P-POD®

PEDIATRIC PLAGIOCEPHALY
ORTHOTIC DEVICE

INSTRUCTIONS FOR USE

FOR PRACTITIONERS

866.877.PPOD • ppodpediatrics.com

PD-1223 Rev 11302022

INSTRUCTIONS

FOR PRACTITIONERS

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.

INDICATIONS FOR USE: The P-POD Helmet is a cranial orthosis device that applies passive pressure to prominent regions of an infant's cranium. This helps improve cranial symmetry and/or shape in infants from 4 to 18 months of age who have moderate to severe nonsynostotic positional plagiocephaly. This includes infants with plagiocephalic, brachycephalic, and scaphocephalic shaped heads.

CONTRAINDICATIONS: This device is not for use on infants with craniosynostosis or hydrocephalus. Patients outside the indicated age range of 4 to 18 months should not be fitted with the device.

WARNINGS: Evaluate head circumference measurements and neurological status at intervals appropriate to the infant's age and rate of head growth. A clinician or caregiver must evaluate the patient's skin at frequent intervals.

The helmet is fitted to one child and should not be reused for other applications. Only clinicians trained in the treatment of cranial deformities (or who have completed the P-POD professional training) should use this device.

Chemicals used in generating the foam and modelling putty should be kept out of reach of children. The chemicals are flame resistant, but should be considered to be an eye irritant and should not be handled near heat, sparks, or an open flame.

Gloves are not required when handling the putty. However, after using the putty, the user should wash hands with soap and water.

Biocompatibility testing perfomed on the chemicals addresses the categories of evaluation for cytotoxicity, skin sensitization and skin irritation specified in USP Class VI and / or ISO 10993 for patient contact of less than 30 days duration.

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All components associated with this device are latex-free.

PRECAUTIONS:

- If the positional plagiocephaly is associated with torticollis, the torticollis must also be treated.
- Evaluate the device's structural integrity and fit carefully.
- Care should be taken when fitting the cranial helmets.
- Read the "How to Assemble" document to reduce the potential for the device to slip out of place and cause asphyxiation or trauma to the infant's eyes or skin.
- A protective smock and latex-free gloves should be worn by the clinician when foaming the helmet.
- A protective covering should be provided to the patient and caregiver holding the patient when foaming the helmet.
- If the foam contacts the user or patient's skin, the area should be rinsed with soap and water to prevent irritation.

INSTRUCTIONS: See pages 7-18 of this document for proper instructions for use, proper creation of the helmet, and troubleshooting. Care and use of the helmet is included in the Caregiver Instructions for Use. Circumference and diagonal measurements can be taken during each appointment to monitor patient progress.

Perform helmet fabrication in a well ventilated room.

Potential Risks

There are potential risks with the fabrication process for the P-POD helmet. These risks include:

- Discomfort / Stress related to helmet foaming process
- Exposure to foaming chemicals if there is a leakage in the foam chemical packet
- Exposure of the infant's scalp to pressure if incorrectly fitted

Discomfort / Stress related to Process

As with any medical intervention performed on infants, there is a likelihood of children becoming upset during the intervention. The process of fitting the helmet lasts approximately 25-30 minutes. During this time, the infant can be held by a parent or familiar caregiver in an effort to comfort and distract the infant throughout the fitting process.

Chemical Exposure from Foam

During the fabrication of the helmet, as the chemical solution cures, the infant may feel slight discomfort as the foam expands. The chemicals cure at room temperature and there is no possibility of burn. The material is biocompatible; however, irritation is possible on very sensitive skin. As an additional safety measure, the infant should be monitored for signs of undue distress. The procedure should be aborted if the child seems to be in pain.

The foaming solution pouch, as seen in the following figure, contains the chemical components and directions on how to create the foam. There are two sections of the pouch. Part A and B contain addition cured silicone. The chemical components are separated by seals to ensure mixing does not occur before it is necessary. The chemical foaming process is explained in detail in Section IV discussing the manufacturing of the helmet.

INSTRUCTIONS

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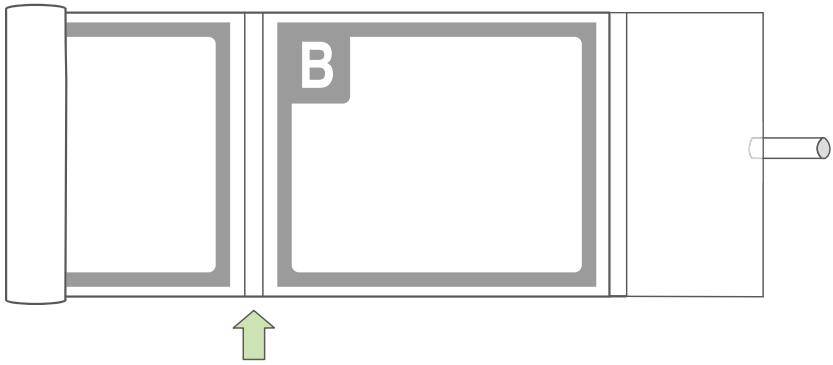
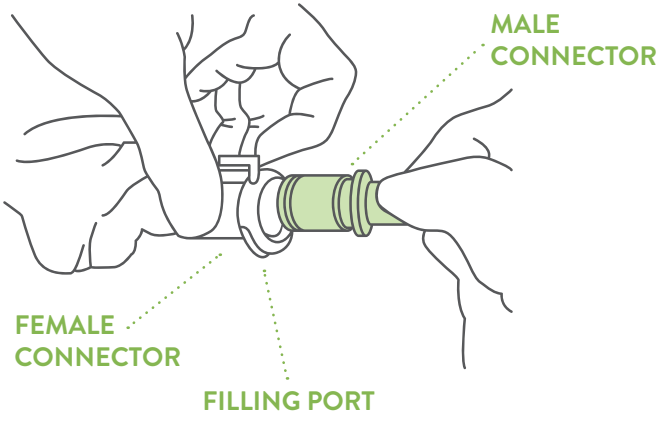


The clinician will examine the foaming solution to ensure there are no leaks in the packaging. If there are leaks, the clinician will discard the pouch and obtain a new pouch. Next, the clinician will rupture seal 1 on the foaming solution pouch, press down on section B to pop the seal, and mix the components in sections A & B by dragging the pouch across the edge of a table or counter until visually mixed or up to 30 seconds.

Once this mixing is complete, the clinician will quickly attach the male connector of the foaming solution pouch to the female connector of the bladder located on top of the helmet. The chemical pouch and connector on the helmet bladder connect via a leak-proof snap connector called the “filling port”.



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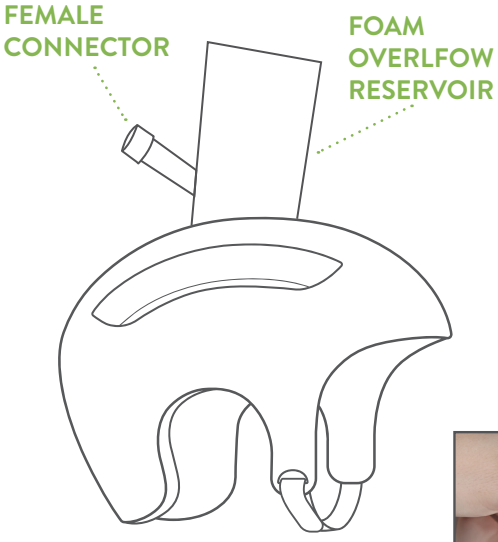
Additional safety precautions include the rupture of the final seal on the chemical pouch and allowing the foaming chemical to flow only after the filling port connector is appropriately engaged (clinician will hear audible “click”). Once the connector is engaged, the connector will not disengage until the tab is pushed and connectors are pulled apart by the clinician. As a final precaution, the infant can be draped in a protective smock and the chemical pouch is always positioned posteriorly (as shown in the figure) so that if accidental leakage occurred, it would not contact the child’s skin or eyes. The risk of the clinician or the infant being exposed to the non-toxic foaming chemicals due to leakage from the chemical pouch is extremely low.



INSTRUCTIONS

FOR PRACTITIONERS

STEP ONE

PREPARING HEAD FOR MOLDING

1. REMOVE CONTENTS FROM PACKAGING

Verify all kit contents are present:

- Helmet
- Two Part Molding Putty (A&B)
- 2 Cotton Cranial Socks (white)
- Foaming Solution Pouch

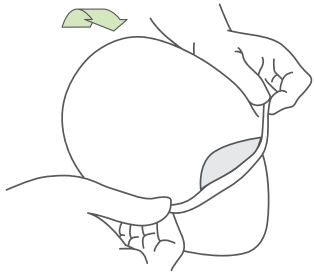
Other optional items (not included):

- Trimming Tool
- Digital Timer

Examine the Foaming Solution Pouch for any signs of leakage. Discard the Foaming Solution Pouch if leaks are observed.

2. PLACE COTTON CRANIAL SOCK #1

Find slit in sock and pull to enlarge hole. Make hole large enough for child's face. Pull fully over head, making sure the face is framed evenly in designated fabric cutout. Eliminate folds and wrinkles in the sock by stretching. A fully taut sock will allow the misshapen area to be remodeled more easily.



3. SET TIMER FOR 2 MINUTES

NOTE: The Mix will harden in 1-2 minutes. Be sure that the next step is completed before 2 minutes has elapsed from the beginning of mixing.

4. MIX THE TWO PUTTIES TOGETHER

Start the timer.

Mix equal amounts of the two parts by hand until the mixture becomes uniform in color and consistency, approximately 30 seconds.

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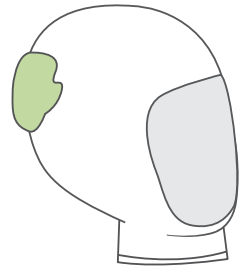
5. REMODEL DEFECT WITH PUTTY

Apply the modeling putty directly to the flattened area and contour directly on the white cranial sock to achieve the desired shape. Work the putty until it is smooth and blends with the curvature of the rest of the head.

PUTTY VERIFICATION: After several minutes have elapsed from the start of mixing, check to see that the putty has hardened. Putty color will lighten and should not deform when touched.



6. PLACE COTTON CRANIAL SOCK #2

Once the putty is firm to the touch (approximately 2-3 min), place the second sock over the head to hold the molded putty in place. You will need to enlarge the hole for the child's face as in step 1.2. Ensure that the cap is taut with no wrinkles.

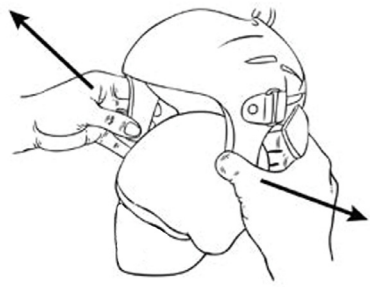
STEP TWO

PLACING HELMET ON PATIENT'S HEAD

1. PLACING HELMET ON PATIENT'S HEAD

Before placing the helmet, verify that the helmet lining is securely attached with the hook and loop Velcro to the helmet shell. If any section is loose, align the pads and apply pressure until reattached.

Detach and loosen the side velcro strap.



2. ADJUSTING POSITION OF THE HELMET

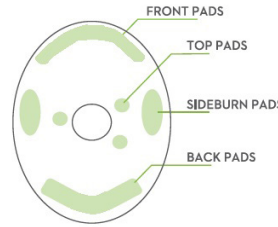
Place the helmet over the head by stretching the earpieces/temple extensions outward. Carefully align it prior to releasing the ear pieces. Do not let the foam pads drag along the head.

STEP THREE

ENSURING A PROPER FIT

1. CHECKING THE PLACEMENT OF FOAM PADS

Verify that all foam pads are making good contact and are not misaligned or distorted. Also check that the pads are all intact and attached. If pads have unattached, apply pressure until reattached.

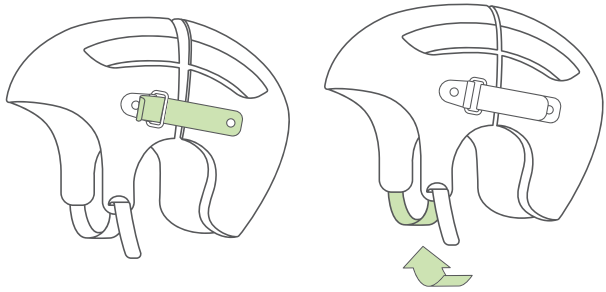


2. FASTEN THE STRAPS

Fasten both the side strap and chin strap so the helmet fits snugly.

The helmet should comfortably accommodate the head with adequate room for foam to flow in all quadrants.

NOTE: Some infants may find the chin strap uncomfortable. Please adjust the chin strap to maximize the patient's comfort while still ensuring the helmet fits snugly.



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STEP FOUR

MIXING THE FOAM

CAUTION: The foaming reaction step is time sensitive. The user should be able to perform each step without the assistance of the instructions.

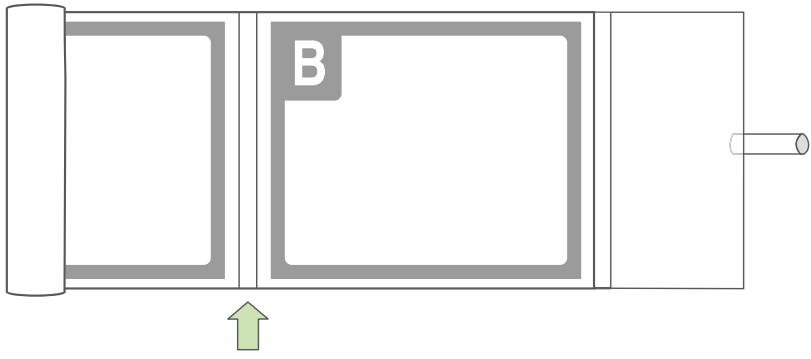
1. SET TIMER FOR 12 MINUTES

In this step you will set the time for 12 minutes without beginning the timer. Do not start the timer until step 3, once you have ruptured the seal in step 2.

10 minutes

2. GET READY TO RUPTURE SEAL 1

SEAL 1 is located between compartment **A** and **B** in the foaming solution. Roll one end of the pouch towards SEAL 1 until pouch is taut, like a tube of tooth-paste.



SEAL 1

3. START DIGITAL TIMER

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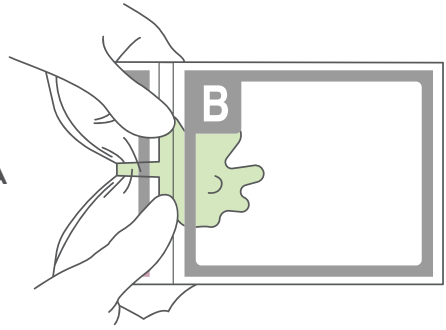
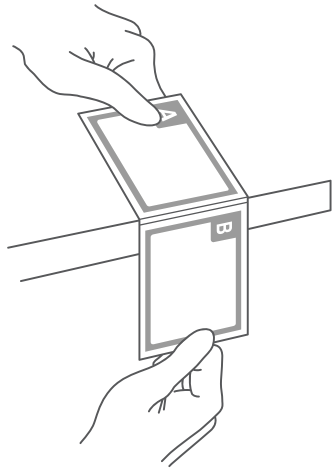
4. RUPTURE SEAL

Apply pressure with both thumbs until the seal ruptures and there is a visual confirmation of the contents of **PART A** beginning to mix with **PART B**.



5. THOROUGHLY MIX THE CONTENTS

Mix the contents of compartments **A** and **B** thoroughly by dragging the pouch across the edge of a table or countertop until visually mixed, 15 times or 45 seconds - 1 minute. Seal 1 may be completely pulled apart and separated to improve foam mixing during this 1 minute window.

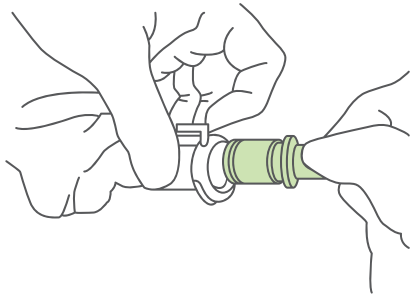


STEP FIVE

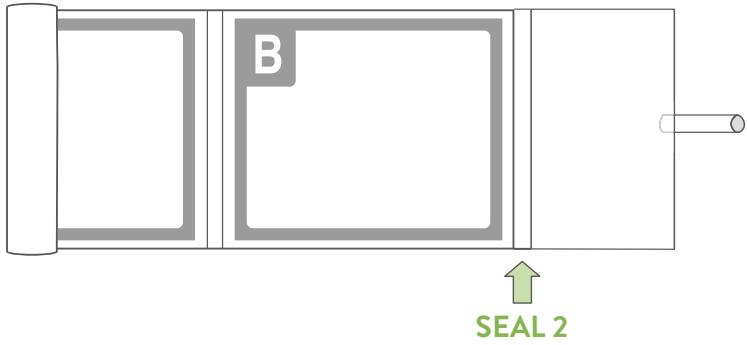
FOAMING THE HELMET

1. QUICKLY SECURE THE CONNECTOR

Quickly secure the connector - This is a time-sensitive step. Do not delay. Attach pouch to the helmet using the quick-connect on the helmet. You will hear an audible click on the foaming solution pouch when properly secured.



2. RUPTURE SEAL 2



3. QUICKLY ROLL UP THE FOAMING SOLUTION POUCH

Beginning at the sealed end, continue to roll up the pouch to thoroughly dispense the chemical solution into the helmet. The pouch can be straightened and rolled more tightly to retrieve the residual chemicals. Fill helmet with foaming solution in a circular motion, making sure foam fills all areas of helmet.

NOTE: Please have the patient sit upright if possible during the foaming process to allow the chemicals to flow through
the entire bladder. The parent or the caregiver may need to hold the child in an upright position and hold head of child still and straight.

WARNING: During the foam reaction period the helmet foam will tend to rise. The infant should be monitored closely. The helmet should be removed immediately if there are signs of significant distress.

4. WAIT FOR FOAM TO SET

To ensure proper foaming and fit, hold helmet down with gentle pressure throughout the curing process, to ensure air bubbles escape and reduce helmet rise off infants head. Pouch can hang loose from the helmet while foam sets. The cylindrical overflow tube (the stovepipe at the top of the bladder) has horizontal seals that can be ruptured to allow for excess pressure and bubbles to be released.

STEP SIX

REMOVING THE HELMET

1. CHECK THAT FOAM HAS SET

After 12 minutes have elapsed, gently press the foam at the top and around the edges of the helmet to determine if the foam has set. The foam is set if it returns to its original shape after pressing it. You can also check the foam in the pouch to ensure proper cure time.

If the foam has not set, wait a few minutes and reevaluate the foam.

2. REMOVE FOAM SOLUTION POUCH

At around the 12-15min mark, remove the foam solution pouch by disconnecting the connectors with a twisting motion or simply pull off the entire connector assembly from the cylindrical overflow. Discard once disconnected.

3. REMOVE AND DISCARD CHIN STRAP

Remove chin strap first, then loosen the side strap. The chin strap must be discarded now and is not part of the final device.

4. REMOVE THE HELMET

Gently remove the helmet by pulling ear pieces outward and lift off. Grabbing onto the nylon cap, along with the helmet, may make it easier to slide the helmet off the patient's head.

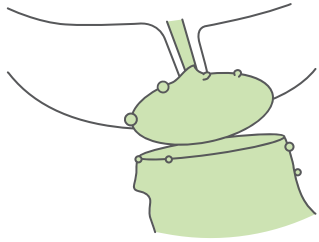
STEP SEVEN

FINISHING THE P-POD

1. TRIM THE FOAM OVERFLOW

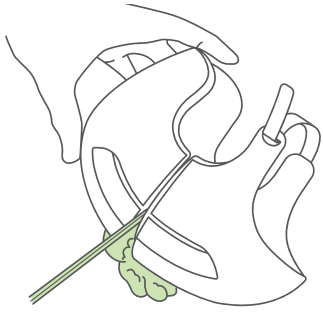
Using the trimming tool, remove the cylindrical overflow area protruding from the top of the helmet.

CAUTION: Handle with care. Trimming tool contains sharp blades. Refer to trimming tool manufacture instructions manual for safeguards and use information.



2. CUT A SLIT

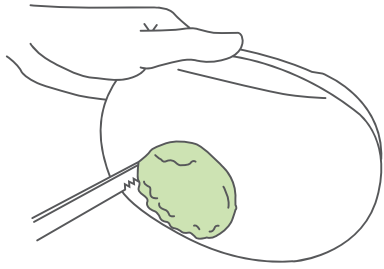
Using the trimming tool, cut a slit in the side of the foam that aligns with the slit in the helmet shell.



3. CUT A CENTER HOLE

Using the trimming tool, cut the foam along the center hole in the helmet shell. If necessary, use the trimming tool to clean up any rough edges.

NOTE: Be careful to avoid cutting other parts of the foam with the tip of the trimming tool while cutting out the center hole.



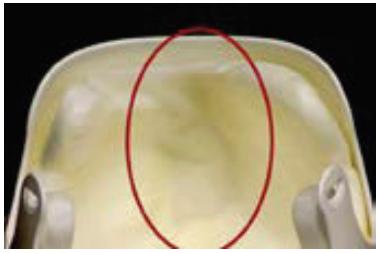
STEP EIGHT

EVALUATION OF VOIDS

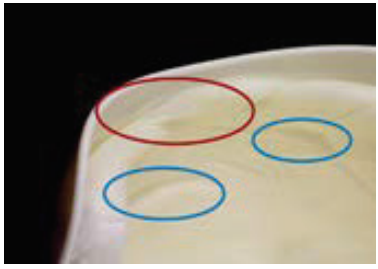
1. VERIFY FOAM THICKNESS AND PLACEMENT

Verify the foam completely filled the bladder with minimal voids, and the foam is not too thin. Foam thickness should be a minimum of about 1/4" thick, and should be verified in these 4 critical areas (forehead, nape of neck, both ear regions).

Below are examples of unacceptable voids as circled in red usually resulting from the chemicals not being dispensed quickly enough thus having insufficient foam in helmet.



Unacceptable due to large void and thin areas.



Unacceptable due to thin areas (circled in red) and obvious voids (circled in blue).

Acceptable - sufficient uniform thickness with no voids

TROUBLESHOOTING COMMON ISSUES

ISSUE: HELMET HAS VOIDS

(listed from most to least common)

Chemicals were not dispensed fast enough into the helmet

Once seal 2 is ruptured, the chemicals should be mixed and dispensed into the bladder within approximately 45 seconds - 1 minute.

Chemicals were not mixed well enough

The timer should be started as the seal is broken.
Once the seal is broken, the chemical pouch should be held taut and mixed vigorously across the table edge from side to side, at least 10-15 times, as indicated in the Instructions for Use.

Seal 1 was not broken prior to mixing

Seal 1 must be broken before mixing the chemical pouch from side to side.

Helmet is too small for head

Verify sizing helmet indicates the helmet is correctly sized for the head.

Helmet is too large for head

Verify sizing helmet indicates the helmet is correctly sized for the head.

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ISSUE: FOAM THICKNESS IS NOT ADEQUATE
(listed from most to least common)

Helmet is too small for head
Verify sizing helmet indicates the helmet is correctly sized for the head.

Helmet is not oriented on head appropriately
Verify the helmet is straight and positioned correctly on the head.

Helmet shell is not pulled together
Verify the helmet side strap pulls the helmet closed.

ISSUE: CRANIAL SOCK IS NOT TAUT
(listed from most to least common)

Cranial sock is placed on head backwards
Verify orientation of cranial sock.

Head may be too small for cranial sock and helmet
Verify sizing helmet indicates the helmet is correctly sized for the head. Trimming of the cranial sock may be completed to obtain proper fit and reduce material bunching.

ISSUE: FOAM PADS PROTRUDING FROM THE FOAM
(listed from most to least common)

Foam pads were twisted during helmet foaming
Follow IFU to verify pads are not twisted.

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SKIN CHECK AND TROUBLESHOOTING

1) For the first few days an infant wears the helmet, a caregiver should do skin checks every one to two hours and at frequent intervals thereafter.

2) If the skin is bright red in a specific area (does not disappear in the 15 minutes), then instruct the caregiver to contact the prescribing physician.

3) Most pressure problems are usually seen in the first week and towards the end of treatment when the child begins to outgrow the helmet. If there are pressure problems at times other than these, refer to the adjustments in #2 above.

4) Infants often perspire excessively for the first few days in the helmet until the child's body accommodates to the orthosis. Some children develop skin irritation due to perspiration. The irritation usually looks like a large area of redness in the area of total contact such as the forehead or occiput. If perspiration or irritation is a problem, ask the caregiver to remove the helmet for a few minutes throughout the day to clean and dry the infants head before replacing the helmet. An ointment can be prescribed at the physician's discretion.

5) Infants sometimes develop white flaking over large areas of skin without redness. This is acceptable and no modification is needed.

6) Only use rubbing alcohol to clean the inside of the helmet. Other products using fragrance, Clorox, etc. can leave residue and cause irritation.

7) The orthosis must be worn 23 hours a day to constrain any undesired growth and encourage growth in the correct locations. Even at the end of treatment the helmet should be worn 23 hours a day until treatment is stopped. There are a few times when it is acceptable to remove the helmet. These include when the child has a high fever, flu, day surgery, bath time, and when swimming. A new helmet may be necessary if the helmet is not worn for the recommended treatment time.

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LENGTH OF TIME THE ORTHOSIS MAY BE EFFECTIVE

AGE AT BEGINNING OF TREATMENT	AVERAGE TIME FOR THE ORTHOSIS TO BE EFFECTIVE
4 month old child	2 months
5 month old child	3 months
7 month old child	4 months

The orthosis becomes ineffective between 3 and 4 months of use because it is no longer able to exert corrective forces on the head. This is true even if the orthosis still fits after wearing it for four months. When the child outgrows the orthosis or the orthosis fails to provide corrective forces, reassess whether to fabricate a new P-POD Helmet to gain further correction or stop treatment if the results are satisfactory.

MEASUREMENTS

The physician should take circumference and both diagonal measurements of the patients head prior to device use. These measurements will help evaluate patient progress over time. See pages 20-21 of this document for details on these measurements.

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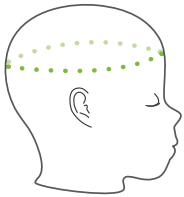
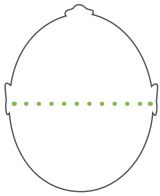


CIRCUMFERENCE

HOW TO MEASURE HEAD CIRCUMFERENCE

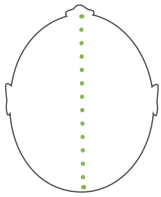
- Use a measuring tape that cannot be stretched
  - Securely wrap the tape around the widest possible circumference of the head
- Broadest part of the forehead above eyebrow
- Above the ears
- Most prominent part of the back of the head



WIDTH M/L

$$CI = \frac{M/L}{A/P} \times 100$$

CEPHALIC INDEX (CI)



LENGTH A/P

CEPHALIC INDEX (CI) SCALE

Below 75% - Scaphocephaly
75-80% - Normal
80-85% - Acceptable
85% and above - Brachycephaly

BRACHYCEPHALY SCALE

80-90% - Mild Brachycephaly
90-100% - Moderate Brachycephaly
100%+ - Severe Brachycephaly

GENDER	AGE	-2 SD	-1 SD	MEAN	+1 SD	+2 SD
MALE	16 days - 6 months	63.7	68.7	73.7	78.7	83.7
	6-12 months	64.8	71.4	78.0	84.6	91.2
FEMALE	16 days - 6 months	63.9	68.6	73.3	78.0	82.7
	6-12 months	69.5	74.0	78.5	83.0	87.5

The cephalic index is considered abnormal if it is two standard deviations (SD) above or below the mean measurements. (American Academy of Orthotists and Prosthetists (AAOP), 2004; Farkasand Munro, 1987)

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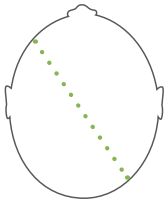
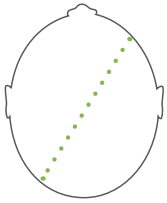


LEFT ANTERIOR - RIGHT POSTERIOR

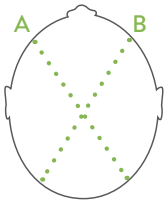


RIGHT ANTERIOR - LEFT POSTERIOR

DIFFERENCE

CRANIAL VAULT ASYMMETRY (CVA)

0-3mm - Normal
3-8mm - Mild
8-12mm - Moderate
12-15mm - Moderately Severe
15mm+ - Severe



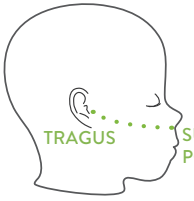
DIAGONAL A

DIAGONAL B

$$CVAI = \frac{|A-B| \times 100}{A \text{ or } B \text{ (whichever is greater)}}$$

CRANIAL VAULT ASYMMETRY INDEX (CVAI)

<3.5 - Normal
3.5-6.25 Mild
6.25-8.75 - Moderate
8.75-11.0 - Severe
>11.0 - Very Severe

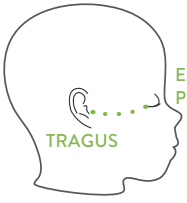


RIGHT SIDE

LEFT SIDE

DIFFERENCE

CRANIAL BASE ASYMMETRY



RIGHT SIDE

LEFT SIDE

DIFFERENCE

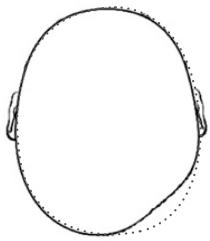
ORBITOTRAGIAL DEPTH ASYMMETRY

INSTRUCTIONS

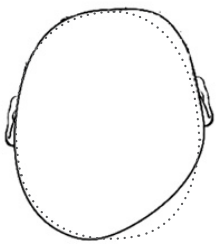
FOR PRACTITIONERS

VISUAL ASSESSMENT - VERTEX / TOP DOWN VIEW

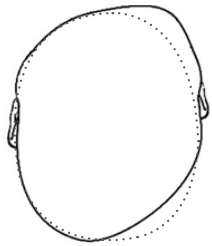
LATERAL DEFORMATIONAL PLAGIOCEPHALY



MILD
Flattening of back of skull only

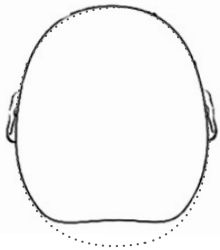


MODERATE
Ipsilateral ear anteriorly displaced, ipsilateral frontal bossing

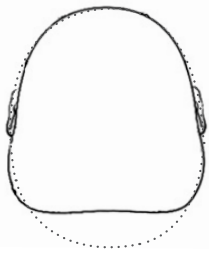


SEVERE
Ipsilateral temporal skull growth

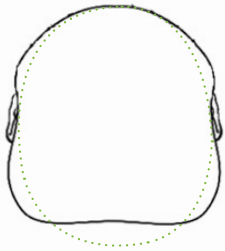
POSTERIOR DEFORMATIONAL PLAGIOCEPHALY (BRACHYCEPHALY)



MILD
Central posterior deformity



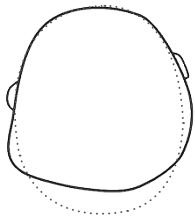
MODERATE
Widening of posterior skull



SEVERE
Temporal bossing

LAMBDOID CRANIOSYNOSTOSIS

Ipsilateral mastoid bossing
Ipsilateral posterior ear displacement



INSTRUCTIONS
FOR PRACTITIONERS

FOLLOW-UP VISITS

A series of follow-up appointments will be needed to monitor the child's progress, potentially make recommendations for caregiver questions, and/or replace an insufficient helmet due to the growth of the child. These scheduled visits should be two to three weeks apart to optimize treatment. If the family is having any problems with the helmet between visits, the child should be seen as soon as possible to ensure the orthosis is fitting properly. More frequent appointments may be needed with some patients at times of rapid growth, to correct problems, or to ensure compliance. Circumference and diagonal measurements can be taken during each appointment to monitor patient progress.

Begin each visit by asking the parents how the helmet treatment has been progressing. Ask specifically about the number of hours the child has been wearing the orthosis, and discuss the importance of wearing the helmet 23 hours per day if this has not been happening. The following items should be addressed at each visit:

SKIN INTEGRITY: Remove the helmet and inspect the child's skin. If problems occur, such as redness in areas, the side strap can be loosened or a new helmet can be manufactured to better fit the child s growth changes.

FLAT AREAS: Assess head symmetry during each follow up visit. Also, place the helmet on the child's head, then look and feel for space in the helmet for the flattened areas to expand. The side strap on the helmet can be adjusted to allow for the child's head to expand. A new helmet is a more viable option for those patients who need changes to the helmet.

OVERALL FIT: Make sure the helmet is well seated on the child's head. As the head circumference grows, loosening the side strap or creating a new helmet are options to accommodate the growth.

END OF TREATMENT: When the child outgrows the helmet, or the helmet is discontinued for any reason, circumference and diagonal measurements should be taken to determine if there is a need for a new helmet for more cranial correction.

It is important to stress the importance of compliance with the helmet-wearing schedule. Adherence to the 23-hour a day wear schedule is critical for successful completion of treatment. It can be helpful to speak with the family at the onset of treatment about potential compliance issues such as difficulty adjusting to helmet wearing, increased fussiness, pressure from extended family not to helmet, and compliance by other childcare providers. Discussing how to work through these issues can help increase the likelihood of successful treatment.

FOR TRANSLATIONS OF THESE INSTRUCTIONS FOR USE AS WELL AS OTHER SUPPORTING DOCUMENTS, PLEASE VISIT:

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PEDIATRIC PLAGIOCEPHALY
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