

o r t h o p a e d i c s

VancogenX[®]



Winning Synergy

TECRES[®]
MEDICAL
Advancing High Technology





Vancogenx:

**the first bone cement
with Gentamicin and
Vancomycin.**

Continual research at Tecres has culminated in **an exclusive and innovative line of cements** meeting the needs of surgeons who day after day have to tackle increasingly difficult cases of antibiotic-resistance in prosthetic infections.

Vancogenx is the ideal complement in the fixation of antibiotic-loaded spacers and permanent fixation of prostheses following two-stage septic revision procedures; particularly where there is the risk or presence of infection caused by bacteria sensitive to **Gentamicin and/or Vancomycin**.

Vancogenx ensures:

1) Ideal viscosity for every requirement:

- ▶ suitable for manual application;
- ▶ suitable for syringe application.

2) All the advantages of a Tecres cement:

- ▶ reduced polymerization temperature;
- ▶ reduced toxicity;
- ▶ excellent mechanical performances.

3) Presence of Gentamicin and Vancomycin:

- ▶ broad spectrum of action;
- ▶ antimicrobial synergy;
- ▶ effective and prolonged release.

Why Gentamicin and Vancomycin?

The problem of infections caused by resistant bacteria is continually growing and is a serious complication in orthopaedic surgery, especially for infections caused by MRSA (methicillin resistant *Staphylococcus aureus*) and MRSE (methicillin resistant *Staphylococcus epidermidis*).

The **Gentamicin - Vancomycin** combination ensures a broad spectrum of action that helps treatment of infections in particularly complex cases as in presence of infections caused by resistant bacteria (MRSA and MRSE) Enterococci, Streptococci and CoNS. ^(3, 4)

Winning Synergy

- ▶ Have a **synergic action**. In association, they enhance their anti-bacterial effectiveness. ^(1, 2, 3)
- ▶ Have a spectrum of activity which covers **about 90% of pathogens** normally isolated in orthopaedic infections. ^(3, 4)
- ▶ Is the association **most described and used** when bone cement is utilized alongside the treatment of infections. ^(5, 6, 7)

Patogens isolated in prosthetic infections

| Microorganism | frequency (%) |
|----------------------------------|---------------|
| Coagulase-negative staphylococci | 30-40 |
| <i>Staphylococcus aureus</i> | 12-23 |
| Streptococci | 9-10 |
| Enterococci | 3-7 |
| Gram-negative bacilli | 3-6 |
| Anaerobes | 2-4 |
| Polymicrobial | 10-12 |
| Unknown | 10-11 |

Zimmerli et al., 2005⁽⁴⁾

Growth and adhesion after 24 hours of incubation

| | S. aureus 3A10 | | S. epidermidis 137/25 | | S. epidermidis 8/28 | | S. epidermidis 3/2 | | S. haemolyticus 8/28 | | S. hominis 126/26 | | S. aureus 5/7 | | E. coli 7A27 | |
|--------------|-------------------|----|--------------------------|----|------------------------|----|-----------------------|----|-------------------------|----|----------------------|----|------------------|----|-----------------|----|
| | MS-GS | | MR-GI | | MR-GR | | MR-GR | | MR-GR | | MR-GI | | MR-GR-VR (VRSA) | | GS | |
| | G | A | G | A | G | A | G | A | G | A | G | A | G | A | G | A |
| PMMA | ++++ | ++ | ++++ | ++ | ++++ | ++ | ++++ | ++ | ++++ | ++ | ++++ | ++ | ++++ | ++ | ++++ | ++ |
| PMMA + G | NG | NA | NG | NA | ++++ | ++ | ++++ | ++ | ++++ | ++ | ++++ | + | ++++ | ++ | ++++ | + |
| PMMA + V | NG | NA | NG | NA | + | + | + | ++ | ++++ | ++ | ++++ | ++ | ++ | + | ++++ | ++ |
| PMMA + G + V | NG | NA | NG | NA | NG | NA | NG | NA | NG | NA | NG | NA | NG | NA | NG | NA |

Score: NG no growth; + poor; ++ good; +++ intense; ++++ very intense
Score: NA no adhesion; + slight-; ++ good; +++ intense; ++++ very intense

Bertazzoni Minelli E. et al., 2009⁽³⁾

Resistance to G >32 mg/L
Intermediate resistance to G 8 mg/L
Susceptibility to G < 4 mg/L
Resistance to V > 4 mg/L



The **Vancogenx** range boasts an easy-to-use and reliable **bone cement mixing and delivery system**.

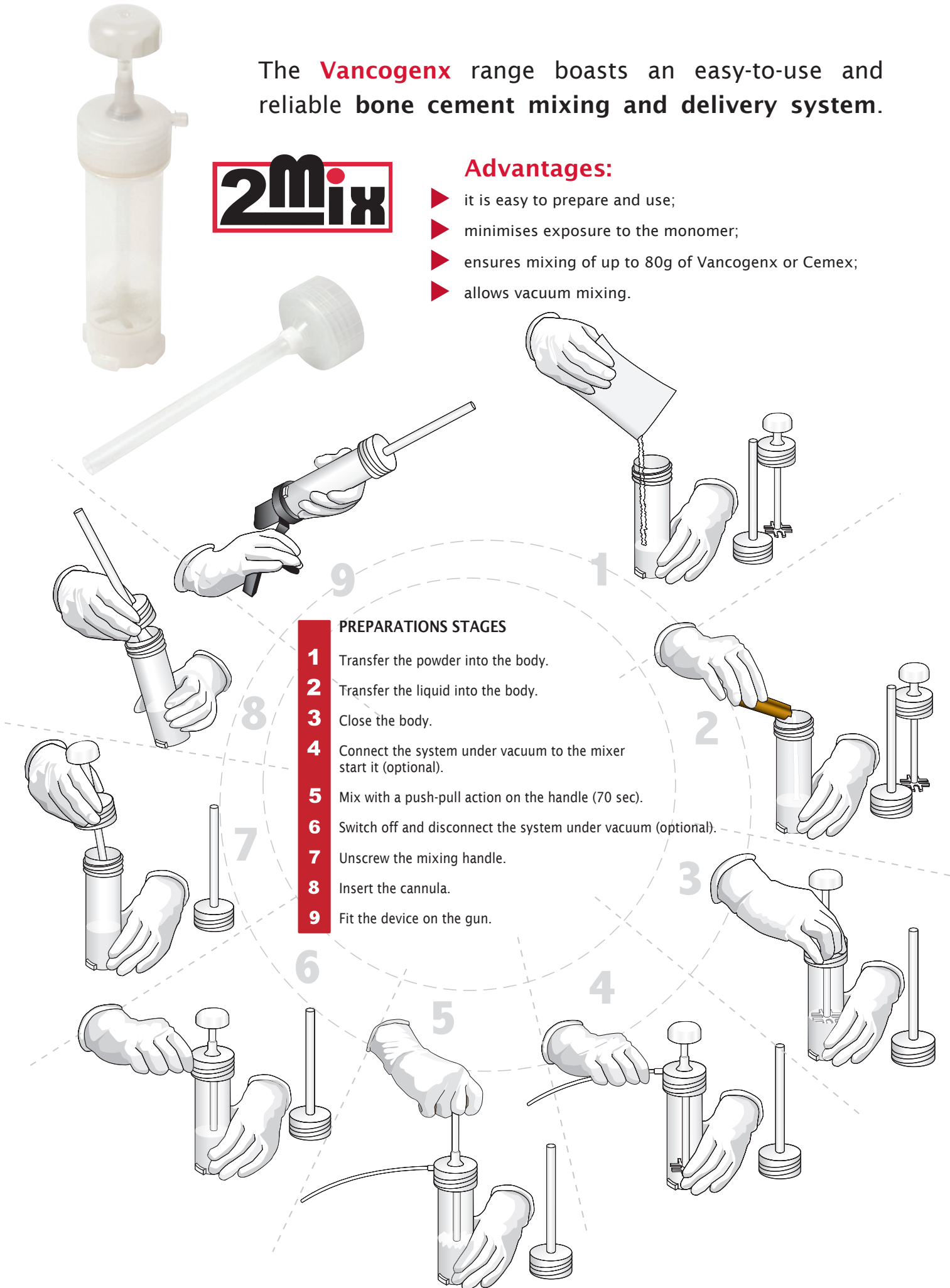


Advantages:

- ▶ it is easy to prepare and use;
- ▶ minimises exposure to the monomer;
- ▶ ensures mixing of up to 80g of Vancogenx or Cemex;
- ▶ allows vacuum mixing.

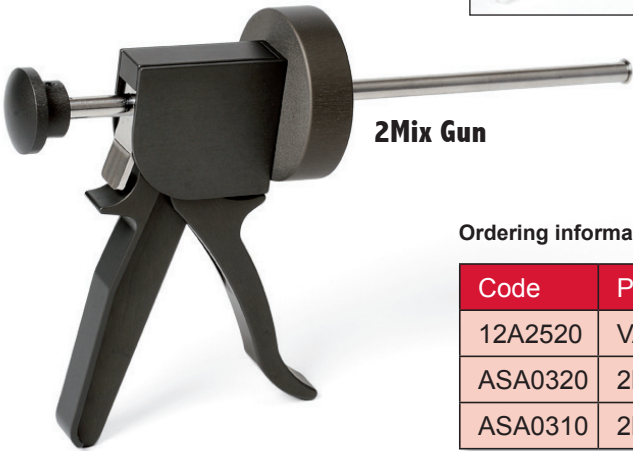
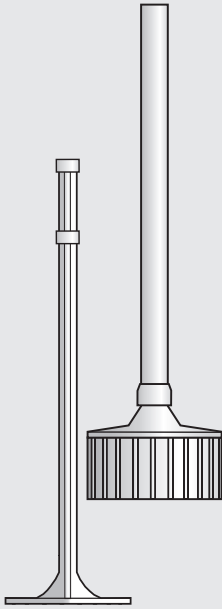
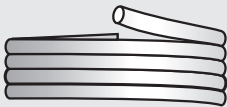
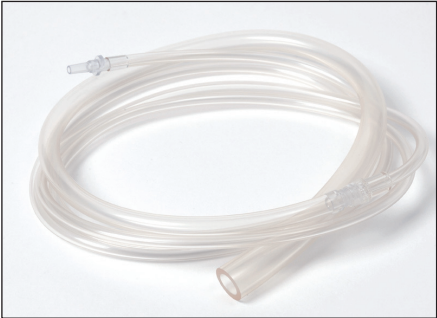
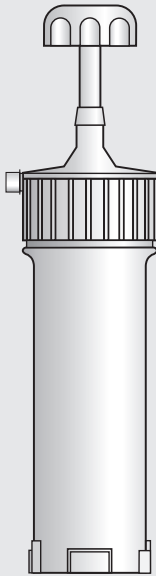
PREPARATIONS STAGES

- 1 Transfer the powder into the body.
- 2 Transfer the liquid into the body.
- 3 Close the body.
- 4 Connect the system under vacuum to the mixer start it (optional).
- 5 Mix with a push-pull action on the handle (70 sec).
- 6 Switch off and disconnect the system under vacuum (optional).
- 7 Unscrew the mixing handle.
- 8 Insert the cannula.
- 9 Fit the device on the gun.



2Mix includes:

- ▶ mixing device;
- ▶ system connection tube under vacuum;
- ▶ cannula for extrusion of the bone cement.



2Mix Gun

Ordering information

| Code | Product | Details |
|---------|-----------|---------|
| 12A2520 | VANCOGENX | 40g |
| ASA0320 | 2Mix | |
| ASA0310 | 2Mix GUN | |



Vancogenx-Space



Vancogenx-Space devices are exclusive pre-formed spacers prepared with **Vancogenx** bone cement: **a real help in cases of complex two-stage septic revision.**

They are temporary implantable devices, indicated to replace temporarily a joint prosthesis removed as a result of a septic process.

They are made using bone cement with **Gentamicin** and **Vancomycin** additives, antibiotics that are released into the surrounding tissues as an aid to treatment of infections.

Infection of an orthopaedic prosthesis is a serious complication for the patient and a complex problem for the surgeon. In recent years, the two-stage procedure has become the elective treatment since it ensures better clinical outcomes compared to the one-stage procedure. ⁽¹²⁾

The **Vancogenx-Space** pre-formed spacers offer **standardised geometries** and **reliable and reproducible mechanical and pharmacological performances**, as well as **helping to save time in the operating theatre.**



Advantages:

- ▶ Upkeep of articular space and mobility.
- ▶ Possibility of deambulation with a partial load.*
- ▶ Easier definitive re-implantation surgery.
- ▶ Reduction of functional recovery times after definitive review.
- ▶ Effective, prolonged and constant *in situ* release of **Gentamicin** and **Vancomycin**.



* Partial loading must be assessed case by case in relation to anatomical conditions, bone trophism and the clinical status of the patient during rehabilitation stages. In particular, the risk that excessive loading or enforced mobilisation may cause the structure of the spacer to damage the biological structures must be avoided.

Winning Synergy

Controlled and effective release of the dual antibiotic:

Thanks to the association of two antibiotics and their synergic action, **Vancogenx-Space** spacers ensure a broad spectrum of action that **covers about 90% of pathogens** normally isolated in orthopaedic infections.

Vancogenx-Space is useful especially in complex cases and where infection is caused by resistant bacteria (MRSA and MRSE) Enterococci, Streptococci and CoNS. ^(4,11)

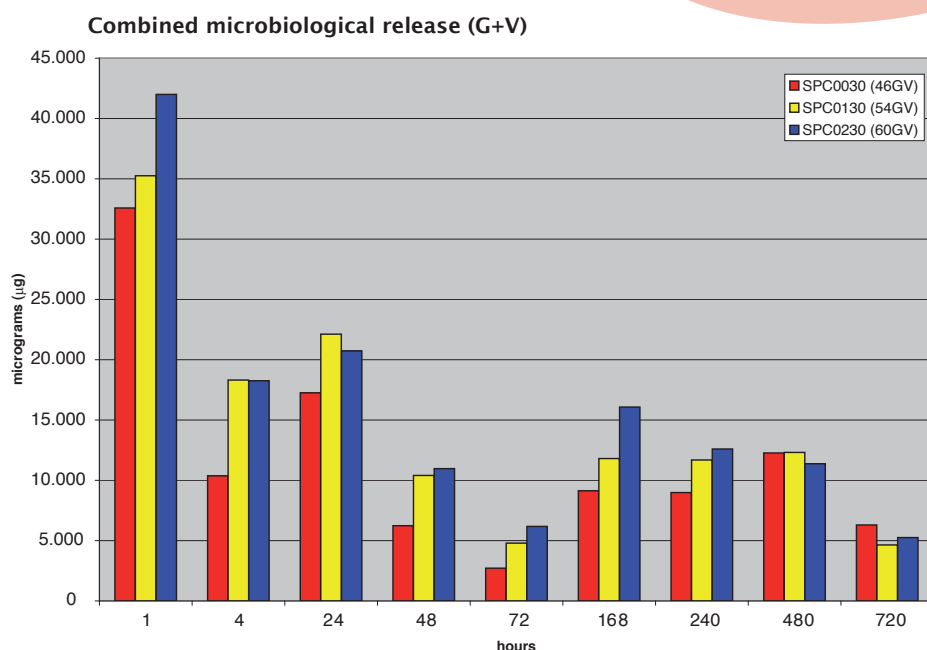
The microbiological effectiveness is achieved by the special manufacturing process developed by Tecres that increases the porosity of the device without compromising its mechanical performances. ⁽⁸⁾

This ensures a **prolonged release of antibiotic over time, standardized and higher** compared to devices prepared manually in the operating theatre with antibiotic-loaded bone cement.

Biological function:

Vancogenx-Space ensures:

- ▶ continual presence of antibiotic on the device that **prevents bacterial growth and colonisation**; ⁽³⁾
- ▶ local release of antibiotic throughout the device implant period and **negligible risk of systemic toxicity**; ⁽⁹⁾
- ▶ **reduction of the risk of bacterial resistance.** During the implant period, the spacers release levels of antibiotic into the fluids surrounding the joints that are higher than MIC (minimum inhibitory concentration). ⁽¹⁰⁾



Tecres internal lab test, 2008

Vancogenx-Space provides high initial release of antibiotic that is maintained over time. Laboratory studies have demonstrated that concentrations higher than MIC for the most common pathogens ($MIC > 10 \mu g/ml$) are maintained for at least 30 days.

Vancogenx®

DESCRIPTION:



Vancogenx-Space spacers are available for the hip and knee

Vancogenx-Space Hip is similar to a femoral prosthesis and is fitted with an internal load-bearing structure in 316L steel.

Vancogenx-Space Hip is positioned in the femoral channel and the acetabular cavity after removal of the previous implant and complete surgical debridement.

When distal fixation is required - in the absence of proximal support, in the presence of a major metaphyseal defect or after a trans-femoral approach - the long stem version (XL) is recommended.

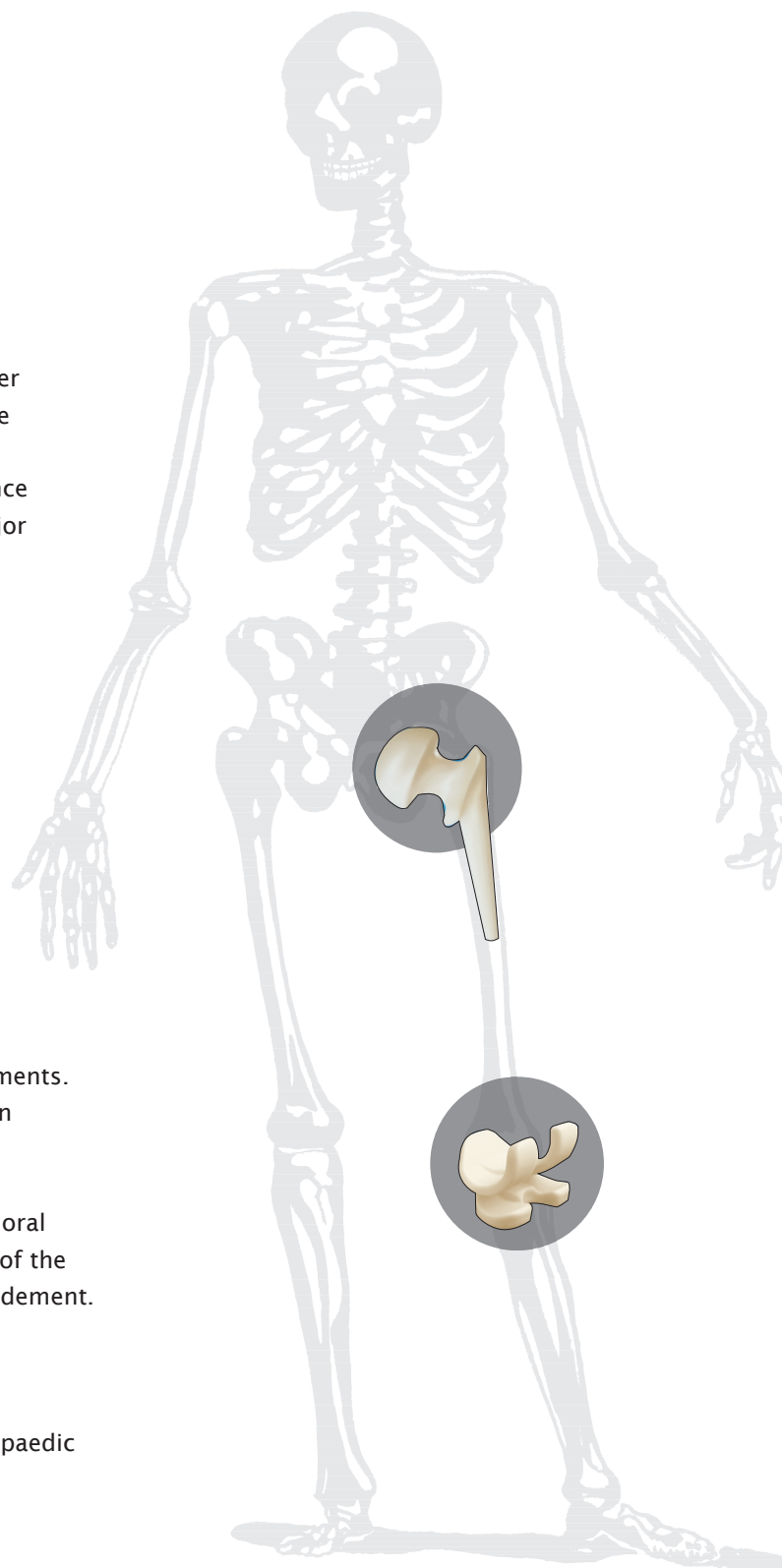
In the event of rotational instability of the device that may cause pain and increase the risk of dislocation, proximal cementing of the neck is suggested, that must be performed with **Vancogenx** bone cement.

Vancogenx-Space Knee is similar to an ultra-congruent condylar knee prosthesis. It comprises two independent articulated elements. The tibial component comprises a flat base on which the femoral part articulates.

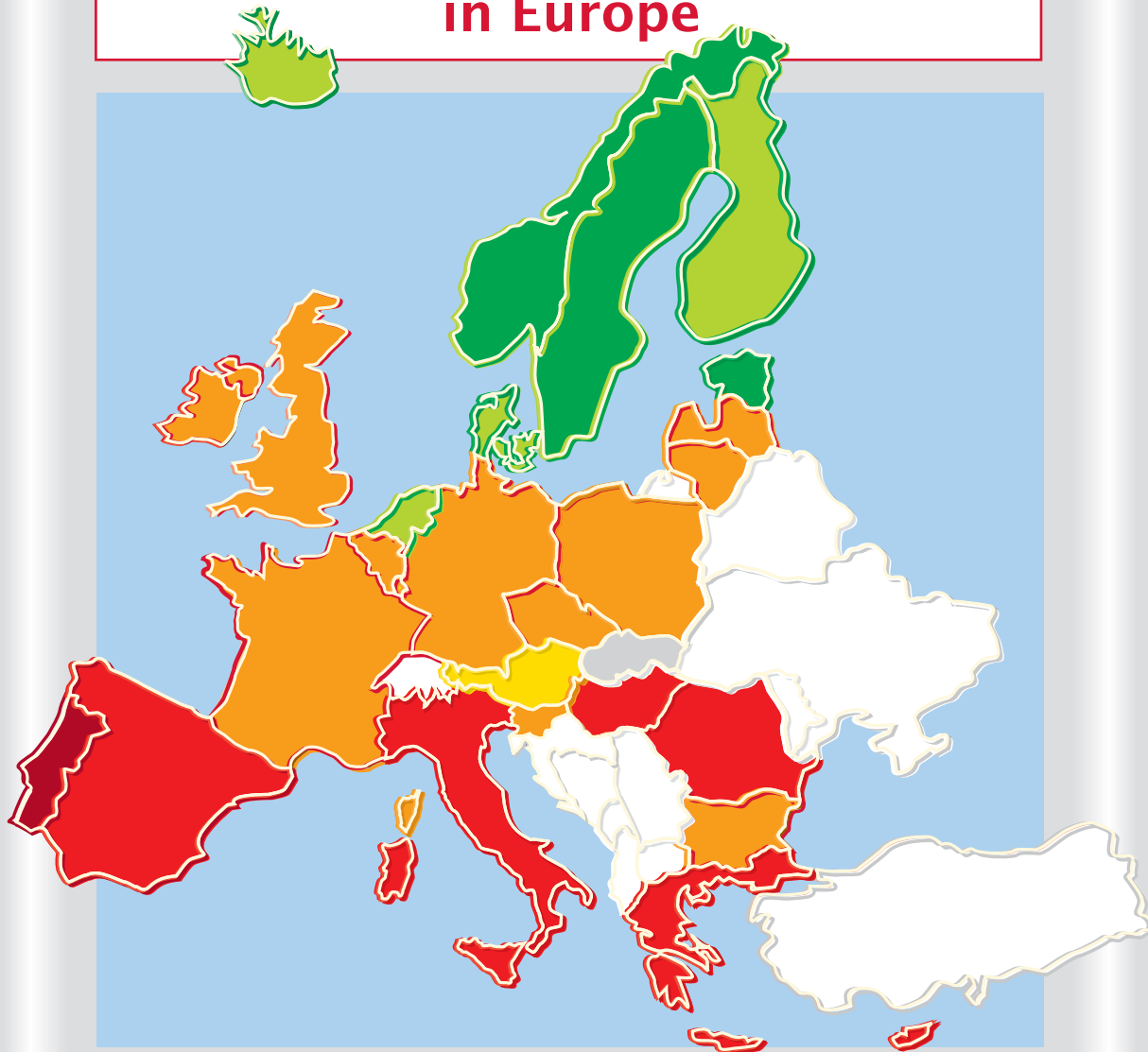
Vancogenx-Space Knee is applied to the femoral condyles and the tibial plateau after removal of the previous implant and complete surgical debridement.

Both components must be secured using Vancogenx bone cement.

In the event of instability, the use of an orthopaedic brace is suggested.



The MRSA problem in Europe



LEGEND



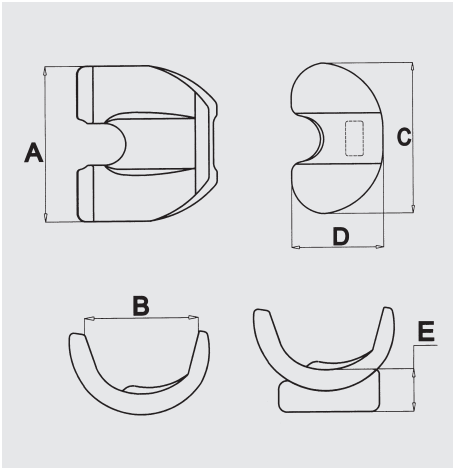
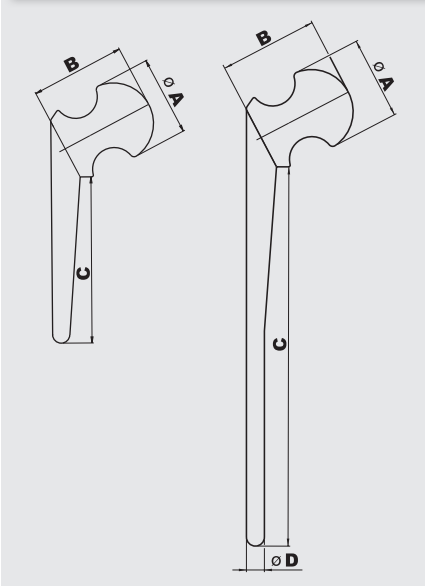
S. Aureus: percentage of invasive isolates resistant to methicillin (MRSA) in 2010.¹⁴

Ordering information and dimensions

| REF. | A (mm) | B (mm) | C (mm) | D (mm) | Gentamicin (g) | Vancomycin (g) |
|---------|--------|--------|--------|--------|----------------|----------------|
| SPC0030 | 46 | 54,5 | 96 | - | 1,1 | 1,1 |
| SPC0130 | 54 | 60 | 94 | - | 1,9 | 1,9 |
| SPC0230 | 60 | 73 | 98 | - | 3 | 3 |
| SPC0330 | 46 XL | 54,5 | 211 | 10 | 1,3 | 1,3 |
| SPC0430 | 54 XL | 60 | 209 | 10,5 | 2,1 | 2,1 |
| SPC0530 | 60 XL | 73 | 211 | 11 | 3,2 | 3,2 |

To select the right size to be implanted templates and trial spacers are available.

| REF. | DESCRIZIONE |
|---------|-----------------------------------|
| SPG03 | Spacer-G Trial (three-size set) |
| SPG03XL | Spacer-GXL Trial (three-size set) |



| REF. | A (mm) | B (mm) | C (mm) | D (mm) | E (mm) | Gentamicin (g) | Vancomycin (g) |
|---------|--------|--------|--------|--------|--------|----------------|----------------|
| SPK0030 | 54 | 40 | 60 | 36 | 16 | 0,9 | 0,9 |
| SPK0130 | 64 | 47 | 70 | 42 | 17 | 1,3 | 1,3 |
| SPK0230 | 74 | 54 | 80 | 48 | 18 | 1,8 | 1,8 |
| SPK0330 | 84 | 58 | 90 | 54 | 20 | 2,6 | 2,6 |

To select the right size to be implanted templates and trial spacers are available.

| REF. | DESCRIPTION |
|---------|---------------------------------|
| SPK03 | Spacer-K Trial (three-size set) |
| SPK03Z0 | Spacer-K Trial XL |

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