MectaCem® SYSTEM

ORTHOPAEDIC BONE CEMENT & ACCESSORIES

A COMPREHENSIVE SOLUTION FOR CEMENTED ARTHROPLASTY

Brochure

Joint | Spine | Sports Med

Medacta International

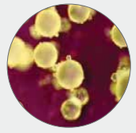
MECTACEM-X: A MODERN SOLUTION WITH A SOLID HISTORY

MectaCem-X is the Medacta-branded bone cement supplied by **Tecres Spa**, a leading company in the manufacturing of acrylic resins. MectaCem-X is a **safe** and **reliable** bone cement with **excellent mechanical performance** and more than **30 years of clinical heritage**.[1-4] With MectaCem-X, Medacta provides a **modern** bone cement that is **easy to handle** in modern vacuum mixing systems.

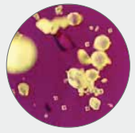
INNOVATIVE LOW MONOMER FORMULATION

Thanks to an exclusive process manufactured by Tecres, MectaCem-X powder particles are **consistent in shape** and **size**, in contrast to other commercially-available cements (see particle comparison). These characteristics result in **uniform spheres** with **no irregularities** that yield decreased total surface area. This feature means **less liquid monomer** is needed to prepare the cement dough.

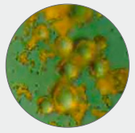
Since the monomer is the most dangerous component, the revolutionary **3:1 powder/liquid ratio** puts MectaCem-X in a different league from the traditional 2:1 ratio, providing **significant and proven advantages** to the surgeon, the O.R. staff, and the patients.



MectaCem-X
Spherical-uniform;
few micro particles



Cement A
Spherical-irregular

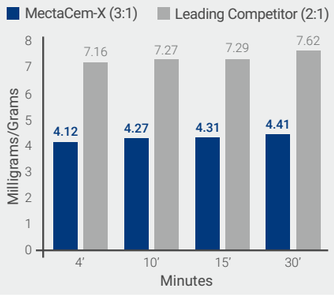


Cement B
Spherical-many
micro particles

REDUCED TOXICITY

MectaCem-X has proven to be **less toxic** than its competitors with higher amount of monomer. The **monomer release** into patients is **reduced by 30%**, as well as the exposure of surgeon and O.R. staff to toxic fumes.[5]

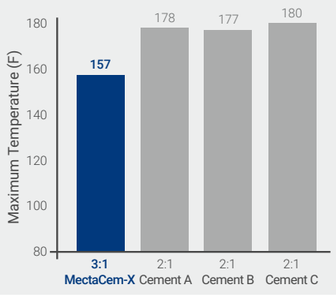
MONOMER RELEASE



LESS HEAT EMISSION

MectaCem-X has a **10% reduction in the polymerization temperature** compared to other commercially available formulations. This results in a lower maximum curing temperature, thus **reducing thermal damage** to surrounding bone and soft tissues.[6]

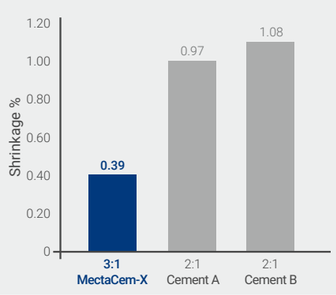
POLYMERIZATION TEMPERATURE



REDUCED SHRINKAGE

Bone cement shrinkage depends mainly on the amount of monomer present in the cement mixture and contributes to the loosening of the prostheses.[7] **MectaCem-X shrinks well over 50% less** than its competitors with 2:1 powder/liquid ratio, thus greatly **improving implant fixation**.[8]

BONE CEMENT SHRINKAGE



A COMPREHENSIVE PRODUCT OFFERING

The MectaCem-X offering comprises an **extensive range** of high-quality bone cements that allow for **great flexibility** with respect to different surgeon's needs.

HIGH and **LOW VISCOSITY**

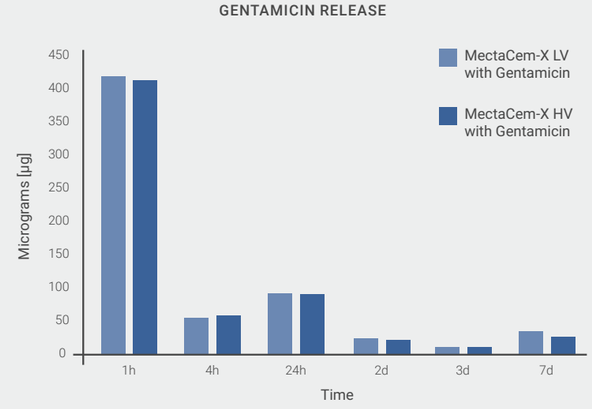
WITH and **WITHOUT GENTAMICIN**

A broad antibacterial spectrum

MectaCem-X with Gentamicin is pre-blended with 1.0 g (2.5%) of gentamicin base, which has a **broad antibacterial spectrum** and **long-lasting antibacterial protection**. Antibiotic loaded bone cements are proven to **reduce the risk of infection** to 1.2% compared to 2.3% when no antibiotic is used in the bone cement.[9]

MectaCem-X with Gentamicin has a **fast** and **high release of antibiotic extending over several days**. Antibiotic elution is particularly strong during the first few hours post-operatively, the time when the risk of infection is at its greatest.[6,10]

GENTAMICIN RELEASE

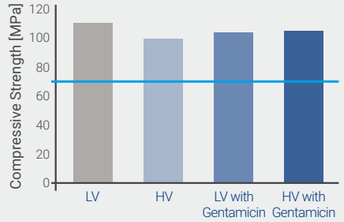


MECHANICAL PROPERTIES EXCEEDING INTERNATIONAL STANDARDS

Porosity has been found to be the major cause of decreased mechanical strength and fatigue life of bone cement.[11] The **high consistency in shape** and **size** of MectaCem-X powder particles allows for obtention of a **more dense structure** that traps less air, resulting in a bone cement with a very **low porosity**.

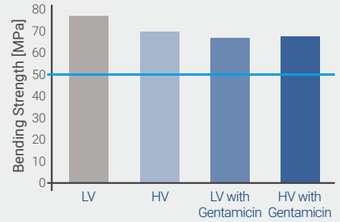
The **mechanical properties** of MectaCem-X have successfully been tested for compressive strength, bending strength and bending modulus according to international standards.[6,12]

MECTACEM-X COMPRESSIVE STRENGTH [MPa]



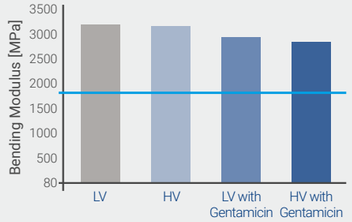
ISO 5833:2002 Minimum Standard: **70 MPa**

MECTACEM-X BENDING STRENGTH [MPa]



ISO 5833:2002 Minimum Standard: **50 MPa**

MECTACEM-X BENDING MODULUS [MPa]



ISO 5833:2002 Minimum Standard: **1800 MPa**

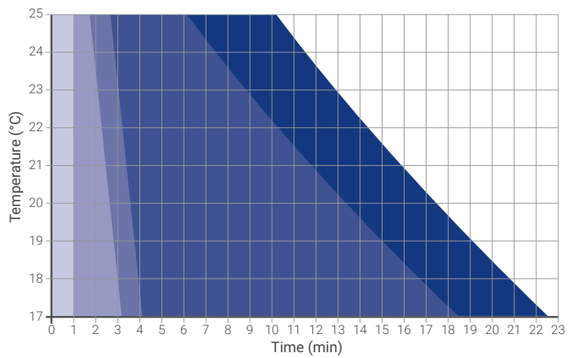
SETTING TIME VS. TEMPERATURE CHARTS

Bone cement setting time is affected by several factors, including storage and O.R. temperatures, humidity, mixing conditions, and mixing speed.[13]

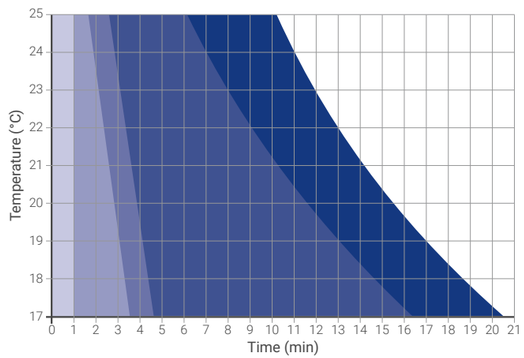
All these conditions can be affected by variables in the operating room environment, which could potentially result in an unpredictable working phase and overall setting time. Controlling the variables can limit complications and may lead to more reproducible results.

The times here displayed refer to a manual mixing. Higher temperatures will result in a shorter manual application phase and faster setting time.[6]

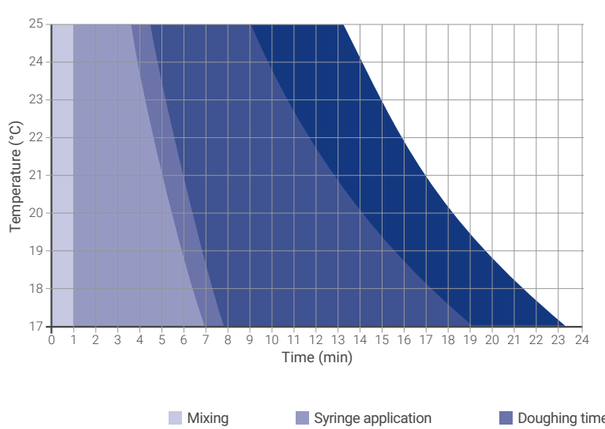
MectaCem-X HV



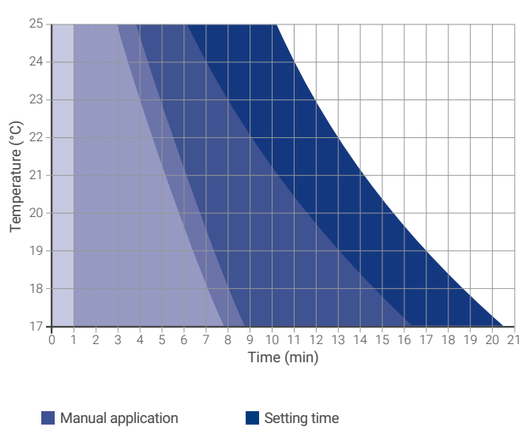
MectaCem-X HV with Gentamicin



MectaCem-X LV



MectaCem-X LV with Gentamicin



CEMENTATION KIT

A COMPREHENSIVE OFFERING OF STERILE DISPOSABLE TOOLS

To facilitate orthopaedic bone cement handling, Medacta has added to its product portfolio a **comprehensive range of options for cement and bone preparation**.

1. **MectaCem Bowl**
2. **EASYMIX® bowl**
3. **EASYMIX® pro single mixing system**
4. **MectaCem BonePrep**

1 MECTACEM BOWL

MectaCem Bowl consists of a **sterile disposable open bowl** and **spatula**, designed for an **easy** and **fast bone cement mixing**.

Designed to mix up to two 40 g packs of all bone cement viscosities, it features **proximal grooves** to provide an **optimal grip** while mixing.

2 EASYMIX® BOWL

The **EASYMIX® bowl** is a **sterile disposable vacuum mixing bowl** featuring an optimized design which allows for a thorough mixing of up to 120 g of bone cement. While keeping exposure to monomer fumes to the minimum, the surgical team effortlessly produces a cement mix with minimum porosity. This is proven to be crucial to the long-term success of a joint replacement procedure.[11]

Ergonomic design
Easy to operate and the optimized gearing makes mixing effortless.

Shaped spatula and curette
The spatula exactly matches the contour of the bowl. Spatula and curette are ergonomically shaped.

Vacuum tubing with charcoal filter
Mixing under vacuum eliminates porosity in the cement mix and reduces exposure to monomer fumes.

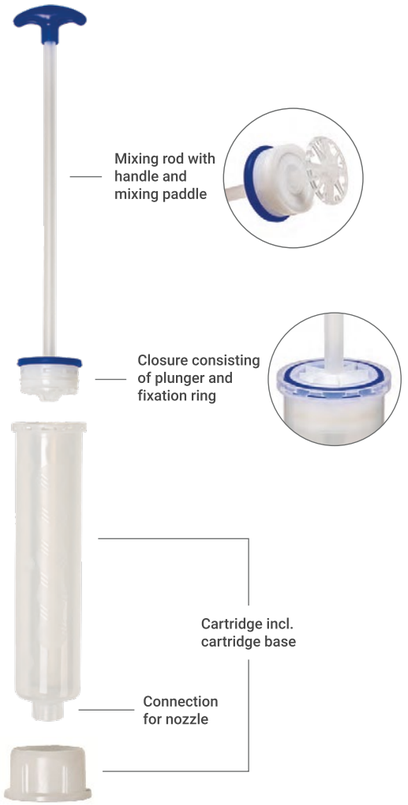
Rotational axis paddle design
Mixing from all angles to create a homogeneous cement mix with the least possible amount of unmixed powder.

High capacity
Mixes up to 120 g bone cement of any viscosity.

Photo credit: OSARTIS GmbH

3 EASYMIX® PRO SINGLE MIXING SYSTEM

EASYMIX® pro single mixing system is a **sterile disposable vacuum system** for safely mixing and injecting bone cements through dedicated nozzles.



Optimal Mixing Results

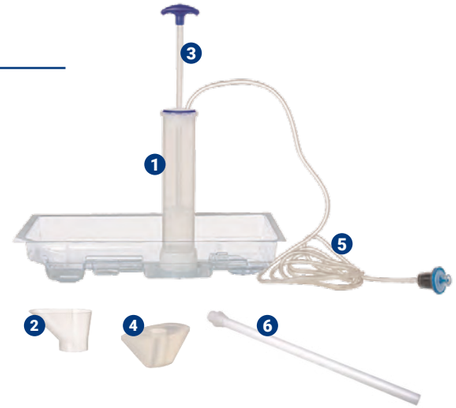
Mixing with the EASYMIX® pro vacuum mixing system generates a homogenous mixed cement dough, reduces the porosity of the cement and the emission of monomer fumes.[14]

Easy to Handle

The innovative closing mechanism of EASYMIX® pro ensures a fast setup and easy handling, while ensuring a reliable vacuum level throughout the entire mixing process. The closure with fixation ring does not have to be positioned with a specific orientation and can be locked with low force.

The **EASYMIX® pro single mixing system** is composed of:

1. Mixing cartridge (suitable for 40 to 80 g cement powder)
2. Funnel
3. Closure consisting of plunger with fixation ring and mixing rod
4. Femoral pressurizer
5. Tubing to connect to the vacuum pump
6. Break-away cement nozzle, offering two nozzle lengths in one design



EASYMIX® Disposable Nozzles

I. Nozzle slim (ø8 mm, length 160 mm)
II. Nozzle (ø11 mm, length 195 mm - already included in set)
III. Nozzle revision (ø13 mm, length 270 mm)
IV. AMIS Nozzle

The **AMIS Nozzle** is a **disposable curved cannula** specifically designed to be used for the **anterior approach** in hip replacement. It is supplied in a sterile package containing two curved cannulas of ø9 and ø12 mm.

EASYMIX® Reusable Instruments

A. Cement injector
B. Vacuum pump
C. Compressed air hose
(3 different types available)

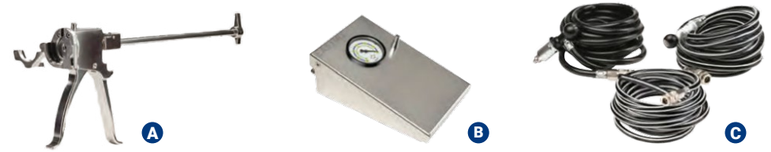


Photo credit: OSARTIS GmbH

4 MECTACEM BONEPREP

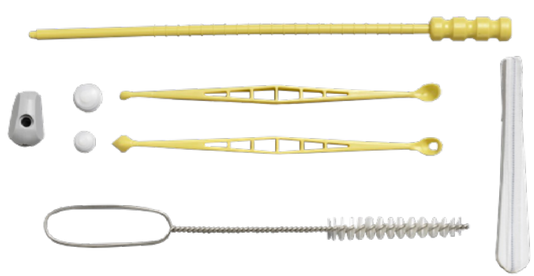
The **MectaCem BonePrep** kit is used for the preparation of the medullary canal and acetabulum prior to placement of bone cement and/or prosthesis.

Reduced risk of infection

The use of single-use instrumentation can potentially reduce the risk of non-sterile instrument occurrences.[15]

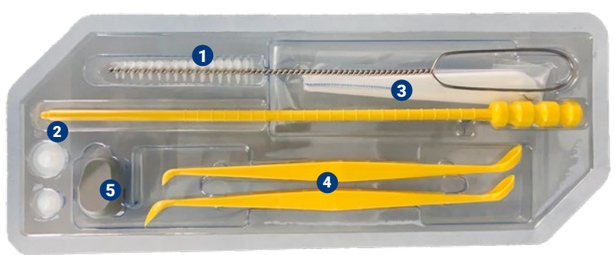
Fully disposable, sterile and brand new

Time and costs related to instrument checking and collection, washing and sterilization are eliminated, resulting in savings for the hospital.



The **MectaCem BonePrep** kit is composed of:

1. Femoral canal brush
2. Two cement restrictors
(ø12-18 mm and ø18-24 mm) and inserter
3. Femoral canal absorber
4. Two cement sculps
5. Femoral pressurizer



CATALOG INFORMATION

MectaCem-X HV
Radiopaque high-viscosity bone cement with rapid moldability and suitable for manual application.
Package: 1x 40g. Reference: 65.01.101.

MectaCem-X HV with Gentamicin
Radiopaque high-viscosity bone cement with gentamicin, with rapid moldability and suitable for manual application.
Package: 1x 40g. Reference: 65.01.111US.

MectaCem-X LV
Radiopaque low-viscosity bone cement suitable for syringe application.
Package: 1x 40g. Reference: 65.01.103.

MectaCem-X LV with Gentamicin
Radiopaque low-viscosity bone cement with gentamicin, suitable for syringe application.
Package: 1x 40g. Reference: 65.01.113US.

Single-use, sterile articles	Reference	Unit
EASYMIX® pro single mixing system (incl. nozzle ø11 mm, length 195 mm)*	02-0305	1
Nozzle slim (ø8 mm, length 160 mm)*	02-0104	1
Nozzle revision (ø13 mm, length 270 mm)*	02-0105	1
AMIS Nozzle (ø9 and ø12 mm)	20.00002	1
EASYMIX® bowl*	LD2000	1
MectaCem Bowl**	20.00004	1
MectaCem BonePrep**	20.00003	1

Reusable accessories	Reference	Unit
EASYMIX® cement injector*	02-0504-04	1
EASYMIX® vacuum pump II with indicator*	02-0201	1
Hose for vacuum pump 5 m, wall connection Medap*	00002401	1
Hose for vacuum pump 5 m, wall connection Dräger*	00002385	1
Hose for vacuum pump 5 m, without wall connection*	00002708	1

REFERENCES

[1] *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. October 2010.* ***[2]*** *Rossi R, Bruzzone M, Bonasia DE, Ferro A, Castoldi F., No early tibial tray loosening after surface cementing technique in mobile-bearing TKA. Knee Surg Sports Traumatol Arthrosc. 2010 Oct;18(10):1360-5. Epub 2010 Jun 10.* ***[3]*** *Li ZJ, Zhang K, Yang H, Liu Y, Lü JQ., Intraoperative monitoring for safety of total hip arthroplasty using third-generation cementing, January 2009.* ***[4]*** *Söderlund P, et al. 10-year results of a new low-monomer cement: follow-up of a randomized RSA study. Acta Orthop. 2012 Dec;83(6):604-8. doi: 10.3109/17453674.2012.742392. Epub 2012 Nov 1.* ***[5]*** *Neotron Laboratory, Gatti G, Modena, Italy. 1989.* ***[6]*** *Data on File at Tecres S.p.a..* ***[7]*** *Orr JF, Dunne NJ, Quinn JC. Shrinkage stresses in bone cement. Biomaterials. 2003 Aug;24(17):2933-40. doi: 10.1016/s0142-9612(03)00055-3. PMID: 12742733.* ***[8]*** *Trieu H, et al. Comparative measurement of shrinkage of 5 commercial cements prepared under vacuum mixing. In: Grasse F, et al [ed]. Bone cements in the year 2000: state of the art and prospects. Italy: Varese; 2000. 23.* ***[9]*** *Parvizi J, Saleh KJ, Ragland PS, Pour AE, Mont MA. Efficacy of antibiotic-impregnated cement in total hip replacement. Acta Orthopaedica, 2008; 79 (3): 335-341.* ***[10]*** *Macdonald DA. The infected joint replacement: Prevention, diagnosis and treatment. Curr Orthop 1995; 9: 21-27.* ***[11]*** *Wang JS. (2005) The Benefit of Vacuum Mixing. In: The Well-Cemented Total Hip Arthroplasty. Springer, Berlin, Heidelberg.* ***[12]*** *ISO 5833, Implants for Surgery - Acrylic Resin Cements (2002).* ***[13]*** *BAC-DATA, The Bacteriological Report, Vol. 1 (Dec 1986-Feb 1987).* ***[14]*** *Horas, U., Seidel, P. and Heiss, C. (2002) Vakuummischsysteme zur Knochenzementfertigstellung: ein Vergleich unterschiedlicher Systeme. Zeitschrift für Orthopädie und ihre Grenzgebiete, 140, 603-610.* ***[15]*** *Siegel G. W., Patel N. N., Milshteyn M. A., Buzas D., Lombardo D. J., Morawa L. G., M.D., Cost Analysis and Surgical Site Infection Rates in Total Knee Arthroplasty Comparing Traditional vs Single-Use Instruments. The Journal of Arthroplasty 30; (2015): 2271-2274.*

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