

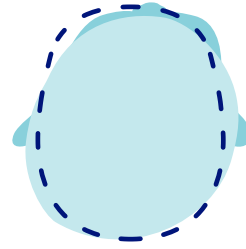
Clinical uses and effects.



Plagiocephaly



Brachycephaly



Asymmetric Brachycephaly

Indications for use

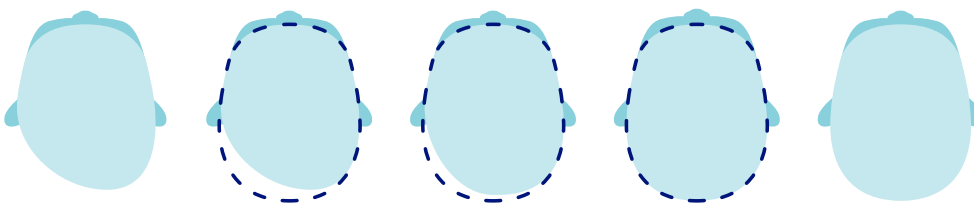
The *MyCRO Band* is for use on infants from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, such as:

- Plagiocephaly
- Brachycephaly
- Asymmetrical Brachycephaly

The *MyCRO Band* is also for use on those with surgically corrected synostosis (but who still have moderate-to-severe cranial deformities), including infants with misshapen heads due to cephalic disorders.

Contraindications for use

The *MyCRO Band* is not for use on infants with pre-surgical craniosynostosis, hydrocephalus or scaphocephaly.



Effects of contact and growth zones

The *MyCRO Band* uses contact and growth zones to guide the growth of the head.

The contact zones define gentle limits for growth, while the growth zones leave space in areas required for forming the natural head shape. The MySize Closure System™ allows for adjustability as the child grows.

Reshaping the future of cranial remodeling therapy.



Precise scanning and fit

It all begins with our advanced, digital scanning process that captures the exact contours of the patient's head. Then we use this data and 3D-printing technology to produce a unique *MyCRO Band* that fits just right. No rubbing, no chaffing, no grinding out bits to find a better fit. From day one, your patient's *MyCRO Band* provides constant, gentle guidance with little-to-no adjustment required.



Easy to wear

Traditional CRO devices require frequent visits and adjustments as the patient's head grows. But the innovative MySize Closure System™ of the *MyCRO Band* adapts to continuously prompt proper growth possibly resulting in fewer clinic visits.



Convenient to maintain

The removable lining can be washed in simple soap and water for proper hygiene, healthier skin and no undesirable "sweaty helmet" smell.



Clinically proven

The *MyCRO Band* has been successfully fit on over 4000 patients worldwide. Practitioners and caregivers appreciate the innovative product design with the MySize Closure system™.



Cool and comfortable design

The slimmer, lighter, open-air design of the *MyCRO Band* makes it cool and less cumbersome. The *MyCRO Band* anatomical contact zones are gentle to the child's head. From play time to naptime, the *MyCRO Band* continually improves the contours of your patient's head without ever getting in the way. Everything parents and babies enjoy doing can still be done together – with little time needed to get used to it.

Unlimited creativity

The *MyCRO Band* can be easily individualized by parents, so that they can give their kid's helmet a unique and personal touch. Caregivers can choose from more than 40 icons, which will be embedded into their child's helmet. When the *MyCRO Band* is delivered, parents can paint and design the helmet individually – only the embedded icon or even the complete helmet.



The difference is in the details.

Breathable, open-air design.

- Covers only necessary contact points
- Maximizes air circulation

Soft, fabric inner lining.

- Comfortable and more hygienic
- Includes 2 removable linings
- Washable with soap & water

Embossed icons.

- Wide variety of options for personalization



Lightweight, low-profile, 3D-printed thermoplastic.

- 20-40% lighter than other models
- Little-to-no adjustment needed

MySize Closure System™

- Self-expanding for head growth
- Fewer office visits may be needed

Flexible material.

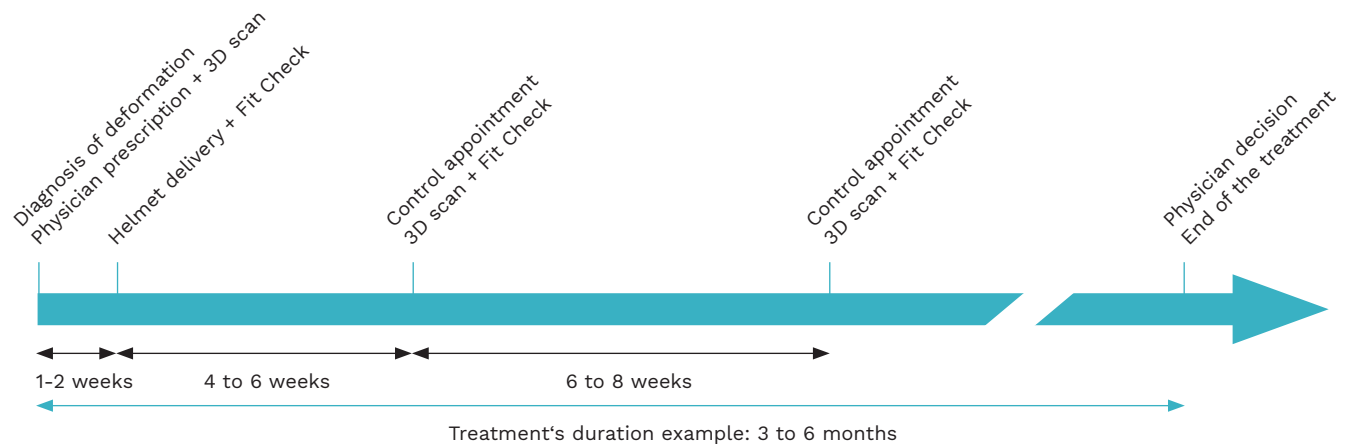
- Less cumbersome
- Easy donning & doffing



The world's first 3D-printed cranial remodeling orthosis cleared for use by the FDA.

Performing patient's treatment.

- Each band arrives precisely configured for the patient, minimizing initial fitting time in the clinic. There is no need for time consuming grinding of foam to try to get the correct fit.
- If needed, the flexible, durable polyamide frame can be easily adjusted throughout the patient's treatment.
- After fitting, the innovative self-expanding design and flexible material adapts to patient's growth with minimal modifications. That means fewer visits to the clinic and more time in everyone's day from start to finish.
- After 3-6 months, patient's treatment is complete, depending on the initial age of the infant and the severity of deformity.



”

The 3D-printed helmet is very well suited, very light, very flexible. This helmet has very few drawbacks, it is very well supported by children and accepted by parents.

Dr. Jacques Griffet, MD, PhD

Simplifying the patient experience.



1. High-resolution scanning

Our proprietary scanning process is accurate up to 0.5 mm to ensure exact cranial profiling.



2. Custom crafted precision

The ideal final head shape is morphed with the patient's scanning data to 3D-print a device that fits perfectly and adapts as the child grows.



3. Reliable patient monitoring and reporting

The *MyCRO Band* clinical software supports every step of your patient's treatment and progress by providing clinicians with numerical data, normative scales and other actionable reports.



”

This helmet is really easier to fit. What is interesting and practical is its dynamic closure, which allows variations in cranial remodeling and cranial perimeter growth. The fact that there is no foam inside the helmet reduces the need for frequent adjustments.

Pauline Seniow, Cranial Orthotist

