
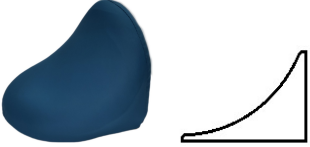
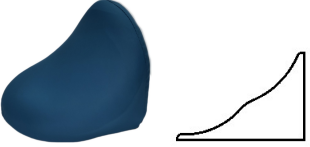





- TECHNICAL SHEET -
AUXIFORM Positioning Devices

<u>Manufacturer identification</u>	Pro Medicare s.r.l. Via Montagna Z.I. Lotto 41 72023 Mesagne (Br) VAT Number 01803920741 tel. 00 39 0831 777840 fax 00 39 0831 730739 website: www.promedicare.eu e-mail: info@promedicare.it
<u>Device Commercial Name</u>	AUXIFORM RANGE – INFLECT/CONTENS/IMPLES/ARTICULA Models
<u>UDI-DI BASIC</u>	805571347SOLLIEVO8
<u>Device Code</u>	INFLECT: D00-027-X CONTENS: D00-028-X IMPLES: D00-029-X ARTICULA: height 6 -> D00-037-X height 8 -> D00-034-X height 11 -> D00-030-X height 15 -> D00-031-X height 14 -> D00-032-X height 18 -> D00-033-X REVERSO A -> D00-035-X REVERSO B -> D00-036-X
<u>Code of Classification (CND)</u>	V080302
<u>Medical Device Class</u>	<i>These Devices are CE marked according to EU Regulation 2017/745 and they are classified as non sterile Class I Medical Devices without measuring function.</i>
<u>Intended Use</u>	<i>INFLECT/CONTENS/IMPLES/ARTICULA are modular devices for positioning and/or containment and/or support and/or unloading of the posture of a body segment during the lying and/or semi-reclining position following a temporary or permanent pathological condition and/or during clinical/surgical treatment. INFLECT/CONTENS/IMPLES Devices can be adapted to the user's morphological and anthropometric specifications thanks to its specific modular construction. INFLECT is a device for positioning and/or support and/or unloading of the hip/pelvis tract, also can be used for positioning and/or support of a spinal curve following a temporary or permanent pathological condition and/or during clinical/surgical treatment. CONTENS is a device for positioning and/or support and/or containment and/or unloading a tract of the rachis following a temporary or permanent pathological condition and/or during clinical/surgical treatment. IMPLES is a device for positioning and/or support and/or unloading of a rachis tract following a temporary or permanent pathological condition and/or during clinical/surgical treatment. ARTICULA is a device/device system for positioning and/or support and/or containment and/or unloading of upper/lower limbs following a temporary or permanent pathological condition and/or during clinical/surgical treatment. ARTICULA REVERSO model is available in two versions: “REVERSO A” wich is without anti-slip rigid band/ base and “REVERSO B” wich is with anti-slip rigid band/ base. The combination of various height and length elements, with or without leveling wedge, provides an articulated modular system for the positioning of lower/upper limbs. Their intended use is to: - treat postural disorders; - provide a suitable and fully comfortable positioning of the user or one of his/her body segments; - ensure the containment of a user’s body segment; - facilitate the distribution of body pressures.</i>

	<p>Positioning devices are for paediatric and adult users and are intended for professional and also for non-professional use in order to relieve and/or prevent clinical pathological conditions related to posture or post-traumatic, surgical and post-surgical conditions as well as for rehabilitation; such devices must be used in internal spaces.</p> <p>AUXIFORM devices do not have load-bearing structural features, so they do not replace the user's support (bed/mattress)</p>																															
<p>Technical features</p>	<p>STANDARD CONFIGURATION: Each model and size chosen include the padded and covered element, the removable cover is with anti-slip bottom surface.</p> <p>DIMENSIONS: Different for each model as shown by tables below</p> <table border="1" data-bbox="368 539 1447 1301"> <thead> <tr> <th colspan="10">DIMENSIONS (cm)</th> </tr> <tr> <th colspan="2">INFLECT Model</th> <th colspan="2">CONTENS Model</th> <th colspan="2">IMPLES Model</th> <th colspan="2">ARTICULA Model</th> <th colspan="2">ARTICULA REVERSO A/B Model</th> </tr> </thead> <tbody> <tr> <td>Size (L x P x H)</td> <td>Size 1 (16x14x8) Size 2 (19x17x8) Size 3 (27x14x9) Size 4 (29x20x11)</td> <td>Size (L x P x H)</td> <td>Size 1 (11x12x10) Size 2 (14x16x12) Size 3 (17x16x15) Size 4 (22x16x18)</td> <td>Size (L x P x H)</td> <td>Size 1 (11x12x10) Size 2 (14x16x12) Size 3 (17x16x15) /</td> <td>Size (L x P x H)</td> <td>Height 6 Height 8 Height 11 Height 15 Height 14 Height 18</td> <td>Size 0 (18x15x6) Size 1 (18x20x6) Size 2 (18x27x6) Size 3 (18x33x6) Size 0 (18x15x8) Size 1 (18x20x8) Size 2 (18x27x8) Size 3 (18x33x8) Size 0 (18x15x8) Size 1 (18x20x11) Size 2 (18x27x11) Size 3 (18x33x11) Size 0 (18x15x15) Size 1 (18x20x15) Size 2 (18x27x15) Size 3 (18x33x15) Size 1 (18x30x14) Size 2 (18x40x14) Size 3 (18x50x14) Size 4 (18x60x14) Size 1 (18x30x18) Size 2 (18x40x18) Size 3 (18x50x18) Size 4 (18x60x18)</td> <td>One Size (L x P x H)</td> <td>(24x23x22)</td> </tr> </tbody> </table> <p>Weight: INFLECT: < 300 gr CONTENS: < 180 gr IMPLES: < 180 gr ARTICULA: < 450 gr each</p>	DIMENSIONS (cm)										INFLECT Model		CONTENS Model		IMPLES Model		ARTICULA Model		ARTICULA REVERSO A/B Model		Size (L x P x H)	Size 1 (16x14x8) Size 2 (19x17x8) Size 3 (27x14x9) Size 4 (29x20x11)	Size (L x P x H)	Size 1 (11x12x10) Size 2 (14x16x12) Size 3 (17x16x15) Size 4 (22x16x18)	Size (L x P x H)	Size 1 (11x12x10) Size 2 (14x16x12) Size 3 (17x16x15) /	Size (L x P x H)	Height 6 Height 8 Height 11 Height 15 Height 14 Height 18	Size 0 (18x15x6) Size 1 (18x20x6) Size 2 (18x27x6) Size 3 (18x33x6) Size 0 (18x15x8) Size 1 (18x20x8) Size 2 (18x27x8) Size 3 (18x33x8) Size 0 (18x15x8) Size 1 (18x20x11) Size 2 (18x27x11) Size 3 (18x33x11) Size 0 (18x15x15) Size 1 (18x20x15) Size 2 (18x27x15) Size 3 (18x33x15) Size 1 (18x30x14) Size 2 (18x40x14) Size 3 (18x50x14) Size 4 (18x60x14) Size 1 (18x30x18) Size 2 (18x40x18) Size 3 (18x50x18) Size 4 (18x60x18)	One Size (L x P x H)	(24x23x22)
DIMENSIONS (cm)																																
INFLECT Model		CONTENS Model		IMPLES Model		ARTICULA Model		ARTICULA REVERSO A/B Model																								
Size (L x P x H)	Size 1 (16x14x8) Size 2 (19x17x8) Size 3 (27x14x9) Size 4 (29x20x11)	Size (L x P x H)	Size 1 (11x12x10) Size 2 (14x16x12) Size 3 (17x16x15) Size 4 (22x16x18)	Size (L x P x H)	Size 1 (11x12x10) Size 2 (14x16x12) Size 3 (17x16x15) /	Size (L x P x H)	Height 6 Height 8 Height 11 Height 15 Height 14 Height 18	Size 0 (18x15x6) Size 1 (18x20x6) Size 2 (18x27x6) Size 3 (18x33x6) Size 0 (18x15x8) Size 1 (18x20x8) Size 2 (18x27x8) Size 3 (18x33x8) Size 0 (18x15x8) Size 1 (18x20x11) Size 2 (18x27x11) Size 3 (18x33x11) Size 0 (18x15x15) Size 1 (18x20x15) Size 2 (18x27x15) Size 3 (18x33x15) Size 1 (18x30x14) Size 2 (18x40x14) Size 3 (18x50x14) Size 4 (18x60x14) Size 1 (18x30x18) Size 2 (18x40x18) Size 3 (18x50x18) Size 4 (18x60x18)	One Size (L x P x H)	(24x23x22)																						
<p>Technical features</p>	<p>PERFORMANCE AND DURABILITY: The realistic life span of these devices is 2 years (padding) valid under normal conditions of use and proper maintenance in accordance with the specifications of the instruction manual.</p>																															
<p>Technical features</p>	<p>MATERIALS: They are made of polymeric material combining different features: elasticity, bearing capacity and shape memory; the interior and removable covers are made of PU/PES combined materials with the following characteristics:</p> <ul style="list-style-type: none"> - antibacterial according to the standard ISO 20743-2 (Staphylococcus aureus, Methicilin Resistant Staphylococcus Aureus 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 																															

	<p>MANTENANCE AND CLEANING: The internal and the removable covers can be superficially sanitized with the following detergents/disinfectants:</p> <ul style="list-style-type: none"> • PERSIL EXPERT coldzyme/HENKEL • 70% etanol • PERFORM/Schuelke • TPH PROTECT/Schuelke • MIKROZID AF liquid/Oktal pharma • DESCOGEN liquid/Antiseptica • MANORAPID/Antiseptica • PLIVASEPT/Pliva • INCIDIN PLUS/Ecolab <p>The removable cover can be washed at high temperatures (95° max 10 washings or dry), can be sterilized at 134°/5 min (10 times maximum). <u>Do not use cleaners based on natrium hipo-chlorite.</u></p> <p>PACKAGING: It is supplied in a plastic bag</p>		
<p><u>Accessories</u></p>	<ul style="list-style-type: none"> - External leveling wedge for all code/size (only for ARTICULA) - Trapezoidal upper limb support 		
<p><u>Spare Parts</u></p>	<ul style="list-style-type: none"> - Additional cover for each model/code and size 		
<p><u>Additional Elements</u></p>	<ul style="list-style-type: none"> - <u>Mobile station with complete element kit and additional covers</u> (to be configured according to needs) - <u>Bag for a set of elements</u> (to be configured according to needs) 		
<p><u>Product image</u> (images are purely illustrative)</p>	 <p><u>INFLECT Model</u></p>	 <p><u>CONTENS Model</u></p>	 <p><u>IMPLES Model</u></p>
 <p><u>ARTICULA Model</u></p>	 <p><u>ARTICULA REVERSO A Model</u></p>	 <p><u>ARTICULA REVERSO B Model</u></p>	