

- **HELIX Postural Device Technical Sheet** -

<p><u>Manufacturer Identification</u></p>	<p>Pro Medicare S.r.l. Via Montagna Z.I. Lotto 41 72023 Mesagne (Br) ITALY P IVA 01803920741 Tel 0039 0831 777840 Fax 0039 0831 730739 www.promedicare.eu email: info@promedicare.it</p>
<p><u>Device Commercial Name</u></p>	<p>Helix - Total Body Pronation positioning System</p>
<p><u>Intended Use</u></p>	<p>Modular positioning system for Total Body pronation to be used on a mattress</p>
<p><u>Device Code</u></p>	<p>D00-001-1</p>
<p><u>Code of Classification (CND)</u></p>	<p>V0899</p>
<p><u>Main Features</u></p>	<p>Helix positioning system is CE marked according to EU Regulation 2017/745 and it is a non sterile Class I Medical Device.</p> <p>DESCRIPTION: HELIX is the positioning system made up of a modular structure composed of 7 group of independent, modular and adjustable components with non-slip base and 6 flexible and non-slip mats as a base.</p> <p>It is composed of:</p> <ul style="list-style-type: none"> -Head Elements and its flexible Mat; -Elbow joint support and containment Elements and its flexible Mat; -Sub Clavicular support Elements and its flexible Mat; -Thorax support and containment Elements; -Hip joint support and containment Elements; -Knee joint support and containment Elements and its flexible mat; -Leg/Foot support and containment Elements and its flexible mat. <p>USE: The system can be used as a result of the patients positioning and mobilizing indications of the Medical Staff and of the Healthcare facility protocol. The start-up and subsequent adjustments must be performed only by the Professional User that has the responsibility.</p> <p>INSTRUCTIONS:</p> <p>Helix positioning system has been design to allow:</p> <ul style="list-style-type: none"> -Patient's prone body support, positioning, mobilizing and repositioning on mattress; perfect fit to different morphologies, anthropometric measures of men and women, body mass, necessary inclinations and rotations. -Homogeneous distribution of pressures and discharge of the body segments pressure loads (such as head, genitals, chest), in order to prevent trauma and pressure sores; -Total body postural containment and alignment; -Thoracic, diaphragmatic and abdominal decompression; -Suitable head positioning for the therapeutic function of pronation; -Discharge of the lower limbs, knees and elbows; -Complete management and prevention of contractures and edema. <p>The harmonic and combined use of each element and subsystem has been designed to allow an individualized and relaxed support of the whole patient's body.</p>

PERFORMANCE AND DURABILITY:

Helix positioning system can be used on multiple patients. Its performances and durability may be influenced by the number of professionals who used it and the number of patients for whom it was used.

MATERIALS:

All the elements of the system are made of polyurethane and polyethylene foam combining different features: density, high-resistance and shape memory.

Helix cover and flexible mats are made of PU/PES combined materials with the following characteristics:

- antibacterial according to the standard ISO 20743-2 (Staphylococcus aureus, Methicilin Resistant Staphylococcus Aereus MRSA)
- non cytotoxic according to the standard ISO 10993-5 and ISO 10993-12
- non irritating according to the standard ISO 10993-10 and ISO 10993-1
- resistant to virus penetration according to the standard ISO 16604
- antifungal according to ASTM G 21-96
- fireproof according to the standard BS 7175; crib 5
- biocompatible according to the standard ISO 10993
- OEKO-TEX®
- latex free
- breathable according to the standard ISO 15496
- waterproof according to the standard EN 20811

MAINTENANCE AND CLEANING:

The removable cover can be washed at high temperatures (95°/10 washing maximum or dry clean), can be sterilized at 134°/5 min (10 times maximum) and sanitized with the following detergents/ disinfectants:

- PERSIL EXPERT coldzyme/ HENKEL
- 70% Ethanol
- PERFORM/Schuelke
- TPH PROTECT/ Schuelke
- MIKROZID AF liquid/ Oktal pharma
- INCIDIN PLUS/Ecolab
- DESCOGEN liquid/ Antiseptica
- MANORAPID/ Antiseptica
- PLIVASEPT/Pliva

SODIUM HYPOCHLORITE-BASED PRODUCTS CANNOT BE USED

PACKAGING:

Helix positioning system is supplied with an equipped mobile station and it is packed individually in carton.

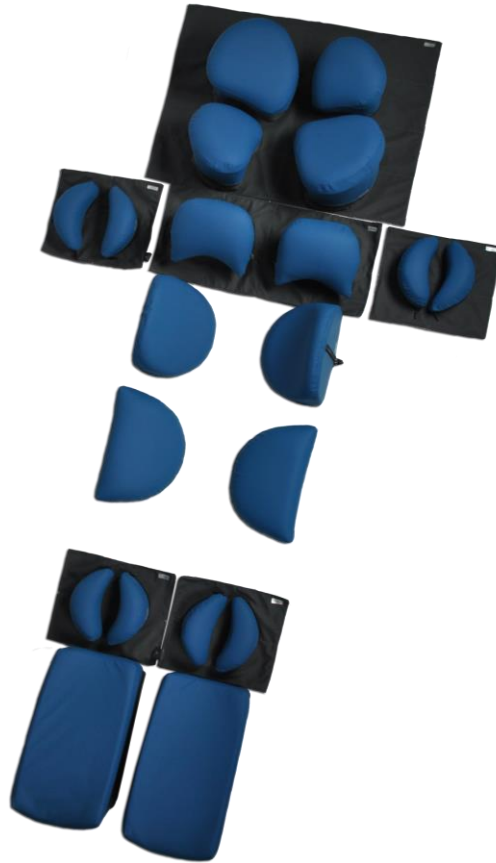
CONSUMABLE KIT:

-Separate cover kit for Helix elements are available;

-Kit of 100% polypropylene, water-repellent, breathable, non-irritating, and non-cytotoxic disposable non-woven covers/sleepers are available. The use of the disposable covers/sleepers is not mandatory but suggested.

Both Kit comes packaged in pouch and they can be ordered separately.

Product Image



Weight and Dimensions

The whole system has a total weight of 3.5 kg(7,72lb) and it is used on adult and adolescent patients whose height is between 160cm(5 Feet 2.99 Inches) and 190cm(6 Feet 2.8 Inches) (after checking the size of the mattress).