Commercial name	Vancogenx-Space Hip
Manufacturer's reference	See table below
Packaging	Device: inserted in a double Tyvek-sealed PETG blister. The double blister is closed in an aluminium pouch bearing the labelling. External container: heavy weight cardboard box.
Sterilization – Shelf life	Sterilization: Gamma irradiation Shelf life: 5 years
Product description	Temporary hip spacer made of bone cement (PMMA) added with gentamicin and vancomycin.
Composition	See table below
Quality controls	Raw materials: chemico-physical and microbiological controls; check of supplier's certificates, visual inspection Semi-finished product: visual inspection, chemical-physical and functional controls, sterilization certificate check, verification of the dye toning of the sterilization indicator Packaging: visual inspection, label's verification, control on the validity of Declaration of Conformity.
Configuration	1 spacer
M.D. classification	III according to CEE 93/42
Intended use	The device is indicated for temporary use (maximum 180 days) as an adjunct to total hip replacement (THR) in patients undergoing a two-stage procedure due to a septic process. The device is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion etc.). It is particularly indicated for operations which present risks of or existing infections caused by organisms susceptible to Gentamicin and/or Vancomycin.
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 Stainless steel suitable for medical use (ISO 5832-1)
Warnings and storage conditions	The use of the device should be carefully evaluated in patients suffering from kidney problems, are old, have hearing impairement, are taking medications that may affect renal function (Aminoglycosides, polymyxin B, colistin, diuretics...), have bleeding disorders, in patients with severe cardio-pulmonary insufficiency, and in patients with pre-existing renal insufficiency. Alter the structural identity of the device may cause damage to the device itself. Make sure the device has the correct dimensions for the implant site. Do not insert the device if are present other osteosynthesis devices which may mechanically interfere with it. Remove the device not later than 6 months from the date of implantation. Do not re-sterilize and / or reuse. The device is single-use and intended for use on a single patient. Store in a cool, dry place. Do not use if the inner container is damaged or opened.
Disposal	Disposal of the device or its components should be in accordance with local waste regulations.
Release of chemicals	The device contains and releases gentamicin and vancomycin. No other substances capable of altering the chemical equilibrium of surrounding tissue are released.

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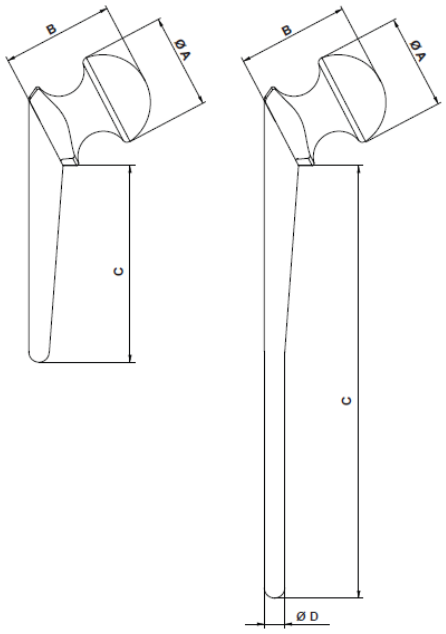
VANCOGENX-SPACE HIP

Composition	Material	Percentage
Resin	Polymethylmethacrylate	84,9 % w/w
	Barium sulphate	10,0 % w/w
	Gentamicin sulphate	3,2 % w/w
	Vancomycin hydrochloride	1.9 % w/w
Inner core	AISI 316 ESR	

Product variants

Product code	Description	Dimensions				Gentamicin	Vancomycin
		A	B	C	D		
SPC0030	46 mm Ø - short stem	46	54,5	96	-	1,1g	1,1g
SPC0130	54 mm Ø - short stem	54	60	94	-	1,9g	1,9g
SPC0230	60 mm Ø - short stem	60	73	98	-	3,0g	3,0g
SPC0330	46 mm Ø - long stem	46	54,5	211	10	1,3g	1,3g
SPC0430	54 mm Ø - long stem	54	60	209	10,5	2,1g	2,1g
SPC0530	60 mm Ø - long stem	60	73	211	11	3,2g	3,2g



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