G21
STRENGTH FOR LIFE

Bone Cements
for Orthopaedics

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G21 was set up in 2009 by expert entrepreneurs originating from the medical and pharmaceutical sector.
G21 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.
G21 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 programs 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 G21's in-house production unit, which includes clean rooms certified up to Class ISO 5 to guarantee a production process under sterile conditions.
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.
Since 2010 G21 has been operating according to a quality system in compliance with EN ISO 13485 "Quality Management Systems - Requirements for regulatory purposes applicable to Medical Devices".

Bone Cements for Orthopaedics

G21 BONE CEMENTS FOR ORTHOPAEDICS are intended to be used during surgical interventions caused by:

- Arthroplasty revision
- Joint replacement after a traumatic event
- Osteoarthritis
- Osteoporosis hangover

G1 and G3 bone cements are radiopaque bone cements for surgical use to perform arthroplasty procedures, such as hip replacement, knee replacement, ankle replacement, shoulder replacement and other joint replacements [1, 2, 3, 4], specifically formulated to allow fixation of prosthetic devices on the living bone.

G21 bone cements for orthopaedics with antibiotic a self-curing, radiopaque, polymethyl methacrylate based cement which is used for securing a metal or polymeric prosthesis to living bone in arthroplasty revision procedures such as hip replacement, knee replacement, ankle replacement, shoulder replacement and other joints replacement, specifically formulated for patients:

- where the general or local conditions indicate an increased risk of infection
- with a compromised general state (malnutrition, diabetes, systemic infections,…)
- needing a revision of hip or other joints prosthe-sis where a local infection has developed.

G1A and G3A are indicated for use in the second stage of a two stages revision for total joint arthroplasty after the initial infection has been cleared.

The G21 bone cements for orthopaedics are 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 the right viscosity for the type of application and such that, once hardened, it assumes a compact structure which enhances the mechanical strength of the implant.

COMPARISON FROM BONE CEMENTS WITH DIFFERENT VISCOSITY

The G21 bone cements for orthopaedics are available in different viscosities and with and without antibiotic:

- Low Viscosity: (G3-G3A): The G3™ sterile radiopaque bone cements consistency and working time are particularly suitable for cementation of hip prostheses and for working on medium/small joints.
- Standard Viscosity (G1-G1A): The G1™ sterile radiopaque bone cements have a consistency and working time particularly suitable for cementation of knee prostheses. In the initial phases, the G1™ has properties that also make it suitable for cementation of hip prostheses.

G1A and **G3A** bone cements with antibiotic contain gentamicin sulphate in the powder.

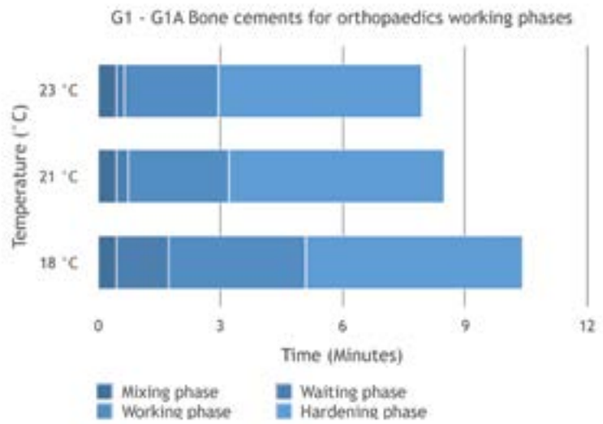
Ideal viscosity will be high enough to avoid any cement mixing with blood or fat/bony material from the implantation region yet low enough to penetrate the bone adequately [5].

STANDARD VISCOSITY CEMENTS: G1 AND G1A

G1 and G1A bone cements are a standard viscosity cement, primarily intended for manual application.

G1 and G1A bone cements are particularly suitable for cementation of knee prostheses thanks to its viscosity [1, 6].

The version with antibiotic is indicated in revision operations and in cases where there is a risk of infections caused by organisms sensitive to gentamicin [7]. The G1A bone cement contains and releases the aminoglycoside antibiotic gentamicin to protect the cured cement and contiguous tissue against contamination by microbes sensitive to gentamicin [8, 9].



CHARACTERISTICS [10]

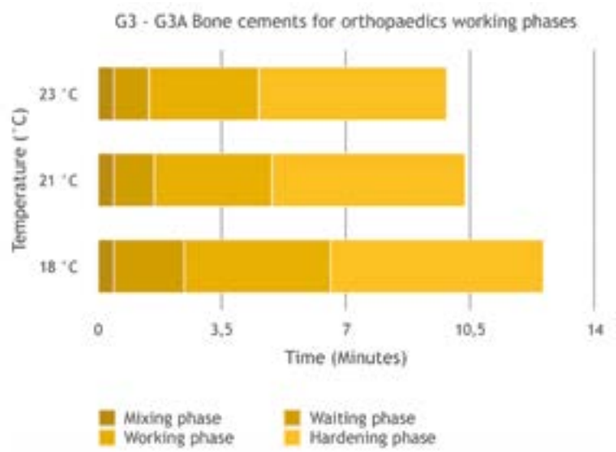
1. reduced mixing time (under a minute to obtain a homogeneous product),
2. working time suited to the type of application (4-5 minutes),
3. polymerisation is completed after 10 minutes so as to reduce the risk of micro movements of the prosthesis once applied,
4. mechanical properties in conformity to regulatory requirements,
5. low polymerisation temperature so as to reduce the risk of thermal shock on the tissues.

CONTENT OF GENTAMICIN IN G1A BONE CEMENT:

Bone cement	Content of Gentamicin
G1A 20	Equivalent to 0.3 g (0.3 M.I.U.) Gentamicin Base in a 20.5 g unit of powder
G1A 40	Equivalent to 0.6 g (0.6 M.I.U.) Gentamicin Base in a 41 g unit of powder

LOW VISCOSITY CEMENTS: G3 AND G3A

G3 and G3A bone cements are a low viscosity cement, primarily intended for syringe application. If G3A is applied digitally, the surgeon must use their clinical judgment to decide when the cement viscosity is suitable to allow the surgical procedure to continue. G3 and G3A bone cements are particularly suitable for cementation of hip and shoulder prostheses [1, 11].
The version with antibiotic is indicated in revision operations and in cases where there is a risk of infections caused by organisms sensitive to gentamicin [7].



The G3A bone cement contains and releases the aminoglycoside antibiotic gentamicin to protect the cured cement and contiguous tissue against contamination by microbes sensitive to gentamicin [9].

CHARACTERISTICS [10]

1. reduced mixing time (under a minute to obtain a homogeneous product),
2. working time suited to the type of application (6-8 minutes),
3. polymerisation is completed after 13 minutes so as to reduce the risk of micro movements of the prosthesis once applied,
4. mechanical properties in conformity to regulatory requirements,
5. low polymerisation temperature so as to reduce the risk of thermal shock on the tissues.

CONTENT OF GENTAMICIN IN G1A BONE CEMENT:

Bone cement	Content of Gentamicin
G3A 20	Equivalent to 0.3 g (0.3 M.I.U.) Gentamicin Base in a 20.5 g unit of powder
G3A 40	Equivalent to 0.6 g (0.6 M.I.U.) Gentamicin Base in a 41 g unit of powder
G3A 60	Equivalent to 0.9 g (0.9 M.I.U.) Gentamicin Base in a 61,50 g unit of powder

G21 Low viscosity bone cements are tested to be used with G21 SpaceFlex devices for the realization of, hip and knee spacers in PMMA to be implanted in case of revision of infected prosthesis with the aim of preserving soft tissues avoiding the degeneration typically related to their incorrect tensioning. The peculiarity of the device is the possibility to obtain the PMMA spacer directly in the operating theater, and loaded with the desired quantity of antibiotic.

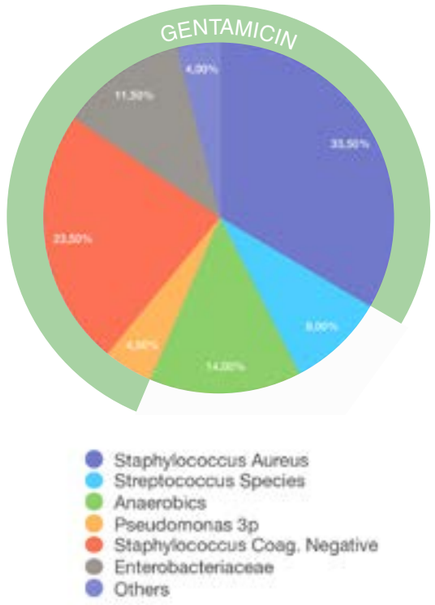
Polymethyl methacrylate (PMMA), is commonly known as bone cement, and is widely used for implant fixation in various Orthopaedic and trauma surgery. PMMA acts as a space-filler that creates a tight space which holds the implant against the bone and thus acts as a ‘grout’. Bone cements have no intrinsic adhesive properties, but they rely instead on close mechanical interlock between the irregular bone surface and the prosthesis.

In order to make the cement radiopaque, a contrast agent (Barium sulphate) is added.

Bone cement has proven particularly useful because specific active substances, e.g. antibiotics, can be added to the powder component. This makes bone cement a modern drug delivery system that delivers the required drugs directly to the surgical site. The local active substance levels of bone cements are significantly below the clinical routine dosages for systemic single injections [5].

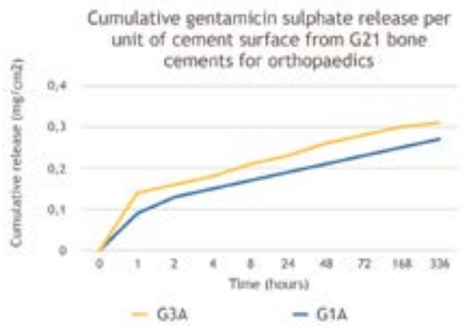
G21 carries out an in vitro study [17] with the aim of evaluating the mechanical and elution properties of G3 Bone Cement loaded with different doses of up to three antibiotics (12 specimens). The results obtained in this pilot study using G3 Bone Cement, demonstrated that mechanical properties not decrease significantly by adding large doses of antibiotics, while the Vancomycin elution increase until swelled to twice.

Total joint replacement is one of the most common and successful orthopaedic operations. One of the most serious complications associated with total joint replacement is the development of infections. In cases of infection, a high dose of antibiotics is required to reach effective concentrations at the implantation site. Nevertheless, high doses of antibiotics can cause toxicity. To prevent the genesis of complications associated with the development of infections, the inclusion of antibiotics in the bone cement intended for mechanical attachment of the prosthesis to bone tissue has been suggested.
The main advantage of this use of antibiotics derives directly from antibiotic release in the effect-site, allowing achievement of high concentrations at the site of action, and minimal or no systemic toxicity. Currently, polymethylmethacrylate (PMMA) is the most widely used bone cement material for loading antibiotics and represents the current standard as an antibiotic delivery vehicle in orthopaedic surgery [12].



CHARACTERISTICS OF THE ANTIBIOTIC

Most of the orthopaedic prosthesis infections are caused by: Cocchi Gram+, Negative Staphylococcus coagulase and Streptococcus Aureus [13, 14]. Antibiotic-loaded bone cements are used both during primary implant and as therapeutic tool to eradicate the periprosthetic joint infection. The microorganisms were found to be susceptible to gentamicin antibiotic and the antibacterial effects against methicillin-resistant Staphylococcus Aureus and Klebsiella Pneumoniae lasted for one day in the cement loaded with gentamicin, lasted three days against methicillin-resistant Staphylococcus Aureus and coagulase-negative staphylococci and lasted respectively six days and ten days for Escherichia coli and Pseudomonas aeruginosa [15], but G21 in vitro study [10] demonstrate the release of gentamicin from bone cement until fourteen days.

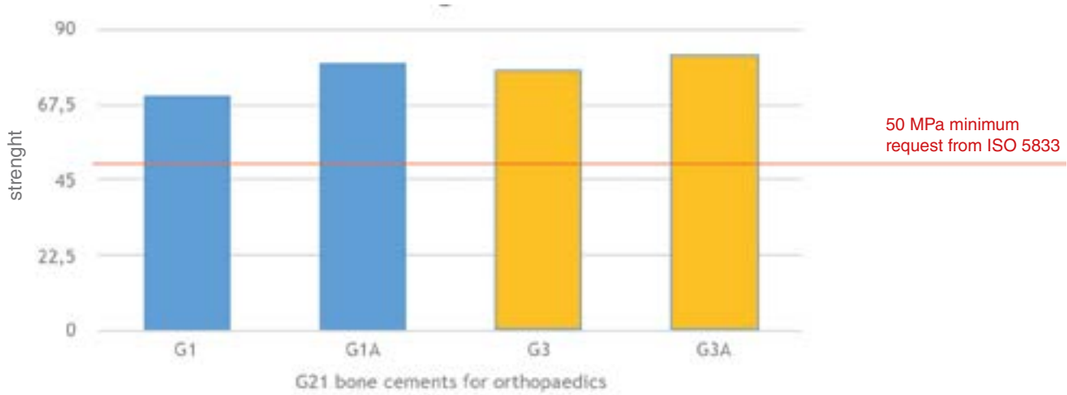


The nature of the Gentamicin release from the sterile radiopaque bone cement with antibiotic is biphasic, with a peak release in the first few hours, followed by a steadily decreasing but ongoing release that can be measured for weeks.

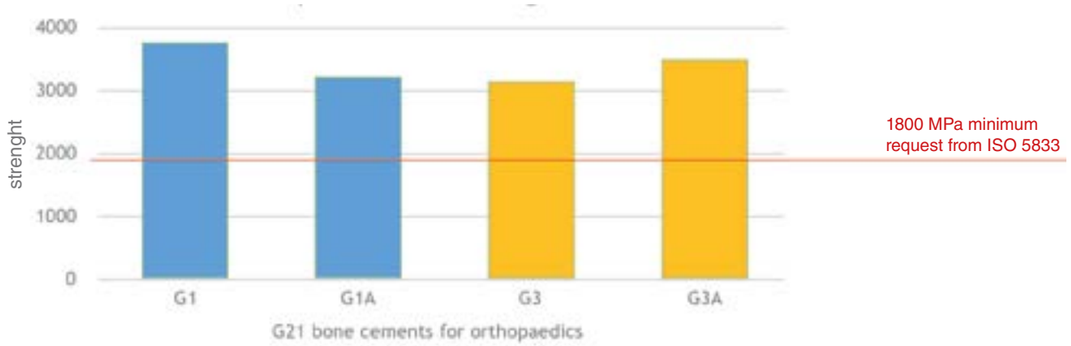
Following the implantation of a cemented prosthesis, bone cement is subjected to different stresses.

In order to demonstrate that the mechanical characteristics of the G21 bone cements for orthopaedics comply with the international standard for Acrylic Bone cements [16], G21 has performed the following tests:

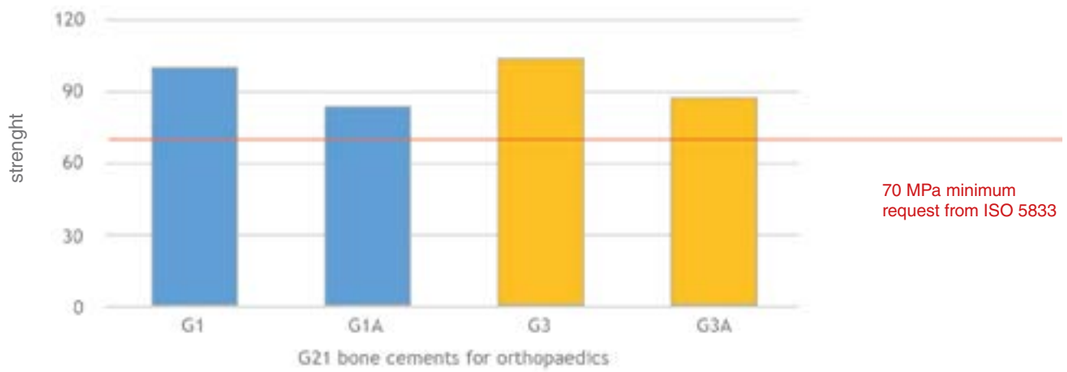
DETERMINATION OF BENDING STRENGTH OF POLYMERIZED CEMENT [10]:



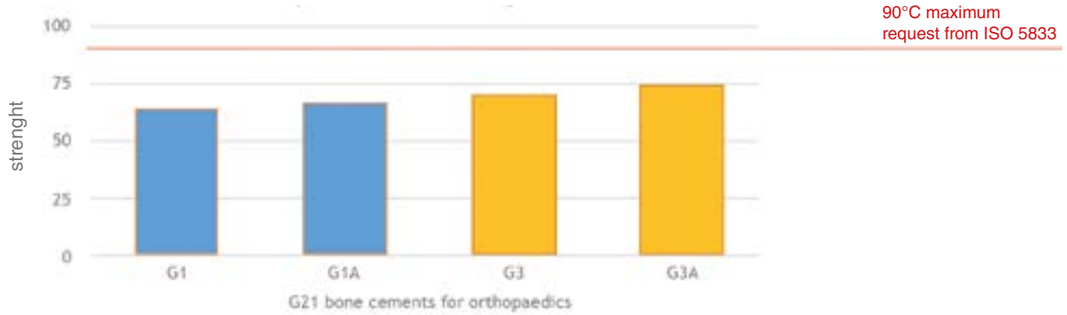
DETERMINATION OF BENDING STRENGTH OF POLYMERIZED CEMENT [10]:



DETERMINATION OF BENDING STRENGTH OF POLYMERIZED CEMENT [10]:



DETERMINATION OF BENDING STRENGTH OF POLYMERIZED CEMENT [10]:



The G21 bone cements are in compliance with all the request from the international standard for Acrylic Bone cements ISO 5833 [16].

G21 BONE CEMENTS FOR ORTHOPAEDICS

PRODUCT	DESCRIPTION	REF
G1 20	Radiopaque bone cement	800001
G1 40	Radiopaque bone cement	800002
G1A 20	Radiopaque bone cement with antibiotic	800006
G1A 40	Radiopaque bone cement with antibiotic	800007
G3 20	Radiopaque bone cement	800003
G3 40	Radiopaque bone cement	800004
G3 60	Radiopaque bone cement	800005
G3A20	Radiopaque bone cement with antibiotic	800008
G3A 40	Radiopaque bone cement with antibiotic	800009
G3A 60	Radiopaque bone cement with antibiotic	800010

PICOMIX BOWL
CLOSED BONE CEMENT MIXING SYSTEM

Closed system with high capacity for mixing bone cement. The PicoMix Bowl variable rotation axis mixing system allows optimal mixing of the cement, ensuring superior quality and reproducibility compared to fixed rotation axis systems or manual preparation.

PicoMix Bowl also allows to minimize the residual porosity of the material, in order to enhance its resistance to fatigue. It is also possible to connect a system to create a vacuum at 550 mmHg, an optimal value for improving the mechanical properties of cement. PicoMix Bowl has a carbon filter to minimize the level of exposure (to the methyl methacrylate fumes) of the personnel involved in the preparation of the cement.

The transparency of the materials allows to easily monitor the preparation process.

PicoMix Bowl is latex free [10] and includes a spatula and a disposable curette for scraping, shaping and cutting bone cement.

PRODUCT	DESCRIPTION	REF
PicoMix Bowl	Closed bone cement mixing system	900122

PICOMIX SYRINGE
CLOSED BONE CEMENT MIXING AND DELIVERY SYSTEM

Closed systems for mixing and injection of bone cement suitable for mixing up to 120 g and 180 g of cement.

The transparency of the materials allows to carefully check the quality of the mixing before proceeding with the administration of the product. It is also possible to connect a system to create a vacuum at 550 mmHg, an optimal value for improving the mechanical properties of cement. PicoMix Syringe has a carbon filter to minimize the level of exposure (to the methyl methacrylate fumes) of the personnel involved in the preparation of the cement.

Used in combination with the new injection system, it allows the operator to have absolute control during the application.

PRODUCT	DESCRIPTION	REF
PicoMix Syringe	Closed bone cement mixing and delivery system (120 g)	900123
PicoMix Syringe	Closed bone cement mixing and delivery system (180 g)	900123-1
HiVac rachet delivery gun	Bone Cement Delivery Gun	H759L

DISP MIXING BOWL-O
OPEN MIXING SYSTEM FOR BONE CEMENT PREPARATION

The device is used to mix the powder and the liquid that make up the standard viscosity sterile radiopaque bone cements.

Latex free, disposable plastic bowl supplied sterile packed with a spatula for mixing and a surgical drape [10].

PRODUCT	DESCRIPTION	REF
Disp Mixing Bowl - O	Open mixing system for bone cement preparation	900050

VACUUM FOOTPUMP 550
VACUUM PUMP WITH FOOT SWITCH

PRODUCT	DESCRIPTION	REF
Vacuum Footpump 550	Vacuum pump with foot switch	H550

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