TECRES
Advancing High Technology

TECHNICAL SHEET — MENDEC SPINE KIT

Commercial name	Mendec Spine Kit
Manufacturer's reference	13C2000
Packaging	Powder: PP tube with Luer Lock cap; Liquid: amber glass phial. Mendec Spine Kit is packaged in a double PVC blister sealed with Tyvek and put inside an aluminium pouch. Outer packaging: heavy cardboard box
Sterilization – Shelf life	Powder and kit's components: ethylene oxide; phial: dry heat; liquid: filtration Shelf life: 3 years.
Product description	Kit for percutaneous vertebroplasty composed by a screw-based injection system and a radiopaque acrylic resin. Closed mixing
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 tube, 1 liquid phial, 1 Spine Gun, 1 Extension Tube
M.D. classification	IIb according to CEE 93/42
Intended use	Vertebral body filling following osteoporotic vertebral compression fracture, metastases, myelomas, ecc. (Percutaneous Vertebroplasty)
Latex content	The medical device and its packaging are latex-free
Biocompatibility (ISO 10993)	Tests for cytotoxicity, mutagenicity, sensitization, implant (ISO 10993) done for acrylic cement
Warnings and storage conditions	Before to use MENDEC SPINE KIT, be sure that the device has been kept at 23°C ± 1° C for at least 24h. 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. Mendec Spine Kit has to be used only with specific needles, suitable for the chosen procedure. The use of Tecres' needles is strongly recommended. If needles made by other manufacturers are use, be sure they have a Luer Lock connection and that they can be firmly assembled to the safety ring on the extension tube of Mendec Spine Kit.
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 and barium sulphate release from Mendec Spine is comparable to those of other commercial cements used for vertebroplasty. Chemical compatibility tests between the O-ring and monomer and between monomer and polyamide have been done.

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Composition	Material	Percentage
Powder (20 g)	Polymethylmethacrylate	67,50 % w/w
	Barium sulphate	30,00 % w/w
	Benzoyl peroxide	2,50 % w/w
Liquid (9,4 g)	Methylmethacrylate	99,10 % w/w
	N,N-dimethyl-p-toluidine	0,90 % w/w
	Hydroquinone	75 ppm

Technical data

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

*since the ISO limit refers to the setting time of bone cements for orthopaedic use, which greatly differs from that of cements used for vertebroplasty, this limit is not considered.

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