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# VANCOGENX BONE CEMENT

**Manufacturer: Tecres SpA**

Tecres SpA was founded in 1981 by Mr Giovanni Faccioli. In 1986 the first orthopaedic bone cement was launched in the market (Cemex Standard) with the unique powder to liquid ratio of 3 to 1 for enhanced safety and performances. In 1989 the products started to be sold also outside Italy. Japan was the first market, while today we have a worldwide presence in more than 70 countries.

In 1991 the first closed system pre-loaded with cement was born (Cemex System): for the first time, a bone cement is being delivered in a fully sealed system, protecting the OR staff and ensuring perfect mixing.

In 1995, the preformed bone cement spacer to be used in PJI was patented for the first time in the world, and the following year was used clinically (Spacer-G, hip spacer with Gentamicin).

In 1998 Tecres passed the first US FDA inspection. New products were launched: Spacer-K (knee spacer with Gentamicin), Cranos (custom made cranial prosthesis) and Mendec Cranio (acrylic cement for cranial defect). In 2001, we started to sell in US. In 2002 we entered the market of vertebral augmentation with the launch of the Mendec Spine acrylic resin. In 2003 we started selling in China. In 2010 we launched the first complete line of dual antibiotic bone cement and spacers with the antibiotic combination Gentamicin+Vancomycin (Vancogenx line).

In 2016 Tecres created Demetra Holding, which today includes other companies (Osartis, Germany; OsteoRemedies, US; YiJiuTai, China; GetSet Surgical, Switzerland, Orthofundamentals, US).

**Vancogenx bone cement**

Vancogenx bone cement started to be developed in the early years of 2000

CE mark under MDD was received in 2010; CE mark under MDR (2017/745) in 2023 (Certificate N.: 738100 R000).

Vancogenx is available in two viscosities: medium and high.

**Intended purpose**

Vancogenx bone cement is intended for:

a) temporary fixation of PMMA antibiotic-loaded spacer for two-stage procedure;

b) permanent fixation of joint prosthesis implants (hip, knee) to the host bone following a two-stage procedure due to a septic process.

**Indications for use**

Vancogenx is indicated where there is the risk or presence of infections caused by organisms susceptible to Gentamicin and/or Vancomycin.

**Markets**

| | |
|---|---|
| Europe | Albania, Belgium, Bulgaria, Czech Republic, Estonia, France, Germany, Greece, Hungary, Italy, Moldova, The Netherlands, Norway, Poland, Portugal, Romania, Serbia, Spain, Switzerland, Turkey, Ukraine, United Kingdom |
| Asia-Pacific | Hong Kong, Kuwait, Iraq, Israel, Lebanon, Mongolia, Philippines, Saudi Arabia, Singapore, Sri Lanka, Taiwan, Unites Arab Emirates |
| Africa | Algeria, Egypt, South Africa |
| America | Argentina, Brazil, Canada, Chile, Colombia, Ecuador, Nmexico, icaragua, Paraguay, Peru, Trinidad & Tobago United States |

## Competitor

On the market only another cement brand has the same antibiotic combination (Gentamicin+Vancomycin). It is manufactured by Heraeus Medical and its name is Copal G+V.

Copal G+V obtain the CE mark under MDD some years later compared to Vancogenx.

Vancogenx is approved also in the United States under the brand name Spectrum GV Bone Cement, and is distributed by OsteoRemedies Ltd, part of Demetra.

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**Formulation: antibiotics %**

The two products have slightly different formulations and include different dosages of the antibiotics.

| | Viscosity | Use | Codes | Gentamicin (g) | Vancomycin (g) |
|---|---|---|---|---|---|
| Vancogenx<br>Vancogenx HV | Medium<br>High | Syringe/manual<br>Manual | 12A2520<br>12A2530 | 1 | 1 |
| Copal G+V | High | Manual | 66038973 | 0.5 | 2 |

The choice of the antibiotic formulation of both products originates from the gentamicin version of the two companies: Copal G+V originates from Palacos R+G, while Vancogenx originates from Cemex Genta.

| | Gentamicin (g) in 40g PMMA | Vancomycin (g) in 40g PMMA |
|---|---|---|
| Cemex Genta | 1 | - |
| Vancogenx | 1 | 1 |
| | | |
| Palacos RG | 0.5 | - |
| Copal G+V | 0.5 | 2 |

In terms of kinetics of release, the two products have similar elution, as documented in a comparative study presented in Prague during the EBJIS 2013 by Cannon T, Nichol T, Smith T, Stockley I, Townsend R. "What's Better – in-house mixing or industrial preparation? A comparison of antibiotic elution from commercially available bone cement and in-house prepared cement".

**Radiopacifier: barium sulphate vs zirconium dioxide**

Another difference in the formulation regards the radiopacifier: as it happens with all the bone cements manufactured by Heraeus Medical the radiopacifying agent is zirconium dioxide, while as it happens with all the bone cements manufactured by Tecres SpA the radiopacifying agent is barium sulphate.
These two radiopacifiers are the same used by all bone cement manufacturers worldwide: since zirconium dioxide is less radiopaque than barium sulphate, the percentage of Zirconium dioxide is generally higher compared to the percentage of barium sulphate.

| | Radiopacifier |
|---|---|
| Vancogenx<br>Vancogenx HV | 10% |
| Copal G+V | 14% |

The use of both radiopacifiers is widely used in bone cement production. No clinical study has ever demonstrated that the presence of barium sulphate or zirconium dioxide leads to better or worse clinical performances. In addition, the presence of both radiopacifiers does not affect the elution properties of the material.
The qualification of the orthopaedic bone cement is done using international standards, which need to be met.
In addition, the recent MDR has introduced a very demanding process for CE mark registration, which guarantees the clinical safety and effectiveness of medical devices based on clinical data.
**Vancogenx bone cement has obtained the CE mark under MDR in 2023 thanks to in vitro, in vivo and clinical testing. Clinical evidence available is able to guarantee clinical safety and effectiveness.**

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**Literature**

Vancogenx bone cement has been on the market for more than 15 years, and plenty of invitro, in vivo and clinical studies have been published indicating excellent clinical results in the medium and long-term.
Here below a short table detailing the most important papers published on peer-reviewed journals.

| Year | Study type | Objective | Reference |
|---|---|---|---|
| **Non-clinical studies** | | | |
| 2002 | In vitro study | Antibiotic elution<br>Synergy evaluation | Bertazzoni Minelli E et al. Release of antibiotics from polymethylmethacrylate cement. J Chemother. 2002 Oct;14(5):492-500. |
| 2008 | In vivo (rabbit) study | Antimicrobial and anti-biofilm activity in established infection (osteomyelitis rabbit model) | Giavaresi G et al. Preliminary investigations on a new gentamicin and vancomycin-coated PMMA nail for the treatment of bone and intramedullary infections: an experimental study in the rabbit. Journal of Orthopaedic Research, June 2008: 785 - 792 |
| 2011 | In vitro study | Antibiotic elution<br>Anti-adhesion and anti-growth activity vs clinical isolates | Bertazzoni Minelli E et al. Different microbial biofilm formation on polymethylmethacrylate (PMMA) bone cement loaded with gentamicin and vancomycin. Anaerobe (2011) 380-383 |
| 2013 | In vitro study | Antibiotic release<br>Anti-biofilm performances | Gallo J et al. Microbiological and pharmacological properties of bone cement Vancogenx. Acta Chirurgiae Orthopaedicae et Traumatologiae čechosl.,80, 2013, p 69-79 |

| **Clinical studies** | | | | | |
|---|---|---|---|---|---|
| **Year** | **Study type** | **N. pts** | **Follow-up** | **Type** | **Reference** |
| 2014 | Proceedings | 24 | 24M<br>(12 – 36) | TKA | Abbas A et al. Vancogenx pre-mixed, antibiotic cement in revision total knee replacement. EBJIS Proceedings – 2014 Utrecht (NL) |
| 2018 | Clinical study | 24 | 48M<br>(18 – 82) | THA<br>TKA | Corona PS et al. Use of modular megaprosthesis in managing chronic end-stage hip and knee PJI: Is there an increase in relapse rate? Eur J Orthop Surg Traumatol. 2018 May;28(4):627-636 |
| 2018 | Register study | 54 | 2.5Y<br>(max 6.5Y) | THA | National Joint Register of UK & Northern Ireland |
| 2018 | Register study | 49 | 2,0Y<br>(max 5.6Y) | TKA | National Joint Register of UK & Northern Ireland |
| 2020 | Clinical study | 108 | 46M<br>(12 – 95) | THA<br>TKA | Corrò S et al. Vancomycin-Gentamicin prefabricated spacers in 2-stage revision arthroplasty for chronic hip and knee PJI: insights into reimplantation microbiology and outcomes. J Arthroplasty. 2020 Jan;35(1):247-254. |
| 2020 | Clinical study | 148 | 57M<br>(12 – 116) | THA<br>TKA | Corona PS et al. Current actual success rate of the two-stage exchange arthroplasty strategy in chronic hip and knee PJI.<br>Bone Joint J. 2020 Dec;102-B(12):1682-1688. |
| 2020 | Clinical study | 94 | 19M<br>(8 – 31) | HA | Pellegrini A et al. One-stage revision surgery provides infection eradication and satisfying outcomes for infected TKA in selected patients. Expert Rev Anti Infect Ther. 2020 Dec 3:1-4. |
| 2021 | Clinical study | 20 | 6.2Y<br>(2 – 10) | TKA | Lakhani K et al. Direct anterior approach provides better functional outcomes when compared to direct lateral approach in HA following FNF. Eur J Orthop Surg Traumatol. 2022 Jan;32(1):137-143. |

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|---|---|---|---|---|---|
| 2021 | RCT study | 140 | 3M | HA | Rodríguez-Pardo D et al. Role of asymptomatic bacteriuria on early PJI after HA. BARIFER randomized clinical trial. Eur J Clin Microbiol Infect Dis. 2021 Nov;40(11):2411-2419. |
| 2022 | Case report | 3 | 21M (15 – 30) | TKA | Joshi N et al. Complex distal femoral fractures in the fragile elderly patient treated by distal femoral replacement: A report of three cases. Revista espanola de cirugia ortopedica y traumatologia. 2022;66(2):149–53. |
| 2023 | Clinical study | 52 | 46.2M (13 – 113.5) | TKA | Corona PS et al. Sequential repeated tibial tubercle osteotomy in a two-stage exchange strategy: a superior approach to treating a chronically infected TKA? Eur J Orthop Surg Traumatol. 2023 Dec;33(8):3347-3355. |
| 2023 | Clinical study | 11 | 30.1M (1 – 74) | TKA | Pujol O rt al. High reoperation and mortality rate after distal femoral replacement for periprosthetic knee fracture in the elderly. Eur J Orthop Surg Traumatol. 2023 May;33(4):911-918 |
| 2024 | Clinical study | 78 | 4.3Y (2 -11.4) | TKA | Pérez M et al. Outcomes of a cemented modular rotational-hinge design as the final implant in a two-stage replacement due to chronic knee PJI. Archives of Orthopaedic and Trauma Surgery. 2024;1–12 |