

CEMEX[®]

Line



TECRES

ADVANCING HIGH TECHNOLOGY

"Knowing
that our products
every day improve
the lives of many people.
This is our ambition.
This is our reward."

Giovanni Faccioli, President.



TECRES

Cutting-edge technologies and constant research to improve the lives of many people. This is the vision of Tecres since 1981, operating in synergy with surgeons, Universities and Research Institutes in order to invent, realize and provide the market with safe, effective and innovative products. We are specialized in acrylic resins since 1986 with medical applications in fields such as orthopaedics, spinal surgery and neurosurgery. Our excellence and reliability are recognized in more than 70 Countries around the world.

CEMEX® LINE

Cemex® is the bone cement designed by Tecres for joint implants. Right from the start, the company focused on research and development of acrylic resins, creating a unique and revolutionary product in 1986. Since then, the outstanding features of Cemex® have remained unchanged and they are now available in every product of the complete range, making it the ideal cement for all needs. As shown by several international publications, Cemex® is a safe and reliable cement¹⁻³, with excellent mechanical performance¹² and long-term clinical follow-up^{1,9,11,13,14}.

Cemex® line is composed by manual cements, closed system cements (Cemex® System) and accessories.



30% LESS MONOMER

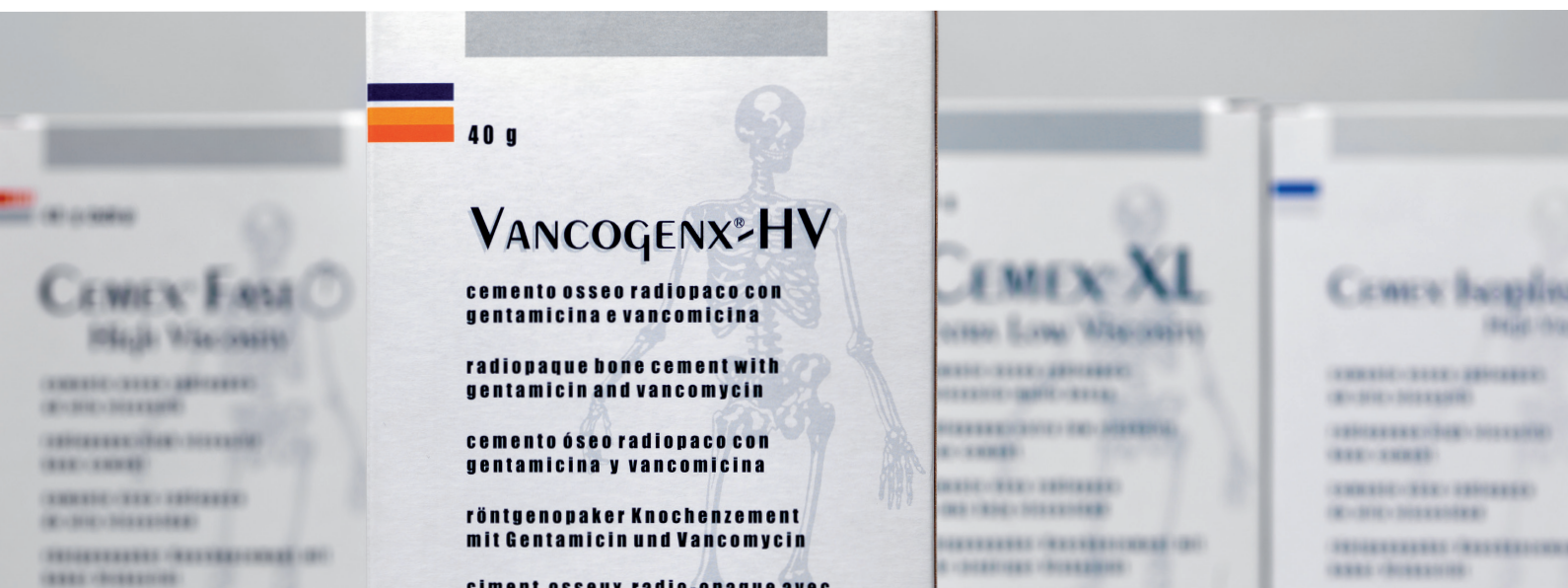
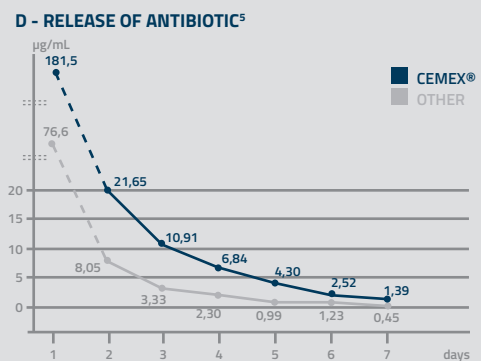
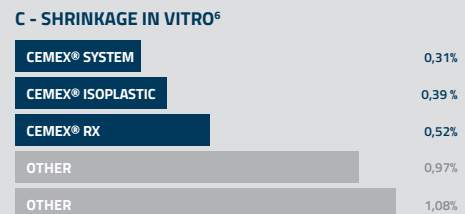
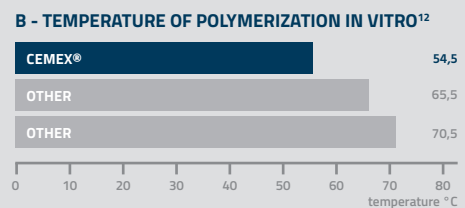
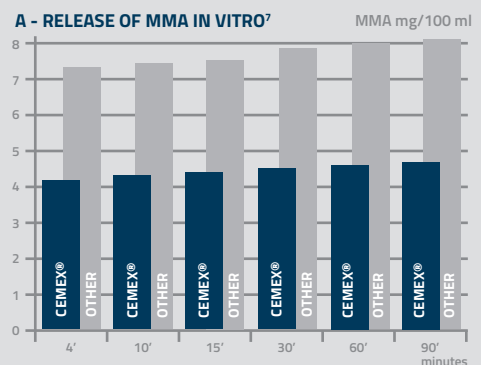
Bone cement is made up of polymers (powder) and a monomer (liquid); when the liquid component wets the surface of the powder it sets off a chemical reaction (known as polymerization). An exclusive process patented by Tecres gives to the powder particles of Cemex® a very smooth and uniform surface, making the cement very compact with extremely low porosity. The special powder of Cemex® needs 30% less monomer than conventional bone cements found on the market. The revolutionary 3:1 ratio between powder and liquid puts Cemex® in a different league from the traditional 2:1 ratio, providing the surgeon, the operating theatre staff and the patients with a number of significant and proven advantages:

A - Greater safety: with less monomer than any other cement on the market, Cemex® is the acrylic resin with the lowest toxicity for anyone coming into contact with it⁷.

B - Less heat given off: every gram of monomer generates heat amounting to 130 Kcal. Cemex® requires less liquid, so the maximum temperature reached at the end of the chemical reaction is substantially lower, thus preserving surrounding tissues^{8,12}.

C - Reduced shrinkage: shrinkage is the reduction in volume of the cement following its polymerization. It is directly proportional to the amount of liquid present. As the amount of monomer required is reduced by a third, shrinkage is also reduced, thus greatly improving implant fixation⁶.

D - Release of antibiotic: some antibiotics are heat-labile, but as Cemex® only reaches quite a low temperature during polymerization, this reduces the risk of antibiotic degradation, thus ensuring effective release of the antibiotic^{4,5}.



CEMEX® - MANUAL BONE CEMENTS

Cemex® Line adapts to the surgeon's requirements, and provides a complete product range with or without antibiotics, and with different viscosities, ensuring maximum flexibility for all surgical procedures.

RANGE

Cemex® Isoplastic: high viscosity, recommended for manual applications, particularly for cementing the acetabulum and the knee.

Cemex® RX: medium viscosity, suitable for both syringe and manual applications (wait is a few minutes longer).

Cemex® XL: low viscosity, suitable for syringe applications.

Cemex® Fast: high viscosity, suitable for manual applications where fast application times are required.

Cemex® Genta LV: low viscosity with Gentamicin suitable for syringe applications.

Cemex® Genta HV: high viscosity with Gentamicin suitable for manual applications.

Cemex® Genta Fast: all the specifics of Cemex® Fast with Gentamicin.

Cemex® Genta ID Green: medium viscosity, suitable for both syringe and manual applications with Gentamicin. Green, radiopaque.

Vancogenx®: medium viscosity, Vancomycin and Gentamicin loaded bone cement suitable both for manual and syringe application.

Vancogenx® HV: high viscosity, Vancomycin and Gentamicin loaded bone cement suitable for manual application.

Cal-Cemex®: reinforced bone substitute, hybrid formula



Preparation of manual bone cement: scan the QR code and watch the video tutorial.

CEMEX®			
	NO AB	GENTA	GENTA + VANCO
HV	Cemex® Isoplastic (20/40g) Cemex® Fast (20+20g)	Cemex® Genta HV (40g) Cemex® Genta Fast (20+20g)	Vancogenx® HV (40g)
MV	Cemex® RX (40g)	Cemex® Genta ID Green (40g)	Vancogenx® (40g)
LV	Cemex® XL (50g)	Cemex® Genta LV (40g)	



VANCOGENX®

Periprosthetic infections constitute one of the most critical post-operative complications in arthroplasty. The surface of the implant is a perfect environment for the adhesion and growth of bacteria. It is particularly difficult to treat infections due to MRSA (Methicillin-Resistant *Staphylococcus aureus*), MRSE (Methicillin-Resistant *Staphylococcus epidermidis*), and other resistant pathogens, which continue to represent a serious and widespread problem.

For this reason Tecres was the first company to offer a **bone cement with added Gentamicin and Vancomycin: Vancogenx®**. Vancogenx® is the ideal bone cement for the fixation of antibiotic-loaded spacers during two-stage procedures in case of periprosthetic joint infection (PJI) and prosthetic components fixation during revision surgery following a septic process.

ADVANTAGES:

- Broad spectrum of activity due to antibiotic synergy
- Effective as a coadjuvant in the treatment of an infection
- High and effective release of Vancomycin and Gentamicin
- Bacterial anti-adhesion thanks to the presence of antibiotics
- Approved for fixation of definitive revision prostheses
- Approved for cementation of antibiotic-loaded spacers
- Available in two viscosities for manual and syringe application

Vancogenx® HV
High-viscosity bone
cement Spacers with
Gentamicin and
Vancomycin
Code 12A2530 - 40g



Vancogenx®
Medium-viscosity
bone cement Spacers
with Gentamicin and
Vancomycin
Code 12A2520 - 40g

VANCOGENX®: SYNERGY

When combined, Gentamicin and Vancomycin have a synergistic action against bacteria.¹⁵⁻¹⁶⁻¹⁷

Their range of action covers approximately 90% of the pathogenic agents generally isolated in surgical infections.¹⁷⁻¹⁸

The Gentamicin and Vancomycin combination is the most commonly used and published combination in cases of concomitant treatment of orthopaedic infections.¹⁹⁻²⁰⁻²¹

	GRAM+					GRAM-	
	MRS METHICILLIN RESISTANT STAPHYLOCOCCI	MSS METHICILLIN SUSCEPTIBLE STAPHYLOCOCCI	ENTEROCOCCI	STREPTOCOCCI	CUTIBACTERIA	ENTEROBACTERIACEAE	PSEUDOMONAS SPP
Gentamicin	Medium	Low	Medium		-	Medium	
Vancomycin	High				Medium	-	-
Gentamicin and Vancomycin	SYNERGISTIC			HIGH	MEDIUM		

VANCOGENX®: EFFICACY

Vancogenx® bone cement has been shown to be able to prevent bacterial adhesion¹⁷ (in vitro tests) and as a coadjuvant in treatment of the infection (in vivo animal tests).²²

Bacterial anti-adhesion

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

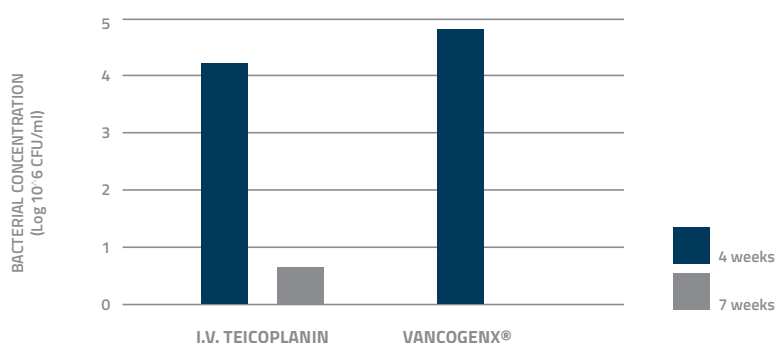


The chart shows the adhesion of clinical isolates to PMMA loaded with gentamicin and the Vancomycin-Gentamicin combination (Vancogenx®). The Gentamicin-Vancomycin combination prevents bacteria from adhering to the PMMA.¹⁷

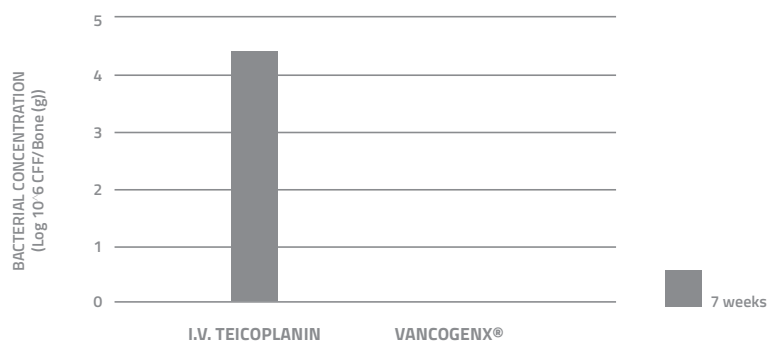
Coadjuvant in the treatment of infection

In vivo animal studies* have proven Vancogenx®'s therapeutic efficacy in experimental osteomyelitis models. The results of the study indicate that local therapy with Vancogenx® is able to eradicate infection and provides better results than systemic therapy with teicoplanin.²² Following surgical debridement, the local therapy achieved with Vancogenx® eradicates infection and provides better results than systemic therapy.

MICROBIOLOGICAL ANALYSIS OF THE CULTURE SWAB



BACTERIAL LOAD IN THE BONE



*Description of the study: a femoral osteomyelitis was induced with MRSA. After 4 weeks the animals were subjected to surgical debridement of the femoral canal and were divided into various groups to represent different treatment options, among which: insertion of an SS nail covered with Vancogenx® (group 1) and a one-week systemic treatment with I.V. Teicoplanin (group 2). After 3 weeks the animals were sacrificed, and the femurs explanted to assess the outcomes of the infection: local therapy with Vancogenx® was able to eradicate the infection (from a radiological, histological and microbiological point of view) providing better results than systemic therapy with I.V. Teicoplanin.

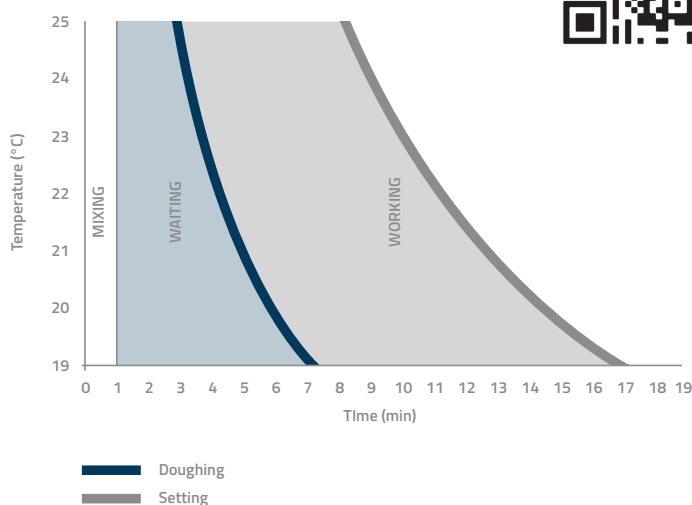


VANCOGENX®: TWO DIFFERENT VISCOSITIES

The Vancogenx® dual antibiotic cement is available in two versions:

Medium viscosity Vancogenx®, ideal for application with a syringe for fixation of hip spacers or prostheses.

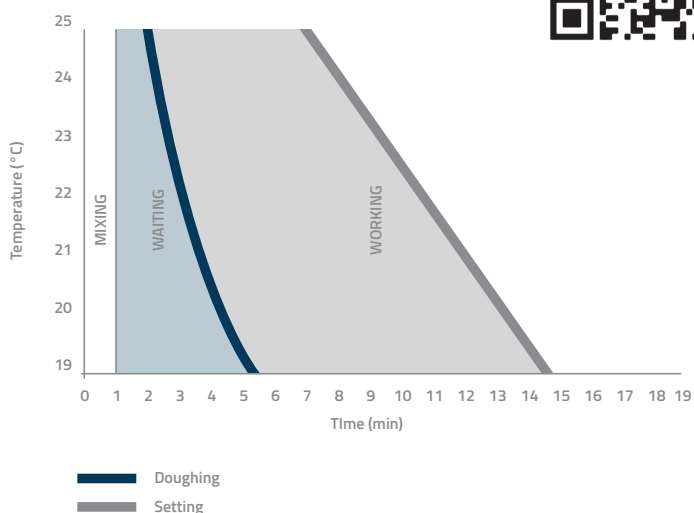
VANCOGENX®



Scan the QR code and watch the tutorial video on the preparation of Vancogenx®.

High viscosity Vancogenx® HV, ideal for manual application for the fixation of knee spacers or prostheses.

VANCOGENX® HV



Scan the QR code and watch the tutorial video on the preparation of Vancogenx®.

CEMEX® SYSTEM

The Cemex® product range has a unique cementation system that already has both powder and liquid inside it. Cemex® System is an “all-in-one” system capable of providing safety and simplicity in a single device. In just a few simple steps, the cement is ready to use and combines the excellent features of Cemex® cement alongside a series of major advantages:

No risk of contamination: Cemex® System is completely sealed. Operators do not come into contact with the material at any stage of the mixing process, nor do the components come into contact with the environment.

No vapours: The system is completely odour-free, thus protecting operators from being exposed to monomer fumes.

Easy to use and store: Cemex® System combines a bone-cement mixing system with a bone-cement delivery system. There are no bags to open up, nor tubes to connect together – all that is needed is the purpose-built Gun. Cement can be prepared in a very short time and this can be done by just one person. Its practicality and compactness mean more room on shelves and in the operating theatre.



Preparation of Cemex® System:
scan the QR code and watch the video tutorial

CEMEX® SYSTEM	
NO AB	
FAST	Cemex® System Fast (40/70g) Cemex® System Fast ID Green (70g)
STANDARD	Cemex® System (60/80g)
GENTA	
FAST	Cemex® System Genta Fast (40/70g) Cemex® System Genta ID Green (70g)
STANDARD	Cemex® System Genta (60/80g)

Cemex® System preparation stages are available on Tecres website.

RANGE

Cemex® System: Bone cement ideal in any surgical situation.

Cemex® System Genta: Gentamicin loaded version of Cemex® System.

Cemex® System Fast: bone cement ideal in any surgical situation, suitable when fast application times are required.

Cemex® System Genta Fast: Gentamicin loaded version of Cemex® System Fast

Cemex® System Fast ID Green: Green version of Cemex® System Fast with a stable and durable colour.

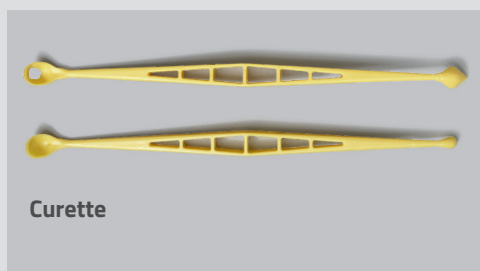
Cemex® System Genta ID Green: Green version of the Cemex® System Genta Fast, with a stable and durable colour.



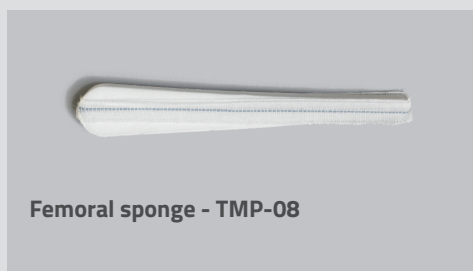
ACCESSORIES

The vast range of Cemex® accessories includes everything that might be needed for an effective cementation procedure in any surgical situation.

CEMEX® PREP KIT - KIT-01



Curette



Femoral sponge - TMP-08



Pressurizer - PRZ-01



Femoral brush - SPZ-01



Cement Restrictors + Inserter

Available in the following sizes: 12-18 mm, 18-24 mm.

OTHER ACCESSORIES



2 Mix - ASA0320

Easy and reliable mixer that allows vacuum mixing



2 Mix Gun - ASA0310

Gun for 2 Mix extrusion



CPSP-02

Mixing bowl and spatula



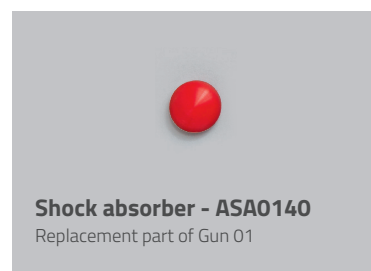
Gun 01

To be used with Cemex® System for extruding bone cement



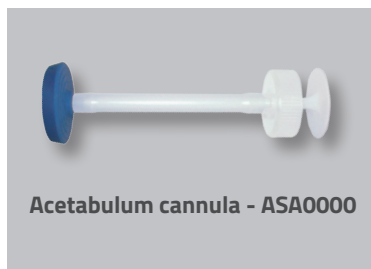
4 Mix Bowl - ASA0420

Bone cement mixing bowl



Shock absorber - ASA0140

Replacement part of Gun 01



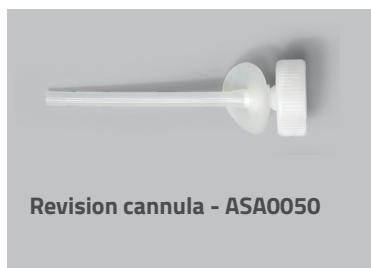
Acetabulum cannula - ASA0000



Knee cannula - ASA0010



Shoulder cannula - CNL-09



Revision cannula - ASA0050



Cemex® System Mixer* ASA0021 - 110V

Is the first and currently the only totally automatic mixer for bone cement. It can ensure reproducibility of results, optimised mixing and it is easy to use. (to be used exclusively with Cemex® System and its Cemex® System Container).

*Available in US only

ORDERING INFORMATION

CODE	PRODUCT	DETAILS
1200/A	CEMEX® RX	40g
1200/I	CEMEX® ISOPLASTIC	40g
1220/I	CEMEX® ISOPLASTIC 1/2 pack	20g
1200/S	CEMEX® XL	50g
12A3000	CEMEX® FAST	20g+20g
12A3100	CEMEX® GENTA FAST	20g+20g with Gentamicin
1400/AG	CEMEX® GENTA LOW VISCOSITY	40g with Gentamicin - (steril. Eto)
1400/IG	CEMEX® GENTA HIGH VISCOSITY	40g with Gentamicin - (steril. Eto)
1400/AG INT	CEMEX® GENTA LOW VISCOSITY	40g with Gentamicin- (steril. Gamma)
1400/IG INT	CEMEX® GENTA HIGH VISCOSITY	40g with Gentamicin- (steril. Gamma)
1310/S	CEMEX® SYSTEM 60g	60g
1500/S	CEMEX® SYSTEM 80g	80g
1510/S	CEMEX® SYSTEM FAST 70g	70g
13A2020	CEMEX® SYSTEM FAST 40g	40g
1310/SG	CEMEX® SYSTEM GENTA 60g	60g with Gentamicin
1500/SG	CEMEX® SYSTEM GENTA 80g	80g with Gentamicin
13A2110	CEMEX® SYSTEM GENTA FAST 40g	40g with Gentamicin
13A2100	CEMEX® SYSTEM GENTA FAST 70g	70g with Gentamicin
13A2420	CEMEX® SYSTEM GENTA ID GREEN 70g	70g with Gentamicin
13A2320	CEMEX® SYSTEM FAST ID GREEN 70g	70g
12A2420	CEMEX® GENTA ID GREEN	40g with Gentamicin
CPSP-02	BOWL AND SPATULA	
CNL-09	SHOULDER CANNULA	
ASA0010	CANNULA FOR KNEE	
ASA0000	ACETABULUM CANNULA	
ASA0050	REVISION CANNULA	
ASA0150	HIP CANNULA	
KIT-01	CEMEX® PREP KIT	
KIT-02	CEMEX® PREP KIT 2	without restrictors
TPA-18	CEMENT RESTRICTOR (12-18 mm) + INSERTER	12-18 mm
TPA-24	CEMENT RESTRICTOR (18-24 mm) + INSERTER	18-24 mm
TMP-08	FEMORAL SPONGE	
PRZ-01	CEMENT PRESSURIZER	
SPZ-01	FEMORAL BRUSH	
GUN-01	GUN 01	
ASA0130	GUN 02	with opening compartment
ASA0140	SHOCK ABSORBER	
ASA0021	CEMEX® SYSTEM MIXER 110V	110 Volts
ASA0030	CEMEX® SYSTEM CONTAINER	sterile and disposable
12A2520	VANCOGENX®	40g with Gentamicin + Vancomycin
12A2530	VANCOGENX® HV	40g with Gentamicin + Vancomycin
ASA0320	2 MIX	
ASA0310	2 MIX GUN	
ASA0420	4 MIX BOWL	

BIBLIOGRAPHY

1. Nivbrant B, Kärrholm J, Röhrl S, Hassander H, Wesslén B. **Bone cement with reduced proportion of monomer in total hip arthroplasty: preclinical evaluation and randomized study of 47 cases with 5 years' follow-up.** *Acta Orthop Scand.* 2001 Dec;72(6):572-84.
2. Bialoblocka-Juszczyk E, Cristofolini L, Erani P, Viceconti M. **Effect of long-term physiological activity on the long-term stem stability of cemented hip arthroplasty: in vitro comparison of three commercial bone cements.** *Proc. Inst. Mech Eng H.* 2010;224(1):53-65.
3. Pitto RP. **Cemex Genta bone cement in total hip arthroplasty. Clinical outcome and Radiostereanalysis. A 5-year Follow-up. Report April 2007.** *Department of Orthopaedic Surgery. South Auckland Clinical School. University of Auckland.*
4. Squire MW, Ludwig BJ, Thompson JR, Jagodzinski J, Hall D, Andes D. **Premixed antibiotic bone cement: an in vitro comparison of antimicrobial efficacy.** *J Arthroplasty.* 2008 Sep;23(6 Suppl 1): 110-4. *Epub* 2008 Jul 9.
5. Takahira N, Itoman M, Higashi K, Uchiyama K, Miyabe M, Naruse K. **Treatment outcome of two-stage revision total hip arthroplasty for infected hip arthroplasty using antibiotic-impregnated cement spacer.** *AJ. Orthop. Sci.* 2003;8(1):26-31.
6. Trieu H, Morris L. **Comparative measurement of shrinkage of 5 commercial cements prepared under vacuum mixing.** In "Bone cement in the year 2000. State of the art and perspectives". Grassi F, Soffiatti R (Eds.).
7. Gatti G. **Monomer (MMA) release test from bone cement dough.** *Neutron High Qualified Laboratory, Modena, Italy.* 1989.
8. De Bastiani G, Gabbi C, Magnan B, Regis D, Ricci M. **Experimental study of the interface cement-bone: effect of the polymerization heat.** *Biomateriali* 3/4 (1990):85-93.
9. Garelick G, Kärrholm J, Rogmark C, Herberts P. **Annual Report 2009. Swedish Hip Register.** <https://www.jru.orthop.gu.se/> (Last access date: June 20, 2011).
10. Lidgren L, Sundberg M, W-Dahl A, Robertsson O. **Annual Report 2010. Swedish Knee Arthroplasty Register.** <http://www.knee.nko.se/english/online/thePages/publication.php> (Last access date: June 20, 2011).
11. Engesaeter L. **The Norwegian Arthroplasty Register. Annual Report 2010.** <http://nrlweb.ihelse.net/eng/default.html> (Last access date: June 20, 2011).
12. Spierings PTJ. **Properties of bone cement: testing and performance of bone cements.** In "The well cemented total hip arthroplasty. Theory and practice". Breusch S, Malchau H. (Eds.) Springer, 2005.
13. Söderlund P, Dahl J, Röhrl S, Nivbrant B, Nilsson KG. **10-year results of a new low-monomer cement: follow-up of a randomized RSA study.** *Acta Orthop.* 2012 Dec;83(6):604-8.
14. Dahl J, Söderlund P, Nivbrant B, Nordsletten L, Röhrl SM. **Less wear with aluminium-oxide heads than cobalt-chrome heads with ultra high molecular weight cemented polyethylene cups: a ten-year follow-up with radiostereometry.** *Int Orthop.* 2012 Mar;36(3):485-90.
15. Watanakunakorn C, Bakie C. **Synergism of vancomycin-gentamicin and vancomycin-streptomycin against enterococci.** *Antimicrob Agents Chemother.* 1973 Aug;4(2):120-4.
16. 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.
17. 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
18. Trampuz A, Zimmerli W. **Prosthetic joint infections: update in diagnosis and treatment.** *Swiss Med Wkly.* 2005 Apr 30;135(17-18):243-51. *Review.*
19. 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.
20. 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.
21. Bertazzoni Minelli E, Caveiari C, Benini A. **Release of antibiotics from polymethylmethacrylate cement.** *J Chemother.* 2002 Oct;14(5):492-500.
22. 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.

TECRES S.P.A.

Via A. Doria, 6 - 37066 Sommacampagna (VR) - Italy
T +39 045 92 17 311 - F +39 045 92 17 330
www.tecres.it - info@tecres.it

