



## **HELMET** Cranial Remodelling Orthosis Patient-matched Medical Device

### **EN** Instructions for Use



# About Us

Serkel® is medical device manufacturer who specialise in the design, manufacturing, and treatment planning of some of the world's most advanced orthotic devices. The range of orthoses provided by Serkel® complements the wide variety of specialisations practiced by our channel partners. These specialisations include orthoses for cranial remodelling and Ankle Foot Orthotics (AFO's) supporting standing, walking, and positioning.

We work with Orthotists in the treatment planning and supply of devices that support positive change on the lives of patients. Serkel® specialise in the design and manufacturer of patient-matched medical devices to ensure optimum treatment effect and comfort. Non-invasive digital scanning and 3D computer aided manufacturing systems ensure that our Orthoses are manufactured to a high degree of accuracy utilising 3D printing technologies.

Our team of Orthotists, Engineers and Designers maintain a training regime which ensures they are up to date with the latest treatment technologies and methods. This means that each patient can be provided with appropriate treatments, optimised designs and lightweight materials.

Serkel® maintains a Quality Management System to ensure that products continue to meet customer, statutory and regulatory requirements.

## Product Description

In partnership with Orthotists, Serkel® have developed a patient-matched 3D printed helmet to treat infants with an abnormal head shape due to conditions such as Plagiocephaly and Brachycephaly. The Serkel® helmet aims to be aesthetically pleasing, whilst meeting clinical and practical needs.

The Serkel® Helmet is a patient-matched cranial orthosis. It is defined by the medical devices regulation as a device manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other person authorized to write such a prescription by virtue of their professional qualification.

Serkel® helmets are 3D-printed helmets, which are custom-made based on patient specifications through a cranial scan, and the prescription from an Orthotist, which are manufactured using a durable biocompatible Nylon powder.

Serkel® helmets are packaged with interchangeable sets of liners used as padding between the patient's head and the helmet.

# Intended Use

A patient-matched cranial orthosis helmet is intended to be worn on the head of an infant with an abnormal head shape during daily activities and sleep to improve cranial symmetry and shape during growth over a period of months for in excess of 23 hours per day.

The helmet is made of durable materials and is a single-patient device that can be reapplied during the treatment period before being discarded at the conclusion of treatment.

The most common conditions include:

- Plagiocephaly
- Brachycephaly

Serkel® helmets are prescribed and designed to meet the individual needs of each user, rather than to treat an individual condition.



# Everyday Use

Serkel® helmets apply a slight, constant pressure to the head, to redirect head growth. The interface components have been designed to avoid unacceptable pressure on and stress levels in body tissues.

We advise patients should not wear any head coverings under the helmet.

When putting the helmet on, the following steps should be taken:

1. Place fingers inside the side opening of the helmet and pull the edges apart.
2. Slide the helmet over the infant's head and into position.
3. Slowly release the edges.
4. Position the helmet so that the infant's ears are in the spaces provided, and the front of the helmet is just above/on the infant's eyebrows.
5. Secure the closure tab(s) firmly, by applying a small amount of pressure, so that the helmet does not move.
6. Verify the front and side positioning of the helmet.

When taking the helmet off, the following steps should be taken:

1. Undo the closure tab(s).
2. Place fingers on the edges of the side opening and pull the edges apart.
3. Slide the helmet off the infant's head.

At first, the helmet may feel uncomfortable, so the time it is worn for at a time should be gradually built up. Your Orthotist will tell you how long you should build up to, or what activities to wear it for.

- Always check skin contact areas for signs of rubbing.
- It is normal to see red marks where pressure has been applied. These should disappear within 30mins. IF NOT, CONTACT YOUR HEALTHCARE PROFESSIONAL.

Although the helmet is well ventilated, ensure that infant is not overheating. Infants may be required to dress down a layer or change to a cooler item of clothing to minimise risk of overheating. If the infant appears to be overheating (i.e., sweat on the neck and arms), remove the helmet until they have cooled down.

The helmet does not require any adjustment by the user as part of the everyday use.

# Maintenance

## Cleaning

Cleaning a Serkel® helmet is very important for both user safety and ensuring the longevity of the medical device. The helmet should be wiped clean daily with either a damp cloth or baby wipe. Please note that stains caused by bodily fluids should be removed immediately. To dry the helmet, wipe down any excess moisture with a clean cloth, and either allow it to dry naturally or used forced ventilation to speed up the process.

The helmet liners can be hand washed and dried flat as needed.



Do not utilise a heat source (i.e., commercial dryer, radiative heater, hair dryer on heating mode) to dry the product.

**Note:** If you are not sure how best to clean your Serkel® Helmet please contact your prescribing medical professional.

## Maintenance Schedule

No scheduled maintenance activities are required for the Serkel® Helmet. However, during each assessment with the prescribing medical professional they shall ensure that there is appropriate spacing between the helmet and infant's head for subsequent growth and that the helmet remains tight on the high spots.

## Lifetime

Serkel® Helmets are to be regularly evaluated by a healthcare professional to ensure continued effectiveness of the device. Serkel® does not recommend that the device is used for greater than 18 months.

# Safety Information



If after use of the helmet you see any red marks on the infant's skin, which do not disappear after 30 minutes, stop using the Serkel® Helmet and contact your healthcare professional for advice as it may need adjusting.



The Serkel® Helmet has been designed and prescribed for an individual's needs and should only be used by that sole user.



Should any significant or sudden changes occur in shape of the infant's head, you should contact your healthcare professional as it may affect the helmet's performance.



Should the functional requirements or condition of the infant change during the life cycle of the helmet therapy please contact your healthcare professional as this could affect the helmet's performance.



The Serkel® Helmet must be regularly cleaned per the instructions this IFU.



Should the helmet display any unusual behaviour, changes of performance, please immediately stop use and contact your healthcare professional.



Repairs and modifications to the helmet must be carried out by a qualified, trained healthcare professional. Please consult a qualified medical professional should you have any problems with this product.



Wearing of the helmet may result in overheating. Monitor the infant during use for signs of overheating. If overheating is observed, remove the helmet until the infant has cooled down, and adjust clothing as necessary to mitigate the risk of overheating.



Do not place on or near any heat source. Do not leave in direct sunshine or inside a car in hot weather.



The device is not intended for use when immersed in water or as a showering orthosis, unless specified for this purpose by your healthcare professional.



Helmet may include flammable materials. Be aware of fire hazards where possible.



The helmet is not designed to mitigate the risks associated with head impacts.



Single Patient Multiple Use Device



Consult Instructions for Use



Medical Device

Please ensure that any serious incidents, that have occurred in relation to the device, are reported to the manufacturer of the device and your health care professional.



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