Hi-Fatigue G Bone Cement, Hi-Fatigue Bone Cement and Optivac® Vacuum Mixing System

ZIMMER BIOMET
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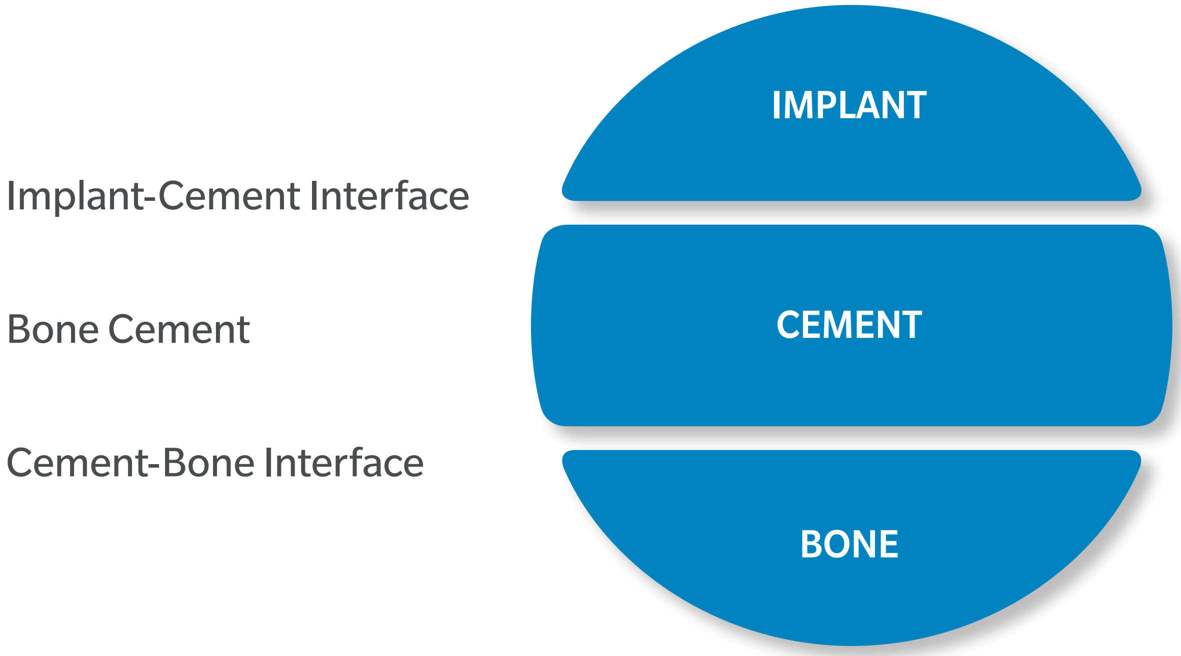
Solutions for Modern Cementing Technique[1,2]



Modern Cementing Technique is a documented and clinically proven procedure.[1-3] The objective is to improve mechanical interlock between bone and cement in order to establish a durable interface. Modern Cementing Technique, compared to earlier techniques, has been linked to a 20% reduction for the risk of revision.[4]

Zimmer Biomet offers a comprehensive portfolio of products and educational courses to support the use of Modern Cementing Technique.

The four key pillars of Modern Cementing Technique play a critical part to improve the interfaces between bone-cement, and cement-implant.

BONE BED PREPARATION

Preparation of the bone bed with a high pressure pulse lavage system helps to ensure solid cement fixation and reduces the risk for fat embolism.[5-7]

BONE CEMENT

Polymethyl methacrylate (PMMA) bone cements fill the space between prostheses and bone. The transfer of the forces bone-to-implant and implant-to-bone is the primary task of the bone cement.[8]

MIXING AND DELIVERY

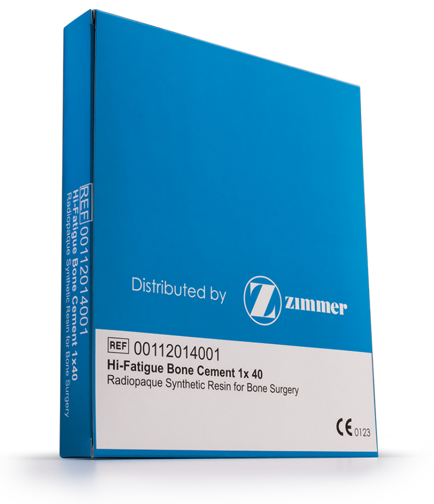
Mixing and collecting the bone cement under vacuum reduces both micro and macro pores to a minimum, thereby increasing fatigue life.[9-14]

PRESSURIZATION

Pressurization increases penetration into cancellous bone and reduces cement porosity.[15]

Hi-Fatigue G Bone Cement
with gentamicin

- Clinically proven with reliable results[16]
- On the market since 2008
- Formulation specially developed for increased fatigue properties[17]
- High viscosity - for lower risk of revision[18]
- Easy handling and wide application window
- Long-lasting local antibiotic release for reduced risk of revision[19,20,31]



Hi-Fatigue Bone Cement
non-antibiotic

- Clinically proven with reliable results[16]
- On the market since 2008
- Formulation specially developed for increased fatigue properties[17]
- High viscosity - for lower risk of revision[18]
- Easy handling and wide application window

Optivac Vacuum Mixing System

- On the market since 1993 and highly documented[9-13]
- Mixing **and** collecting under vacuum, improving cement strength and fatigue life[10-13]
- Secure - the closed vacuum mixing system minimizes exposure to monomer fumes[21,22]

*In published articles and lab reports

Hi-Fatigue G Bone Cement and Hi-Fatigue Bone Cement

Clinically Proven with Reliable Results[16]

In a 2-year RSA study, Jørgensen *et al.* evaluated the long-term fixation in hip stem arthroplasty when using Hi-Fatigue G Bone Cement compared to Palacos® R+G.[16]

Since stem subsidence and stem migration has shown to be good predictors of implant survival, the stem location was measured at 3 months, 6 months, 1 year and 2 years after surgery using radiostereometry (RSA).[16]

Key findings of the study were equivalent hip stem fixation and clinical results for the two bone cements used. Until the 2-years' follow up, similar and generally low migration of the stem was found, indicating good long-term survival with both bone cements. Both Hi-Fatigue G Bone Cement and Palacos R+G showed good cement distribution (whiteout), but Palacos R+G was more often classified with slight radiolucency. In addition, at 2 years' follow-up, there had been no revisions due to aseptic implant loosening.[16]

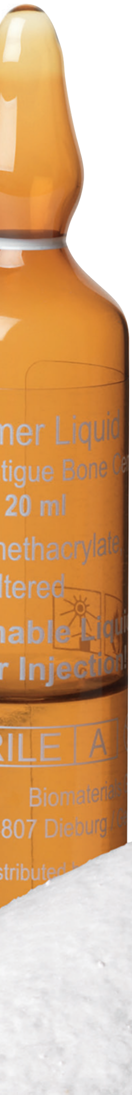
High Viscosity

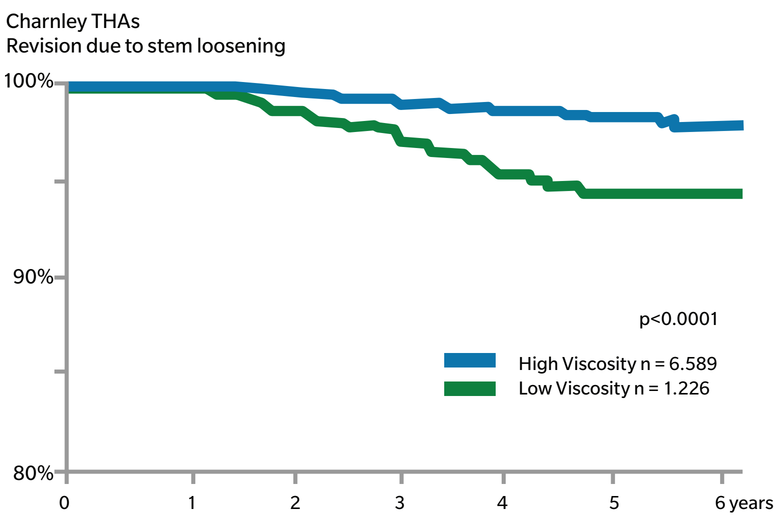
Hi-Fatigue G Bone Cement and Hi-Fatigue Bone Cement are high viscosity bone cements.

High viscosity cements have a short waiting phase and a longer working phase, giving the surgeon more time for application.[24]

For cement on bone application, it has been shown that applying cement of low viscosity may lead to lamination, as the cement cannot withstand bleeding pressure.[25]

The arthroplasy registers in Norway and Sweden have shown lower risk ratio when a high viscosity bone cement is used compared to a low viscosity.[18,26]



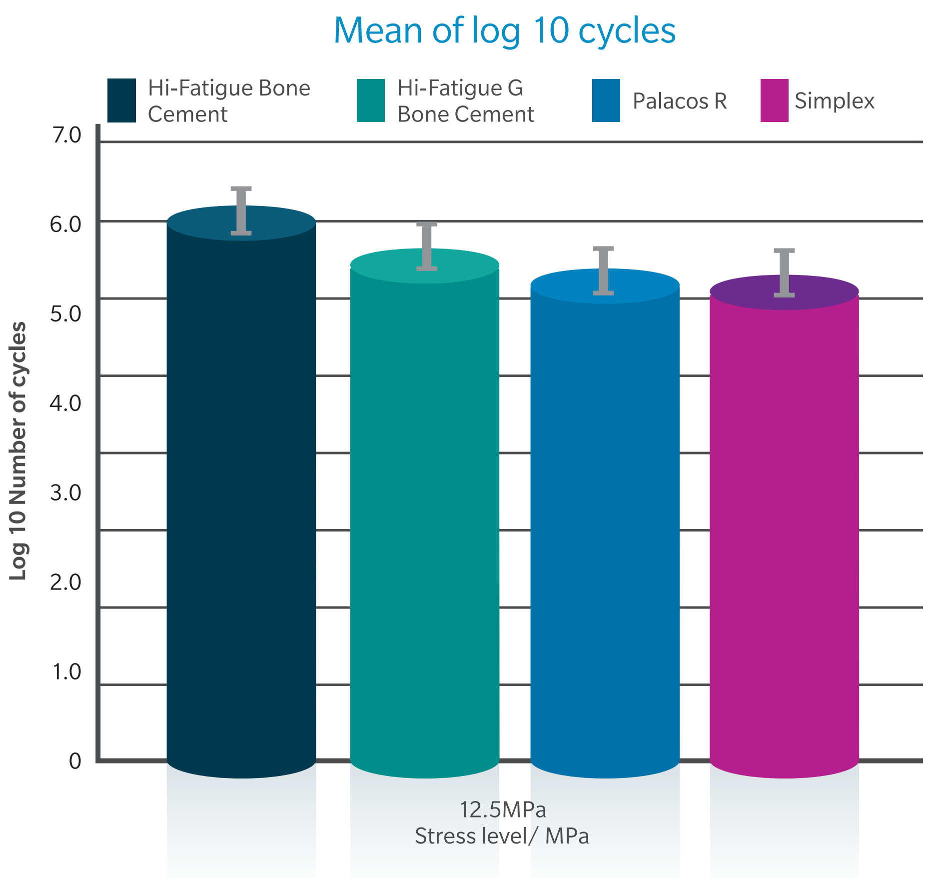


In the Norwegian Arthroplasty Register the use of high viscosity cement with gentamicin has been shown to result in the lowest incidence of revision.[18]

Formulation Specially Developed for Increased Fatigue Properties

After implantation, bone cements are not only static but also exposed to mechanical stress. The fatigue strength is the ability of the bone cement to resist dynamic loads. This represents an essential factor for the long time implant survival.[23]

Hi-Fatigue G Bone Cement and Hi-Fatigue Bone Cement consist of a combination of well-known chemical substances Poly(MMA) and Poly(MMA/ Styrene). The added styrene has high long-term fatigue resistance. The Hi-Fatigue Bone Cement and Hi-Fatigue G Bone Cement show high fatigue strength after long term cyclic exposure.[17]



Mean Number of cycles to failure (12.5MPa)

Easy Handling and Wide Application Window

The handling properties of the Hi-Fatigue Bone Cement are especially developed to meet the user needs:

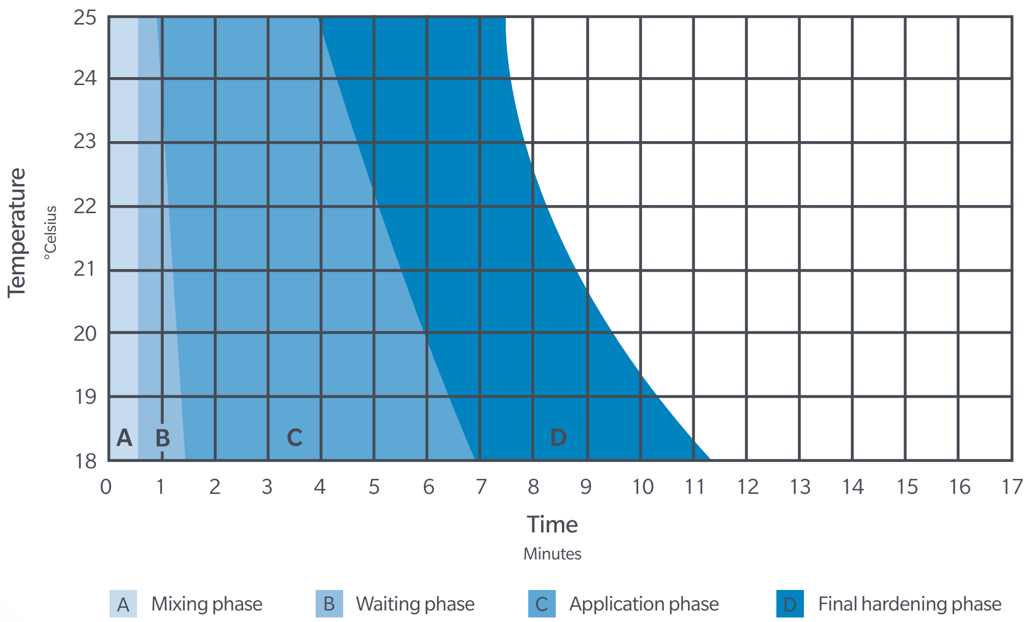
- Initial lower viscosity for easy mixing in a modern mixing system without pre-chilling
- The bone cement will reach its dough phase early and then provide sufficient time for application of cement on bone and implant insertion

The handling properties of Modern Cementing Technique recommends using a vacuum mixing system, like the Optivac system, for mixing and delivery of bone cement. This makes standardized handling easy and helps achieve a reproducible, homogeneous bone cement of highest quality.[2,12]

Handling properties are highly dependent on the temperatures of the bone cement and the operating room. Higher temperatures provides a shorter working phase and a faster setting time. Pre-chilling prolongs the working phase as well as the setting time.

It is very important that the cement user becomes familiar with the cement properties, handling and use, and uses the same standardized handling technique every time.

Hi-Fatigue G Bone Cement Non-prechilled, mixed under vacuum

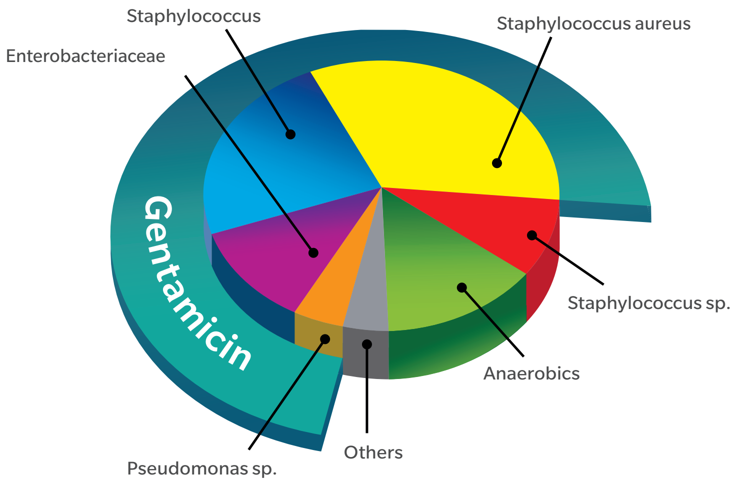


Antibiotic-loaded Cement for Reduced Risk of Revision[19,20,31]

Gentamicin for a Broad Antibacterial Spectrum

Hi-Fatigue G Bone Cement includes gentamicin, which has shown to be the antibiotic of choice for bone cement, as its broad therapeutic spectrum covers gram-positive and gram-negative bacteria. Gentamicin is bactericidal on proliferating and resisting pathogens, and its release from the bone cement is superior to that of other antibiotics.[27]

Gentamicin covers most bacteria common to infected arthroplasty cases.[28]

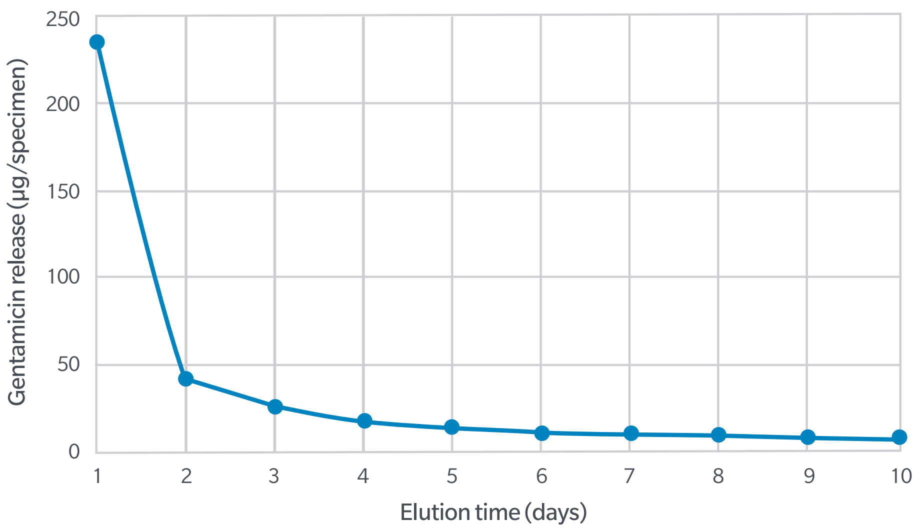


Gentamicin – for Long-Lasting, Local Antibiotic Release

By using antibiotic-loaded bone cement, high local concentrations of antibiotics can be administered in the surrounding of the implant, preventing germs from settling. Furthermore, a protracted release of gentamicin from cured bone cement was proven as early as 1972.[29,30] The protracted release of the antibiotics protects the implant for an extended period of time, thus reducing the risk of revisions.[31]

Hi-Fatigue G Bone Cement provides high local concentrations of gentamicin over several days.[19] In addition, Hi-Fatigue G Bone Cement has shown a high initial burst with rapid decline in vivo. The serum concentrations never exceeded toxic levels, which confirmed the effectiveness and safety of the gentamicin release.[31]

Release of Gentamicin from Hi-Fatigue G Bone Cement[19]



OPTIVAC

Optivac Mixing and Delivery

Aseptic loosening due to porosity in bone cement has been a major problem since the start of cemented joint arthroplasty. The first experiments to reduce porosity in bone cement took place in the 1980s. This later led to the invention of bone cement collection under vacuum which has been proven to reduce macropores. In 1993, the Optivac system was introduced on the market.

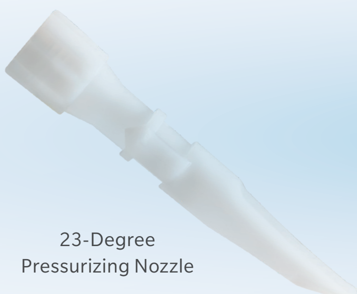
With mixing and collection under vacuum, the Optivac system reduces both microporosity and macroporosity, thereby improving cement strength and fatigue life. The Optivac system is highly documented and has been the standard against which other systems have been measured for the last 25 years.[21,22]

- Improved cement strength and fatique life[10-13]
- Lower risk of aseptic loosening caused by cracks in the cement[9,12]
- Reproducible results[9-13]
- Safer working environment[21,22]

Optivac S

ACCESS

Knee Nozzle, breakable
(1 included in Optivac S and Optivac M)



23-Degree
Pressurizing Nozzle

Breakable cement nozzle
(1 included in all sizes, excluding S)

IS AVAILABLE IN DIFFERENT PACK SIZES

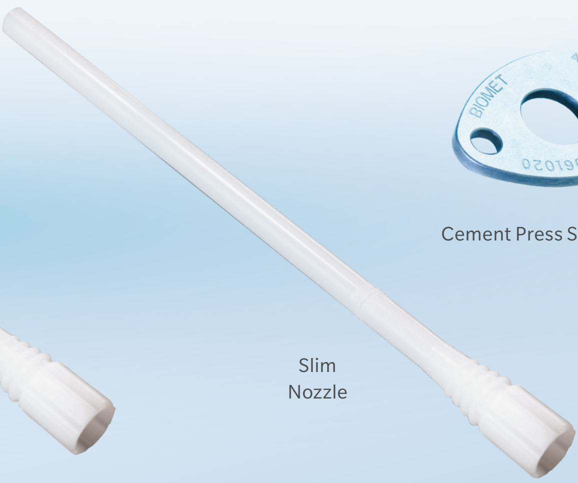
Optivac M

Optivac L

Optivac Hip Set

ORIES

Revision Nozzle

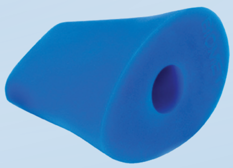


Slim Nozzle

Cement Press Support Plate II

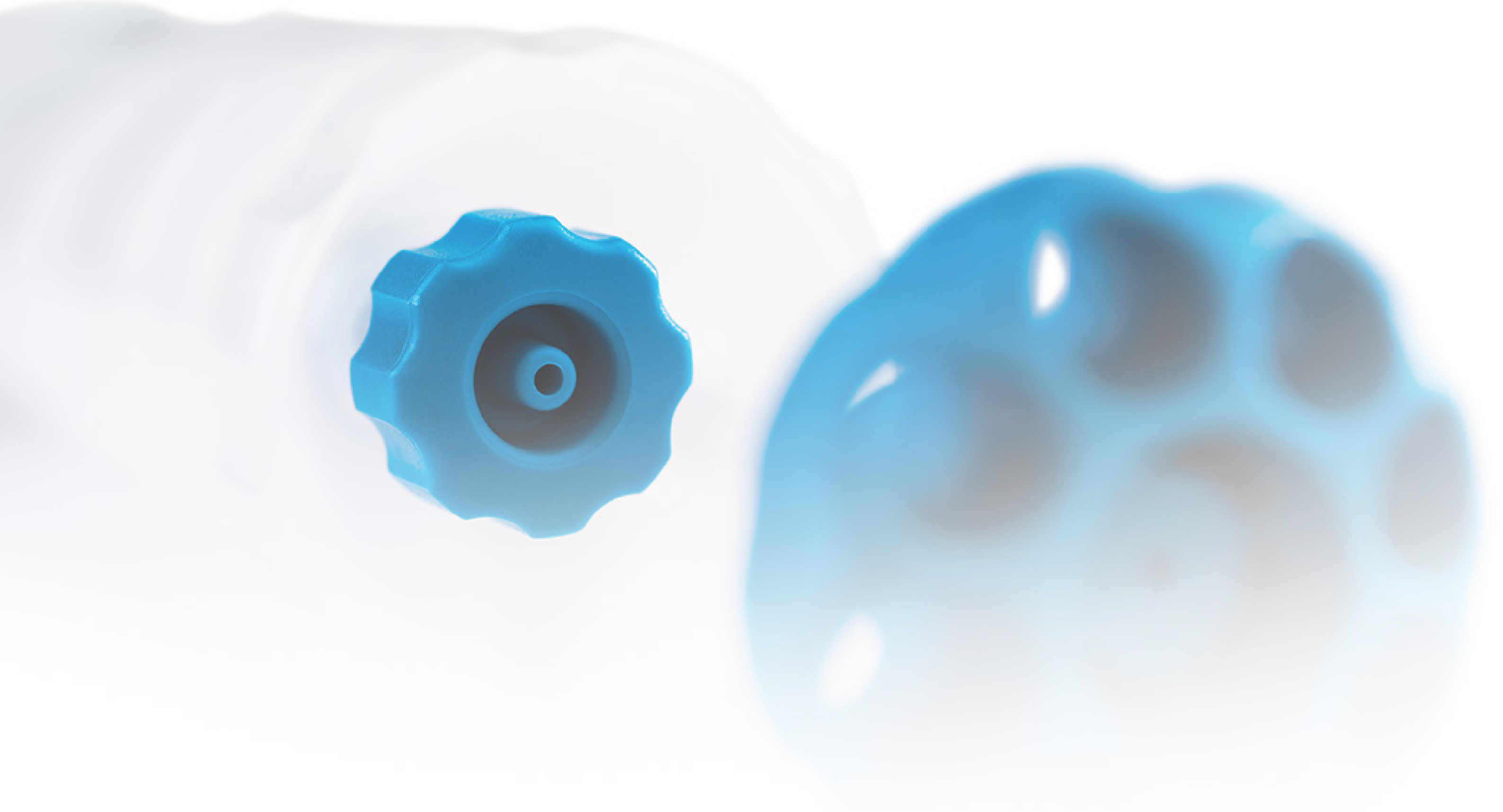
Knee Cementation Nozzle

Acetabular Press



Femoral pressurizer
(1 included in the Optivac M, Optivac Hip Set and Optivac Hip+ Set)

Mixing and Collection Under Vacuum



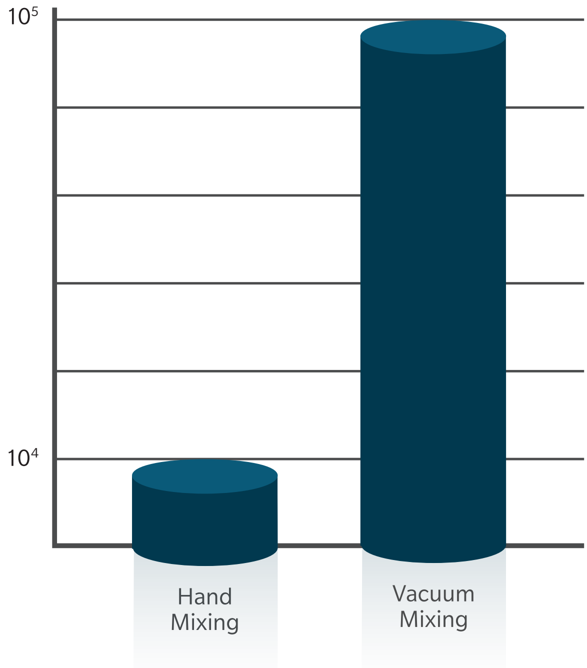
Minimized Porosity and Improved Mechanical Strength

Cement porosity directly affects the fatigue behaviour of the bone cement. Reducing the number of pores can lead to substantial improvements in cement fatigue life. Several methods have been introduced to reduce cement porosity, with applying vacuum throughout the process of mixing and collection of the cement being efficient.[32]

The Optivac vacuum mixing system utilizes this feature, the effect of which has been validated by Mau *et al.*[33] The laboratory study concluded that if cement is not collected under vacuum, porosity is increased.

Improving cement quality by using a vacuum mixing system is one of the key pillars of Modern Cementing Technique.

Cycles to Failure



The fatigue life improves 10 times with vacuum mixing compared to hand mixing[34]

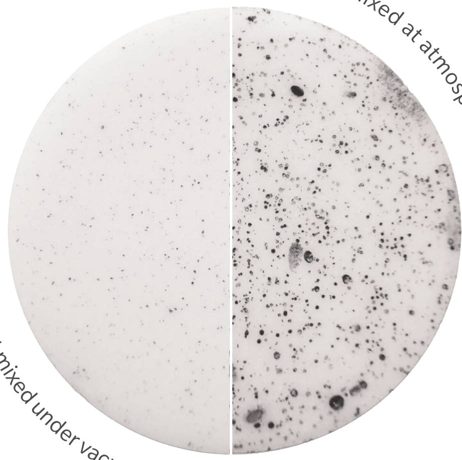
Mixing and Collection Under Vacuum Reduces Both Macropores and Micropores[10,14]

Two types of pores are classified in fully polymerized bone cement:

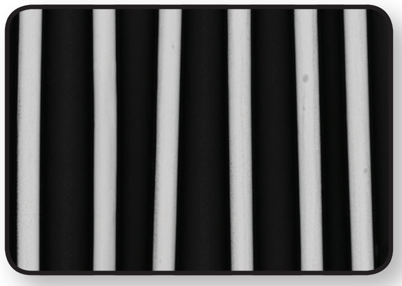
1. Macropores, with a pore diameter of more than 1.0 mm.[14]
2. Micropores, with a pore diameter of 0.1–1 mm.[14]

Mixing under vacuum reduces the cement's microporosity, but has less effect on macroporosity. Continuous vacuum – from mixing to collection – helps to prevent macropore entrapment in high viscosity cement. With its design for collection under vacuum, the Optivac system reduces both microporosity and macroporosity.[9-13]

By materially reducing macroporosity, the Optivac system helps to prolong cement fatigue life.[11]



Bone cement mixed with a vacuum mixing system without collection under vacuum. High occurrence of macropores.[32]



Bone cement mixed with, a vacuum mixing system with collection under vacuum.[32]

Safer Working Environment

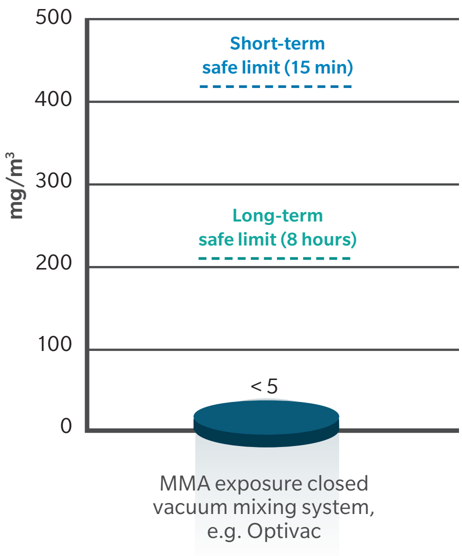
The Optivac system meets modern safety standards and the high demands of mixing bone cement. Bone cement in the Optivac system is mixed and delivered in the same cartridge, preventing direct contact of the user with the bone cement.

By drawing monomer fumes through special filters, the Optivac system minimizes methylmethacrylate (MMA) exposure in the OR to barely detectable levels.[21,22]

The packaging is PVC free and the blister pack, which also serves as a working tray, reduces waste.

- Designed to reduce skin contact and sensitizing risk
- Reduced air exposure to methylmethacrylate[21,22]
- Latex free

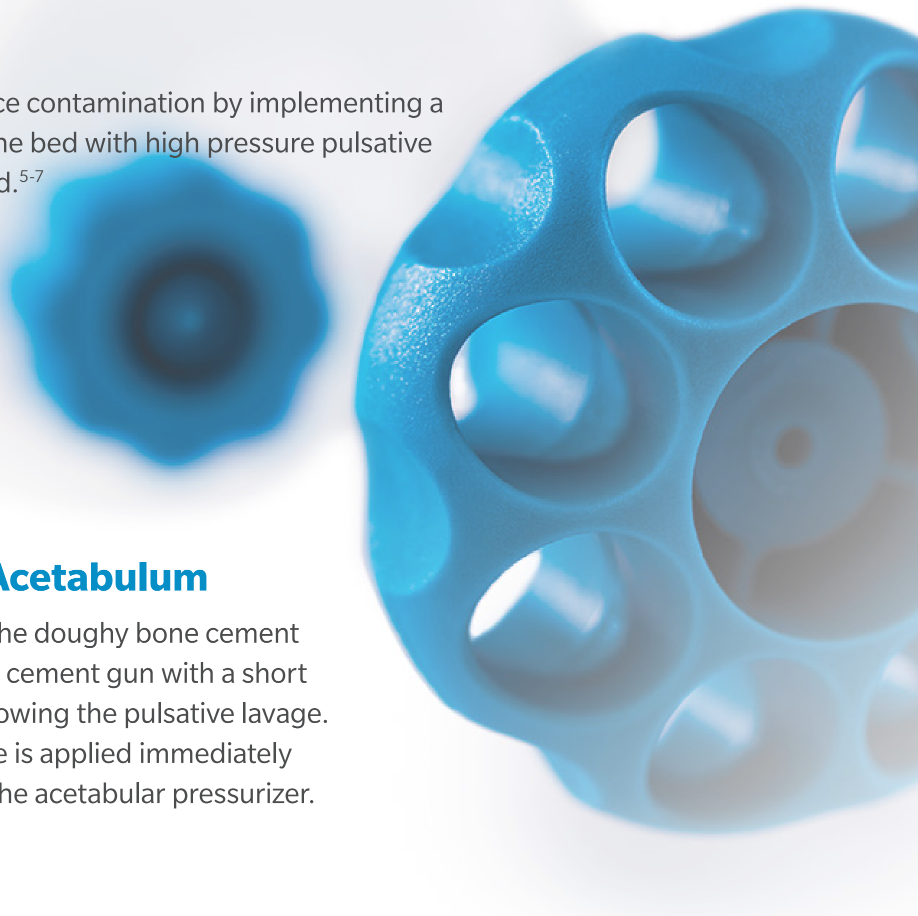
MMA Exposure Levels

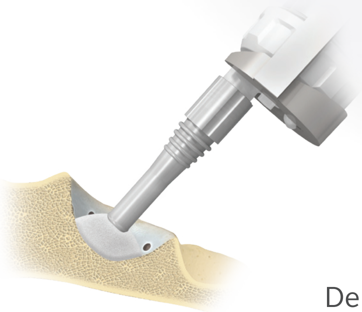


Monomer (MMA) exposure when using the Optivac system has been measured at barely detectable levels far below the safety limits established by law.[35]

Delivery of Bone Cement

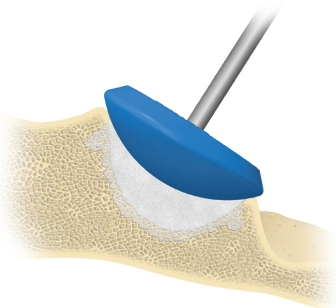
Prevent implant-cement interface contamination by implementing a ”no-touch” policy. Clean the bone bed with high pressure pulsative lavage until clear fluid is recieved.[5-7]





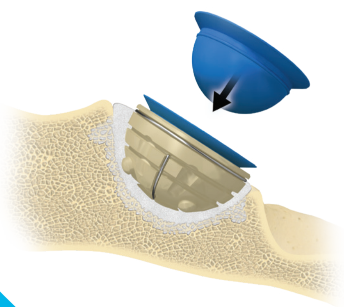
Acetabulum

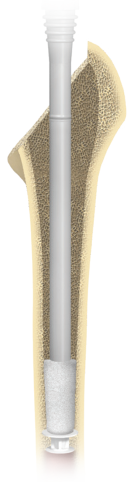
Deliver the doughy bone cement using the cement gun with a short nozzle, following the pulsative lavage. Pressure is applied immediately by using the acetabular pressurizer.



Femur

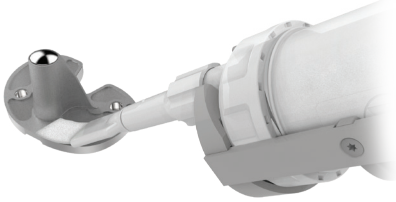
Deliver the doughy bone cement in a retrograde fashion. Apply the proximal seal and pressurize the bone cement.

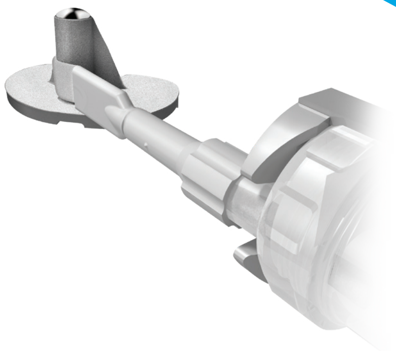




Hip Replacements

Knee Replacements



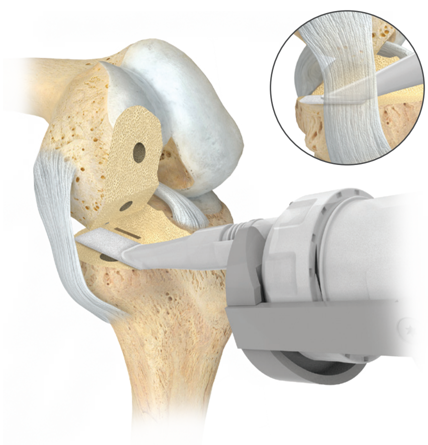


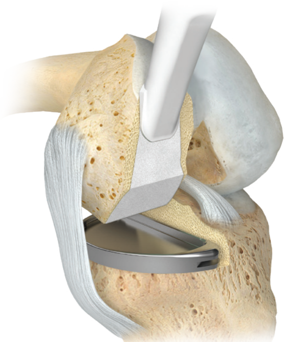
Implant-Cement Interface

Apply the sticky bone cement on implant as early as possible. Use cement gun and appropriate delivery devices, such as knee nozzles.

Cement-Bone Interface

Deliver the doughy bone cement
with a cement gun and appropriate delivery devices,
such as knee nozzles and pressurizers.





Factors Influencing Bone Cement Handling Characteristics

Temperature

- Cement temperature
- Body temperature
- OR temperature
- Storage temperature

Higher temperature = faster setting time

Time

- From storage to mixing
- From mixing to application
- Application time
- Setting time
- Start the clock immediately when the powder and liquid meet

Test – get to know your cement

Mixing Method

- Vacuum (closed system)
- Bowl (open air)

Read relevant information*

Type of Cement

- Low viscosity
- Medium viscosity
- High viscosity

Read relevant information*

Handling

- Vigorous kneading of the cement may speed up the polymerization process
- Use the right proportion of powder and liquid

Standardize your cement handling

Improved Working Environment

- Use an extra pair of PE gloves
- A closed system minimizes monomer fumes and skin contact
- Use a combined system for mixing and delivery

Rubber gloves do not protect against momomer

* See Product Instructions for Use

Notes

Ordering Information

Hi-Fatigue Bone Cements

Product	Description	Part Number	Units/Box
	**Hi-Fatigue Bone Cement 1 x 40G**	00-1120-140-01	20
	Hi-Fatigue Bone Cement 2 x 40G	00-1120-240-01	15
	Hi-Fatigue G Bone Cement (with Gentamicin) 1 x 20G	00-1121-120-01	20
	Hi-Fatigue G Bone Cement (with Gentamicin) 1 x 40G	00-1121-140-01	20
	Hi-Fatigue G Bone Cement (with Gentamicin) 2 x 20G	00-1121-220-01	15
	Hi-Fatigue G Bone Cement (with Gentamicin) 2 x 40G	00-1121-240-01	15

Optivac® Vacuum Mixing Systems

Product	Description	Part Number	Units/Box
	**Optivac S**	4161	10
	Optivac M	4160	10
	Optivac L	4152	10
	Optivac Hip Set	4150	10

Optivac Delivery Guns

Product	Description	Part Number	Units/Box
	**Optigun™**	4193	1
	**Optigun Ratchet**	4195	1

Vacuum Pumps

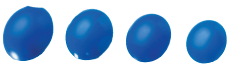
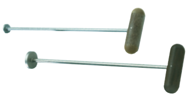
The Vacuum Pump can be powered by air or nitrogen. The air/nitrogen source should deliver a minimum of 5 bar absolute pressure (0.5 MPa, 70 psi) and a maximum of 9 bar. The pump requires an air flow of 50 l/min. The pump design provides a constant and optimal vacuum level of at least 85%, i.e. 0.15 bar.

Product	Description	Part Number	Units/Box
	**Zimmer® Vacuum Foot Pump II-Air Connector**	00-5049-086-00	1
	**Vacuum Pump**	4232	1
	**Vacuum Pump without Hose**	4235	1

Accessories

Product	Description	Part Number	Units/Box
	Slim Nozzle	4154	5
	**Revision Nozzle**	4155	5
	**23-Degree Pressurizing Nozzle**	4148	5
	**Knee Nozzle**	4146	5
	**Knee Cementation Nozzle**	4312	10
	**Pressurizer Femur II**	430900	5
	**Cement Press Support Plate II**	4197	1

Acetabular Pressurizers

Product	Description	Part Number	Units/Box
	**Acetabular Pressurizer 50 mm**	4316	1
	Acetabular Pressurizer 57 mm	4317	1
	Acetabular Pressurizer 63 mm	4321	5
	Acetabular Pressurizer 71 mm	432-2	1
	**Handle For Acetabular Pressurizer 4321, 4322**	4327	1
	Handle For Acetabular Pressurizer 4316, 4317	4318	1

Notes

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* Laboratory test results not necessarily indicative of clinical performance.

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