

DandleROO™ Lite

Neurodevelopment Support System



INTENDED USE / CLINICAL BENEFIT:

DandleROO Lite is a neurodevelopmental support system that can be used for hospitalized preterm and ill infants in prone, supine and side-lying positions and during phototherapy where the percentage of light depends on number of layers used.

DandleROO Lite helps to continue physical and neuro development of infants by mimicking mother's womb and providing proper positioning. This also keeps baby calm during phototherapy treatment.

WARNINGS / CONTRAINDICATIONS:

- Hospital use only.
- Single Patient Use unless washing procedure has been validated by the hospital. Product is not guaranteed for laundering. Visually inspect product before use and after each laundering.
- Do not place wings or pouch around the baby's neck or face or use in any manner that might restrict infant's airway.
- Be sure Velcro® is attached securely by pressing it together from both sides. Avoid contact between the Velcro hook and the baby's skin.

CLEANING INSTRUCTIONS:

Product is intended for single patient use, may be hand laundered and line dried. Product may be used between patients if hospital validates a laundry protocol, however DandleLION Medical does not guarantee product performance after machine laundering. Visually inspect product after each laundering. Discard if stitching is not intact or edges are frayed.



INSTRUCTIONS FOR USE:

- Select the correct size DandleROO Lite according to the infant's weight and body proportions.
- If used without phototherapy, DandleROO Lite accessories are recommended: multi purpose roll, gel pillow with cover, and brim.
- If used during phototherapy, follow instructions on reverse side and adhere to recommendations from phototherapy unit manufacturer.

PRONE POSITION:

1. Place baby's head so it is touching top of headroll. Use multi-purpose roll, folded gel pillow or other support device as prone roll to support head, neck and spine in neutral alignment with knees and hips flexed and shoulders rounded forward so arms fall naturally with hands near face.
2. Bring shorter wing across body, supporting shoulder in flexion. Repeat with longer wing and attach Velcro to underside of base. Ensure wings are not near baby's face.
3. Ensure feet and hips are appropriately flexed and feet are in neutral alignment. Safely arrange all tubing and medical equipment. The multi-purpose roll accessory may be used to help maintain lower extremities in a posterior pelvic tilt by placing roll against the back of thighs and attaching it to underside of base with enough tension to help maintain position.
4. Adjust one or both sides of head boundary as needed by folding it over and attaching to bottom/ side of base using Velcro. Boundary may be used to support tubing in neutral position. Ensure head boundary is not causing any breathing obstruction.
5. If brim accessory is used (not during phototherapy), adjust it to block out direct light.

SUPINE POSITION:

1. If gel pillow is used, place it inside base in horizontal orientation to support head neck and scapula or in vertical orientation to support entire head and trunk.
2. Place baby supine on gel pillow with baby's head touching boundary. Gel pillow should support at least head and scapula.
3. Bring upper extremities into midline flexion with hands near face. Pull shorter wrap over arms, rounding shoulder forward. Pull longer wrap over top, rounding shoulders and containing arms. Fasten to underside. Adjust according to baby's needs and medical condition.

4. Flex baby's lower extremities into neutral midline position. Place multi-purpose roll up against baby's buttocks, supporting pelvis in posterior tilt. Attach roll to underside of base with enough tension to support hips and pelvis.
5. Safely arrange medical equipment.
6. Bring pouch up over legs and get with enough tension to help baby stay in flexed position. Bring sides of pouch around and fasten to back.
7. If more visualization of umbilical area is needed, fold pouch down and attached anywhere along sides.
8. Adjust one or both sides of head boundary by folding over and attaching to bottom/side using Velcro fasteners. Check placement of lines or tubes and make sure there are no obstructions to baby's breathing.
9. If brim accessory is used, adjust it to block out direct light.

SIDE-LYING POSITION:

1. If gel pillow is used, place it inside base in either horizontal or vertical position depending on size and needs of baby.
2. Place baby side-lying on gel pillow with baby's head nestling against top boundary.
3. Ensure both shoulders are rounded forward and legs and hips are loosely flexed.
4. Bring longer wing across shoulders to help maintain flexion and good posture. Attach to underside of base with Velcro.
5. Fold tabs of multi-purpose roll to body of roll so the baby's skin is not touching fasteners. Use roll behind back, as a body pillow or as needed.
6. Bring up pouch, keeping legs loosely flexed. Ensure lower end of pouch is available for foot bracing. Attach to underside of base with Velcro.
7. Adjust one or both sides of head boundary by folding over and attaching to bottom/side using Velcro fasteners. Check placement of lines or tubes and make sure there are no obstructions to baby's breathing.
8. If brim accessory is used, adjust it to block out direct light.

PHOTOTHERAPY:

1. Follow all manufacturers' guidelines for phototherapy equipment.
2. If DandleROO Lite is used during phototherapy treatment, please note layers of material will reduce effectiveness of light. Testing has shown that one layer of cotton (pouch or one wing, not overlapping) allows approximately 73% of phototherapy light irradiance to pass through; two layers of cotton (pouch plus one wing, or two wings) allows approximately 52% of the phototherapy light irradiance to pass through, and three layers of cotton (pouch plus both wings) allows approximately 43% of the phototherapy light irradiance to pass through.

STORAGE AND DISPOSAL:

No special requirements.

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

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

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