Swaddler for Phototherapy

Instructions for Use

Swaddling Techniques:

- Select the correct size Swaddler for Phototherapy based on the weight of the infant.
- Position the infant on the Swaddler so that he/she lies over the rear panel section as shown.



- Fold the top panel of the Swaddler for Phototherapy over the infant and around to his/her back, swaddling the arms and legs.
  (For smaller infants, take care NOT to wrap the Swaddler back around to the front of the child.)





- Fold the leg wrap portion of the Swaddler under the legs of the infant, taking care not to bend the feet or toes.



Note: Ensure there is always only one layer of material between the baby and the phototherapy light. Caution: Always monitor swaddled infant for temperature, possible entrapment, suffocation, or strangulation.

Use with Phototherapy



With Overhead Phototherapy

- Swaddle the infant as described.
- After the infant is properly swaddled, position the swaddled infant under the light source, taking care to properly protect the infant's eyes from the phototherapy light by using eye shades and other means.

With Fiber optic Pad Phototherapy

- Swaddle the infant as described.
- After the infant is properly swaddled, slide the fiber optic pad light source inside the pocket behind the rear panel of the Swaddler.
- Position the swaddled infant atop the fiber optic pad light source and administer phototherapy in the usual fashion.

With Double Phototherapy

- Swaddle the infant as described.
- After the infant is properly swaddled, slide the fiber optic pad light source inside the pocket behind the rear panel of the Swaddler.
- Position the swaddled infant atop the fiber optic pad light source and administer phototherapy in the usual fashion.
- Position an overhead light source above the infant, taking care to properly protect the infant's eyes from the phototherapy light by using eye shades or other means.
- Administer phototherapy from both the overhead light source and the fiber optic pad light source in the usual fashion.

Caution: Always monitor swaddled infant for temperature, possible entrapment, suffocation, or strangulation.

Note: Use of the Swaddler for Phototherapy as an adjunct to phototherapy is appropriate for any infant for whom phototherapy has been deemed clinically necessary and who does not have contraindications to either phototherapy or swaddling.

Efficacy: The Swaddler for Phototherapy transmits over 90% of the phototherapy light to the patient and should not affect phototherapy efficacy. It also does not affect infant temperature. As always, the decision to begin or continue phototherapy on any patient should be based on accepted practice guidelines.

While no additional risk factors have been identified with the use of the Swaddler for Phototherapy, all infants using the Swaddler while undergoing phototherapy should be closely monitored for temperature rise, entrapment, suffocation, or strangulation.

Indications: The Swaddler for Phototherapy is intended to be used as an adjunct to phototherapy systems used for the treatment of hyperbilirubinemia in the clinical or home setting.

Caution: Always monitor swaddled infant for temperature, possible entrapment, suffocation, or strangulation.

Note: Use of the Swaddler for Phototherapy as an adjunct to phototherapy is appropriate for any infant for whom phototherapy has been deemed clinically necessary and who does not have contraindications to either phototherapy or swaddling.

Contradictions to Use:

- **Do not use the Swaddler for Phototherapy if any of the following are present:**

  Xeroderma pigmentosum
  Cholestatic Jaundice
  Porphyria
  Gastroschisis
  Omphaloceles
  Neural tube defects
  Ichthyosis or other severe skin diseases

- **Do not use The Swaddler if phototherapy is contraindicated.**

The Swaddler for Phototherapy is Available in the Following Sizes:

- #1100 (Preemie <1500g)
- #1105 (Newborn Regular >1500g)

Use Infants weight to select the proper size of The Swaddler.

BIONIX®

Swaddler for Phototherapy

Instructions for Use

- **Made in the USA.**
- **Federal law restricts this device to sale by or on the other of a licensed medical professional.**
- **For Single-Patient Use Only.**
- **Patent # 8,756,731**

RM95-1100 Rev. 5/27/15 ©2015 Bionix Development Corp.

BIONIX®
5154 Enterprise Blvd. • Toledo, Ohio 43612
Phone: 800.551.7096 • Fax: 800.455.5678
www.BionixMed.com