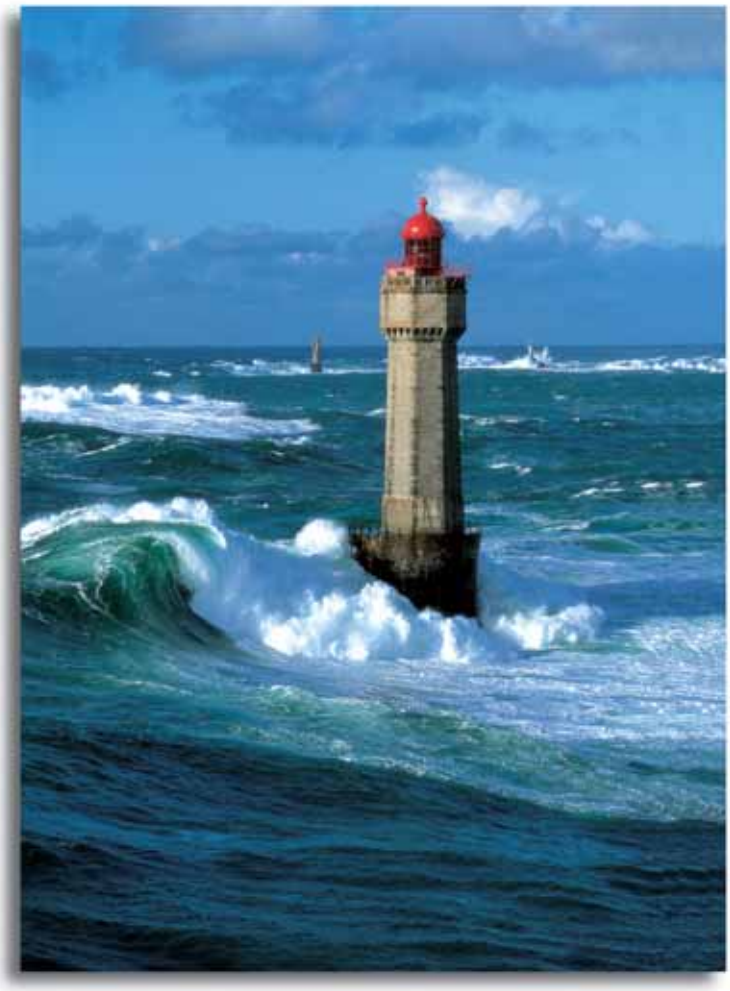
CERAFIX
CERAFIXGENTA

LOW-MEDIUM AND HIGH VISCOSITY



Long lifetime cements

CERAVER
DEPARTEMENT BIOMATERIAUX

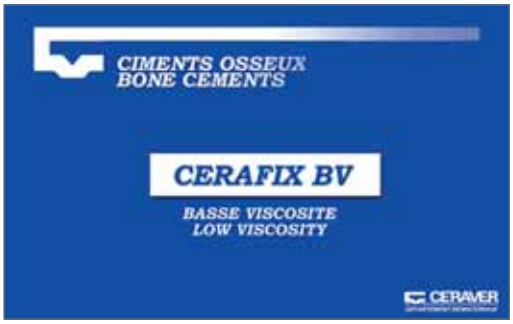
ISO 9001
IQNet
EN 46001

CERAFIX :

In 1984 in Europe, CERAVER **were pioneers in the field of the low-medium viscosity**. Due to acrylic resins since 1980. With a strong position thanks to its experience, CERAVER has developed the low-medium

LOW-MEDIUM VISCOSITY : BV

FLUID MIXTURE
EXCELLENT INTRUSION
EASIER ELIMINATION OF GASES



Pioneers in the field of low-medium viscosity, in 1984 CERAVER developed **CERAFIX** and **CERAFIXGENTA** cements, that are known today as **CERAFIX BV** and **CERAFIXGENTA BV**. These cements have an excellent reproducibility coming from the control of a process constantly improved.

FOR BOTH LOW AN

MANUAL INSERTION OR
LOW TEMPERATURE
EXCELLENT MECHA

Long lifetime ce

A FULL RANGE

this, CERAVER has acquired a **significant clinical background** and a scientific know-how in the high viscosity cements with or without gentamicin which have the same chemical composition as viscosity cements.

HIGH VISCOSITY : HV

FAST IMPLEMENTATION
LONG WORKING TIME
SHORT HARDENING TIME

CERAVER has developed high viscosity cements with the same chemical composition as the low-medium viscosity cements : **CERAFIX HV** and **CERAFIXGENTA HV**.

In comparison with low-medium viscosity, high viscosity is obtained thanks to the use of smaller polymer particles size.

D HIGH VISCOSITY

INJECTION BY SYRINGE

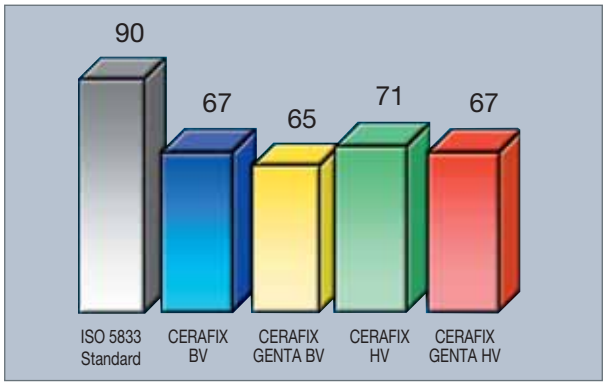
OF POLYMERISATION

NICAL PROPERTIES

ments since 1984

CERAFIX AND CERAFIXGENTA

A LOW TEMPERATURE OF POLYMERISATION



Maximal temperature of polymerisation (°C)

The maximal temperature of polymerisation of all CERAFIX cements is much lower than the maximum temperature specified in the standard.

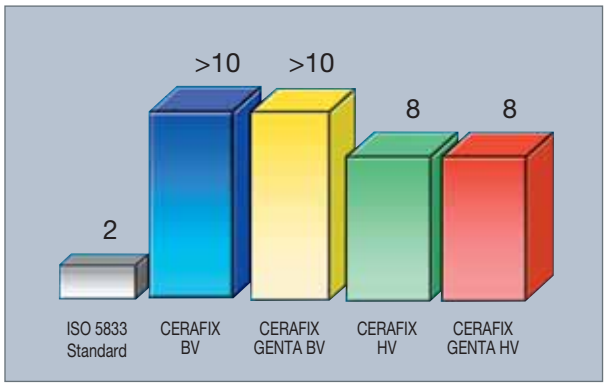
The moderate temperatures make it possible to limit thermal necrosis and **to preserve the bone**.

LIMITATION OF THE THERMAL NECROSIS

HIGH INTRUSION FOR BOTH LOW AND HIGH VISCOSITY

The intrusion, which is the capacity of cement to penetrate the bone microcavities, is more than five times higher than the standard* for our low-medium viscosity cements and four times higher for our high viscosity cements.

The high intrusion generates a **deep anchorage into the bone** and thus a long lasting anchoring of implants. It also allows, in the case of CERAFIXGENTA, an increase in **the surface of diffusion of the antibiotic**.



Intrusion (minimal values in mm)

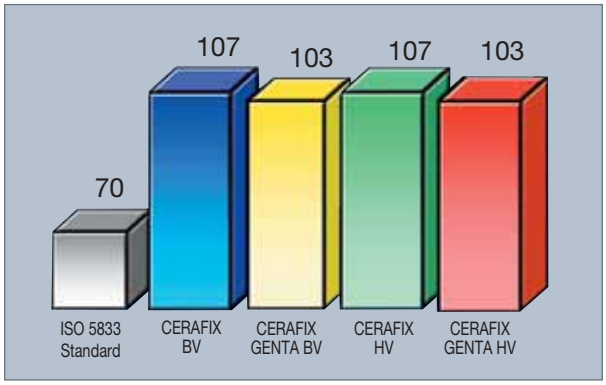
DEEP ANCHORAGE INTO THE BONE

WIDESPREAD DISTRIBUTION OF ANTIBIOTIC

* Norme ISO 5833

: OPTIMAL CHARACTERISTICS

EXCELLENT MECHANICAL PROPERTIES



Compressive strength (MPa)

Compressive strength

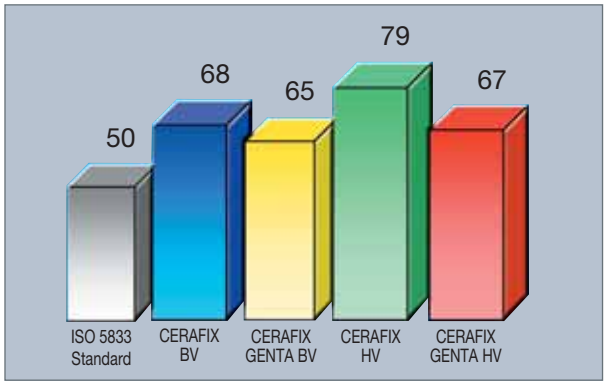
The compressive strength is measured on samples placed 72 h in water at 37°C.

CERAFIX cements show high values, close to the cortical bone one (~150MPa), which ensures **a good distribution of constraints between the bone and the implant**.

4-point flexion strength

The flexion strength is measured on a 4-point flexion machine. CERAFIX cements show high values, much higher than what the ISO 5833 standard requires, which confirms the excellent mechanical properties of our cements.

The flexion characteristics (flexion strength and elasticity modulus) are close to those of the cortical bone which allows a better distribution of the constraints.

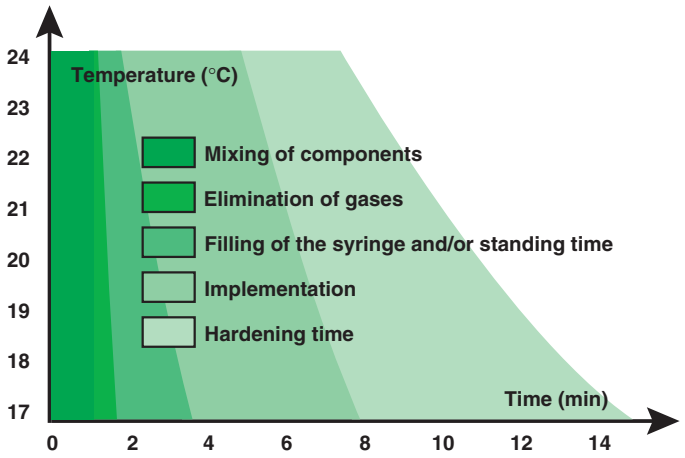


4-point flexion strength (MPa)

MECHANICAL PROPERTIES CLOSE TO THOSE OF THE CORTICAL BONE

IMPLEME

CERAFIX HV



HI
VISC

HIGH VISCOSITY	t = 0’	t = 1’	t = 1’30

PHASE 1 : MIXING OF COMPONENTS

PHASE 2 : ELIMINATION OF GASES

FILLING OF THE SYRINGE

PHAS
O

CHARACTERISTIC TIMES AT 21°C

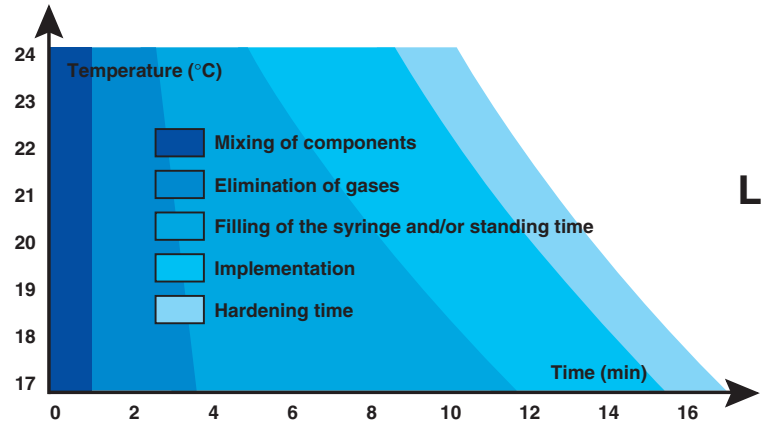
Homogenise the powder
Add the liquid
Mix approximately 1'

Let degas
Keep away from any heat source

Fill the syringe with cement

LOW-MEDIUM VISCOSITY	t = 0’	t = 1’	t = 3’30

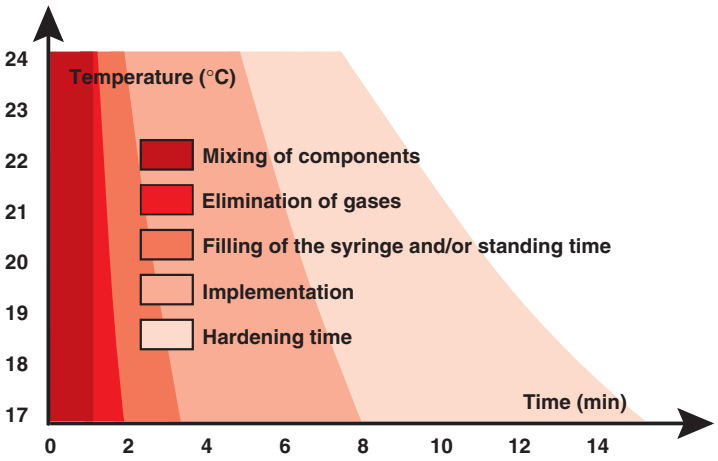
CERAFIX BV



LOW-M
VISC

NTATION

GH
OSITY



CERAFIXGENTA HV

t = 2'30

t = 9'45

SE 3 :
R

CATCHING IN HAND

PHASE 4 :
IMPLEMENTATION

PHASE 5 :
HARDENING TIME

Working time > 4'

Hold the implant
firmly in place

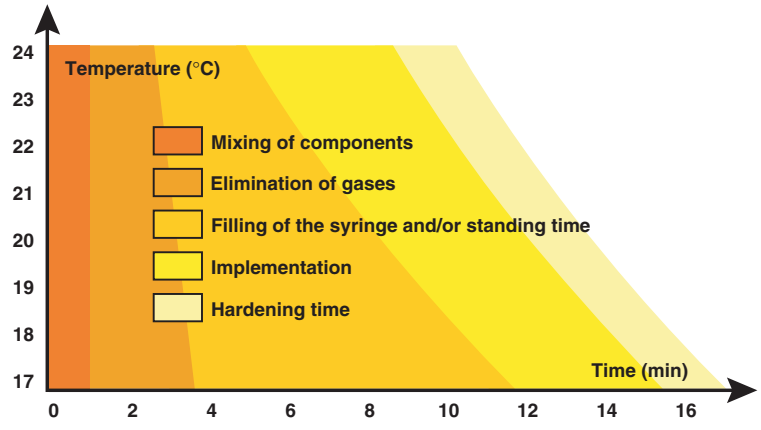
Take cement in hand
after non-sticking time

Insert or inject the cement
Insert the implant
Remove excess cement

t = 7'45

t = 12'30

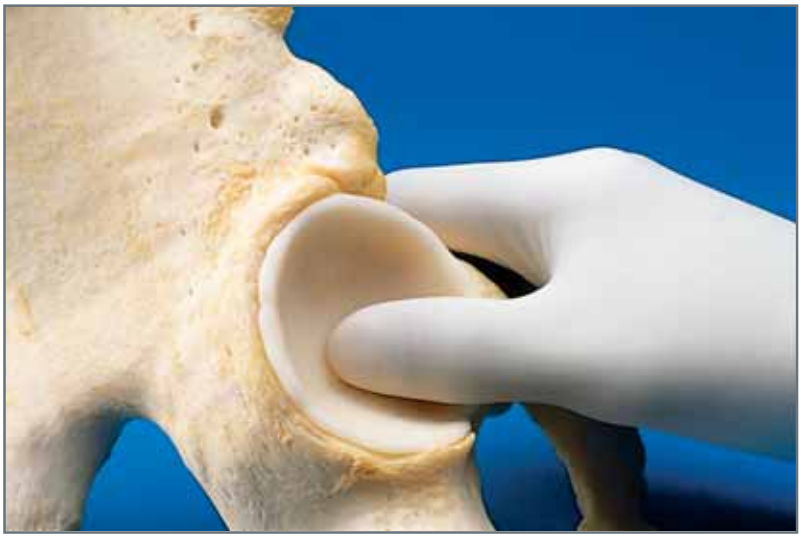
EDIUM
OSITY



CERAFIXGENTA BV

A SIMPLE AND

MANUAL INSERTION OR SYRINGE INJECTION FOR BOTH LOW AND HIGH VISCOSITY



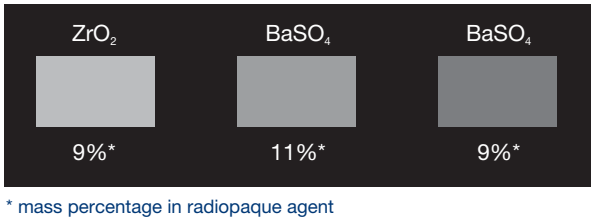
CERAFIX and CERAFIXGENTA are specifically studied for the anchorage of the cemented endoprostheses in the **partial or total arthroplasties of hip, knee or any other articulation**.

A RADIOPAQUE AGENT :

The zirconium dioxide ZrO_2 is used for all CERAFIX cements. It presents a significant **scientific and clinical background** since it has been used in CERAFIX and CERAFIXGENTA **since 1984**.

A LOWER QUANTITY OF RADIOPAQUE AGENT NEEDED FOR A BETTER RADIOPACITY

X-RAYS OPACITY OF CEMENTS
(K-D. Kühn, “Bone cements”, 245-247, 2000)



* mass percentage in radiopaque agent

EFFECTIVE USE

EASIER MIXING

The mass ratio of the solid and liquid phases is a parameter of paramount importance. Its optimisation made it possible **to improve the mixing of the powder and the liquid** and thus **to quickly obtain an homogeneous cement**.

A SIMPLE AND EFFECTIVE ANCILLARY

The zirconium dioxide ZrO_2

- Thanks to its relatively low density and low hydrophily, it allows an **excellent dispersion** in cement. The homogenisation is better and the mechanical properties are optimised.
  - It significantly generates less bone resorption than barium sulfate. (J. Bone Joint Surg., Br, 79-B, 129-134, 1997)
    - It allows a better resistance to fatigue.

OPTIMISED CARACTERISTICS

CERAFIXGENT

GENTAMICIN

Gentamicin (or aminoglycoside), an antibiotic from the aminoside family, **is thermally stable** and **water soluble**. **It has a broad spectrum of action and is compatible with the solid and liquid** phases of cement.

Gentamicin is added to the cement formulation as gentamicin sulphate. **Gentamicin base** corresponds to the molecules that have an anti-bacterial activity. It is an important parameter which must be optimised : CERAFIXGENTA cements contain **800 mg of gentamicin base each**.

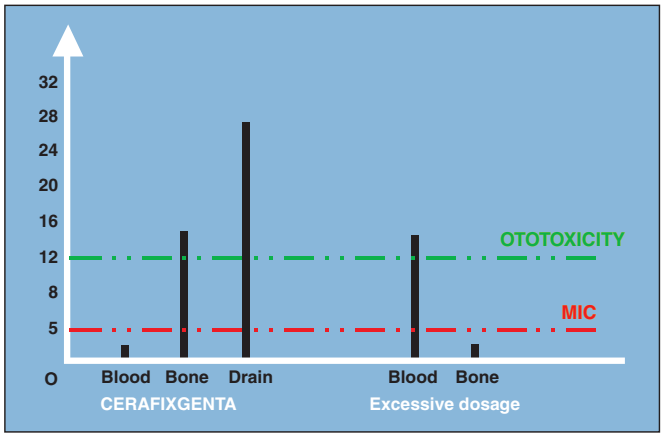
CERAFIXGENTA BV AND HV : A LOCAL ANTIBIOTHERAPY

EFFECTIVENESS AND TOLERANCE

CERAFIX-GENTAMICIN association makes it possible to obtain :

- A **blood level below the ototoxicity threshold**.
- A **bone level above the minimum inhibitory concentration** (MIC = 4 mg/L). The bacterial effect obtained is particularly indicated in the case of thin vascularization of peri prosthetic tissues.
- Local concentrations in the drains, which far exceed the MIC during the first few hours.

This ensures the **prevention of infections contracted immediately after the operation**.



Gentamicin level (mg/kg and mg/L)

AN ACTION TARGETING THE INFECTION SITE

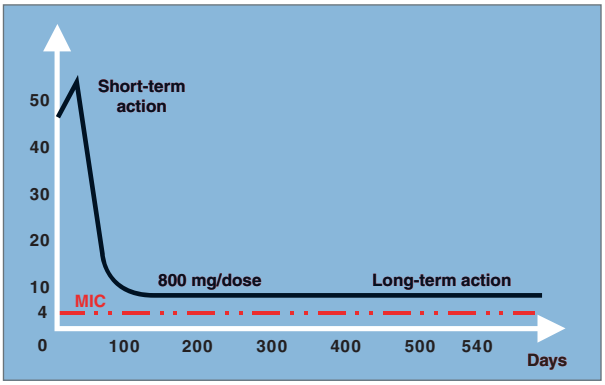
A BV AND HV

CERAFIXGENTA BV AND HV : PHARMACOKINETICS

BONE DIFFUSION

The early high concentration of gentamicin in the bone **allows a short term anti-bacterial action which prevents immediate peroperative contamination**.

Within short and long term period, **the concentration of gentamicin within the bone is higher than the MIC** and thus plays a **bacteriostatic** role, preventing the development of the germs which are then destroyed by the own mechanisms of the human body.



Gentamicin concentration in bone (mg/kg, sheep femur)

URINARY RATES

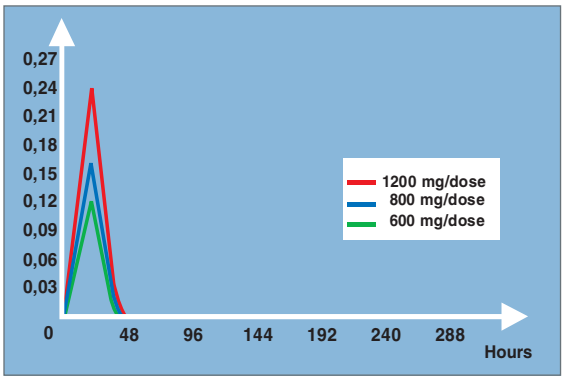
The amount of eliminated gentamicin in urine reaches a peak approximately 24 h after the injection, then decreases slowly towards level of 0,5 mg after 15 days.

Low urinary concentrations confirm the absence of systemic diffusion of the antibiotic from the cement.

SEROKINETICS

Biphasic release shows a serum peak of a maximum value of 0,16 mg/L what is lower than the threshold of ototoxicity (12 mg/L).

This results in no risk of ototoxicity or nephrotoxicity.



Gentamicin elimination serokinetics (mg/L)

A SHORT AND LONG TERM THERAPEUTIC ACTION

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