



## 24H1 MyCRO Band (For prescription use only)

EN Instructions for use (qualified personnel) ..... 2

**INFORMATION**

Date of last update: 2022-08-11

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Instruct the user in the safe use of the product.
- ▶ Please contact the manufacturer if you have questions about the product or in case of problems.
- ▶ Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ▶ Please keep this document for your records.

The initial fitting and application of the product must be carried out by the O&P professional. Please ensure the following points, before handing the product and the instructions for use to the patient:

- The orthosis is the correct one for the child.
- The UDI on the orthosis matches the UDI from the order number.
- The shipping latch is securely in place when the orthosis is received.
- The scope of delivery is complete.
- The orthosis is not damaged.
- The orthosis fits the child.
- Caregiver is able to put the orthosis on the child’s head.
- Schedule examination intervals with the caregiver in order to ensure the safe use of the product.

**2 Product description**

The Ottobock MyCRO Band is a non-sterile 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. An adaptable closure allows for adjustability as the child grows. The orthosis is made of thermoplastic material with a soft, washable lining on the interior.

The orthosis was made based on a 3D-scan. The following scanners are compatible:

Manufacturer	Ottobock	Creafom	Artec
Product name	iFab EasyScan	OMEGA Scanner 3D M4DScan Bodyscan Peel 1/Peel 3D HCP	Eva Eva Lite

### 3 Indications for use and Contraindications

#### 3.1 Indications for use



Intended for medical purposes for use on children from 3 to 18 months of age, with moderate-to-severe non-synostotic positional plagiocephaly, including children with plagiocephalic, brachycephalic, and scaphocephalic shaped heads by applying mild pressure to prominent regions of a child's cranium in order to improve cranial symmetry and/or shape. These devices are also indicated for adjunctive use for children from 3 to 18 months of age whose synostosis has been surgically corrected, but who still have moderate-to-severe cranial deformities including plagiocephalic-, brachycephalic -, and scaphocephalic-shaped heads. The orthosis must be used in accordance with the indications.

#### 3.2 Contraindications

Not for use on children with pre-surgical craniosynostosis or hydrocephalus.

### 4 Safety

#### 4.1 Explanation of warning symbols

 <b>WARNING</b>	Warning regarding possible serious risks of accident or injury.
 <b>NOTICE</b>	Warning regarding possible technical damage.

#### 4.2 General safety instructions

##### **WARNING!**

- ▶ The product may be used only by the person it was made for.
- ▶ Observe the notices regarding intended use and the use of the product.
- ▶ Check the product for damage prior to each application.
- ▶ Evaluate the elastic band for damage and proper seating prior to each application to reduce the potential for the elastic band to slip out of place which could create a choking hazard.
- ▶ Evaluate the structural integrity and fit of the orthosis to reduce the potential for the orthosis to slip out of place which could cause asphyxiation or trauma to the child's eyes or skin.
- ▶ Explain to the caregiver that they may not continue to use a damaged product and the O&P professional needs to be contacted in this case.
- ▶ The expandable clasp is designed to accommodate the child's growth; if the clasp reaches maximum expansion during treatment, a new device may be required. Inform the caregiver to discontinue use of a product that has reached maximum expansion, or if there are indications that the child has outgrown the orthosis and to contact the O&P professional for a follow up appointment.
- ▶ Evaluate the child's skin at frequent intervals for signs of irritation or breakdown. Mild erythema, edema and pressure sores, can be expected during the use of a cranial orthosis.
- ▶ Check the areas of skin that come into contact with the product before and after each use.
- ▶ Only use the product on intact skin.
- ▶ Note that using the product on a shaved head may cause ingrown hairs.

#### Potential adverse effects

- ▶ Skin irritation or breakdown.
- ▶ Potential adverse effects caused by extending treatment against medical advice. Extended treatment can cause skin irritation, skin breakdown and may result in excessive pressure.

##### **NOTICE!**

### Risk of product damage and limited functionality

- ▶ During normal use, the product should not be exposed to temperatures lower than -10 °C (14 °F) and higher than +45 °C (113 °F).
- ▶ Clean the product if it was in contact with salt water or water containing chlorine.
- ▶ Observe the instructions for cleaning and care.

## 5 Scope of delivery



Quantity	Designation	Reference number
1	Instructions for use (qualified personnel)	-
1	Instructions for use (user)	-
1	MyCRO Band with lining	-
1	Spare lining (additional lining if ordered)	-
1	Spare elastic band	24Z2

## 6 Modification

The orthosis is made from polyamide PA12. Grinders and heat may be used to make small adjustments to the orthosis.

### NOTICE

Note that the heat during the flaring or grinding may cause permanent discoloration. Prior to making adjustments, the lining of the orthosis needs to be removed in order to avoid damage to the material that may be caused by the high temperature of the heat gun.

### Heat flaring

- **Material properties:**  
Glass transition temperature : **50 °C (122 °F)**, Melting temperature: **175 °C (347 °F)**
  - **Recommended tools:**  
Heat gun at medium setting, round metal anvil, driving hammer
- 1) Heat the inner and outer surfaces of the orthosis with the heat gun until the material becomes malleable.
    - Make sure that orthosis is heated over a large surface area and that the heat is never localized. If the material is overheated it may become discolored.

- The surface temperature of the plastic should be heated to between **70 °C (158 °F)** and **95 °C (203 °F)**. This process should take approximately **5 to 8 minutes**.
- 2) Reshape the malleable material on the anvil. If necessary, a hammer can be used to apply pressure.
  - 3) Let the orthosis cool down fully.

### Grinding

- **Recommended tools:**

Sander (The grinding speed should not exceed **1500 rpm**, or the material may overheat and melt.)

Abrasive sanding cone

Fine grit sandpaper

- 1) Once complete, use fine grit sandpaper to smooth the edges.
- 2) Sand the edge of the orthosis, moving from the inside to the outside of the orthosis.
- 3) Make sure there are no sharp edges before dispensing the orthosis.

## 7 Handling

During the first few days, the orthosis is worn for shorter periods of time so the child can become accustomed to it (see the table below). The orthosis should subsequently be worn all day and all night (23 hours minimum) in order to obtain the best possible results. The orthosis should be worn with as few interruptions as possible, e.g. removed only for bathing or treatment by a physiotherapist. Wearing the orthosis can cause increased perspiration during the first two to three weeks. This is normal and decreases over time.

If treatment is required for other illnesses such as torticollis during therapy with the MyCRO Band, the orthosis may be removed briefly.

If wearing the orthosis is interrupted for an extended period of time, another familiarisation period may be required.

**If there are problems with the orthosis, the caregiver should make an appointment immediately. The caregiver should not wait until the next scheduled appointment. It is important that the orthosis is worn consistently.**

Day of use	Daily duration of use
<b>1</b>	2 hours
<b>2</b>	4 hours
<b>3</b>	6 hours (including naps)
<b>4</b>	8 hours (including naps)
<b>5+</b>	Day and night (at least 23 hours)

### 7.1 Application

**⚠ WARNING**

**Wearing the orthosis in case of fever**

Risk of injury due to overheating

- ▶ Stop using the orthosis in case of fever.

**⚠ WARNING**

**Incorrect or excessively tight application of the product to the body**

Risk of pressure points and constriction of blood vessels and nerves due to improper application

- ▶ Ensure that the product is applied properly and fits correctly.
- ▶ Do not continue to use the product if it fits incorrectly.

## INFORMATION

Remove the shipping latch (placed inside of the clasp) prior to fitting the orthosis.

- 1) Check the following points before putting on the orthosis:
  - The child is in a stable position with no interfering objects or items near the head.
  - Any lotions or creams being used have been absorbed by the skin.
  - The orthosis is in proper condition with no cracks or other damage.
  - The lining fits inside the orthosis without wrinkles and projects slightly beyond the hard edge all around.



- 2) Using the finger slot, grip elastic band to detach from clasp (see fig. 1).



- 3) Carefully pull the orthosis apart at the closure (see fig. 2).



- 4) Align the orthosis and place it onto the child's head (see fig. 3).
- 5) Check the fit of the orthosis:
  - The arrowhead on the front should form a vertical line with the middle of the nose.
  - The ears should sit freely in the openings in the orthosis.
  - The orthosis must not cover the child's eyes.
  - The orthosis can be turned side to side by max. **1 cm**.
  - The lining should project beyond the edge of the orthosis all around and protect the skin against contact with the plastic.
- 6) **If the orthosis fits correctly:** Hold the orthosis carefully so it cannot turn and close the elastic band of the closure. A gap in the closure is normal and no cause for concern.
- 7) Make sure the elastic band fits properly in the guide of the closure.
- 8) **CAUTION! To avoid injuries, always open the closure before positioning the orthosis.**  
**If the orthosis does not fit correctly or has shifted:** Repeat the previous steps.

## 7.2 Removal

### INFORMATION

Redness of the skin after removing the orthosis is not unusual, and should go away within 2 hours.

- > **Prerequisite:** The child is in a stable position with no interfering objects or items near the head.
- 1) Open the elastic band of the closure.
  - 2) Carefully pull the orthosis apart at the closure.
  - 3) Take the orthosis off the child's head.  
**TIP:** Gently massage the child's head with your fingertips after removing the orthosis in order to promote self-perception.
  - 4) Remove the lining from the orthosis and clean it (see page 11). Insert the replacement lining into the orthosis.

## 7.3 Changing the lining

The lining is attached to the orthosis with micro-hook. It has to fit inside the orthosis without wrinkles and must be in contact with the orthosis over the entire surface area.

### Removing the lining

- 1) Detach the folded lining in the neck area.
- 2) Starting at the closure, detach the lining all around the orthosis.

## Inserting the lining



- 1) Roll up the lining into a tight roll (see fig. 4).



- 2) **WARNING! Ensure that the lining is smooth and securely fastened to the microhooks, to avoid pressure points due to bunching of the lining.**  
Position the lining at the closure of the orthosis. Carefully unroll the lining, pressing it into the orthosis without wrinkles (see fig. 5).
- 3) Ensure that the lining projects slightly beyond the hard edge all around.





- 4) In the neck area, fold over the lining to the outside and press it into place (see fig. 6).

#### 7.4 Replacing the elastic band

##### INFORMATION

The elastic band that holds the closure is intended to last the lifetime of the orthosis. If the elastic band needs to be replaced during treatment, use the following instructions.

- > **Prerequisite:** Orthosis is taken off
- 1) Remove the lining from the orthosis.
  - 2) **Inside the orthosis:** Carefully, remove the elastic band with a small tool (e.g. an allen key) from the pin that holds it in place.



- 3) Remove the elastic band.



- 4) **Outside the orthosis:** Push a new elastic band through the opening.



- 5) **Inside the orthosis:** Push the new elastic band in place around the pin.



- 6) **Outside the orthosis:** Pull on the elastic band to test if it is secured properly.  
7) Re-attach the lining (see page 7).

## 8 Cleaning

### NOTICE

#### Improper cleaning

Damage to the product due to improper cleaning

- ▶ Only clean the product with the approved cleaning agents.
- ▶ Only clean the product by hand.

### INFORMATION

Remove the lining from the orthosis before cleaning. Clean the lining and the shell of the orthosis separately.

> **Recommended cleaning agent:** pH neutral soap

- 1) Clean the product by hand with clean water and a pH neutral soap.
- 2) Rinse the soap away with clean water.
- 3) Dry the product with a soft cloth.
- 4) Allow to air dry fully before donning.

## 9 Disposal

In some jurisdictions it is not permissible to dispose of the product with unsorted household waste. Improper disposal can be harmful to health and the environment. Observe the information provided by the responsible authorities in your country regarding return, collection and disposal procedures.

## 10 Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

### 10.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

### 10.2 Local Legal Information

**Caution:** Federal law restricts this device to sale by or on the order of a qualified orthotist or physician or any other practitioners licensed by the law of the State in which that person practices to use or order the use of the device.

---

┌

┌

Otto Bock HealthCare LP  
3820 West Great Lakes Drive  
Salt Lake City, UT 84120 · USA  
T +1 800 328 4058 · F +1 800 655 4963