orthopaedics

# VANCOGENX® LINE


*Innovation,*
*Synergy,*
*Efficacy,*
*Evolution...*
*serving surgeons.*

TECRES®
*Advancing High Technology*

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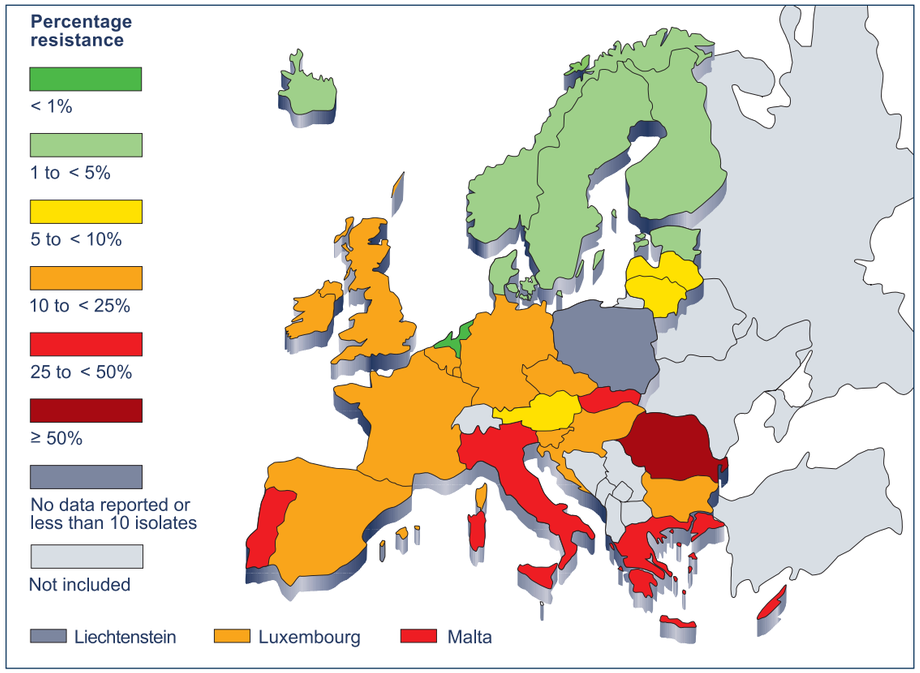
# Innovation

Tecres research laboratories developed the first **Vancomycin** and **Gentamicin** loaded bone cement.

VANCOGENX is the ideal solution for the fixation of antibiotic-loaded spacers and prosthetic components during revision surgery due to infections caused by resistant micro-organisms.

MRSA (Methicillin resistant *Staphylococcus aureus*) and MRSE (Methicillin resistant *Staphylococcus epidermidis*) infections, in particular, continue to present a serious, yet common problem.
VANCOGENX provides surgeons with the ideal solution for the treatment of these complex cases.

## Proportion of methicillin resistant *staphylococcus auerus* (MRSA) isolates in participating countries in 2014.[14]




## VANCOGENX features:

- allows effective, high-dose release of Vancomycin and Gentamicin
- guarantees excellent mechanical performances
- presents ideal viscosity for all types of use, for both manual and syringe application
- has a non-abrasive action due to the use of barium sulphate as the radiopaque tracer
- reduces the heat developed during curing and lower toxicity due to the low monomer content

# Synergy

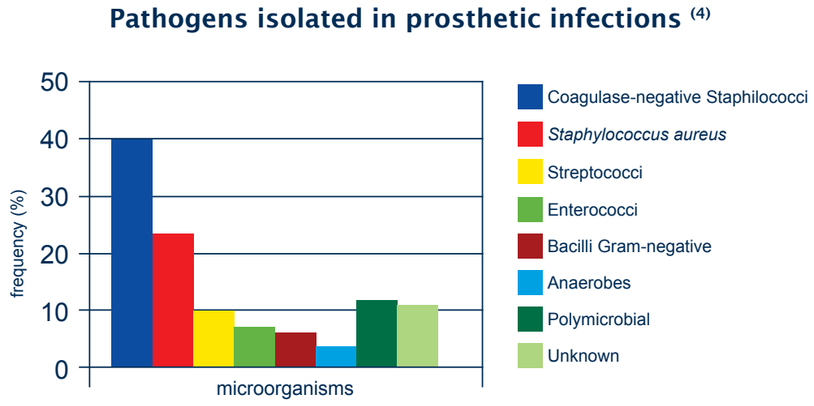
**Vancomycin and Gentamicin**

- Have a **synergic action** as their antibacterial efficacy is more potent when they are used together. [1, 2, 3]
- Boast a spectrum of action covering approximately **90% of the pathogens** commonly isolated in orthopaedic infections.[3, 4]
- Is **the most commonly used** and widely reported combination when bone cement is utilised in cases of concomitant treatment of infections.[5, 6, 7]

## Spectrum of action: microbiological efficacy

| | Gram+ | | | | | Gram- | |
|---|---|---|---|---|---|---|---|
| | Staphilococci MET-S | Staphilococci MET-R | Enterococci | Streptococci | Propionibacteria | Enterobacteria | *P. aeuroginosa* |
| Gentamicin | good | low | good | | no | high | |
| Vancomycin | high | | | | good | no | |
| Vanco-Genta | synergic | | | high | good | synergic | |

## Pathogens isolated in prosthetic infections [4]




## The advantages of VANCOGENX:

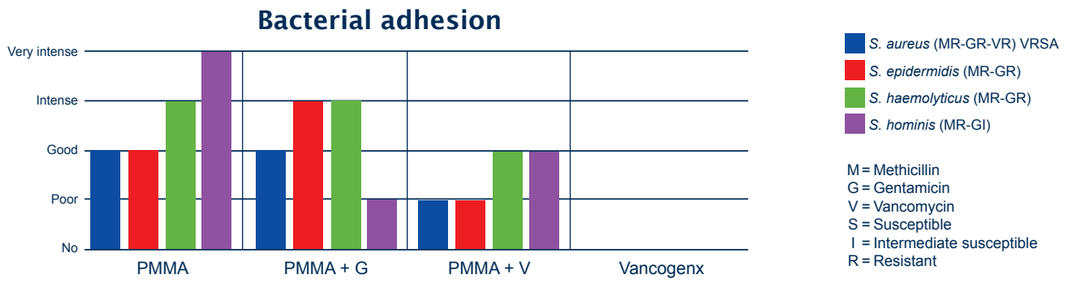
- broad spectrum of action
- synergic antimicrobial effect
- prevention of bacterial adhesion
- effective as a coadjuvant in the treatment of infection

# Efficacy

**Vancogenx is effective:**

**in protecting the device**

*In vitro* studies have shown that Vancogenx exerts an anti-adhesion action by inhibiting bacterial roliferation.

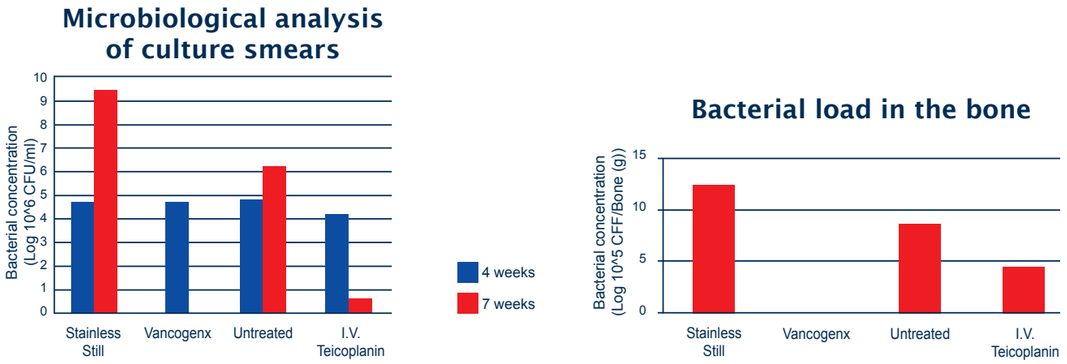



The chart shows the adhesion of clinical isolates to PMMA loaded with Gentamicin, Vancomycin and a Vancomycin-Gentamicin combination (Vancogenx).

**Use of the Vanco-Genta combination prevents bacteria from adhering to the PMMA[3]**

**as a coadjuvant in the treatment of infection**

*In vivo** studies have proven Vancogenx's **therapeutic efficacy** in experimental osteomyelitis models.




**Description of the study:**

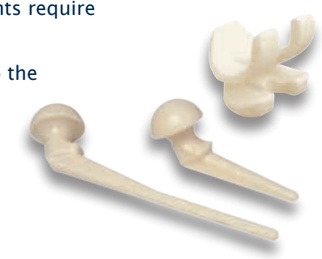
following induction of MRSA infection for 4 weeks, animals underwent debridement and were assigned to 4 groups representing different treatment options: stainless steel nail (group 1); Vancogenx-coated stainless steel nail (group 2); no treatment (group 3); systemic treatment with I.V. Teicoplanin. After 3 weeks, smears and bone fragment specimens were harvested to evaluate the progression of the infection and the effect of/on bacterial load was evaluated following exposure to the various treatment options using both culture swabs and bone analysis.

**Local therapy with Vancogenx eradicates infection and provides better results than systemic therapy with teicoplanin [15].**

* *in vivo* animal studies

# Evolution

Vancogenx-Space devices are the exclusive preformed spacers that bring together the extraordinary mechanical and pharmacological characteristics of Tecres spacers and the efficacy of the Vancomycin-Gentamicin combination. They are indicated for temporary artificial joint replacement when prosthetic joints require removal due to sepsis.



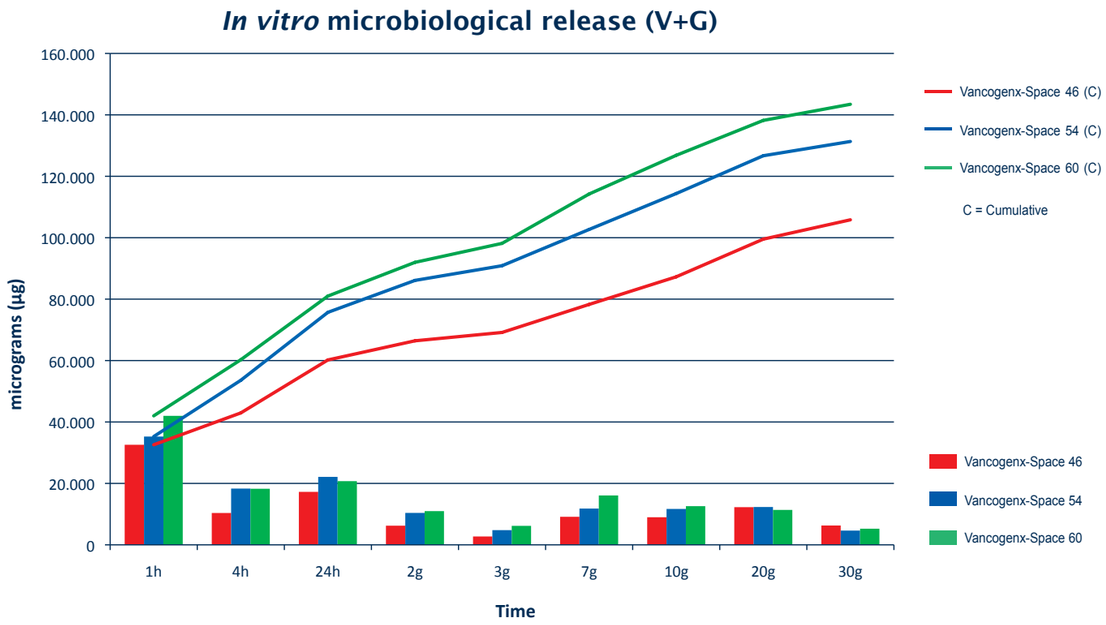
The microbiological efficacy of Vancogenx-Space devices can be attributed to the special production process developed by Tecres that increases the device's porosity without compromising its mechanical performance.[8]

This permits antibiotic release that is:

- sustained and high-dose
- calibrated
- superior to that achieved with theatre-made devices using antibiotic-loaded bone cement.

## Vancogenx-Space features:

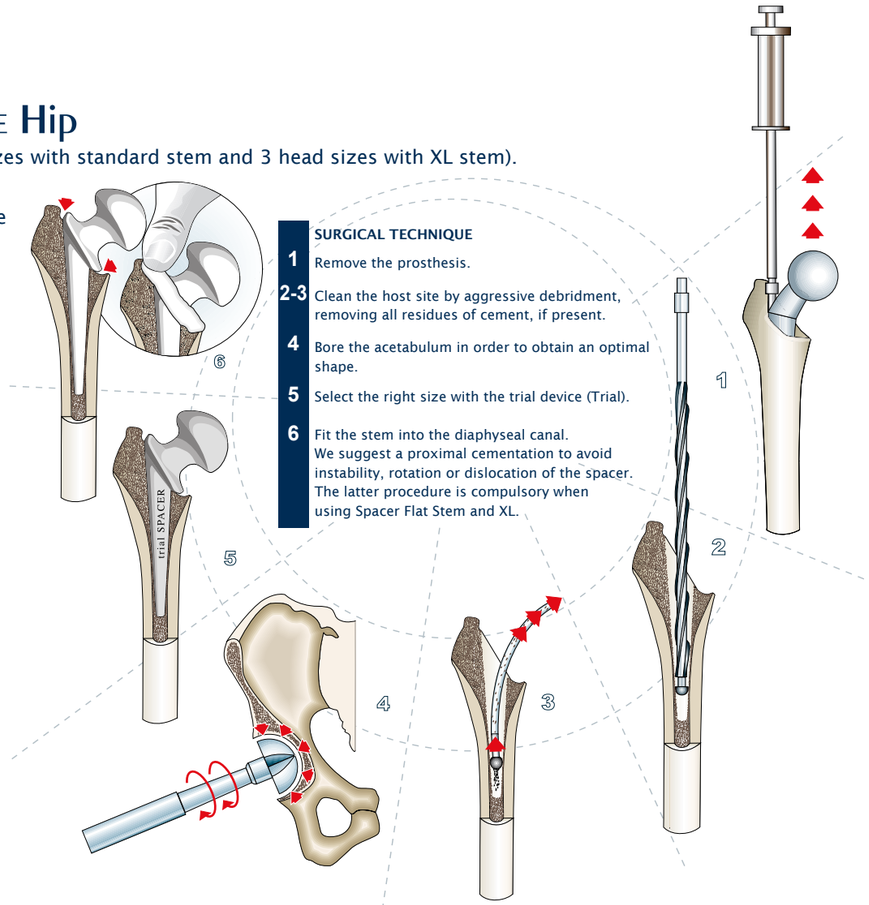
- **boast a spectrum of action** that covers approximately 90% of the pathogens commonly isolated in orthopaedic infections.
- **prevent bacterial colonisation** and proliferation by guaranteeing the continuous presence of antibiotic agents on surface of the device [3]
- **reduce the risk of bacterial resistance.** They permit a consistent initial release of antibiotic that is kept at a high level and sustained over time




Concentrations above the minimum inhibitory concentration (MIC) for the most common pathogens are maintained for at least 30 days (MIC > 10µg/ml). [10]

## Vancogenx-Space Hip

Comes in 6 sizes. (3 head sizes with standard stem and 3 head sizes with XL stem).
If the stem is unstable and when using Vancogenx Space Hip XL, proximal cementing of the neck should be performed using Vancogenx cement.

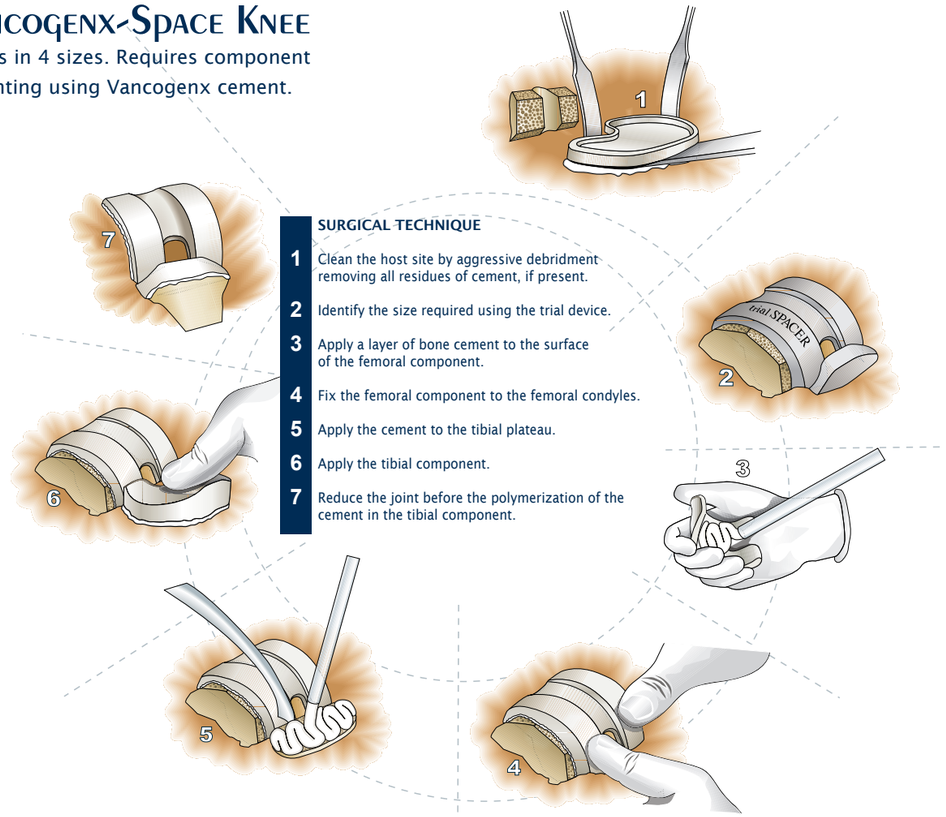



**SURGICAL TECHNIQUE**

1. Remove the prosthesis.
2-3. Clean the host site by aggressive debridment, removing all residues of cement, if present.
4. Bore the acetabulum in order to obtain an optimal shape.
5. Select the right size with the trial device (Trial).
6. Fit the stem into the diaphyseal canal. We suggest a proximal cementation to avoid instability, rotation or dislocation of the spacer. The latter procedure is compulsory when using Spacer Flat Stem and XL.

## Vancogenx-Space Knee

Comes in 4 sizes. Requires component cementing using Vancogenx cement.




**SURGICAL TECHNIQUE**

1. Clean the host site by aggressive debridment removing all residues of cement, if present.
2. Identify the size required using the trial device.
3. Apply a layer of bone cement to the surface of the femoral component.
4. Fix the femoral component to the femoral condyles.
5. Apply the cement to the tibial plateau.
6. Apply the tibial component.
7. Reduce the joint before the polymerization of the cement in the tibial component.

## Ordering information

### VANCOGENX

| Code | Product | Details |
|---|---|---|
| 12A2520 | Vancogenx | 40 g |

### Spacer for HIP

**Spacer G - Gentamicin Loaded**

| Stem | Head Size (mm) | Round Stem | Flat Stem |
|---|---|---|---|
| Short Stem | 46 | SPC46/G | SPC0620 |
| | 54 | SPC54/G | SPC0720 |
| | 60 | SPC60/G | SPC0820 |
| Long Stem | 46 | SPC46/GXL | SPC0920 |
| | 54 | SPC54/GXL | SPC1020 |
| | 60 | SPC60/GXL | SPC1120 |

**Vancogenx Space Hip - Genta + Vanco Loaded**

| Stem | Head Size (mm) | Round Stem | Flat Stem |
|---|---|---|---|
| Short Stem | 46 | SPC0030 | SPC0630 |
| | 54 | SPC0130 | SPC0730 |
| | 60 | SPC0230 | SPC0830 |
| Long Stem | 46 | SPC0330 | SPC0930 |
| | 54 | SPC0430 | SPC1030 |
| | 60 | SPC0530 | SPC1130 |

**Trial Set (3-size set)**

| | |
|---|---|
| Short Round Stem | SPG03 |
| Long Round Stem | SPG03XL |
| Short Flat Stem | SPC90Z0 |
| Long Flat Stem | SPC91Z0 |

### Spacer for KNEE

**Spacer K - Gentamicin Loaded**

| Tibial Dimension (mm) | Code |
|---|---|
| 60 – small | SPK6054/G |
| 70 – medium | SPK7064/G |
| 80 – large | SPK8074/G |

**Vancogenx Space K - Genta + Vanco Loaded**

| Tibial Dimension (mm) | Code |
|---|---|
| 60 – small | SPK0030 |
| 70 – medium | SPK0130 |
| 80 – large | SPK0230 |
| 90 – extralarge | SPK0330 |

**Trial Set**

| | |
|---|---|
| Trial Set (small-medium large) | SPK03 |
| Trial extralarge | SPK03Z0 |

### Spacer for SHOULDER

**Spacer S - Gentamicin Loaded**

| Head Size (mm) | Code |
|---|---|
| 41 | SPS0020 |
| 46 | SPS46/G |

**Trial**

| | |
|---|---|
| Two-size | SPS90Z0 |

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## Bibliography


1. Watanakunakorn C, Bakie C.
**Synergism of vancomycin-gentamicin and vancomycin-streptomycin against enterococci.**
*Antimicrob Agents Chemother. 1973 Aug;4(2):120-4.*

2. Watanakunakorn C, Tisone JC.
**Synergism between vancomycin and gentamicin or tobramycin for methicillin-susceptible and methicillin-resistant Staphylococcus aureus strains.**
*Antimicrob Agents Chemother. 1982 Nov;22(5):903-5.*

3. **E.** Bertazzoni Minelli, T. Della Bora, A. Benini
**Different microbial biofilm formation on polymethylmethacrylate (PMMA) bone cement loaded with gentamicin and vancomycin**
*Anaerobe. 2011 Dec; 17(6): 380-3*

4. Trampuz A, Zimmerli W.
**Prosthetic joint infections: update in diagnosis and treatment.**
*Swiss Med Wkly. 2005 Apr 30;135(17-18):243-51. Review.*

5. Penner MJ, Masri BA, Duncan CP.
**Elution characteristics of vancomycin and tobramycin combined in acrylic bone-cement.**
*J Arthroplasty. 1996 Dec;11(8):939-44.*

6. Masri BA, Duncan CP, Beauchamp CP.
**Long-term elution of antibiotics from bone-cement: an in vivo study using the prosthesis of antibiotic-loaded acrylic cement (PROSTALAC) system.**
*J Arthroplasty. 1998 Apr;13(3):331-8.*

7. Bertazzoni Minelli E, Caveiari C, Benini A.
**Release of antibiotics from polymethylmethacrylate cement.**
*J Chemother. 2002 Oct;14(5):492-500.*

8. Soffiatti R.
**In "Infection and local treatment in orthopedic surgery"**
*2007, Springer Verlag. The preformed spacers from the idea to the realization of industrial device.*

9. Springer BD et al.
**Systemic safety of high-dose antibiotic-loaded cement spacers after resection of an infected total knee arthroplasty.**
*Clin Orthop Relat Res. 2004 Oct;(427):47-51.*

10. Bertazzoni Minelli E et al.
**PK-PD parameters ratio of antibiotics released from antibiotic-loaded spacers in drainage fluids**
*ESCMID Munich, Germany 2007.*

11. Bertazzoni Minelli E., Benini A.
**In "Infection and local treatment in orthopedic surgery"**
*2007, Springer Verlag. The Gentamicin.-Vancomycin Spacer: A Pharmacological study.*

12. Garvin KL, Hanssen AD.
**Infection after total hip arthroplasty. Past, present, and future.**
*J Bone Joint Surg Am. 1995 Oct;77(10):1576-88. Review.*

13. Moojen DJ, Hentenaar B, Charles Vogely H, Verbout AJ, Castelein RM, Dhert WJ.
**In vitro release of antibiotics from commercial PMMA beads and articulating hip spacers.**
*J Arthroplasty. 2008 Dec;23(8):1152-6. Epub 2008 Mar 4.*

14. EARSS Annual Report 2014.
**Antimicrobial resistance surveillance in Europe.**

15. Giavaresi G. et al.
**Preliminary investigations on a new Genta and Vanco-coated PMMA nail for the treatment of bone and intramedullary infections: an experimental study in the rabbit.**
*J Orthop Res. 2008. n; 26(6):785-92.*


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