



BONE CEMENTS FOR VERTEBRAL CONSOLIDATION

who we are

G-21 was set up in 2009 by expert entrepreneurs originating from the medical and pharmaceutical sector.

G-21 is situated in proximity of the main cities and infrastructures in northern Italy, approximately 40 km from Modena and Bologna, in the Italian "Medical Valley" famous all over the world for its **tradition, know-how** and **innovative spirit** in the field of Medical Devices.

The company is strategically managed by a team of young people that stand out for their integrity, expertise and professionalism and who continuously bring the **energy, enthusiasm** and **dynamism** necessary to satisfy the requirements of an ever more demanding and developing market.

G-21 has its **own product portfolio** (among which long-term implantable devices and Class III medical devices) of which it fully possesses the know-how as well as the **design and production technology**, the result of **Research and Development** programmes conducted in-house and in collaboration with major international research institutes and Universities.

High-quality raw materials, absolute process control, compliance with the most stringent international standards, continuous personnel training and **painstaking care to details**: this is the profile of G-21's in-house production unit, which includes clean rooms certified up to Class ISO 5 for process execution in 100% sterile conditions.

mission

Develop **innovative** and more **reliable solutions** in the field of biomaterials and procedures for vertebral consolidation and articular functional rehabilitation, dedicated to improving therapeutic treatment of orthopaedic patients and designed to **anticipate the future needs** of Medical Professionals.

Manufacture the products complying with the most stringent **quality standards** and distribute them internationally in collaboration with trade partners with whom establish and maintain **long-term** relationships based on trust, cooperation and responsibility.

certifications

Since 2010 we have been operating according to a quality system in compliance with **EN ISO 13485** "Quality Management Systems - Requirements for regulatory purposes applicable to Medical Devices".

Our Quality Management System and the CE marking on our products (in accordance with **Medical Device Directive 93/42/EEC** and subsequent amendments) are certified by the Cermet (no. 0476) and Det Norske Veritas (DNV, no. 0434) Notified Bodies, who also keep strict control to ensure that the quality levels achieved are maintained over time.

BONE CEMENTS FOR VERTEBRAL CONSOLIDATION

Acrylic-based (poly-methyl-meth-acrylate, PMMA) radiopaque bone cements indicated for consolidation and stabilization of a fractured, collapsed or compressed vertebral body through the effect of traumas or pathological conditions, such as osteoporosis or tumours.

Each cement - which comes in the form of a two-component system (powder and liquid) to be mixed at the time of application in the operating theatre - is formulated so as to develop properties in terms of **optimal workability and visibility for minimally invasive percutaneous procedures** (such as vertebroplasty and kyphoplasty), also by means of small-gauge cannulas.

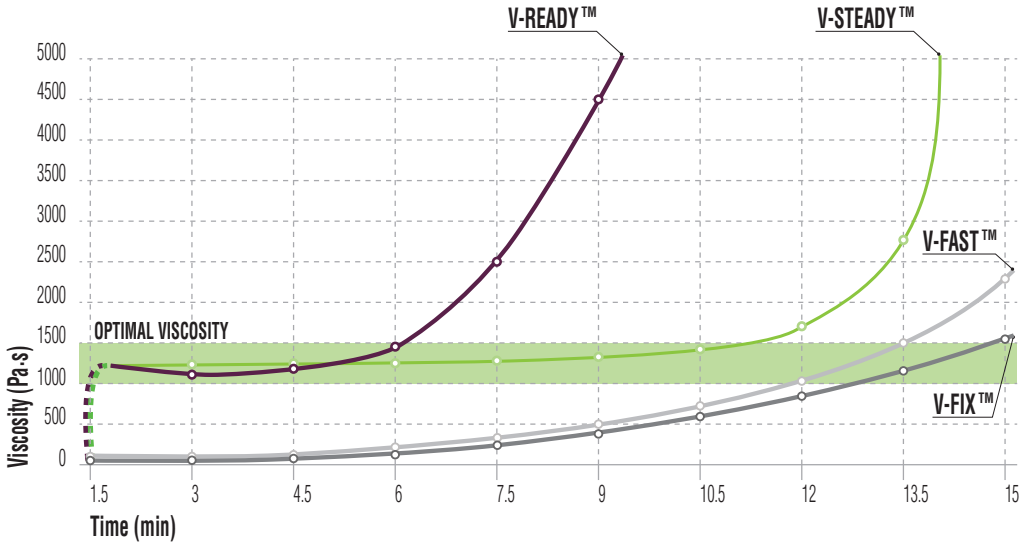
In order to respond to the specific needs of individual health professionals, the cements differ between them in useful working time and viscosity, designed to encourage interdigitation between the biomaterial and the bone structure and exclude the risk of leakage and the related complications.

The high amount of radiopaque agent offers the operator the **maximum level of safety and control** during the procedure, at the same time ensuring development of mechanical properties much higher than the reference standards.

It is advisable to use the cements in conjunction with the **G-21 vertebroplasty and kyphoplasty kits**.

VISCOSITY DEVELOPMENT

Data on file at G-21 S.r.l.

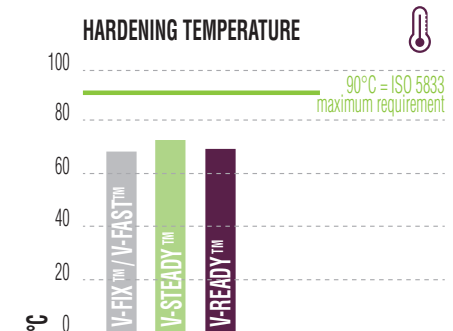
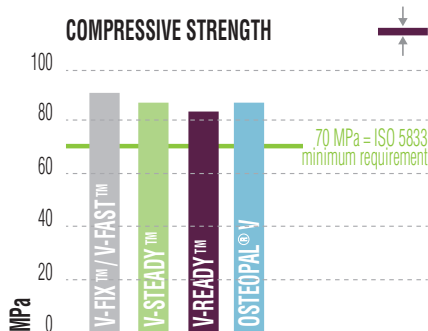
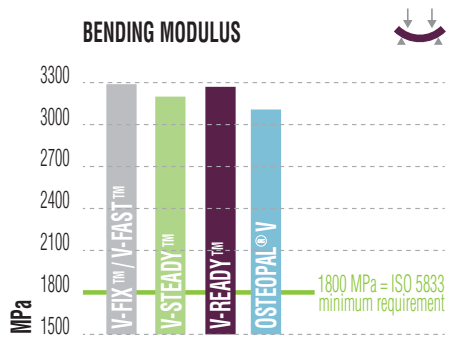
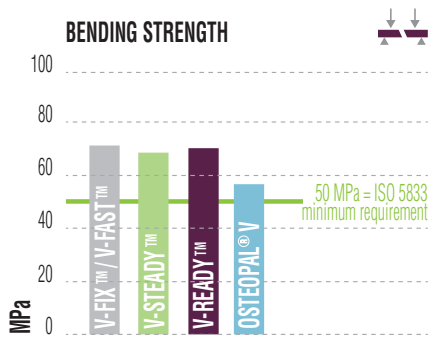


MECHANICAL STRENGTH AND HARDENING TEMPERATURE ACCORDING TO ISO 5833⁽¹⁾

BONE CEMENTS FOR VERTEBRAL CONSOLIDATION

V-FIX™ / V-FAST™(2) V-STEADY™(2) V-READY™(2) OSTEOPAL® V(3)

- ISO 5833, Implants for surgery - Acrylic resin cements (2002).
- Data on file at G-21 S.r.l.
- Brochure Osteopal V - Heraeus Medical GmbH. IT CH 0808 66030455.



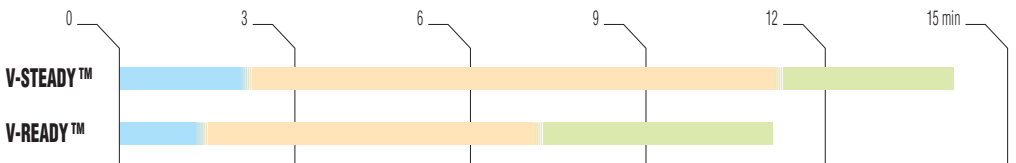
HIGH VISCOSITY CEMENTS: V-STEADY™ and V-READY™



WORKING PROPERTIES AT 23°C ACCORDING TO ISO 5833⁽¹⁾

V-STEADY™⁽²⁾ V-READY™⁽²⁾

1. ISO 5833, Implants for surgery - Acrylic resin cements (2002).
2. Data on file at G-21 S.r.l.



PREPARATION

from the moment that liquid and powder are mixed to the time until when the cement is ready for use

WORKING

the period during which the cement maintains a viscosity suitable to be injected into the bone

HARDENING

the time during which the cement hardens to form the final, hard PMMA

Notes:

Timings obtained using systems for controlled injection of high-viscosity cements.
Timings may vary as a function of temperature and humidity. The higher the temperature, the shorter the phases.
Refer to Instruction for use for information on the duration of each period relative to temperature.

V-STEADY™

Acrylic-based radiopaque bone cement with **immediate development of viscosity** and **long working time**. Ready for use immediately after mixing (in less than two minutes), it maintains this consistency for approximately **9 minutes** thanks to a specific formulation to "freeze" the polymerisation reaction. Ideal to perform procedures on several vertebral levels and for those that want a high-viscosity cement that **maintains its properties throughout the useful working time**. The cement completely hardens in 14 minutes.

It can be prepared by hand (bowl and spatula) or using closed or vacuum mixing systems. Because of its fluidity properties, it can be applied with specific systems for controlled injection of high-viscosity cement.

CHARACTERISTICS

1. reduced mixing time (under a minute to obtain a homogeneous product),
2. **practically zero waiting time**,
3. optimal administration control,
4. **working time: 9 minutes**,
5. excellent mechanical properties (especially the compression strength),
6. **high concentration** of contrast medium (30% BaSO₄),
7. **low polymerisation temperature** so as to reduce the risk of thermal shock on the tissues.

V-READY™

Acrylic-based radiopaque bone cement with **immediate development of viscosity**. Ready for use immediately after mixing, it is characterised by having the **shortest working time** among the cements available in our range today (just **5-6 minutes**). Ideal for fast procedures and for those that want to reduce the waiting time during the procedures to a minimum. The cement completely hardens in 11 minutes.

It can be prepared by hand (bowl and spatula) or using closed or vacuum mixing systems. Because of its fluidity properties, it can be applied with specific systems for controlled injection of high-viscosity cement.

CHARACTERISTICS

1. reduced mixing time (under a minute to obtain a homogeneous product),
2. **no waiting time**,
3. optimal administration control,
4. **working time: 5-6 minutes**,
5. excellent mechanical properties (especially the compression strength)
6. improved visibility thanks to the **high concentration** of contrast medium (35% BaSO₄),
7. **low polymerisation temperature** so as to reduce the risk of thermal shock on the tissues.

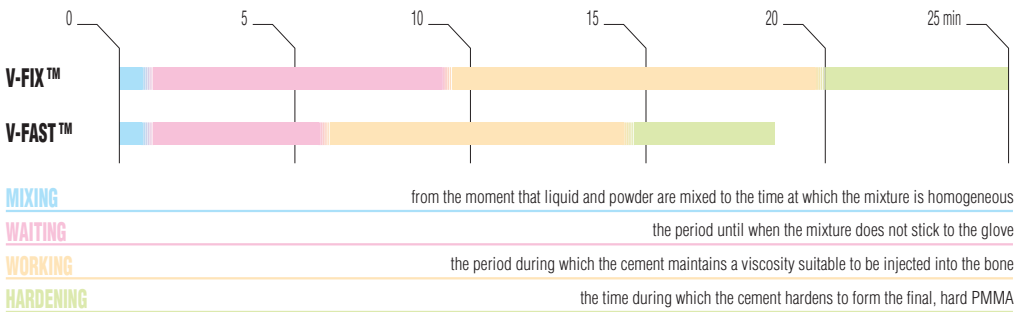
LOW VISCOSITY CEMENTS: V-FIX™ and V-FAST™



WORKING PROPERTIES AT 23°C ACCORDING TO ISO 5833⁽¹⁾

V-FIX™⁽²⁾ V-FAST™⁽²⁾

1. ISO 5833, Implants for surgery - Acrylic resin cements (2002).
2. Data on file at G-21 S.r.l.



Notes:

Timings may vary as a function of temperature and humidity. The higher the temperature, the shorter the phases.
Refer to Instruction for use for information on the duration of each period relative to temperature.

V-FIX™ and V-FAST™

Acrylic-based radiopaque bone cements with a **low initial viscosity** and a **long working time**. They are particularly suitable when needing to work extremely carefully and where a good time margin before polymerisation is required, for example, to perform procedures on several vertebral levels.

V-FIX™ is characterised by having the longest working time among the cements available in our range today.

V-FAST™ has slightly shorter waiting and working times, indicated where the operation time needs to be reduced.

They can be prepared by hand (bowl and spatula) or using closed or vacuum mixing systems. Because of their fluidity properties, they can be used with syringes or specific controlled injection systems.

CHARACTERISTICS

1. reduced mixing time (under a minute to obtain a homogeneous product),
2. **working times: V-FIX™ 11 minutes, V-FAST™ 8 minutes,**
3. **high concentration** of contrast medium (30% BaSO₄),
4. excellent mechanical properties (especially the compression strength),
5. **low polymerisation temperature** so as to reduce the risk of thermal shock on the tissues.

ORDERING INFORMATION

PRODUCT	COMPOSITION	CONTENTS	REF
V-STEADY™	High viscosity radiopaque bone cement for vertebral consolidation	1 x 20 g	800039
V-READY™	High viscosity radiopaque bone cement for vertebral consolidation	1 x 20 g	800018
V-FIX™	Low viscosity radiopaque bone cement for vertebral consolidation	1 x 20 g	800037
V-FAST™	Low viscosity radiopaque bone cement for vertebral consolidation	1 x 20 g	800036
V-FIX DH™	Low viscosity radiopaque bone cement for vertebral consolidation - Two half doses	2 x 10 g	800017
V-FAST DH™	Low viscosity radiopaque bone cement for vertebral consolidation - Two half doses	2 x 10 g	800016

ACCESSORIES

Disp Mixing Bowl-V™

Open mixing system for bone cement preparation

Latex free disposable plastic bowl supplied sterile packed with a spatula for mixing, a surgical drape and 3 syringes (5 ml) with rigid plunger and aspiration tips.



PRODUCT	COMPOSITION	REF
Disp Mixing Bowl-V™	Bowl + Spatula + Surgical drape + Syringes	900051

MiniMix™ LV

Bone cement closed mixing system

The specific aim of the MiniMix™ LV system is to ensure not only a **homogenous mix of 40 g or less** of PMMA bone cement, but importantly for the user a quick, clean and effective transfer of the material into a delivery device. Luer lock interface allows transfer into standard syringes of varying sizes.

Mixer design has been found to significantly influence the quality of cement. MiniMix™ LV design includes a **rotational axis mechanism** to reduce unmixed powder, ensuring a reproducibly high quality mix of bone cement, significantly better than that created by hand mixing or a fixed axis device. MiniMix™ LV allows PMMA cement to be mixed at optimal levels of porosity to maximise the mechanical properties of the material.

The design allows for effective mixing of either bone cements or bone substitute materials meeting the needs of Orthopaedic Surgeons and Interventional Radiologists.

MiniMix™ LV has a **vacuum** option functioning at 550 mmHg, which has been shown to give **improved mechanical properties**.

Charcoal / microbiological filter **reduces exposure** to methylmethacrylate (MMA) fumes in theatre to levels significantly below those set out in the Health and Safety Executive guidelines.

MiniMix™ LV is **latex free**. The high clarity material allows the mixing process to be viewed from any position.



PRODUCT	COMPOSITION	REF
MiniMix™ LV	Bone cement closed mixing system	900126

PicoMix™ V

Bone cement closed mixing system with delivery syringes

PicoMix™ V comprises the **MiniMix™ mixer**, a **funnel**, a **spatula** and **4 syringes** (with rigid plunger) for cement injection.

Allows preparing **up to 40 g** of acrylic-based bone cement (PMMA) to then transfer it in a practical and safe manner directly into the syringes provided thanks to the Luer-lock connection.

PicoMix™ V is **latex free**.



PRODUCT	COMPOSITION	REF
PicoMix™ V	Mixer and delivery syringes with rigid plunger	900129

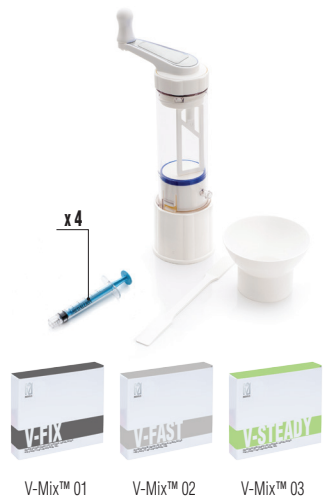
V-Mix™

Bone cement with mixer and delivery syringes

V-Mix™ comprises the **MiniMix™ mixer**, a **funnel**, a **spatula**, **4 syringes** (with rigid plunger) for cement injection and **bone cement for vertebral consolidation**.

Allows preparing acrylic-based bone cement (PMMA) to then transfer it in a practical and safe manner directly into the syringes provided thanks to the Luer-lock connection.

V-Mix™ is **latex free**.



PRODUCT	COMPOSITION	REF
V-Mix™ 01	Bone cement (V-FIX) with mixer and syringes with rigid plunger	800045
V-Mix™ 02	Bone cement (V-FAST) with mixer and syringes with rigid plunger	800046
V-Mix™ 03	Bone cement (V-STeady) with mixer and syringes with rigid plunger	800047

MiniMix™ Precision Delivery Syringe

Controlled injection system

The system allows accurate and controlled **delivery of up to 10 cc** of bone cement or bone substitute material.

It has been designed specially to **assist with vertebroplasty procedures**. The 200 mm catheter with 90° bend allows the operator to inject the material whilst **outside of the X-ray field**. Luer-lock connection ensures secure fixing to the delivery syringe and injection needle. The catheter can be cut to required length for use on small joints.

Push and screw application modes are available: to prime the catheter or eject material quickly, the plunger is pushed forward. For slower more accurate delivery, the screw mechanism is engaged allowing precise control over the delivery rate. Reversing the screw direction will halt the material delivery.

Used in combination with the MiniMix™ LV system, it allows a quick and effective transfer of material from the mixing device to the surgical site.

The product is **latex free**.



PRODUCT	COMPOSITION	REF
MiniMix™ Precision Delivery Syringe	Controlled injection system	900127

Vacuum Footpump 550™

Vacuum pump with foot switch



PRODUCT	COMPOSITION	REF
Vacuum Footpump 550™	Vacuum pump with foot switch	900125

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