



**P-POD®**

PEDIATRIC PLAGIOCEPHALY  
ORTHOTIC DEVICE

# INSTRUCTIONS FOR USE

FOR PARENTS / CAREGIVERS



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PPOD3154-C Rev 11302022

# INSTRUCTIONS

## FOR CAREGIVERS

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### PURPOSE

The P-POD is an FDA cleared device available by prescription only. It is used to treat children between three and eighteen months of age for abnormal head shapes such as positional plagiocephaly, brachycephaly, and turricephaly.

**Plagiocephaly** occurs when a child's head has a flattened appearance, usually when looking down on the top of the child's head.

**Brachycephaly** occurs when the back of a child's head has a flattened appearance.

**Scaphocephaly** occurs when a child's head has a long and narrow appearance.

The P-POD helmet is custom-fitted to your child in a chair side process that takes as little as thirty minutes right in the pediatrician's office. Once fitted, the P-POD helmet will promote the correction of your child's condition through passive pressure during the early period of rapid growth of your child's head. This gentle pressure encourages the head to grow into the rounded shape created by wearing the helmet.

The helmet is made up of an outer plastic shell with a soft inner foam layer. The helmet is custom created to fit your child while they sit comfortably in your lap. A strap and buckle are used for securing the helmet.

Your practitioner will also guide you through the procedures for applying and removing the helmet with guidelines for maintaining the helmet and recognizing possible trouble signs. Your health care provider will monitor the fit of the helmet to ensure that no adverse reaction occurs.

### CAUTION

The P-Pod plagiocephaly orthosis device is a Class II cranial orthosis. Federal (USA) law restricts this device to sale by or on the order of a physician.

# INSTRUCTIONS

## FOR CAREGIVERS

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### INDICATIONS FOR USE

The P-Pod Helmet is a cranial orthosis device that applies gentle pressure to prominent regions of an infant's head. The helmet is intended to improve cranial symmetry and/or shape in infants from 4 to 18 months of age with moderate to severe non-synostotic positional plagiocephaly. This includes infants with plagiocephalic, brachycephalic, and turricephaly shaped heads.

### CONTRAINDICATIONS

The P-POD is not intended for use on infants with cranial synostosis or hydrocephalus.

Cranial synostosis happens when the bones in a child's skull have joined together too soon leaving no room for the child's skull to grow properly.

Hydrocephalus is when an infant experienced a build-up of spinal fluid in their brain.

These conditions are usually corrected by a surgical procedure.

### ADVERSE EFFECTS

There are few potential adverse events, however, you should be aware of what to monitor when your child wears their P-POD helmet.

When you remove the helmet (such as when you give your baby a bath) look at their head and neck for signs of skin irritation such as a sore spot or a rash; and/or areas where rubbing is occurring.

If you notice any irritations or anything unusual, inform your child's prescribing doctor.

# INSTRUCTIONS

## FOR CAREGIVERS

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### PRECAUTIONS

If your child also has a condition known as torticollis, the torticollis must also be treated.

Torticollis is a condition where the muscles on one side of a child's neck contract causing your child's head to twist or nod to one side.

Plagiocephaly and related conditions do not affect the brain, and are not the cause of mental retardation, cerebral palsy or seizures. You should discuss treatment options with your clinician to determine what is best for your child.

### FOLLOW UP APPOINTMENTS

Regular follow up appointments will be scheduled every two to four weeks and it is important you keep these appointments. If you have any questions or concerns about the P-POD or your child's treatment, contact your clinician and do not wait for the follow up appointment . If your child's helmet seems unusually small, it leaves red spots on your child that will last for more than one hour after the helmet is removed or other concerns, don't wait.

If you have concern regarding a matter such as this, speak with the prescribing clinician right away.

### CARE OF THE HELMET

Once each day, wipe the inside and outside of the helmet thoroughly with isopropyl rubbing alcohol to eliminate bacteria and remove any residue that may cause irritations. Follow by rinsing with water.

Do not use soap. This could leave behind residue that can cause skin irritation. When the helmet is completely dry, replace the helmet and continue wearing until the next days bath/cleaning time.

The bladder (the helmet's inner lining) should be patted dry with a clean dry towel. Talcum powder is not recommended, as this dries in the bladder and may be abrasive to the skin.

The helmet should not be worn for baths or in the pool.

# INSTRUCTIONS

## FOR CAREGIVERS

### USAGE TIME FOR THE FIRST WEEK

It is recommended that the P-Pod be worn for 23 hours per day. Over the first several days you will follow the break-in schedule. Over the course of 5 days, you will slowly increase daily wear time until maximum wear time is achieved. Please follow the schedule below and do not accelerate wear time. This schedule has been developed to prevent skin problems and to help your baby adjust to the P-POD.

**DAY ONE** Alternate **1** hour on, **1** hour off. **Remove** helmet for naps and overnight.

**DAY TWO** Alternate **2** hours on, **2** hours off. **Remove** helmet for naps and overnight.

**DAY THREE** Alternate **4** hours on, **4** hours off. **Keep helmet on** for naps and overnight.

**DAY FOUR** Alternate **8** hours on, **1** hour off. **Keep helmet on** for naps and overnight.

**DAY FIVE** Alternate **16** hours on, **1** hour off. **Keep helmet on** for naps and overnight.

This cycle is repeated throughout the day. By Day 6, 23 hrs a day will be considered full-time wear.

If necessary, you may take slight breaks from this schedule, for example, during very hot/humid weather where the helmet is uncomfortable or when you are feeding your child potentially messy foods that may discolor the foam or mark skin with food stain.

**It is important for families to adhere to the 23-hour a day wear schedule as closely as possible.** While many parents feel compelled to give their baby a break or allow them time without the helmet, this can delay head reshaping and prolong the helmet-wearing process. When starting helmet treatment, it is common to encounter a period of adjustment that can lead parents to have difficulty adhering to the treatment protocol. Some include difficulty adjusting to sleeping while helmet-wearing, increased fussiness, pressure from extended family not to helmet, and compliance by other childcare providers.

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## FOR CAREGIVERS

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### OTHER TIPS

Keep the helmet away from pets.

Make sure everyone that helps apply and remove the helmet knows the appropriate technique for doing so and the proper way to clean it.

Call your child's physician for further directions and any questions you may have.

### REGISTER YOUR P-POD

Registering your baby's P-POD is super simple. By registering your helmet you have access to:

- A discount on decal kits from Babbleworthy to customize your baby's helmet
- Periodic tips and information by e-mail
- Support and advice from the P-POD Community
- Wear and care support
- The P-POD Baby of the Month contest submissions

Fill out a registration form at [ppodkids.com](http://ppodkids.com).

### TRACKING PROGRESS

Your child's physician will take measurements at every checkup. Use the chart on the opposite page to track the progress of treatment.

# PROGRESS CHART

DATE	CEPHALIC INDEX (CI)	CRANIAL VAULT ASYMMETRY (CVA)	CRANIAL VAULT ASYMMETRY INDEX (CVAI)	% IMPROVEMENT

**CEPHALIC INDEX (CI) SCALE**

Below 75% - Scaphocephaly

75-80% - Normal

80-85% - Acceptable

85% and above - Brachycephaly





## HELMET GRADUATION

Once your baby has completed their P-POD journey we will be excited to celebrate the milestone with your family. If you've registered your helmet at [ppodkids.com](http://ppodkids.com), we will send you a certificate of completion to celebrate the special day. Be sure to send us your photographs from graduation day and we will share with the rest of the P-POD online community.

You can also check out Babbleworthy's grad kits at [itsbabbeworthy.com](http://itsbabbeworthy.com).



# P-POD®

111 Grant Street, Suite 202, Endicott, NY 13760

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