KLUBA
MEDICAL

MedibinoNEO®
Version 1 REV 0 (14.06.2022)

CE

Thank You for your trust!

The product complies with the requirements of Medical Device Regulation MDR (EU) 2017/745. Please always quote the UDI and LOT Number in the event of a complaint. You will find this on the label on the packaging.

DIN EN ISO 14971 | DIN EN ISO 13485
Dear user of the MedibinoNEO® head support ring for premature babies and infants, we are pleased that you have chosen our product. In this instruction manual we provide you with important information and explain the optimal use of the MedibinoNEO® in the clinical environment. Thank you for your confidence.

Your Kluba Medical Team

CE

Contents

Products and Product Components

MedibinoNEO® consists of various components that can be used in different variations. The basic product consists of three components: A support ring, an inner cushion and an outer protective cover made of fabric. The cover of the MedibinoNEO® support ring can be removed by means of a hotel closure and the gel ring can be taken out. The use of the inner cushion is optional. It can be used if the responsible person wants to balance the height between the gel ring and the mattress.
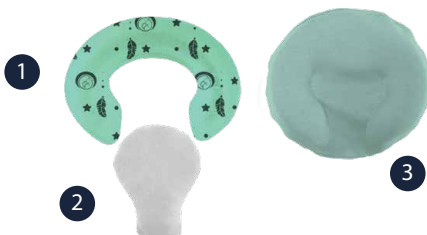
The MedibinoNEO® support system includes 3 different sizes:

Size L   Size M   Size S
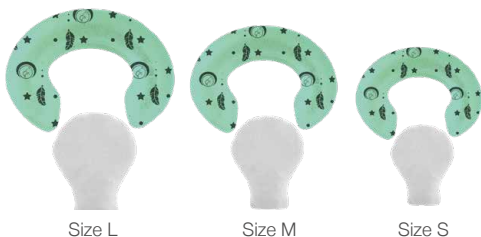
1. MedibinoNEO® size S for premature babies up to 800g,
   Dimensions: 90 mm x 80 mm x 18 mm
2. MedibinoNEO® size M for premature babies between 800g and 2000 g,
   Dimensions: 110 mm x 95 mm x 22 mm
3. MedibinoNEO® size L for premature babies between 2000g and above and newborns,
   Dimensions: 130 mm x 110 mm x 25 mm

Product components
- disposables

MedibinoNEO® disposable Cover cotton knit WITHOUT soft granules - colour coded

Sizes

Size S, for use with support ring and inner cushion Size S - colour coding yarn pink

Size M, for use with support ring and inner cushion Size M - colour coding yarn turquoise

Size L, for use with support ring and inner cushion Size L - colour coding yarn grey

Application

The MedibinoNEO® Cover made of cotton knit is a cover for single use. It can be used together with the cotton cover with hotel closure to protect it. Alternatively, it can be placed directly over the ring and inner cushion (optional). In case the inner cusion is used, the central positioning of the inner cushion should be checked.

MedibinoNEO® disposable cover cotton knit WITH soft granules - colour coded

Sizes

Size S, for use with support ring and inner cushion Size S - colour coding yarn pink

Size M, for use with support ring and inner cushion Size M - colour coding yarn turquoise

Size L, for use with support ring and inner cushion Size L - colour coding yarn grey

Application

The Medibino cover made of cotton knit WITH soft granules is a cover for single use. As it already contains a soft granulate depot, it is used without the inner pillow and is simply slipped over the head ring.

List of product components

UDI-DI	Article No.	Article
MedibinoNEO® ring – TG PUR Gel ǀ PU of 6 pieces & 1 piece		
4260764840557 / 4260764840700	24021703-L / 41021704-L	MedibinoNEO® gelring size L
4260764840564 / 4260764840717	24021703-M / 41021704-M	MedibinoNEO® gelring size M
4260764840571 / 4260764840724	24021703-S / 41021704-S	MedibinoNEO® gelring size S
MedibinoNEO® inner pillow, WWL 200 filled with soft granulat		
4260764840731	25021703-L	MedibinoNEO® inner pillow size L
4260764840748	25021703-M	MedibinoNEO® Innenkissen size M
4260764840755	25021703-S	MedibinoNEO® Innenkissen size S
MedibinoNEO® cover GOTS cotton - size colour coded ǀ PU of 6 pieces		
4260764840762	26021703-L	MedibinoNEO® cover organic cotton Size L with hotel closure
4260764840779	26021703-M	MedibinoNEO® cover organic cotton Size M with hotel closure
4260764840786	26021703-S	MedibinoNEO® cover organic cotton Size S with hotel closure
MedibinoNEO® disposable Cover cotton knit WITHOUT soft granules - colour coded ǀ PU of 50 pieces		
4260764840793	27021703-L	MedibinoNEO® Cover cotton knit size L - colour coded WITHOUT soft granules
4260764840809	27021703-M	MedibinoNEO® Cover cotton knit size M - colour coded WITHOUT soft granules
4260764840816	27021703-S	MedibinoNEO® Cover cotton knit size S - colour coded WITHOUT soft granules
MedibinoNEO® disposable cover cotton knit WITH soft granules - colour coded ǀ PU of 50 pieces		
4260764840823	31021703-L	MedibinoNEO® Cover cotton knit size L - colour coded WITH soft granules
4260764840830	31021703-M	MedibinoNEO® Cover cotton knit size M - colour coded WITH soft granules
4260764840847	31021703-S	MedibinoNEO® Cover cotton knit size S - colour coded WITH soft granules

⚠ Important safety instructions

The MedibinoNEO® is suitable for premature babies and newborns and can be used from the first day of life. The product has been manufactured according to the latest state of the art and recognised safety rules. However, damage cannot be safely ruled out in the event of improper use. Therefore, please observe the following general safety instructions:

- Read these operating instructions and follow all instructions.
- Keep these operating instructions so that they are accessible to all users of the product at all times and always pass the MedibinoNEO® support ring on to third parties together with these operating instructions.
- Before first use, the protective cover shall be washed and the inner cushion and the support ring shall be wipe-disinfected.
- Do not use sharp objects such as needles near the MedibinoNEO® to avoid perforation and gel leakage.

The use of the MedibinoNEO® does not release the user from the general duties of care and supervision.

Non-intended use means that you should not:
- use it in any way other than that described in these operating instructions.
- use it in applications that deviate from the operating instructions and hygiene regulations.
- use it without a protective cover or with a broken protective cover, or use it soiled and not disinfected.

Contraindications
No contraindications known.

Intended Use

Prevention of cranial deformities:

MedibinoNEO® is a medical device that provides a simple, flexible and safe solution to prevent and alleviate positional skull deformity (plagiocephaly, brachycephaly) in babies. As the skull bones are still relatively susceptible to external influences in the first months of life due to their thinness and strength as well as open sutures, the natural round shape can easily change, which is shown for example by a flattening of the back of the head or one side of the back of the head. If this occurs, long-term consequences such as jaw malpositions, developmental delays, movement and posture problems cannot be ruled out.

The ergonomic ring shape of the MedibinoNEO® support ring with its soft, rounded top (support surface) and the even distribution of the weight of the baby's head enable natural, stress-free head growth. The development of undesirable head deformities is thus prevented in the best possible way. Early and frequent use is recommended during the first months of life. It makes sense to use the MedibinoNEO® until the child has sufficient mobility of its own (e.g. turning onto its stomach).

Positioning in the mid-head position (prevention of intraventricular haemorrhages)

For the first 72 hours of life, supine and mid-head positioning is the clinical standard, especially for preterm infants <26 weeks gestation and within the first 72 hours of life, to prevent intraventricular haemorrhages (IVH). If intraventricular haemorrhages occur, the head should be positioned in the midline position. The MedibinoNEO® can be used to stabilize the midline position of the head.

Intra-hospital transport

For intra-hospital transport, the MedibinoNEO® can be used to stabilise the back of the head and soften it for jerky jolts to reduce risks of brain haemorrhage.

Positioning during therapeutic interventions/ surgeries or therapy for asphyxia

During therapeutic interventions (e.g. insertion of a stomach tube, suctioning, surfactant administration, ventilation) and surgeries where the head must be kept in the midline position, the MedibinoNEO® can be used as a stabilising positioning ring. In neonatal asphyxia, the guideline states that the upper body should be elevated and the head kept in the midline position for 72 hours.

Information on side effects

There are no known hazards or side effects for patients within the scope of the application described in these instructions for use.

Notes on Commissioning

Please wash the reusable cover of the MedibinoNEO® before first use and regularly during use. We also recommend cleaning the support ring and the inner cushion with commercially available disinfectants before first use.

Commissioning of the MedibinoNEO® support ring with inner cushion and cotton cover with hotel closure

Step 1:

Open the hotel closure by folding up the top end. Insert the two ends of the MedibinoNEO® into the cover.

Step 2:

Slide the inner cushion into the designated opening in the centre of the cover between the designated seams. *The use of the inner cushion is optional. It can be used if the responsible person wants to balance the height between the gel ring and the mattress.*

Step 3:

Close the hotel closure by putting the upper end over the gel ring. Turn the MedibinoNEO® over. It is now ready for use and can be positioned under the infant's head.

Step 4 (optional):

The disposable cover can be used without washing for immediate, single use as a hygienic change layer over the fabric cover. To do this, simply put the disposable cover over the MedibinoNEO®.

Putting the MedibinoNEO® support ring with inner cushion and disposable cover with elastic band WITHOUT soft granules into operation

You can also put the disposable cover directly over the gel ring and the inner cushion (optional) without using the cover with hotel closure. If you use the inner cushion, please note that the positioning of the inner cushion in this version is less stable and should be checked regularly.

Step 1:

Position the inner cushion in the gel ring and slip the disposable cover over the gel ring and the inner cushion with the elastic downwards. **The use of the inner cushion is optional. It can be used if the responsible person wants to balance the height between the gel ring and the mattress.**

Step 2:

If you are using the inner cushion, check the positioning of the inner cushion inside the ring. Turn the MedibinoNEO® over by placing one hand underneath it so that the inner cushion stays in place. It is now ready for use and can be positioned under the infant's head.

Putting the MedibinoNEO® support ring into operation with disposable cover WITH soft granules
The disposable cover WITH soft granules is used without the inner cushion and is put directly over the gel ring.
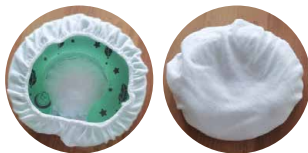
Step 1:

Position the gel ring on a surface and put the disposable cover WITH soft granules over the gel ring with the elastic downwards.


Step 2:

Check that the depot with the soft granules is positioned in the recess provided in the gel ring. Turn the MedibinoNEO®. It is now prepared for use and can be positioned under the infant's head.

Positioning

MedibinoNEO® can be used on any newborn or infant in just a few steps: First, the components of the MedibinoNEO® are put together (see putting into operation). During use, please ensure that the support ring is completely enclosed by the covers with as few folds as possible and that the inner cushion/gel depot (if used) lies in the hollow provided for it in the cushion.

The MedibinoNEO® is placed with the flat side on a flat, preferably non-slip surface. The head of the newborn or infant in the supine or lateral position is placed on the soft, rounded surface (support surface) of the MedibinoNEO® positioning ring.

Not face down

Not around the neck

curvature not downwards

Opening not on the side or above
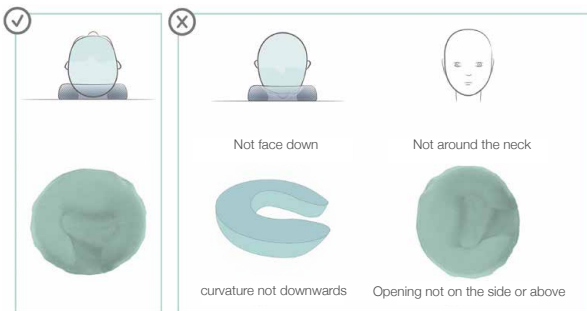
The MedibinoNEO® can be used for supine and lateral positioning of children. The three different sizes allow the positioning ring to be optimally adjusted to the head size of the premature baby, newborn or infant, preventing the head from slipping out and providing increased protection. Since not only the size of the head (circumference) alone is significant for the adjustment, but also the shape of the head, there is no formula with which the correct fit of the ring can be calculated. The correct size results from a size approximation as well as the control of the exact fit to the back of the head and the correct position (see below).

On the following page we explain how to determine the correct size of your MedibinoNEO® support ring in just a few steps.

Sizing

To determine the size variant, the child's head circumference, height and body weight are measured. These provide guide values for the choice of head support ring sizes S, M or L. However, the head-body proportions may vary individually and the shape of the head may also vary individually. Therefore, it should be checked that the head is flush with the ring and that the back of the head comes to rest freely in the inner recess without contact with the mattress.

1. **Size S:** body weight up to approx. 800g
   head circumference: up to approx. 22cm

2. **Size M:** body weight approx. 800-2000g
   head circumference: up to approx. 30cm

3. **Size L:** body weight from 2000g
   head circumference: from circa 30cm
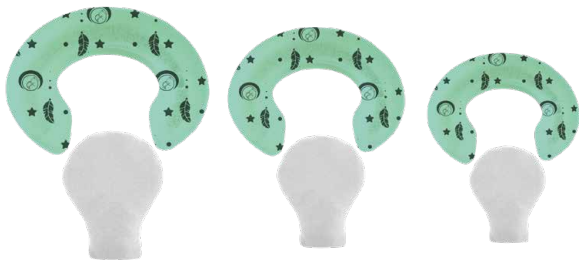
Correct position: The head ring is placed with its flat underside on a flat, preferably non-slip surface. The head of the infant is placed on the soft, rounded raised surface of the MedibinoNEO®, with the back or side of the head placed centrally in the recess of the support ring so that the chin is slightly below the forehead in profile. Viewed from the side, the child's head should lie as straight as possible without the head resting on the mattress. If the support ring is too small or positioned too close to the neck, an inclination, i.e. an approach of the chin to the neck/chest bone, would be seen. If the support ring is too large, the entire back of the head will rest within the opening on the mattress.
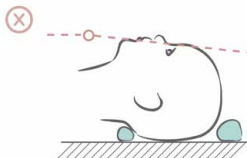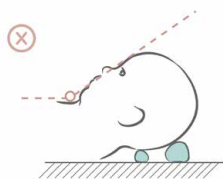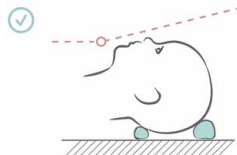
Period of use: Due to the biocompatibility test with the cover, the positioning ring allows a total lying time of 72 hours at a stretch, e.g. 72 hours in the mid-head position if indicated. In case of a longer lying time, short breaks, e.g. in prone or side position or on the parent's arm are suitable to allow a long-term application period of several weeks and months. It is recommended that the

nursing staff reposition premature and newborn infants according to the minimal handling approach. If the premature infants are positioned alternately in the lateral, supine and prone position, the MedibinoNEO® can be used for the supine position. It can also be used for lateral positioning to stabilize the head.

Checking the positioning: With increasing mobility, the child's correct positioning should also be checked more frequently. The more mobile the child becomes, the more often the infant may move out of the ring.

General Information

1.   All materials used have been tested for good skin and tissue compatibility and are used in various medical applications. Allergic skin reactions are currently not known.

2.   Select the size of the support ring according to the instructions for use and check the accuracy of fit in relation to the growth of the baby's head at regular intervals to ensure stable and safe support.

3.   within the scope of the warranty, the components of the MedibinoNEO® and its shape must not be changed. Improper use excludes any assumption of liability for any damage to or in the body.

Cleaning Instruction

Cleaning is carried out using suitable, skin-friendly cleaning agents, disinfectants or detergents and should be carried out at regular intervals or as required. Please remove the soft gel core from the cover before cleaning.

Softgel storage ring: The inner core of MedibinoNEO® is non-sterile. It can be wipe-disinfected and is suitable for cleaning with commercially available disinfectants.

Inner pillow: The inner pillow is non-sterile. It is water-repellent and can be wipe-disinfected and is suitable for cleaning with commercially available disinfectants.

Cover made of GOTS cotton with hotel closure: The cover of the storage ring can be washed at 60°C in the washing machine with light-coloured textiles. The use of low-pollutant detergents is recommended.

Disposable Covers: The disposable covers WITH and WITHOUT soft granules are designed for single use. We recommend replacement once a day for one patient.

Please note that you do not put the MedibinoNEO® "completely", i.e. including the inner cushion and support ring, into the washing machine, but only the cover. Even though the core of the support ring and the inner cushion are water-repellent and can be disinfected by wiping, they can be damaged by the mechanical stress of machine washing.

Shelf Life, durability and technical data

	Dimensions	**Size L:** 130 mm x 110 mm x 25 mm **Size M:** 110 mm x 95 mm x 22 mm **Size S:** 90 mm x 80 mm x 18 mm
	During Use	MedibinoNEO® gel ring should not be exposed to temperatures below -30°C and not to temperatures above +60°C. The permissible humidity range for use is 30% to 80% (non-condensing).
		MedibinoNEO® inner pillow should not be exposed to temperatures below -30°C and not to temperatures above +50°C.
	Shelf Life	**Shelf life:** The MedibinoNEO® gel ring has a shelf life of 36 months from the date of manufacture. The MedibinoNEO® inner cushion and the disposable cover with soft granulat has a shelf life of 24 months from the date of manufacture.
	Duration of use after first use	**Duration of use after first use:** The MedibinoNEO® gel ring can be used for 12 months after the first application. The MedibinoNEO inner cushion can be used for 12 months after the first application.
	During Storage	**MedibinoNEO® gel ring:** The permissible temperature range for transport and storage is between -30°C and +60°C . The permissible humidity range during transport and storage is 10% to 90% (non-condensing). The permissible ambient air pressure is 700 hPa to 1060 hPa. Please protect from intense sunlight, store in the dark.
		MedibinoNEO® inner cushion and MedibinoNEO® cover WITH soft granulate: For longer storage, temperatures above +30°C should be avoided. Due to the granulate, the inner cushion should be stored in conditions with a relative humidity below 65%. Storage should not take place outdoors.
		Textile components: The textile components should be protected from excessive sunlight.
	Disposal	The MedibinoNEO® and the packaging can be disposed of with the recyclable waste.

Manufacturer's Declaration

Within the scope of the statutory provisions, Kluba Medical GmbH warrants the MedibinoNEO® product to the original purchaser for a period of two years from the date of purchase that the product was free from material defects at the time of delivery. Excluded from the warranty obligation are damages caused by wear and tear, by intent as well as by negligent or improper use. Likewise, no liability whatsoever is accepted for any form of intervention, modifications, extensions, repairs and maintenance work carried out by persons not authorised by us. Accessories or spare parts that come from other manufacturers and have not been approved by us must not be used during operation.

The Kluba Medical team wishes you much success with the product!

Contact

Kluba Medical GmbH
Brunnenstraße 23, 40223 Düsseldorf
Phone: +49 (0) 211 5421 2590
E-Mail: info@kluba-medical.com
Internet: www.kluba-medical.com

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