

# P-POD

PEDIATRIC PLAGIOCEPHALY  
ORTHOTIC DEVICE

## INSTRUCTIONS FOR USE

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## FOR PRACTITIONERS



# INSTRUCTIONS FOR PRACTITIONERS

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**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 performed 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.

# INSTRUCTIONS

## FOR PRACTITIONERS

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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.**

# INSTRUCTIONS

## FOR PRACTITIONERS

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### 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.

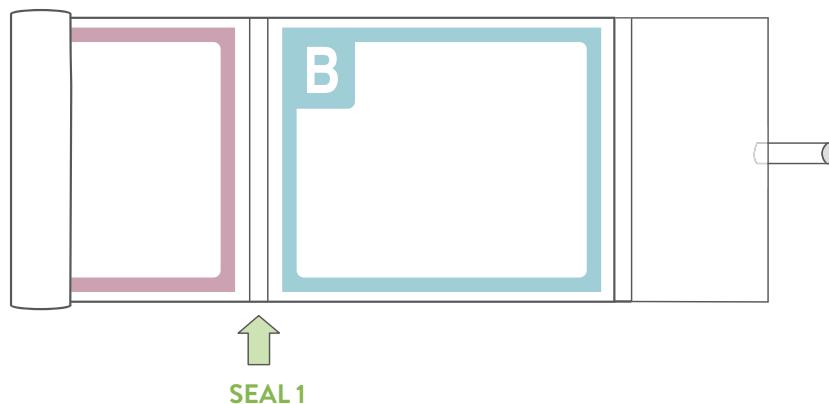
### Chemical Exposure from Foam

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.

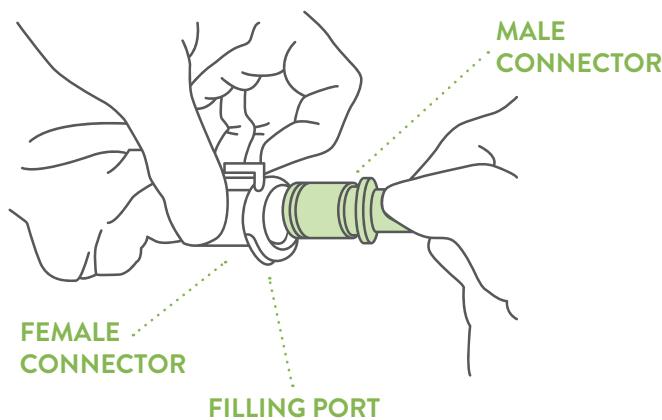
# INSTRUCTIONS FOR PRACTITIONERS

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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”.

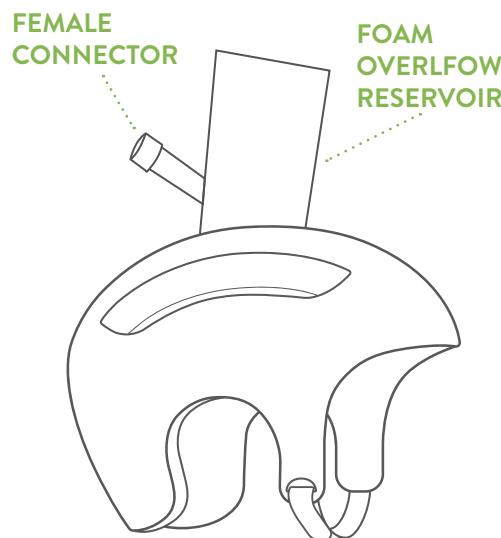


# INSTRUCTIONS

## FOR PRACTITIONERS

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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

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### 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

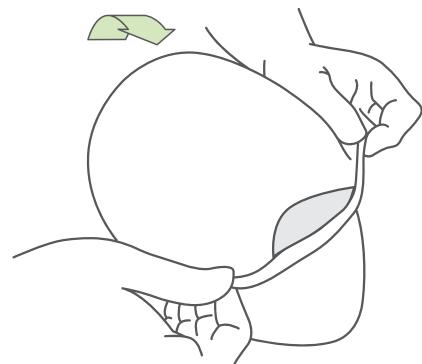
Other optional items (not included):

- 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.

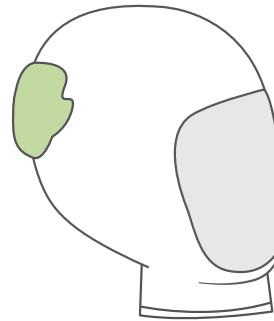
# INSTRUCTIONS FOR PRACTITIONERS

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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 1-2 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.



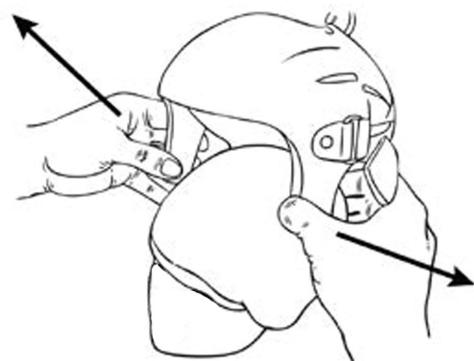
## STEP TWO

## 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.

# INSTRUCTIONS

## FOR PRACTITIONERS

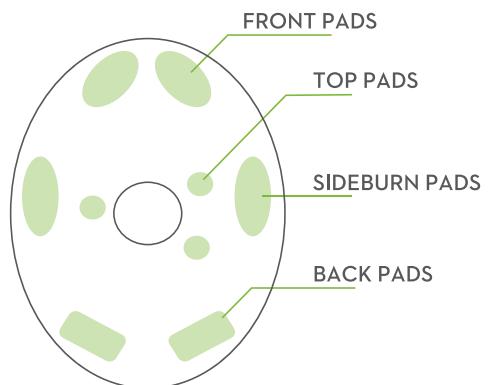
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### STEP THREE

### 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.

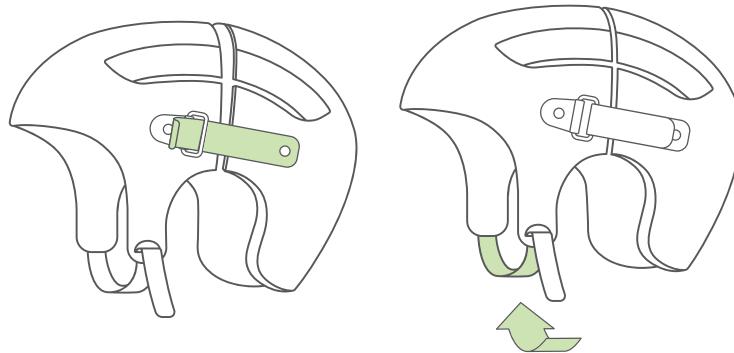


#### 2. FASTEN THE STRAPS

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.



# INSTRUCTIONS

## FOR PRACTITIONERS

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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.

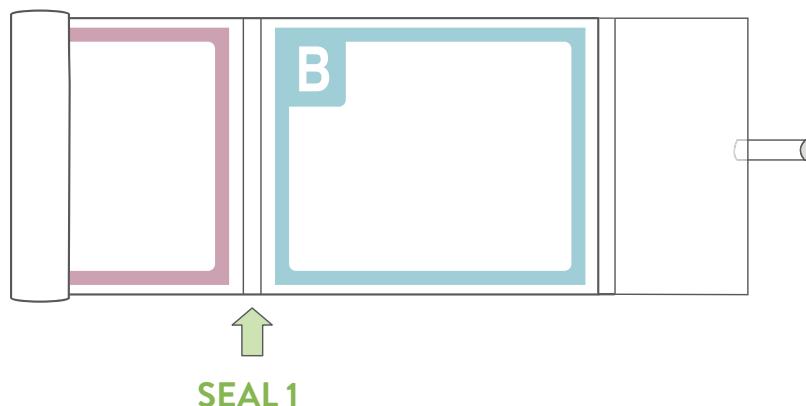
#### 1. SET TIMER FOR 10 MINUTES

In this step you will set the time for 10 minutes without beginning the timer. Do not start the timer until step 3, once you have ruptured the seal in step 2.



#### 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 toothpaste.



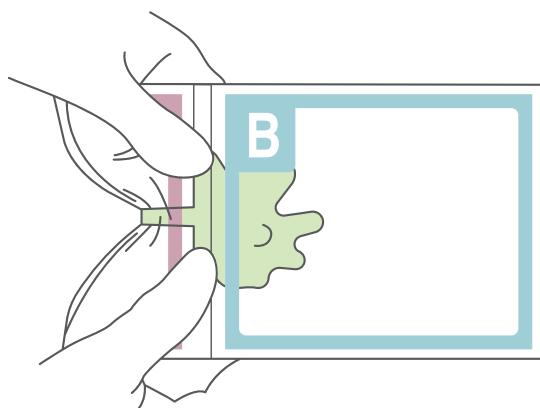
#### 3. START DIGITAL TIMER

# INSTRUCTIONS FOR PRACTITIONERS

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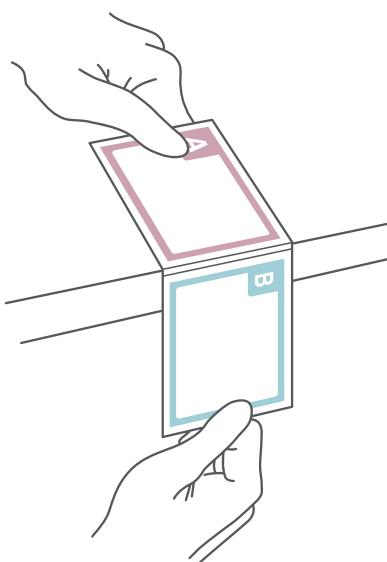
## 4. RUPTURE SEAL

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, up to 30 seconds. Seal 1 may be completely pulled apart and separated to improve foam mixing during this 30 second window.



# INSTRUCTIONS FOR PRACTITIONERS

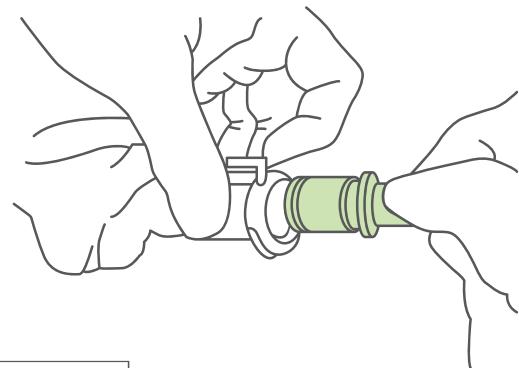
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## STEP FIVE

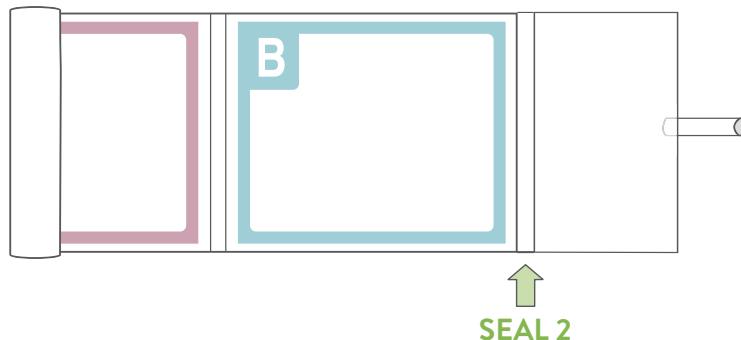
### FOAMING THE HELMET

#### 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.

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.

**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.



# INSTRUCTIONS FOR PRACTITIONERS

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## 4. WAIT FOR FOAM TO SET

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 greater expansion of the foam outward, if needed.

### STEP SIX

## REMOVING THE HELMET

### 1. CHECK THAT FOAM HAS SET

After 10 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.

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

### 2. REMOVE FOAM SOLUTION POUCH

When foam has set, 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

Unfasten the side strap and remove the chin 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.

# INSTRUCTIONS

## FOR PRACTITIONERS

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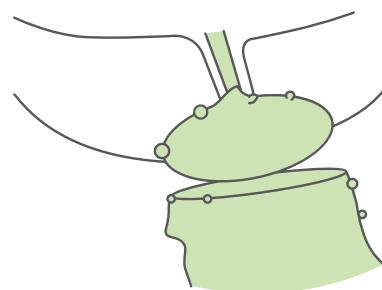
### STEP SEVEN

### FINISHING THE P-POD

#### 1. TRIM THE FOAM OVERFLOW

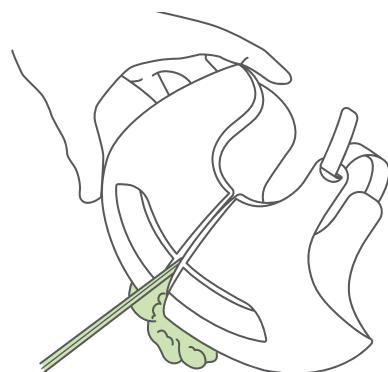
Using the trimming tool, remove the cylindrical overflow area protruding from the top of the helmet.

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

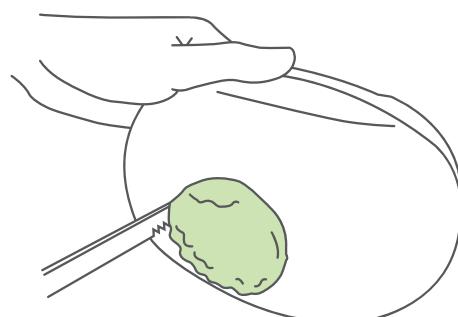
Using the trimming tool, cut a slit in the side of the foam that aligns with the slit in the helmet shell.



#### 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.



# INSTRUCTIONS

## FOR PRACTITIONERS

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### STEP EIGHT

### EVALUATION OF VOIDS

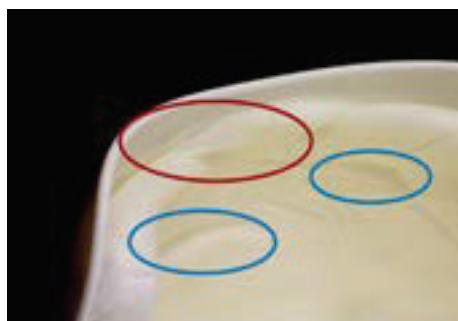
#### 1. VERIFY FOAM THICKNESS AND PLACEMENT

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

# INSTRUCTIONS

## FOR PRACTITIONERS

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### 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 30 to 40 seconds.

##### **Chemicals were not mixed well enough**

The timer should be started after the clip is removed but right before 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 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.

# INSTRUCTIONS

## FOR PRACTITIONERS

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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.

### 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.

# INSTRUCTIONS

## FOR PRACTITIONERS

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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 an extended period of time.

# INSTRUCTIONS

## FOR PRACTITIONERS

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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.

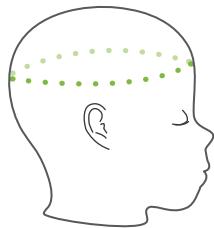
### MEASUREMENTS

The physician should take circumference and both diagonal measurements of the patient's 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.

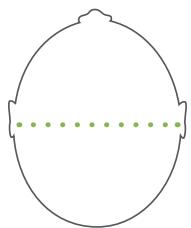
# INSTRUCTIONS

## FOR PRACTITIONERS

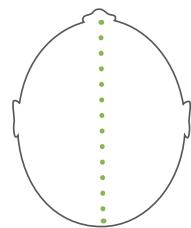
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CIRCUMFERENCE



WIDTH M/L



LENGTH A/P

### 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

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

CEPHALIC INDEX (CI)

### 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

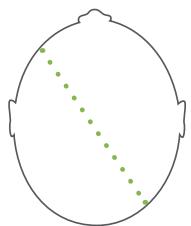
GENDER	AGE	-2 SD	-1 SD	MEAN	+1 SD	+2 SD
MALE	16 days - 6 months	63.7	68.7	73.7	78.7	83.7
	6-12 months	64.8	71.4	78.0	84.6	91.2
FEMALE	16 days - 6 months	63.9	68.6	73.3	78.0	82.7
	6-12 months	69.5	74.0	78.5	83.0	87.5

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; Farkas and Munro, 1987)

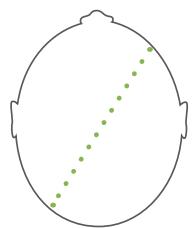
# INSTRUCTIONS

## FOR PRACTITIONERS

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LEFT ANTERIOR -  
RIGHT POSTERIOR

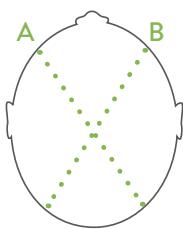


RIGHT ANTERIOR -  
LEFT POSTERIOR

**DIFFERENCE**

CRANIAL VAULT  
ASYMMETRY (CVA)

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



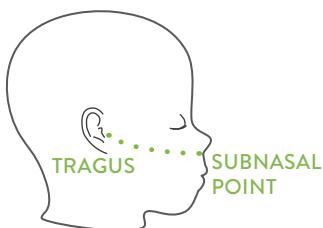
DIAGONAL A

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

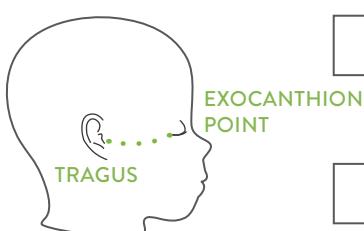


RIGHT SIDE

LEFT SIDE

**DIFFERENCE**

CRANIAL BASE ASYMMETRY



RIGHT SIDE

LEFT SIDE

**DIFFERENCE**

ORBITOTRAGIAL DEPTH  
ASYMMETRY

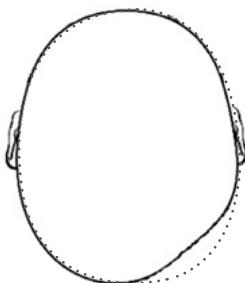
# INSTRUCTIONS

## FOR PRACTITIONERS

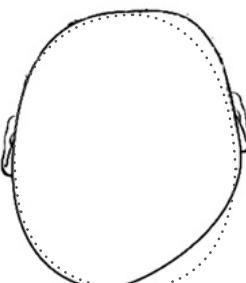
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### VISUAL ASSESSMENT - VERTEX / TOP DOWN VIEW

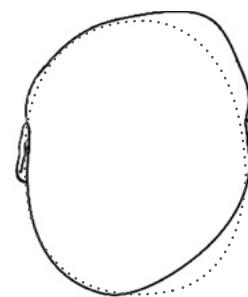
#### LATERAL DEFORMATIONAL PLAGIOCEPHALY



MILD  
Flattening of back  
of skull only

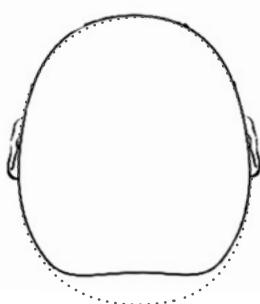


MODERATE  
Ipsilateral ear anteriorly displaced,  
ipsilateral frontal bossing



SEVERE  
Ipsilateral temporal  
skull growth

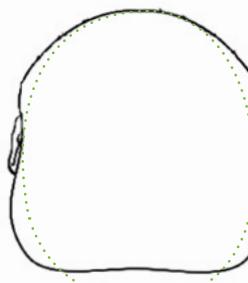
#### POSTERIOR DEFORMATIONAL PLAGIOCEPHALY (BRACHYCEPHALY)



MILD  
Central posterior deformity

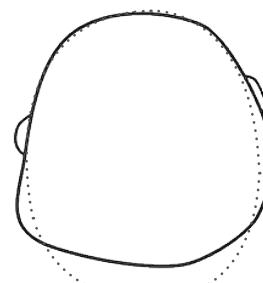


MODERATE  
Widening of posterior skull



SEVERE  
Temporal bossing

#### LAMBDOID CRANIOSYNOSTOSIS



Ipsilateral mastoid bossing  
Ipsilateral posterior ear displacement

# INSTRUCTIONS

## FOR PRACTITIONERS

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### 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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