

Product Data Sheet



PearlFit Positioning Aid

Ref.:	Product name:	Dimensions:	Weight:	Packaging dimensions:
1112-A	PearlFit Roll 40	L = 400 mm, Ø = 180 mm	300 g	500 x 700 mm
1113-A	PearlFit Roll 50	L = 500 mm, Ø = 180 mm	360 g	500 x 700 mm
1114-A	PearlFit Cushion 30x20x4	300 x 200 x 40 mm	80 g	300 x 500 mm
1124-A	PearlFit Cushion 50x20x4	500 x 200 x 40 mm	160 g	400 x 600 mm
1115-A	PearlFit Cushion 50x30x7	500 x 300 x 70 mm	310 g	400 x 600 mm
1116-A	PearlFit Cushion 50x30x10	500 x 300 x 100 mm	630 g	500 x 800 mm
1120-A	PearlFit Cushion 130x60x10	1300 x 600 x 100 mm	2500 g	700 x 1100 mm
1117-A	PearlFit Wedge 26x25x7	260 x 250 x 70 mm	140 g	300 x 500 mm
1118-A	PearlFit Flex 6	900 x 500 x 50 mm	720 g	700 x 1100 mm
1119-A	PearlFit Flex 3	900 x 500 x 70 mm	720 g	700 x 1100 mm
1121-A	PearlFit Head/Neck	350 x 180 x 100 mm	270 g	350 x 700 mm
1122-A	PearlFit Forehead	300 x 280 x 80 mm	250 g	350 x 700 mm
1123-A	PearlFit Inlay Head	280 x 200 x 25 mm	60 g	280 x 470 mm
1132-A	PearlFit Wedge 56x50x25	560 x 500 x 250 mm	1500 g	700 x 1100 mm
1136-A	PearlFit Cushion 22x8x1	220 x 80 x 10 mm	50 g	470 x 280 mm
1137-A	PearlFit Cushion 30x11x2	300 x 110 x 20 mm	60 g	470 x 280 mm
1138-A	PearlFit Wedge 30x50x15	300 x 500 x 150 mm	600 g	500 x 800 mm
1140-A	PearlFit Cushion 200x75x7	2000 x 750 x 70 mm	3000 g	1150 x 900 mm
1142-A	PearlFit Cushion 50x50x5	500 x 500 x 50 mm	400 g	400 x 600 mm
1145-A	PearlFit Cushion 27x6x1	270 x 60 x 10 mm	60 g	470 x 280 mm
1148-A	PearlFit Head/Neck Tilt15	370 x 195 x 105 mm / 15 Grad	240 g	700 x 350 mm

Intended use	Short-term patient positioning and stabilization device during invasive and non-invasive procedures to be used on intact patient's skin. Non-Sterile and not to be used in the sterile field.	
Directives & classification	CE according to MDD – Directive 93/42/ECC and MDR – Regulation 2017/745 Class 1 product	
Applied quality assurance	SN EN ISO 13485:2016	
Instructions for use	Enclosed to the product	
Restrictions of use	Do not use the product for purposes other than those described.	
General safety notes	Non sterile. Do not sterilize. Caution: Federal law restricts this device to sale by or on the order of a licensed health-care professional (Rx only).	
MR safety note	MR Safe	
Materials	Material TPU EPS EPP PET LDPE	Component foils pearls white foam Tilt15 membrane packaging
Marking	CE	
Storage	Store in dry place / room temperature	

Figures are subject to usual tolerances. All information to the best of our current knowledge. They do not guarantee a warranted quality and are no foundation for a contractual relationship. Errors excepted.