

Product Data Sheet



CRANIA

Ref.:	Product name:	Dimensions:	Weight:	Packaging dimensions:
1001-G	Crania Adult	Adult size	210 g	500 x 350 x 50 mm
1004-E	Crania Child	Child size	180 g	500 x 350 x 50 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 with children below the age of 3. Do not use the product for purposes other than those described.	
General safety notes	Non sterile. Do not sterilize. Do not allow direct contact with the skin. Use single-use sanitary cover. Do not use in case of acute open wounds. Do not inflate with compressed air. Position the pump far away from the field of view. 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 PVC LDPE PP TPE IR LDPE	Component foils, tube pearls pump ball valve body valve lid valve sealing element slit valve 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.