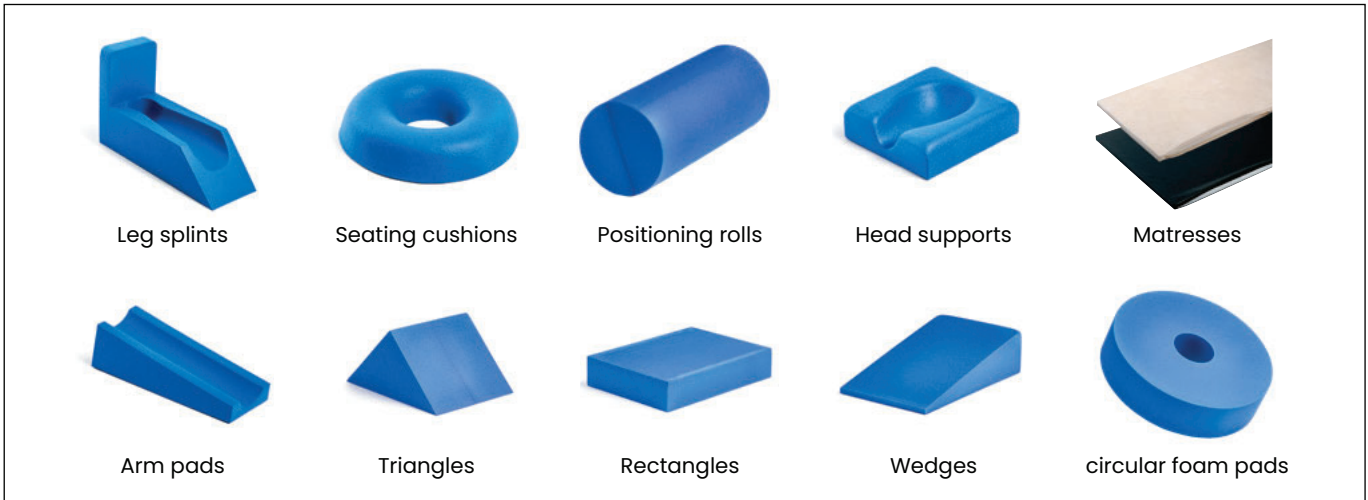


USER MANUAL OF MEDICAL POSITIONING AIDS


















1. General information

The product must be used in accordance with the included user manual, which should be retained carefully in case of any queries. It contains essential information for the intended use and helps to prevent damage or hazards due to misuse.

Any serious incident that occurs in connection with the positioning aids must be reported immediately to Polyform Kunststofftechnik GmbH & Co. Betriebs KG and the responsible authorities.

2. Symbol explanation

	Manufacturer		Date of manufacture		Medical product		Conformity marking in accordance with the European Medical Device Regulation 2017/745 (MDR)
	Attention! Observe the information listed in this document		Follow the instructions for use		Not washable		Do not iron
	Do not tumble dry		Cannot be treated with bleach		Do not dry clean		Suitable for wipe disinfection
	Store in a dry place		Protect from sunlight		Batch number		

3. Intended use and area of application

The positioning aids are intended for positioning the patient's head, torso or outer extremities in medically desirable positions. The positioning aid and, if applicable, its sewn cover, may only be used by trained specialist personnel in clinics, practices or other healthcare facilities. If a case is included in the delivery, it is used exclusively for storing the individual positioning aids and has no medical purpose.

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4. Indication

The positioning aids are versatile and can be used regardless of specific clinical cases, areas of application or diagnoses. They are used to support, stabilize and relieve pressure during positioning patients with corresponding needs. Due to the wide range of possible applications, the indications cannot be limited to individual medical conditions.

5. Contraindication

Contraindications cannot be limited to specific clinical conditions. However, the product should not be used if it causes individual pain during positioning.

6. Product manufacturing process

Thermoforming

With this special manufacturing process, thermoplastic polyethylene foams can be processed under the influence of pressure and heat into high-quality, durable products that are particularly suitable for medical applications.



PUR-foaming / Polyprotect®

Polyprotect® is a special polyurethane-based molding system with a durable, flexible and closed-cell surface. It is solvent- and plasticizer-free, biocompatible (in accordance with EN ISO 10993-5:2009) and is particularly suitable for medical use.



PUR-Coating / Skinfoam

Skinfoam is a polyurethane coating that is applied thinly to the foam to create a surface that can be wiped clean with a damp cloth and disinfectant. The surface is not 100 % waterproof and may have a limited service life depending on how much it is used.



7. Performing patient positioning

The product must only be used by trained personnel. The appropriate positioning aid must be selected according to the patient's individual requirements, as determined by the responsible healthcare professional.

8. Storage and handling



The product must be stored at room temperature in a dry place and protected from light. Direct sunlight and moisture have influences on the material properties and should be avoided.

9. Instruction for use

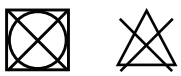
- The positioning aids are only intended for direct contact with intact skin. In case of skin injuries, the wound must be properly covered.
- A visual inspection must be carried out before each use. Damaged products must not be reused.
- The patient must be monitored during the entire duration of use to prevent potential incorrect positioning (see warnings).
- After use, the positioning aids should retain their original shape. Deformed or defective products must be replaced.
- Regional regulations on the disposal of positioning aids must be observed.

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10. Warnings

- The positioning aid must not be immersed in liquids, sterilized or treated with aggressive cleaning agents.
- Only use the product at room temperature.
- Before each use, ensure that the positioning aid is not damaged. The product must not be used if there is visible damage to the surface. This also applies if the product does not return to its original shape after use or shows dents or other surface defects.
- The positioning aids or their covers should not be attached to the patient. Parts of the patient's body are simply placed on them without additional fixation.

11. Care instructions for all surfaces (Thermoforming, imitation leather, Skinfoam, Polyprotect®)



The positioning aids are designed for reuse. On every change of patient, the product must be cleaned and disinfected according to the regulatory requirements of the respective institution. All surfaces must be cleaned and disinfected in accordance with the care instructions. The manufacturers' instructions for the agents used must be observed.



Wipe clean using warm water and a mild detergent with a sponge or soft cloth. Abrasive and chemical cleaning agents are not permitted. The positioning aid must not be soaked in any liquid. Softasept N, Incidin Liquid or comparable agents can be used for disinfection. Observe the manufacturer's instructions for material compatibility, concentration, exposure time, quantity, and drying time.



The care instructions do not release the user from the duty of care when handling the materials and cleaning agents. For further information on cleaning and disinfection, please contact us at any time.

12. Disclaimer of liability

The manufacturer accepts no liability for damage caused by improper use, cleaning or storage. The use of this product is the responsibility of qualified medical personnel.