

INTENDED USE / CLINICAL BENEFIT:

The Crown Cradle is a non-invasive, non-restrictive, adjustable device that comes in two sizes (Small for babies <1800 g and Large for babies 1800-3600 g). Each system contains a mattress, four foam inserts in increasing sizes that support the head, a cloth cover, and a 'plug' to fill in the recessed area when baby is in prone position.

WARNINGS / CONTRAINDICATIONS:

- For use by hospital staff with hospitalized infants
- In order to prevent airway obstruction, do not place infant prone or side-lying so that infant's face is situated in recessed area of mattress
- When infant is in supine position, ensure that infant's neck is not hyperextended and that their head is not tilted toward their chest thereby occluding airway. Change foam insert size to ensure proper head and neck alignment
- Do not insert needles or pins into the mattress, as this may compromise integrity of the mattress covering and create a contamination/infection risk.

CAUTION:

- Regularly inspect Crown Cradle mattress for any visible signs of damage and discard damaged mattress

CLEANING INSTRUCTIONS:

- Reusable Crown Cradle mattress, plug, and foam inserts should be wiped clean with standard hospital quaternary disinfectant any time they become soiled and between patient use
- Machine wash and dry all cloth components at temperatures up to 71°C with non-chlorine bleach. Tumble dry using medium heat



INSTRUCTIONS FOR USE:

- Use Crown Cradle mattress on NICU bed mattress
- Following hospital protocol, maintain routine position changes

To Position Baby in Supine or Side-Lying:

- Determine appropriate mattress and foam insert sizes based on infant's weight. Start by using the following recommendations:

SMALL MATTRESS (babies < 1800 g)

< 750 g	Foam Insert size 1
750-1000 g	Foam Insert size 2
1000-1400 g	Foam Insert size 3
1400-1800 g	Foam Insert size 4

LARGE MATTRESS (babies 1800-3600 g)

1800-2150 g	Foam Insert size 5
2150-2500 g	Foam Insert size 6
2500-3050 g	Foam Insert size 7
3050-3600 g	Foam Insert size 8

A properly-fitted foam insert will allow for approximately 1/8" of space on all sides of the infant's head. The infant's head, neck, and spine should be in a neutral position. The head and neck should not be flexed (foam insert too small) or extended (foam insert too large). Size foam insert up or down as necessary.

Note: When obtaining the infant's weekly growth measurements, check the foam insert size to determine if it needs to be upsized.

- To assemble Crown Cradle:
 - Slide mattress into fabric mattress cover with cup indentation at the top (open end of cover). Unquilted portion of mattress cover should lie over cup indentation and quilted portion should be positioned over the lower half of mattress
 - Slide desired size foam insert into pocket on inside of the fabric mattress cover and position cup inside the recessed area of mattress
 - Pull the cover up over mattress, ensuring foam insert is stable in the recessed area, and tuck the flap in under Crown Cradle mattress
- Place infant supine or semi-side-lying on Crown Cradle, with infant's head comfortably supported by foam insert
 - Gel pillows and other positioning aids should **not** be used under infant's head
 - Position infant in flexed, midline, and contained position. We recommend using Dandle WRAP Stretch and/or Dandle PAL or Cozy Cub to support developmentally-supportive positioning. It is helpful to use a positioner at infant's feet to prevent infant from sliding down on mattress. Stabilize infant's position by crossing mattress cover straps over the infant, as well as any positioning aids used, and then tucking straps under the Crown Cradle mattress

To Position Baby in Prone:

- To position the infant prone, first remove the foam insert, then insert the plug into the recessed area of the mattress so it lies flat with the mattress base
- Use a prone roll or positioner under the trunk and head to help position the infant in a flexed, midline, and contained position
We recommend using the Dandle WRAP Stretch and/or the Dandle PAL or Cozy Cub to support developmentally-supportive positioning. It is helpful to use a positioner at infant's feet to prevent infant from sliding down on mattress. Stabilize infant's position by crossing mattress cover straps over infant, as well as any positioning aids used, and then tucking straps under the Crown Cradle mattress

STORAGE AND DISPOSAL:

No special requirements.

DEHP-free, BPA-free, not made with natural rubber latex

Please contact Dandle•LION Medical with any questions or comments or to report any issue with the use of our product.

