DandleROO™ Lite Neurodevelopmental Support System

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

The 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.



US Patent Nos 9.332.791 9.474.669 & 9.820.907

WARNINGS:

- · Hospital use only.
- Single Patient Use unless washing procedure has been validated by the hospital. Product is not guaranteed for 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.
- · Visually inspect product before use and after each laundering.
- 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 and may be hand laundered. 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.

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 the top of the headroll. Use multi-purpose roll, folded gel pillow or other support device as a 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 the body, supporting the shoulder in flexion. Repeat with the longer wing and attach Velcro to the underside of the base. Ensure wings are not near the 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 the lower extremities in a posterior pelvic tilt by placing the roll against the back of the thighs and attaching it to the underside of the base with enough tension to help maintain the position.
- 4. Adjust one or both sides of the head boundary as needed by folding it over and attaching to bottom/side of the base using Velcro. Boundary may be used to support tubing in a 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.

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PRONE POSITION

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- 2. Bring shorter wing across the body, supporting the shoulder in flexion. Repeat with the longer wing and attach Velcro to the underside of the base. Ensure wings are not near the 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 the lower extremities in a posterior pelvic tilt by placing the roll against the back of the thighs and attaching it to the underside of the base with enough tension to help maintain the position.
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- 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 the base in a horizontal orientation to support head neck and scapula or in a vertical orientation to support the entire head and trunk.
- Place baby supine on the gel pillow with baby's head touching the boundary. Gel pillow should support at least the head and scapula.
- 3. Bring upper extremities into midline flexion with hands near face. Pull the shorter wrap over the arms, rounding the shoulder forward. Pull the 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 a neutral midline position. Place the multi-purpose roll up against the baby's buttocks, supporting the pelvis in a posterior tilt. Attach roll to underside of base with enough tension to support the hips and pelvis.

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 5. Safely arrange medical equipment.

 6. Bring pouch up over legs and get with enough tension to help the baby stay in a flexed position. Bring sides of pouch around and fasten to the back.

 7. If more visualization of the umbilical area is needed, the pouch can be folded down and attached anywhere along the 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 the base in either a horizontal or vertical position depending on the size and the needs of the baby.
- Place baby side-lying on the gel pillow with baby's head nestling against the top boundary.
- Ensure both shoulders are rounded forward and legs and hips are loosely flexed.
- Bring longer wing across the shoulders to help maintain flexion and good posture. Attach to the underside of the base with Velcro.
- 5. Fold the tabs of the multi-purpose roll to the body of the roll so the baby's skin is not touching the fasteners. Use roll behind the back, as a body pillow or as needed.
- Bring up pouch, keeping legs loosely flexed. Ensure lower end of pouch is available for foot bracing. Attach to underside of base with Velcro.
- 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.
- If brim accessory is used, adjust it to block out direct light.

PHOTOTHERAPY:

1. Follow all manufacturers' guidelines for phototherapy equipment.

If the DandleROO Lite is used during phototherapy treatment, please note the layers of the material will reduce the effectiveness of the light. Testing has shown that one layer of cotton (pouch or one wing, not overlapping) allows approximately 73% of the 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.

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