Commercial name	Vancogenx HV
Manufacturer's reference	12A2530
Packaging	Powder: PE sachet inside an aluminium pouch. Liquid: amber glass phial inside a Tyvek-sealed PETG blister. Outer packaging: heavy cardboard box
Sterilization – Shelf life	Powder: gamma rays; Phial: dry heat; Liquid: filtration. Phial blister: ethylene oxide. Shelf life: 5 years.
Product description	High viscosity radiopaque bone cement with gentamicin and vancomycin for manual application.
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	Temporary fixation of antibiotic-loaded PMMA spacers to the host bone. Permanent fixation of revision joint prosthesis following a septic process to the host bone. In particular, these cements are indicated where there is the risk or presence of infections caused by organisms susceptible to gentamicin and/or vancomycin. The device is intended for use by suitable qualified orthopaedic surgeons, experienced in arthroplasty procedures, in an operating theatre environment.
Latex content	The medical device and its packaging are latex-free
Biocompatibility (ISO 10993)	Cytotoxicity, sensitization, intracutaneous reactivity, mutagenicity, acute systemic toxicity, sub-acute/sub-chronic toxicity, implantation.
Warnings and storage conditions	The use as first option in the fixation of a prosthetic implant should be carefully considered as it may increase the risk of development of gentamicin and/or vancomycin resistant bacteria. The use should be carefully considered in patients with coagulation disorders and in patients with severe cardio-pulmonary insufficiency. The application should be carefully considered in patients with pre-existing renal insufficiency, auditory impairment or in elderly. Avoid dividing the product into two or more portions, in order to use it other times. This would be a re-utilization and may lead to an error in the proportion of the powder and liquid components. It can also cause a sterility loss. Never arbitrarily modify the ratios between the liquid and solid components. Never add other substances or foreign bodies to the bone cement. Avoid monomer contact with skin and mucous membranes as the liquid component is irritant to the airways and the skin. Sterility is guaranteed only if the unitary package is not damaged or opened. Do not re-sterilize any of the components. Do not use the product beyond the expiration date because the effectiveness of the product may be impaired. Do not use the product if the powder has a yellowish or brownish colour or if the liquid is syrupy. These conditions indicate that the product has not been stored correctly. Before using the device it is strongly advised to make sure that the package is stored at a temperature of 23°C ± 1°C for the previous 24 hours. The product can be stored and used at different temperatures (see chart at the

	end of the IFU), considering that bone cements are sensitive to temperature. Temperatures of more than 23°C for the product, the preparation accessories and the environment accelerate the various stages in the preparation procedure. Lower temperatures retard the preparation stages. Store at a temperature below 25° C and a relative humidity not exceeding 70%, protect from light. Preparation and application of the device are strongly influenced by storage and operating room temperatures.
Disposal	Because of the volatility and flammability of the liquid monomer of the bone cement, the liquid monomer should be evaporated in a well ventilated hood or absorbed by an inert material and transferred into a suitable container for disposal. The polymer component may be disposed in an authorized waste facility.
Release of chemicals	The device contains and releases gentamicin and vancomycin. Internal tests have been done showing that the monomer and barium sulphate release from the device is comparable to those of other commercial cements used for prosthesis fixation. No other substances able to modify the chemical equilibrium of surrounding tissues are released.

Composition	Material	Percentage
Powder (40 g)	Polymethylmethacrylate	81,80 % w/w
	Barium sulphate	10,00 % w/w
	Benzoyl peroxide	1,50 % w/w
	Gentamicin sulphate	4,20% w/w
	Vancomycin hydrochloride	2,50% w/w
Liquid (17,7 g)	Methylmethacrylate	98,20 % w/w
	N,N-dimethyl-p-toluidine	1,80 % w/w
	Hydroquinone	75 ppm

Technical data

	ISO 5833 limits	Tecres' specs
Setting time (23°C)	< 15'	9'30" ± 2'00"
Polymerization temperature	< 90°C	conforming
Compression strength	> 70 MPa	conforming
Flexural strength	> 50 MPa	conforming
Elastic modulus	> 1800 MPa	conforming

Release date: 22/11/2017

Rev	Release date	Description
00	22/11/2017	New issue

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