

Product Data Sheet



BabyFix Cocoon

Ref.:	Product name:	Dimensions:	Weight:	Packaging dimensions:
1107-A	BabyFix Cocoon	Area: 577 x 816 mm Variable thickness: 20 – 30 mm	610 g	400 x 270 x 45 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. A hygiene barrier (mechanical barrier) must always be used. Do not use in case of acute open wounds. Avoid contact with sharp objects. Remove the pump from the positioning aid during exam. 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 POM PP 2K-Nylon-SD-Color PP PA LDPE	Component foils, tube pearls plate hose clamp screen print color fleece Strip microplast hook fastener 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.