

Product Data Sheet



PearlFit Vacuum Positioning Aid

Ref.:	Product name:	Dimensions:	Weight:	Packaging dimensions:
1125-B	PearlFit Cushion 30x20x4 Vac	300 x 200 x 40 mm	90 g	300 x 500 mm
1131-B	PearlFit Cushion 50x20x4 Vac	500 x 200 x 40 mm	170 g	400 x 600 mm
1126-B	PearlFit Cushion 50x30x7 Vac	500 x 300 x 70 mm	320 g	400 x 600 mm
1188-A	PearlFit Cushion 50x30x5 Vac	500 x 300 x 50 mm	300 g	400 x 600 mm
1127-B	PearlFit Cushion 50x30x10 Vac	500 x 300 x 100 mm	640 g	500 x 800 mm
1129-B	PearlFit Cushion 130x60x10 Vac	1300 x 600 x 100 mm	2500 g	700 x 1100 mm
1189-A	PearlFit Cushion 130x60x5 Vac	1300 x 600 x 50 mm	1700 g	700 x 1100 mm
1128-B	PearlFit Wedge 26x25x7 Vac	260 x 250 x 70 mm	150 g	300 x 500 mm
1130-B	PearlFit Head/Neck Vac	350 x 180 x 100 mm	280 g	350 x 700 mm
1133-B	PearlFit Wedge 56x50x25 Vac	560 x 500 x 250 mm	1500 g	700 x 1100 mm
1186-A	PearlFit Wedge 56x50x25 NUC Vac	560 x 500 x 250 mm	1500 g	700 x 1100 mm
1139-B	PearlFit Wedge 30x50x15 Vac	300 x 500 x 150 mm	600 g	500 x 800 mm
1141-B	PearlFit Cushion 200x75x7 Vac	2000 x 750 x 70 mm	3000 g	1150 x 900 mm
1190-A	PearlFit Cushion 200x75x5 Vac	2000 x 750 x 50 mm	3000 g	1150 x 900 mm
1143-B	PearlFit Cushion 50x50x5 Vac	500 x 500 x 50 mm	400 g	400 x 600 mm
1144-B	PearlFit Cushion 90x60x5 Vac	900 x 600 x 50 mm	750 g	700 x 1100 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 conditional: The device can be safely used in a MR system meeting the following conditions: <ul style="list-style-type: none"> - Static magnetic field of 10 T or less - Maximum spatial field gradient of 60 T/m 	
Materials	Material TPU EPS PVC/ TPU Natural Acetal Stainless Steel BUNA-N LDPE	Component foils, tube pearls white 90° elbow connection connector connector valve spring connector seals 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.