

# Medibino<sup>®</sup>

*the baby head guard* 



**Version REV 7 (13.03.2020)**

The product complies with the requirements of Directive 93/42/EEC. Please always state the batch number in the case of complaints. These can be found on the outside of the packaging.

**DIN EN ISO 14971**  
**DIN EN ISO 13485**

**INSTRUCTIONS FOR USE**

**ENG**



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Dear User of the Medibino® baby head guard,

We are delighted that you have chosen Medibino®, and thus a product that will promote the healthy development of your child. In this operating manual, we provide you with important information and explain the best way to use Medibino®. Thank you for the confidence you place in us.

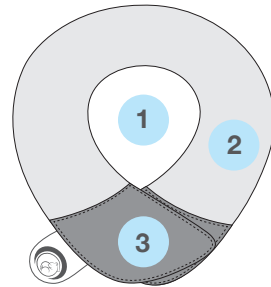
Your Kluba Medical team

## Scope of delivery

- Medibino® baby head guard incl. protective bag
- Operating manual

## Operating manual

- 1 Underlying surface
- 2 Contact area
- 3 Velcro fastener for size adjustment



## Components of the Medibino® baby head guard

Medibino® consists of two components: an inner core made of dimensionally stable foam and an outer, size-adjustable protective fabric cover. The sewn-in zip closure allows the cover of the Medibino® baby head guard to be removed and the inner core to be taken out.

## Important safety instructions



Medibino® is suitable for infants and babies and can be used from the first day of life. The product has been manufactured in accordance with state-of-the-art technology and recognised technical safety regulations. However, damage cannot be safely excluded in case of improper use. Therefore, please observe the following general safety instructions:

- ✓ Read this operating manual and follow all instructions
- ✓ Store this operating manual so that it is accessible to all users of the product at all times, and always handover the Medibino® baby head guard to third parties together with this operating manual
- ✓ Before the first use, the protective cover must be washed and the foam core wiped with a damp cloth
- ✓ Always store Medibino® in the supplied protective pouch after use
- ✓ Please use the pillow only under supervision.

The use of Medibino® does not release you from the general obligations of care and supervision.

### Improper use means that you use the Medibino® baby head guard

- in a way other than described in this manual
- for applications that deviate from the operating manual and hygiene regulations
- to make modifications that are beyond the outlined setting options
- without or with a broken protective cover

### Contraindications

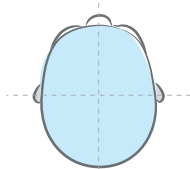
Do not use Medibino® if there is skin irritation, wounds or other injuries in the area of the contact surface.

Infants with muscular hypotonia are at risk of asphyxiation by burping or vomiting if the child is unable to turn his or her head to the side alone in a supine position. If you are uncertain, please consult your paediatrician, physiotherapist or midwife.

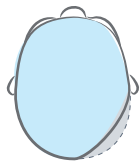
## Position-related head deformations

Since the skull is still relatively soft and susceptible to external influences in the first months of life, its natural, round shape can change slightly, which is shown, for example, by a flattening of the back of the head or a lateral flattening. If left untreated, consequences such as jaw malpositions, developmental delays, movement and postural damage cannot be ruled out. There are different types and characteristics of positional head deformations, which are shown in the following figure:

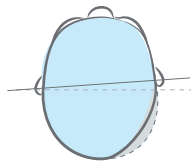
### Plagiocephaly



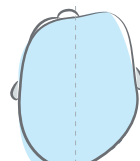
normal head shape



slight lateral flattening

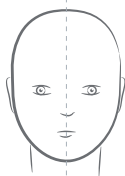


central lateral flattening with displacement of the ear



strong lateral flattening with displacement of the face

### Brachycephaly



normal head shape



slight flattening of the back of the head



middle flattening of the back of the head



strong flattening of the back of the head with a rising back of the head

## **Purpose of use (indications)**

The Medibino® is a medical device that provides a simple, flexible and safe solution to prevent and alleviate a positional head deformation (plagiocephaly, brachycephaly) in babies. Thanks to the ergonomic shape of the Medibino® baby head guard, the baby's sensitive skull can be effectively protected while in the supine position. It is recommended to use the Baby head guard as early and as frequently as possible during the first few months of life. It is prudent to use the Medibino® until the child has sufficient mobility of its own (e.g. turning onto its belly). The ergonomic ring shape of the Medibino®, with its soft, rounded top (contact area), and the even distribution of the weight of the baby's head allow for natural, strain-free head growth. The development of undesirable head deformations is thus prevented in the best possible way.

## **Use for existing head deformations**

Medibino® can, after consultation with the attending physician, also be used in the case of already existing deformities to counteract aggravation and support relief. At the same time, due to the biological uniqueness of each infant, the desired effect cannot be guaranteed in all cases.

The causes of head deformations are very diverse. For this reason, the paediatrician should always be consulted in the case of an existing and incipient deformation. He can clarify the deformity, rule out a blockage or other physiological causes and, if necessary, refer the patient to a specialist.

## **Further measures to prevent / alleviate head deformations**

In addition to a pressure-relieving support, there are other important measures to prevent the development of head deformations and to treat existing diseases. These should be applied additionally.

First of all, it is advisable to ensure frequent changes in the lying position. In doing so, the baby can be laid on its side in active and awake phases and under observation. The prone position, always under observation, is also suitable for avoiding position-related cranial deformations, because this not only relieves the back of the head, but also promotes the baby's overall mobility and strengthens the neck and shoulder muscles.

In addition, you can motivate your baby to change the head position independently through interesting stimuli. For this purpose, the side should be changed regularly during feeding (this is automatically given when breastfeeding) and the impulse should be set again and again by repositioning the bed, light sources, favourite toys or mobiles.

In addition, carrying in a sling or baby carrier is, among many other advantages, also a good prevention against head deformations.

### **Possible undesirable side effects**

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

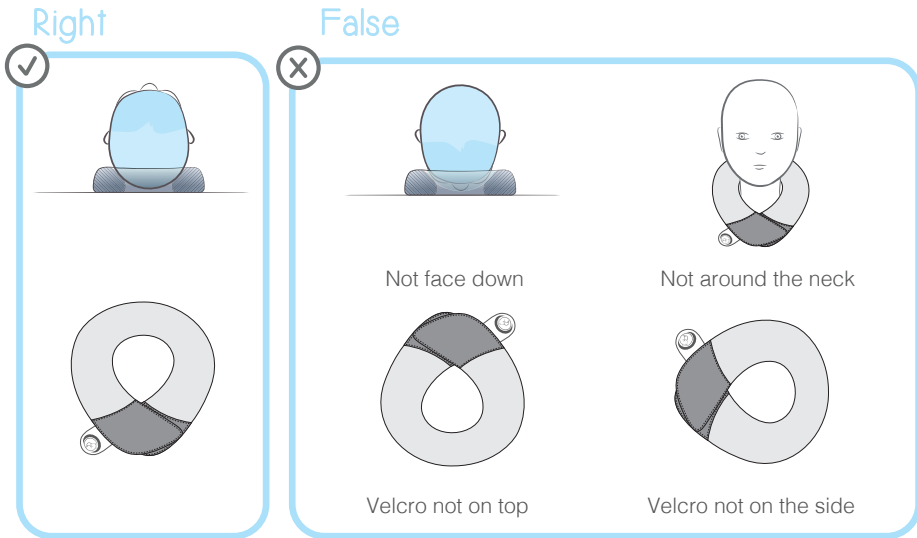
### **Notes on initial operation and use**

Please wash the cover of the Medibino® before using it for the first time. We recommend using a laundry bag to protect the materials. We also recommend wiping the foam core with a damp cloth before use or cleaning it with commercially available disinfectants. The cleaning and care instructions can be found on page 13 of these instructions for use. Before each use: take the Medibino® out of its packaging. Make sure the inner core fits snugly into the outer cover and that the zip is closed and the zip slider is flush inside the pocket provided on the side of the cover. To protect the high-quality materials, always place the Medibino® back in the bag provided after use (e.g. during transport).



## Intended use

The Medibino® can be applied in just a few steps: the head ring is placed with the flat side on a level, non-slip surface. The head of the supine infant is placed on top of the soft, rounded surface (contact area) of the Medibino® Baby head guard. It does not matter here whether the infant is lying in a buggy, basket, bed, or similar. The baby can move its head freely in the ring and position it, for example, also laterally. This does not reduce the protective effect. Rather, it is very important that the baby can move its head freely so that the neck muscles are strengthened.



When applying, please make sure that the zip slider is flush in the designated pocket on the side of the cover. To push out the slider, place your thumb and forefinger around the pocket and carefully push it out. The zip can then be opened and closed as normal.

Since the size of the Baby head guard can be infinitely adjusted, the product can be individually adapted to the size of the baby's head, which prevents the head slipping out and increases the level of protection.

Since it is not only the size (circumference) of the head alone that is important for the adjustment but also the head shape, there is no formula that can be used to calculate the correct fit of the ring. Rather, a certain level of trial and error is necessary. By doing this, the right setting can be easily found.

On the following page, we will explain how you can determine the correct size setting for your Medibino® baby head guard in just a few steps:



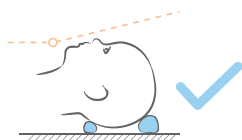


Fig 1

You can correctly adjust the size of the Medibino® by using the Velcro fastener on the cover. In doing so, one outer end of the cover (Velcro top) is attached to the other outer end of the cover (Velcro bottom), so that the Velcro closes and cannot come off by itself.

First of all, set the ring to the smallest size. Then place your infant in the supine position onto the Baby head guard so that your baby's head is resting on the soft, rounded top of the Medibino®.

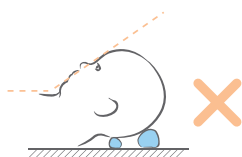


Fig 2

The head should be as straight as possible when viewed from the side, without the back of the head lying completely on the underlying surface (Fig. 1). If this is the case, you're already done. In the first few days and weeks after birth, especially, the smallest possible setting will often be the right one.

If, when viewed from the side, the head is tilted forward (Fig. 2), the Medibino® is too tight. In this case, open the Velcro fastener again and adjust the ring to be slightly wider. Then test again.

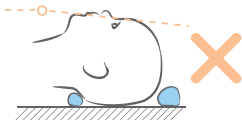


Fig 3

If the Medibino® is too wide, the entire back of the child's head will lie in the middle/opening of the ring and thus on the underlying surface (Fig. 3). The protective function is then no longer guaranteed. In principle, a small area lying on the underlying surface here and there is not a problem – but if you are unsure and your baby's head is not lying so as to be bent far forward, you can nevertheless set the Medibino® to be a little smaller.

## General information

- 1 All materials used have been tested for good compatibility with skin and tissue and are used in various medical applications. No allergic skin reactions are currently known.
- 2 Adjust the size of the head guard in accordance with the growth of the baby's head at regular intervals over the course of its use by using the Velcro fastener, in order to ensure stable and secure positioning.
- 3 For the purposes of the warranty, the components of the Medibino® baby head guard and its shape must not be altered. Improper use rules out any assumption of liability for any damage to or in the body.

## Period of application

Since the mobile development of children in the first months of life is very different, it is difficult to determine the duration of use according to age. We recommend using the Medibino® baby head guard from the first day until the age of 4 - 8 months. The individual duration of application always depends on the mobile development of the baby. As soon as the children turn independently and start to become mobile, the risk of developing a new head deformation decreases continuously. With increasing age, the baby's head also becomes more stable. With increasing mobility, the infants also no longer lie still in one place and move out of the Medibino, which is a normal development. However, the Medibino® can still be used for longer periods in supine position. The Medibino® is designed in terms of size adjustment as well as weight absorption so that it can be used at average size ratios up to 10 - 12 months of age. One product is therefore usually sufficient for the entire period of use.

## Materials used

### Material composition

Cover from Tencel: 60% polyester, 40% lyocell, closure fabric: 100% polyamide

Cover from Sweat: 80% cotton, 20% polyester, closure fabric: 100% polyamide

Inner Core: PUR-Foam

All materials are tested for biocompatibility according to ISO 10993.

## Cleaning instructions

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

### 1.Inner Core

The inner core of the Medibino® can be damp-wiped and is also suitable for cleaning with commercially available disinfectants. When using detergents, make sure that the Medibino® is rinsed with water again at the end of the cleaning process to avoid residues.

### 2.Cover

The cover of the head protection can be washed at 40°C in the washing machine with light-coloured clothes. It is recommended to wash the cover in a laundry bag so that other items of clothing cannot get caught in the velcro. Please note that you should not put Medibino® in the washing machine „completely“, i.e. including the inner part, but only the cover. Even though the core is water-repellent and wipe-disinfectable, the special ergonomics of the inner part could be lost, e.g. due to the centrifugal force of your machine. The following textile care instructions apply to the cover:



Washing  
at 40 degrees



Not  
bleach



do not  
tumble dry



Ironing with  
low temperature



Not chemical  
clean

## Technical data

Dimensions: approx. 15 x 16 cm, weight: ~75 g

Max. Operating temperature: Medibino® should not be exposed to temperatures above 40°C and below -10°C. The cover can be washed at 40°C for cleaning purposes.

Disposal: The Medibino® baby head guard and packaging can be disposed of with the recyclable waste.

## Manufacturer explanation

Kluba Medical GmbH warrants to the original purchaser that the product Medibino® baby head guard was free from defects in quality at the time of delivery for a period of two years from the date of purchase. Excluded from the warranty are damages caused by wear and tear, by intent and by negligent or improper use. Likewise, no liability 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 from other manufacturers which have not been approved by us may not be applied during use. Your Kluba Medical team wishes you much fun and success with the product!

## Contact



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