G21
STRENGTH FOR LIFE

Bone Cements
for Vertebral Consolidation

Bone Cements for Vertebral Consolidation

G21 was founded in 2009 by entrepreneurs with consolidated experience in the medical and pharmaceutical sector.
G21 is located near the main cities and infrastructures of northern Italy (about 40 km from Modena and Bologna) in the so called "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 dynamic group, which stands out for its integrity, competence and professionalism. G21 teamwork continuously brings the energy and the enthusiasm necessary to meet the needs of an increasingly demanding and developing market.
G21 is a manufacturer of medical devices, including the implantable ones and those belonging to class III. Furthermore, the former fully owns the know-how, the design and manufacturing technology.
G21 work is the result of research and development programs conducted both internally and in collaboration with leading international research institutes such as universities.
G21 in-house production unit, includes cleanrooms certified up to ISO Class 5 to ensure a sterile production process. Our business is firmly relying on high quality raw materials, full process control, compliance with the strictest international standards, continuous staff training, and attention to detail.
G21 manufactures its products according to the most severe quality standards and distributes the former internationally, thanks to the growing cooperation with long-term business partners.
Our collaborations are based on mutual trust and commitment.
Since 2010 we have been operating according to a quality management system compliant with EN ISO 13485 "Medical Devices - Management Systems".

Bone Cements for Vertebral Consolidation

G21 bone cements are intended to stabilize and reinforce vertebral body in percutaneous vertebroplasty and kyphoplasty procedures [1, 2, 3] when treating painful pathologic compression fractures of vertebral body which do not respond to antalgic therapy.
This may be caused by:

- Primary and secondary osteoporosis.
- Osteolysis coming from tumours in the vertebral body (metastatic carcinomas or myelomas);
- Osteolysis coming from symptomatic vertebral haemangiomas [1, 2, 3].

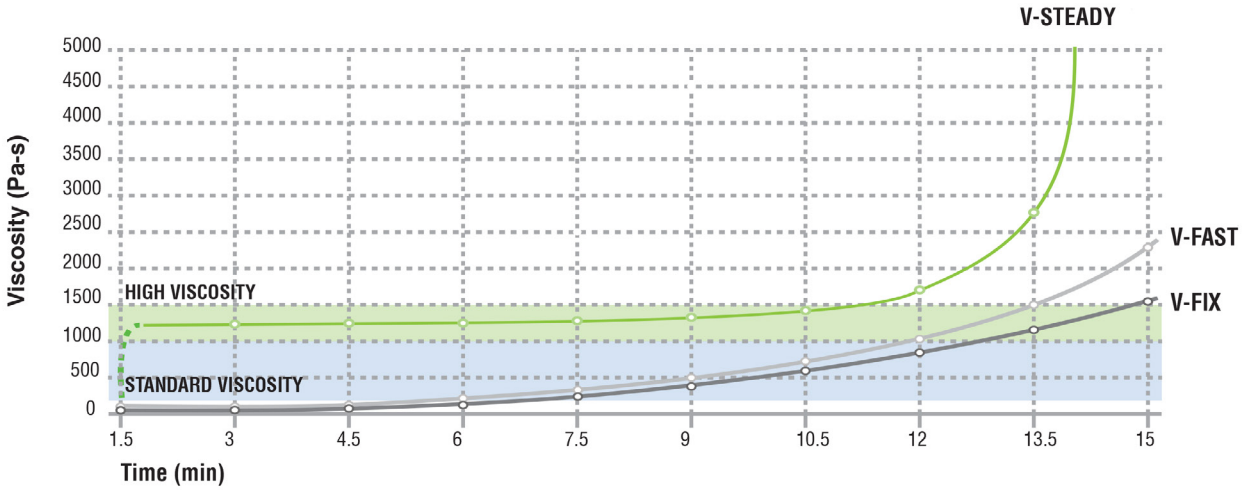
G21 bone cements are dedicated radiopaque bone cements, specifically formulated to perform percutaneous vertebral augmentation procedures, such as vertebroplasty or kyphoplasty [1, 2, 3].

G21 bone cements for vertebral consolidation are made up of two-components (powder and liquid) to be mixed at the time of application in the operating room.
G21 bone cements, are formulated so as to develop the right viscosity for the type of application which, once hardened, assumes a compact structure that enhances the mechanical strength of the implant.

In order to best suit the needs of every surgeon and patient, G21 offers a wide range of cements with diverse levels of viscosity which are also conceived to exclude the risk of leakage and possible complications [4-7].

G21 bone cements for vertebral consolidation are as follows:
- V-FIX and V-FAST: low viscosity bone cements.
- V-STEADY: high viscosity bone cement.

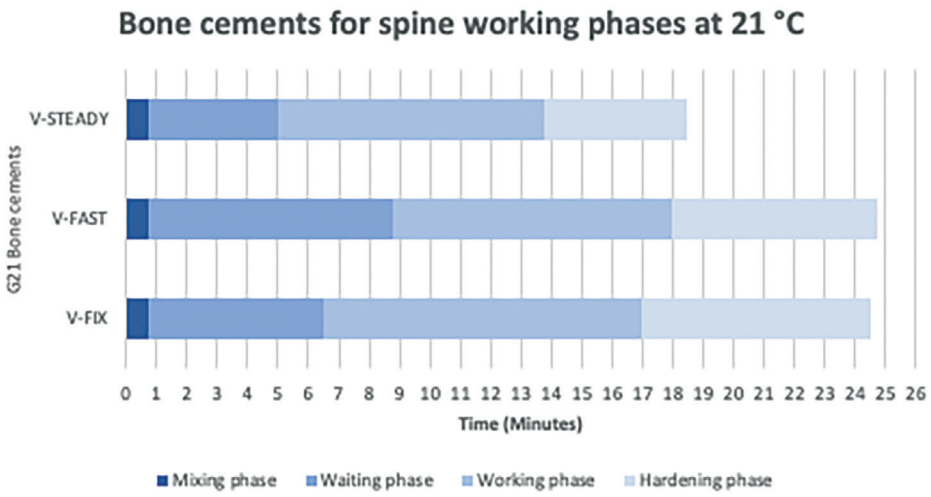
Viscosity Development
Data on file at G21 S.r.l.



Bone Cements for Vertebral Consolidation

WORKING TIMES

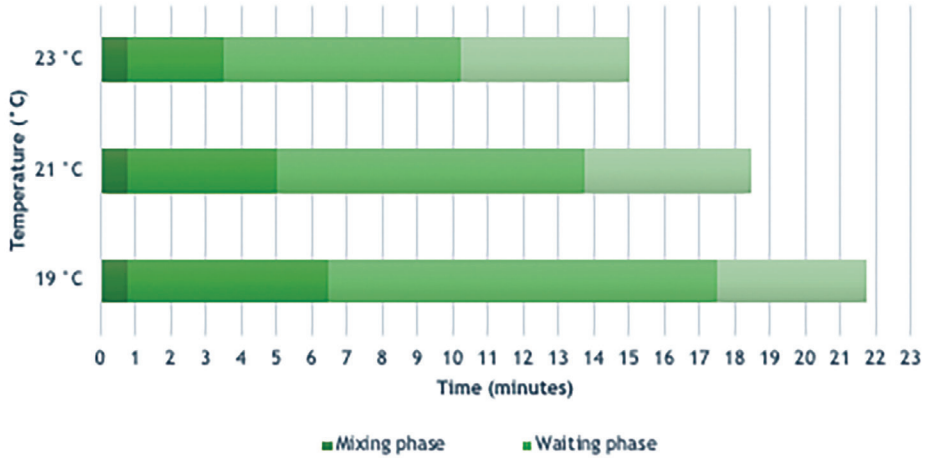
V-FIX, V-FAST and V-STEADY are a radiopaque bone cements specifically formulated for the procedures of percutaneous vertebroplasty or kyphoplasty procedures [4-7].



HIGH VISCOSITY BONE CEMENT: V-STEADY

V-STEADY is high viscosity bone cement. Its technical features are:

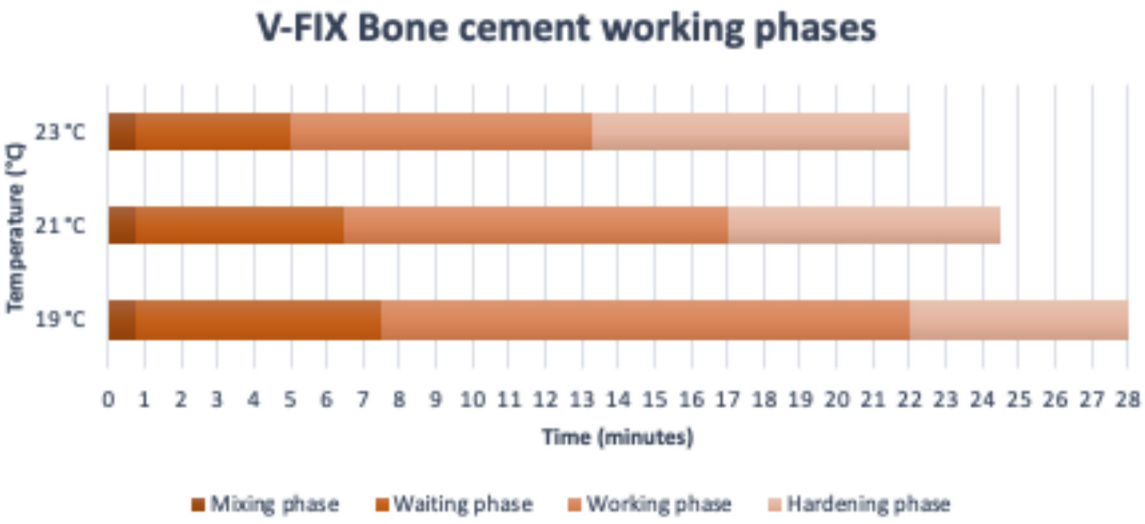
- Prolonged maintenance of the high calibrated viscosity suitable for both kyphoplasty and vertebroplasty surgeries.
- High concentration and homogeneous distribution of the contrast agent which allows an optimal visualization on the radioscopic monitoring devices.
- Specifically formulated to prevent the surgeon from the risk of cement leakage out of the vertebral body. This is especially feasible because of the high viscosity immediately visible after the mixing phase.
- The reduced waiting time and immediate high viscosity do not foreclose the use of the accessories for the mixing and application of the cement during the suction and injection phases.
- Low polymerisation temperature so as to reduce the risk of thermal shock on the tissues [8].

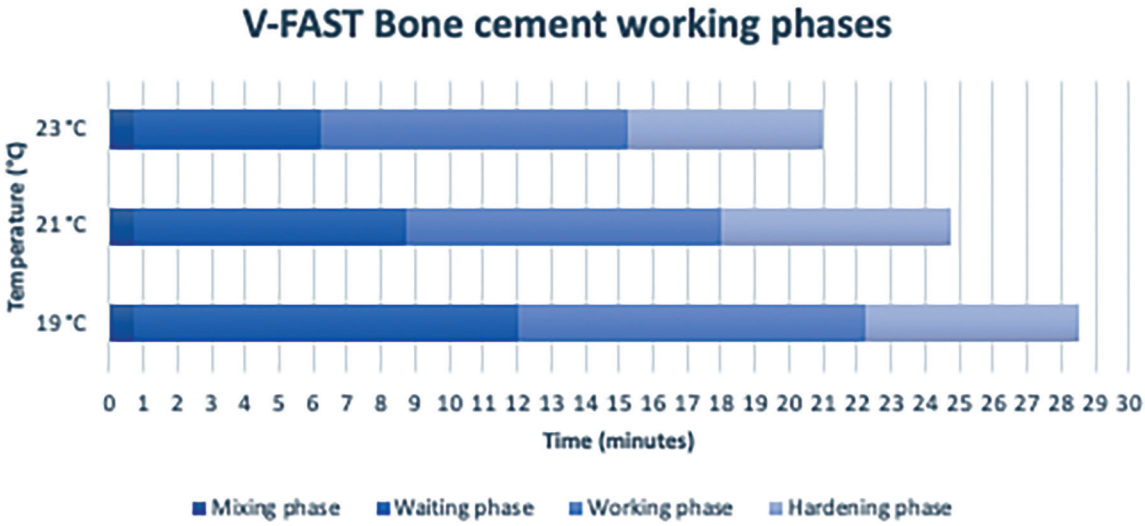


LOW VISCOSITY BONE CEMENTS: V-FIX and V-FAST

V-FIX and V-FAST are low viscosity bone cements. They are characterized by:

- Prolonged maintenance of the viscosity property, developed in such a way that it remains constant during the surgical application, guaranteeing the operator the control of the cement distribution inside the vertebral body.
- Extended usage time (V-FAST bone cement is characterized by a reduced time of polymerization compared to V-FIX bone cement).
- High concentration and homogeneous distribution of the contrast agent which allows an optimal visualization on the radioscopic monitoring devices.
- Low polymerisation temperature so as to reduce the risk of thermal shock on the tissues [8].





Bone Cements for Vertebral Consolidation

CLINICAL EVIDENCE

Polymethylmethacrylate (PMMA), is commonly known as bone cement, and is widely used in vertebral consolidation procedures and in vertebral fracture stabilization procedures.

As the population ages, the incidence of osteoporotic vertebral compression fractures (OVCF) is increasing. This is also aggravated by the appearance of the intravertebral fissure (IVC), which is not uncommon after OVCF.

IVC is considered an important risk factor as it causes prolonged back pain, severe vertebral collapse, progressive kyphosis, and even neurological deficit.

Percutaneous vertebroplasty (PVP) is a minimally invasive technique to treat painful OVCF with IVC. Numerous clinical studies have illustrated that this treatment can quickly relieve pain by partially restoring vertebral height and providing stable biomechanics through the injection of bone cement into the fractured vertebrae. [14]

To make the cement radiopaque and therefore visible in fluoroscopy during the injection phases, a contrast agent (barium sulfate for V- Fix and zirconium oxide for V- Fast and V- Steady) is added.

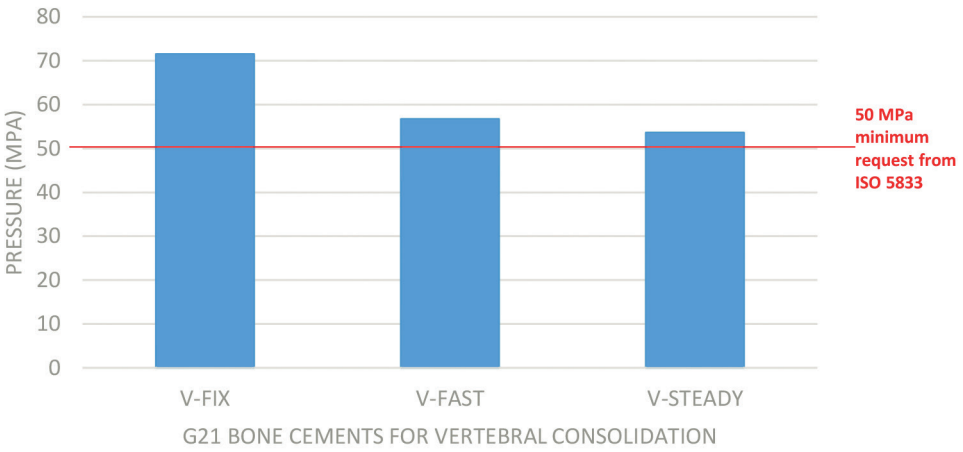
The addition of zirconium dioxide significantly improves tensile strength, fracture toughness and fatigue crack propagation resistance. On the contrary, the addition of barium sulfate produces a decrease in tensile strength but does not affect fracture toughness and improves crack propagation resistance.

Bone Cements for Vertebral Consolidation

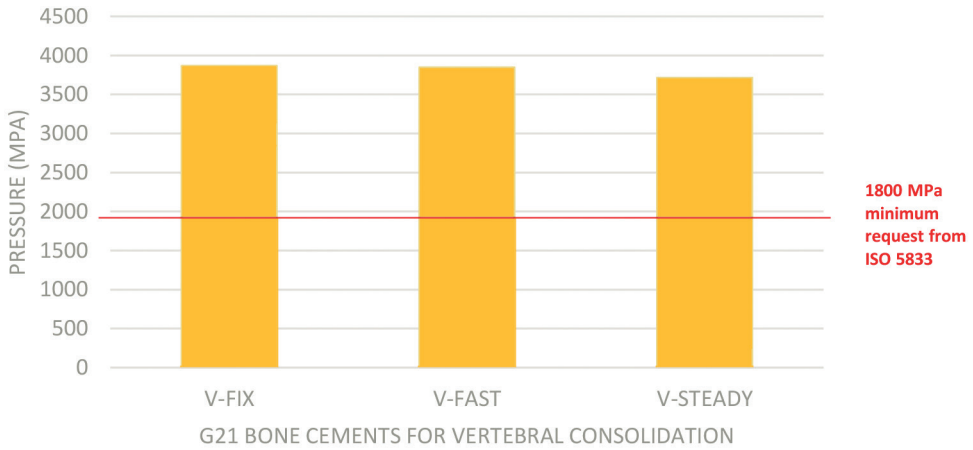
MECHANICAL PROPERTIES

Following the implantation of a cemented prosthesis, bone cement is subjected to different stresses. In order to demonstrate that the mechanical characteristics of G21 bone cements for vertebral consolidation comply with the international standard for Acrylic Bone cements [11], G21 has performed the following tests:

- Determination of bending strength regarding polymerized cements:



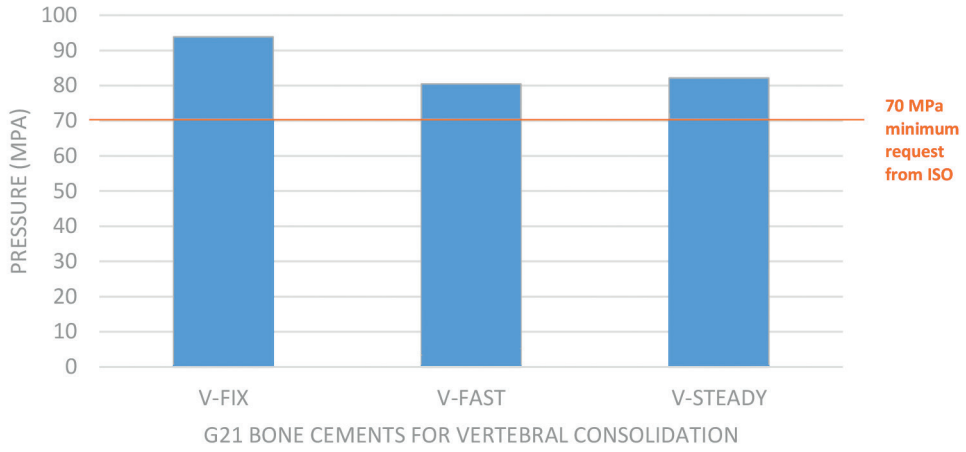
- Determination of bending modulus related to polymerized cements:



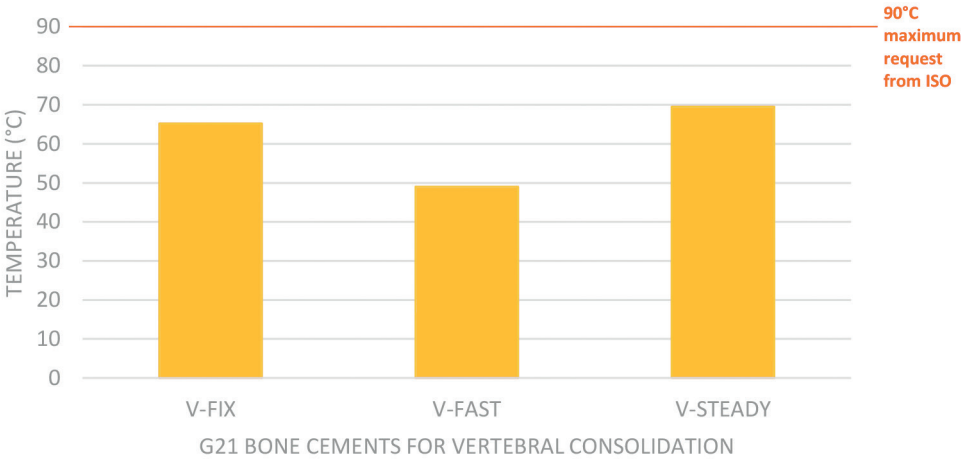
Bone Cements for Vertebral Consolidation

MECHANICAL PROPERTIES

• Determination of compressive strength concerning polymerized cements:



• Determination of maximum temperature referring to polymerized cements:



G21 bone cements comply with all the standards required by the i ISO 5833 [11] International standard for Acrylic Bone cements.

G21 BONE CEMENTS FOR VERTEBRAL CONSOLIDATION

PRODUCT	DESCRIPTION	REF
V-FIX	Low viscosity radiopaque bone cement	800037
V-FAST	Low viscosity radiopaque bone cement	800036
V-STEADY	High viscosity radiopaque bone cement	800039

V- FIX dh and V-FAST dh bone cements have the same functional characteristics of V-FIX and V-FAST bone cements. They differ only in packaging distribution: the standard amount of powder and the liquid, are im fact divided into two distinct packages.

PRODUCT	DESCRIPTION	REF
V-FIX dh	Low viscosity radiopaque bone cement	800017
V-FAST dh	Low viscosity radiopaque bone cement	800016

V-HP GUN

High pressure gun for radiopaque bone cement injection

The V-HP GUN is intended to be used during vertebral consolidation procedures such as vertebroplasty and kyphoplasty.

FEATURES

1. The ergonomic handle, the “screw” injection system and the low weight make the VHP Gun a user-friendly device.
2. High cement injection capacity (15ml) and quick and safe connections via Luer Lock connector with the G21 (PicoMix V) closed mixing system. The device can be loaded with bone cement even if it is mixed in an open mixer: a cone is provided to allow the cement to be aspirated into the syringe, keeping the luer lock connector free of cement obstructions.
3. The injection tube with a 30 cm (12 in) angled tip keeps the operator away from direct X-ray radiation when injecting cement under fluoroscopy.

PRODUCT	DESCRIPTION	REF
V-HP GUN	High pressure gun for radiopaque bone cement injection	900165

PicoMix V

Closed system to mix and dispense bone cement

The PicoMix V is designed to mix, aspirate and inject bone cement. It consists of a semi-manual mixer that allows a homogeneous mixing of the cement by avoiding direct contact with the cement itself and 4 x 5 ml syringes with a rigid plunger used for the aspiration and subsequent injection of cement.
In the device there is also a funnel and a spatula to ease any powder addition operations.

PRODUCT	DESCRIPTION	REF
PicoMix V	Closed system to mix and dispense bone cement	900129

Disp Mixing Bowl-V

Open mixing system to prepare bone cement

The device is used to mix the powder and the liquid which generate the standard viscosity sterile radiopaque bone cements. The system is composed by latex free disposable plastic bowl supplied with sterile packaging, a spatula for the mixing, a surgical drape and 3 syringes (5 ml) with rigid plunger [8].

PRODUCT	DESCRIPTION	REF
Disp Mixing Bowl - V	Open mixing system to prepare bone cement	900051

V-MIX

Kit consisting of bone cement and closed system for mixing and dispensing

V-Mix includes the PicoMix V, a funnel, 4 syringes (with rigid plunger) to inject bone cement for vertebral consolidation , and the box containing the cement itself.

PRODUCT	DESCRIPTION	REF
V-MIX 01	V-FIX bone cement with mixer and syringes with rigid plunger	800045
V-MIX 02	V-FAST bone cement with mixer and syringes with rigid plunger	800046
V-MIX 03	V-STEADY bone cement with mixer and syringes with rigid plunger	800047

KeyFix Bone Cement Filler Cannula for Screw Augmentation

Double diameter filler intended for screw augmentation

The KeyFix_Bone Cement Filler Cannula is a device consisting of a double diameter cannula and a coaxial stylet for the injection of bone cement into the vertebral body. The product is specifically suitable for the injection of bone cement into screws to fix the vertebra.

PRODUCT	REF
KeyFix Bone Cement Filler Cannula for screw augmentation	900146

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