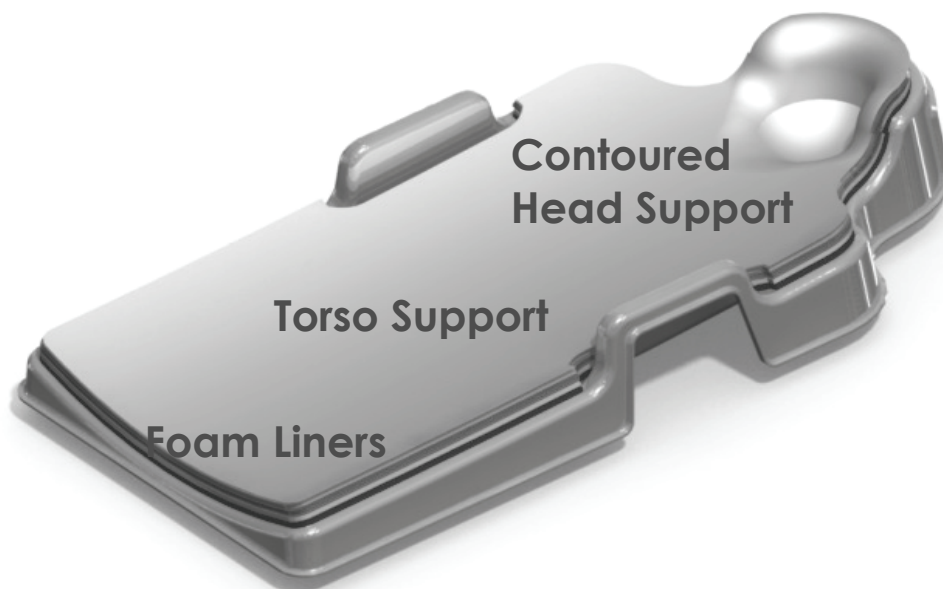


## **The Plagio Cradle™ is for use by Physician's Prescription Only**

### **Indications for Use/Intended Use**

The Plagio Cradle™ (patent pending) is an alternative resting surface designed to help prevent and/or treat developing plagiocephaly during the first 20 weeks of life. The device is intended to fit into a standard sized crib or bassinet and supports the infant's entire body. Patients should receive instructions from their physician regarding the length of time the cradle should be used. **Use should be discontinued when the child can roll over.** The Plagio Cradle™ should not be used as a replacement for a crib, bassinet, or other primary sleep structures and should NEVER be used as a carrying device or in a motor vehicle as a restraint. If the infant presents with brachycephaly (symmetrical flattening of the back of the head) the Plagio Cradle™ should not be used.



### Instructions for use

Determine the appropriate sizing for the infant using the measurement/sizing tool provided. Stabilize the infants head with the measurement tool in the open position, and gently place the long arms of the tool over the head and just behind the infants ears. The tool should be positioned so that the labeling is facing forward and the extended arms are perpendicular to the shoulders. Gently slide the tool closed until light contact is made on both sides of the head. Do not apply any pressure. The measurement tool can now be read to indicate the appropriate size layer as indicated by the designated number and/or color. If the back of the head fits too snugly in the cup, move to the next larger layer. The infant should have no more than a few millimeters space between the head and the foam liner. A significantly oversized cup is generally less effective in correcting flattening.

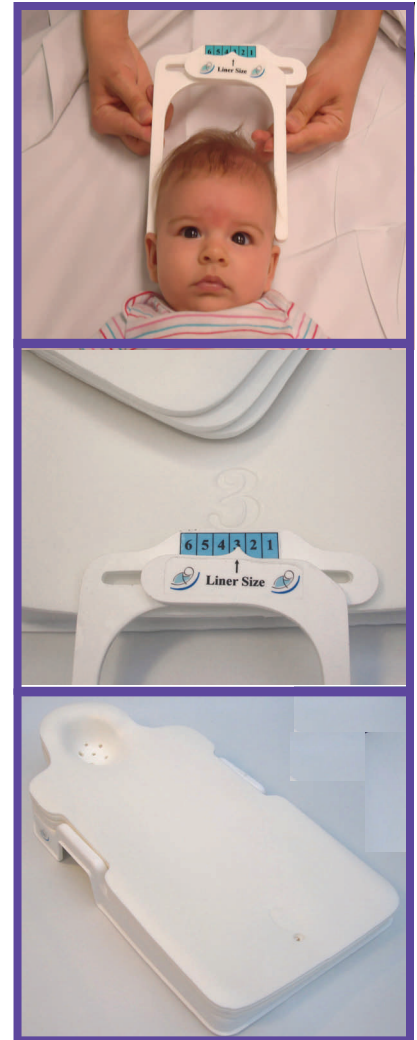
The Plagio Cradle™ is designed to grow as the baby's head grows. This allows for continued prevention/correction, depending on the need. Once sizing is determined, remove the liners until the indicated size liner is reached. The initial liner size (based on measurements) and the higher numbered (larger) liners underneath are to remain on the frame.

Two covers are provided with each Plagio Cradle. Apply one of the form-fitted fabric covers over the device and close on the underside using the snaps.

The assembled device may be placed within a standard crib or bassinet. The placement should be centered and flat on the crib or bassinet mattress. Do not place wedges, towels, or other materials under the Plagio Cradle, or in any way attempt to tilt or angle the device. The infant should only be in the device when it is positioned properly within the standard crib or bassinet. NEVER carry the infant in device.

**Position the infant on his/her back only so that the head fits easily into the contoured head support. The infant's torso should be centered on the torso section of the device. The infant is to be placed only on their back in the Plagio Cradle.**

Sizing should be checked on a weekly basis, or more often if prescribed, to ensure that the proper size is always being used.



**THE PLAGIO CRADLE SHOULD NOT BE PRESCRIBED IF THE INFANT IS OVER 12 WEEKS OF AGE OR ABLE TO ROLL OVER. USE OF THE PLAGIO CRADLE™ MUST BE DISCONTINUED WHEN THE INFANT IS ABLE TO ROLL OVER. IN ALL CASES, USE OF PLAGIO CRADLE MUST BE DISCONTINUED BY 20 WEEKS OF AGE.**



## CAUTIONS AND WARNINGS!



*The Plagio Cradle™ is for use by Physician's Prescription Only*

**DO NOT USE: THE PLAGIO CRADLE™ SHOULD NOT BE PRESCRIBED IF THE INFANT IS OVER 12 WEEKS OF AGE OR ABLE TO ROLL OVER. USE OF THE PLAGIO CRADLE MUST BE DISCONTINUED WHEN THE INFANT IS ABLE TO ROLL OVER. IN ALL CASES, USE OF THE PLAGIO CRADLE™ MUST BE DISCONTINUED BY 20 WEEKS OF AGE.**

**DO NOT USE:** If your infant has any known health or medical issues, consult your physician.

Abnormal head shape development may be a sign or result of a more serious medical condition, consult your physician for evaluation, treatment options, and referrals to a specialist if necessary. If the infant presents with brachycephaly (symmetrical flattening of the back of the head) the Plagio Cradle should not be used.

Use only in Juvenile Product Manufacturers Certified crib, on flat surface ([www.jpma.org](http://www.jpma.org)).

This product is not for side-sleeping. Consult your physician when considering the appropriate sleeping position for your infant.

Use only as directed.

This product is not for resale or for use without a prescription.

**This product makes no guarantee regarding Sudden Infant Death Syndrome (SIDS) prevention.** The Plagio Cradle system makes no claims in terms of its effectiveness as a SIDS prevention device. The Plagio Cradle is designed to symmetrically support an infant during sleep to decrease the risk of developing and/or helping to correct an acquired head shape deformity. The "Back to Sleep Campaign", which calls for all newborn children to sleep on their backs or sides, has reduced the annual incidence of SIDS from 1/500 to 1/1500 infants world wide. Despite this decrease in mortality, 1/1500 children still die annually from SIDS. Therefore, neither our product, nor strict adherence to the "Back to Sleep Campaign" guidelines can completely protect your child from SIDS. Please consult your physician with any further questions

**This product does not guarantee complete plagiocephaly prevention.** Some children with torticollis, soft skull bones, prenatal plagiocephaly, abnormal forces placed against their heads, Craniosynostosis, and other medical and/or growth related conditions may still develop head shape growth anomalies. In addition, Plagio Prevention, LLC makes no claims regarding the Plagio Cradle and its ability to treat plagiocephaly if the device is used improperly or without a physician's prescription.

**Adverse effects:** Some skin types require hypoallergenic mattresses or garments. If your child has any such a skin type, do not use this product. Children with medical conditions that lead to skin breakdown or irritation should only use the device under the direct supervision of their physician.

### **This Product is made of:**

- Fabric Cover: 100% Cotton
- Foam Liners: Biocompatible Foam
- Plastic Frame: Biocompatible Plastic

**For Questions regarding the Plagio Cradle** please call Plagio Prevention, LLC at 800-262-2235, or email us at [info@plagioprevention.com](mailto:info@plagioprevention.com). We are located at 20 Ledin drive, Avon, MA 02322

**In Case of a medical emergency,** contact your local emergency medical system and get your child to the closest emergency room capable of treating infants and children. In the United States, **call 911**. For other non-emergency questions contact our company at 800-262-2235.