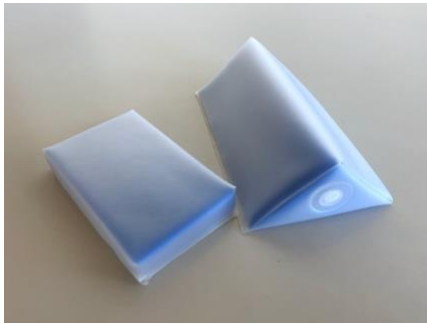


Product Data Sheet



FoamFit Positioning Aid

Ref.:	Product name:	Dimensions:	Weight:	Packaging dimensions:
1225-A	ProFoam Wedge 18x11x5	180 x 110 x 50 mm	40 g	280 x 250 mm
1226-A	ProFoam Wedge 36x11x5	360 x 110 x 50 mm	80 g	280 x 250 mm
1227-A	ProFoam Plate 13x8x2	130 x 80 x 20 mm	40 g	280 x 250 mm
1228-A	ProFoam Plate 36x8x2	360 x 80 x 20 mm	80 g	280 x 250 mm
1233-A	FoamFit Plate 28x18x1	280 x 180 x 10 mm	50 g	280 x 250 mm
1234-A	FoamFit Wedge 5x16x7	50 x 160 x 70 mm	20 g	280 x 250 mm
1235-A	FoamFit Plate 30x10x2	300 x 100 x 20 mm	60 g	280 x 250 mm
1236-A	FoamFit Plate 18x8x2	180 x 80 x 20 mm	20 g	280 x 250 mm
1237-A	FoamFit Plate DIM	variabel	variabel	variabel
1238-A	FoamFit Wedge DIM	variabel	variabel	variabel

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 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 PU (Polyether based) PET LDPE	Component foils foam 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.