TECRES
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TECHNICAL SHEET — MENDEC CRANIO

Commercial name	Mendec Cranio
Manufacturer's reference	1220/D
Packaging	Powder: PE film sachet; Liquid: amber glass phial. Sachet and phial are packaged in PVC blister sealed with Tyvek sheet. Outer packaging: heavy cardboard box
Sterilization – Shelf life	Powder: ethylene oxide; phial: dry heat; liquid: filtration Shelf life: 3 years
Product description	Radiopaque acrylic resin to be used in neurosurgery for the repairing of cranial defects.
Composition	See table below
Quality controls	Raw materials: chemico-physical and microbiological controls; check of supplier's certificates End product: visual inspection, label's verification, chemical-physical and functional controls, sterilization certificate check Packaging: visual and dimensional inspection, weld joint control, in-process controls.
Configuration	1 powder sachet and 1 liquid phial
M.D. classification	III according to CEE 93/42
Intended use	Mendec Cranio is indicated for the repairing of cranial defects.
Latex content	The medical device and its packaging are latex-free
Biocompatibility (ISO 10993)	Tests for cytotoxicity, intracutaneous reactivity, acute systemic toxicity, mutagenicity, sensitization, sub-chronic and sub-acute systemic toxicity, implantation done for acrylic cement
Warnings and storage conditions	Do not arbitrarily change the liquid and solid components ratio. The device is single-use and intended for use on a single patient. Avoid the partition of the product in two or more portions for use at different times. Store at room temperature below 25 ° C and protect from light. Sterility is guaranteed only if the packaging is not damaged or opened. Do not re-sterilize any of the components. Do not use the product if the powder appears yellow or brown or if the liquid looks syrupy.
Disposal	All wastes should be considered surgical material and must be disposed as such at the end of surgery.
Release of chemicals	Internal tests have been done showing that the monomer release from Mendec Cranio is comparable to those of other commercial cements.

Composition	Material	Percentage
Powder (20 g)	Polymethylmethacrylate	84,30 % w/w
	Barium sulphate	13,00 % w/w
	Benzoyl peroxide	2,70 % w/w
Liquid (6,65 g)	Methylmethacrylate	99,10 % w/w
	N,N-dimethyl-p-toluidine	0,90 % w/w
	Hydroquinone	75 ppm

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Technical data			
	ISO 5833 limits*	Tecres' specs	
Setting time (23°C)	< 15'	11'00" ± 2'00"	
Polymerization temperature	< 90°C	conforming	
Compression strength	> 70 MPa	conforming	
Flexural strength	> 50 MPa	conforming	
Elastic modulus	> 1800 MPa	conforming	

* since a standard for cranioplasty bone cements is not available, the ISO for bone cements for orthopaedic use is taken as a reference.

Release date: 05/03/2018

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