

# 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
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
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
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
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
1146-B	PearlFit Cushion MAQSIE Vac	300 x 420 x 90 mm	400 g	400 x 600 mm
1137-A	Vac Adapter	240 mm	20 g	200 x 280 mm

<b>Intended use</b>	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.	
<b>Directives &amp; classification</b>	CE according to MDD – Directive 93/42/ECC and MDR – Regulation 2017/745 Class 1 product	
<b>Applied quality assurance</b>	SN EN ISO 13485:2016	
<b>Instructions for use</b>	Enclosed to the product	
<b>Restrictions of use</b>	Do not use the product for purposes other than those described.	
<b>General safety notes</b>	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).	
<b>MR safety note</b>	MR conditional: The device can be safely used in a MR system meeting the following conditions: <ul style="list-style-type: none"> <li>- Static magnetic field of 10 T or less</li> <li>- Maximum spatial field gradient of 60 T/m</li> </ul>	
<b>Materials</b>	<b>Material</b> TPU EPS PVC/ TPU Natural Acetal Stainless Steel BUNA-N LDPE	<b>Component</b> foils, tube pearls white 90° elbow connection connector connector valve spring connector seals packaging
<b>Marking</b>	CE	
<b>Storage</b>	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.