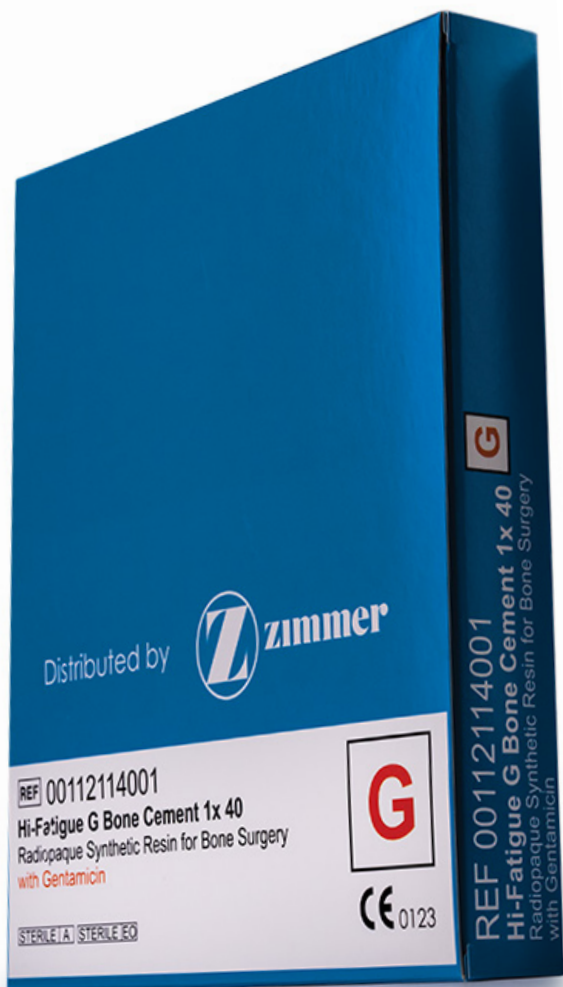


Hi-Fatigue G Bone Cement, Hi-Fatigue Bone Cement and Optivac® Vacuum Mixing System

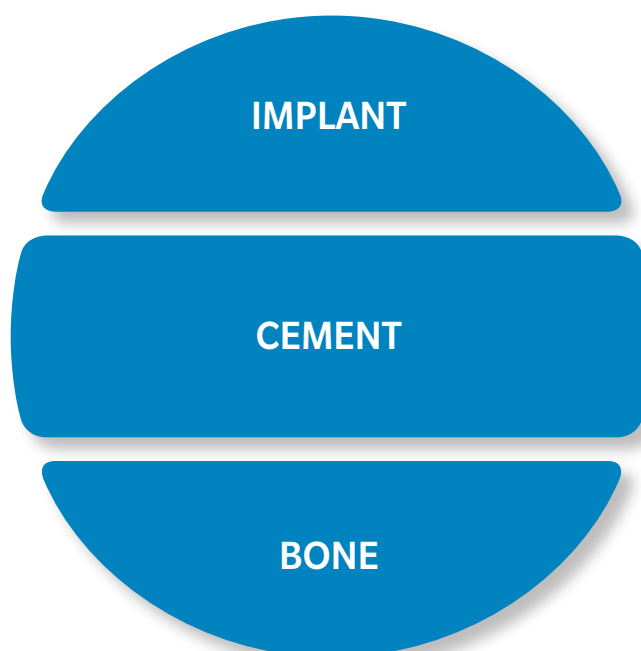


Solutions for Modern Cementing Technique^{1,2}

Implant-Cement Interface

Bone Cement

Cement-Bone Interface



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 results¹⁶
- On the market since 2008
- Formulation specially developed for increased fatigue properties¹⁷
- High viscosity - for lower risk of revision¹⁸
- 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 results¹⁶
- On the market since 2008
- Formulation specially developed for increased fatigue properties¹⁷
- High viscosity - for lower risk of revision¹⁸
- Easy handling and wide application window



Optivac Vacuum Mixing System

- On the market since 1993 and highly documented⁹⁻¹³
- Mixing **and** collecting under vacuum, improving cement strength and fatigue life¹⁰⁻¹³
- 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 Results¹⁶

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

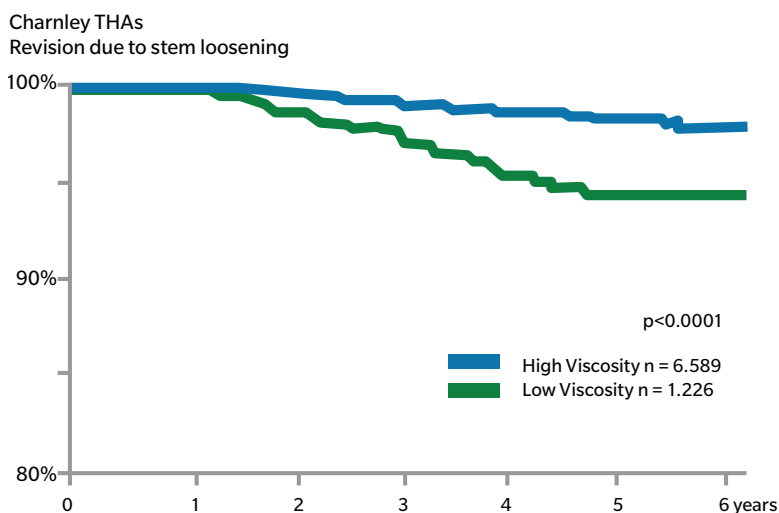
High Viscosity

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 arthroplasty 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}

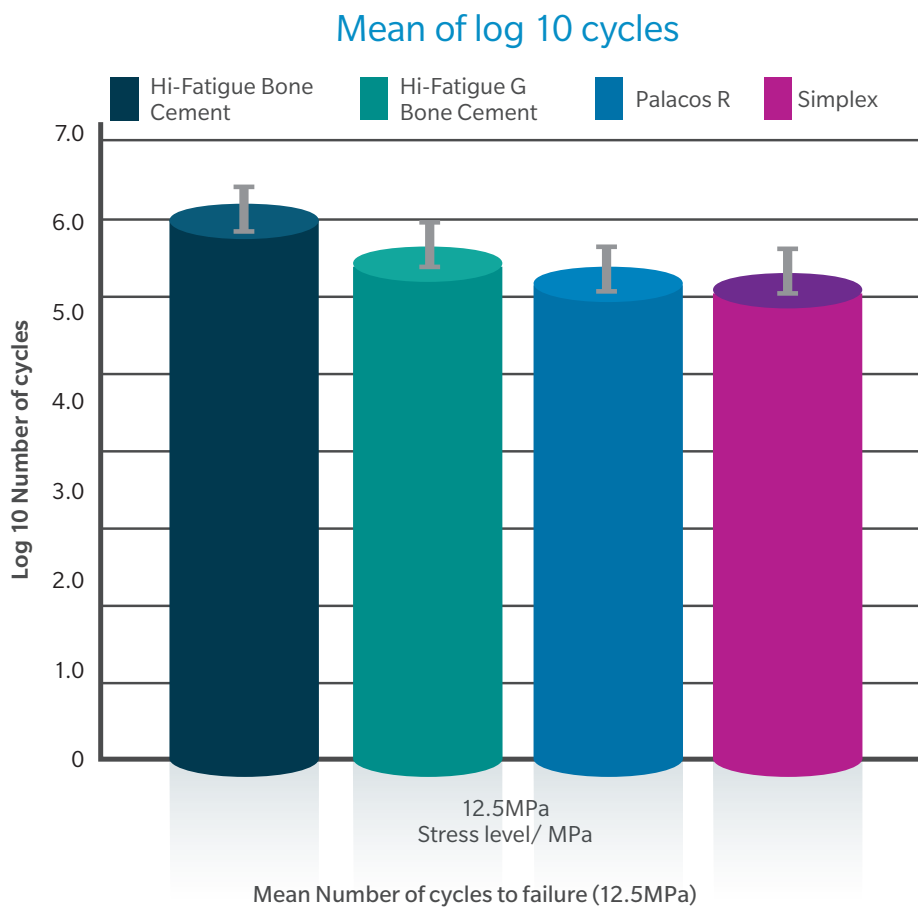


In the Norwegian Arthroplasty Register the use of high viscosity cement with gentamicin has been shown to result in the lowest incidence of revision.¹⁸

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





Easy Handling and Wide Application Window

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

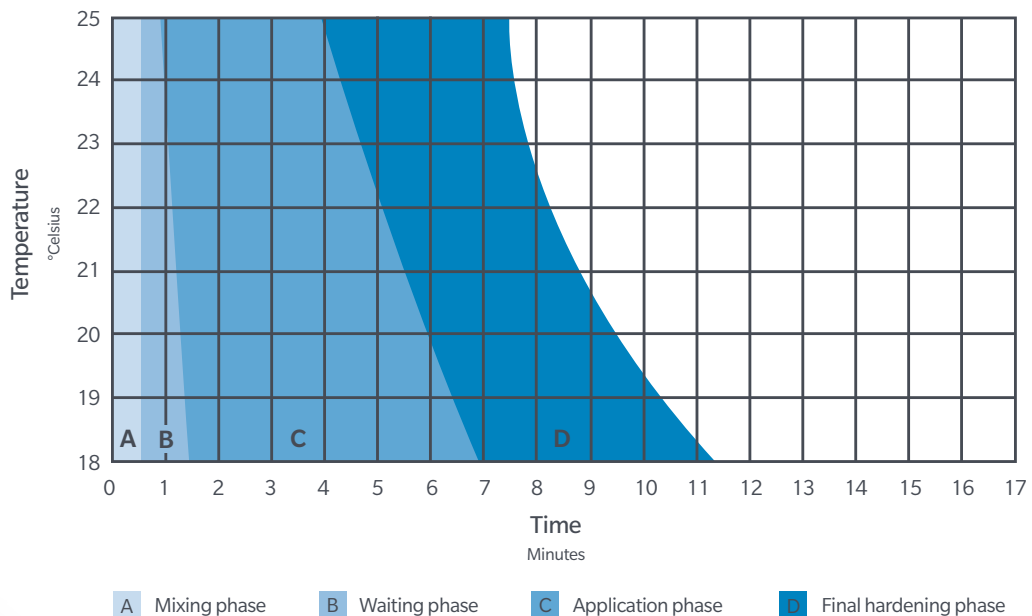
- Initial lower viscosity for easy mixing in a modern mixing system without pre-chilling
- The bone cement will reach its dough phase early and then provide sufficient time for application of cement on bone and implant insertion

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

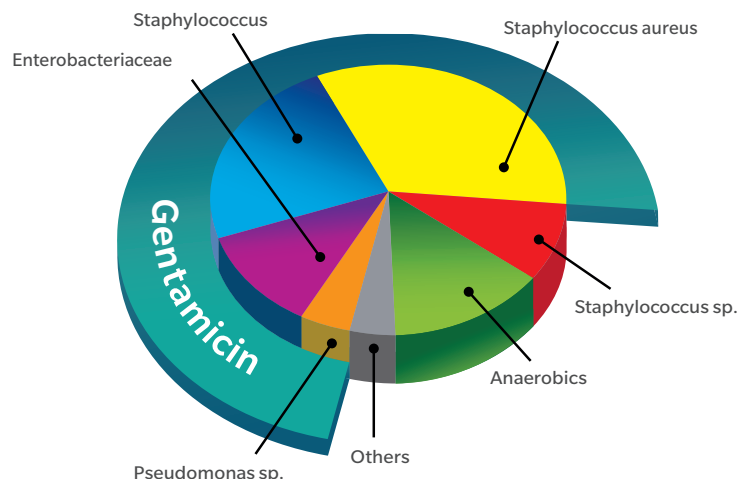


Antibiotic-loaded Cement for Reduced Risk of Revision^{19,20,31}

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

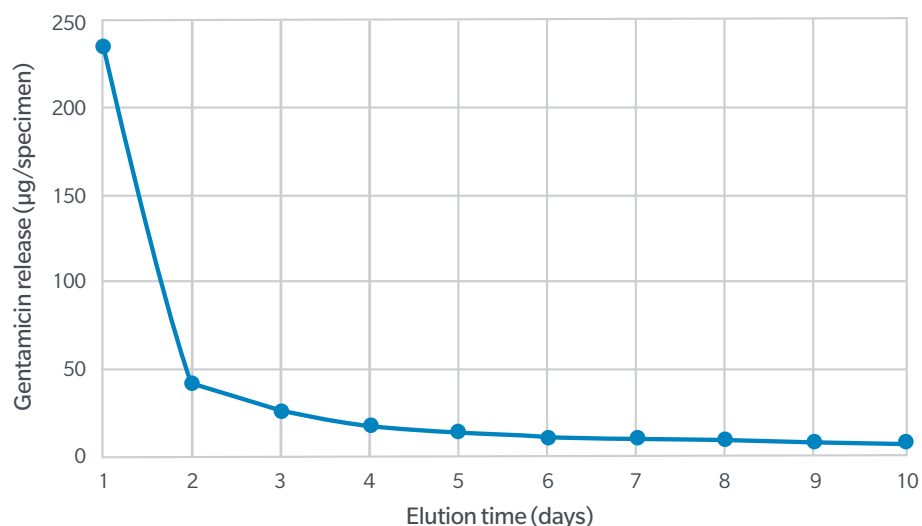


Gentamicin – for Long-Lasting, Local Antibiotic Release

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 Cement¹⁹



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 fatigue life¹⁰⁻¹³
- Lower risk of aseptic loosening caused by cracks in the cement^{9,12}
- Reproducible results⁹⁻¹³
- Safer working environment^{21,22}



Optivac S

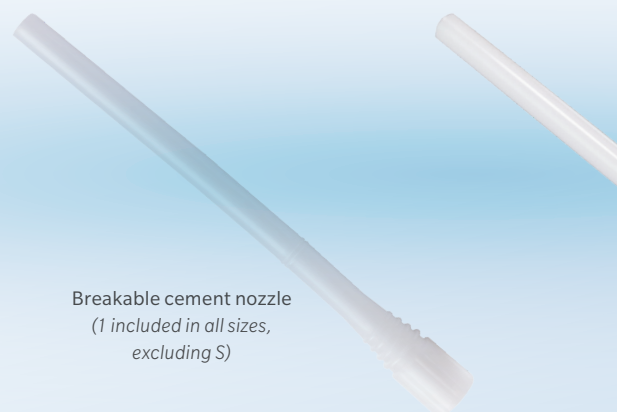
ACCESS



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



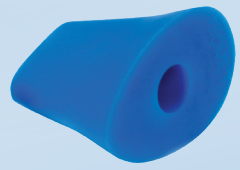
Slim Nozzle



Cement Press Support Plate II



Knee Cementation Nozzle

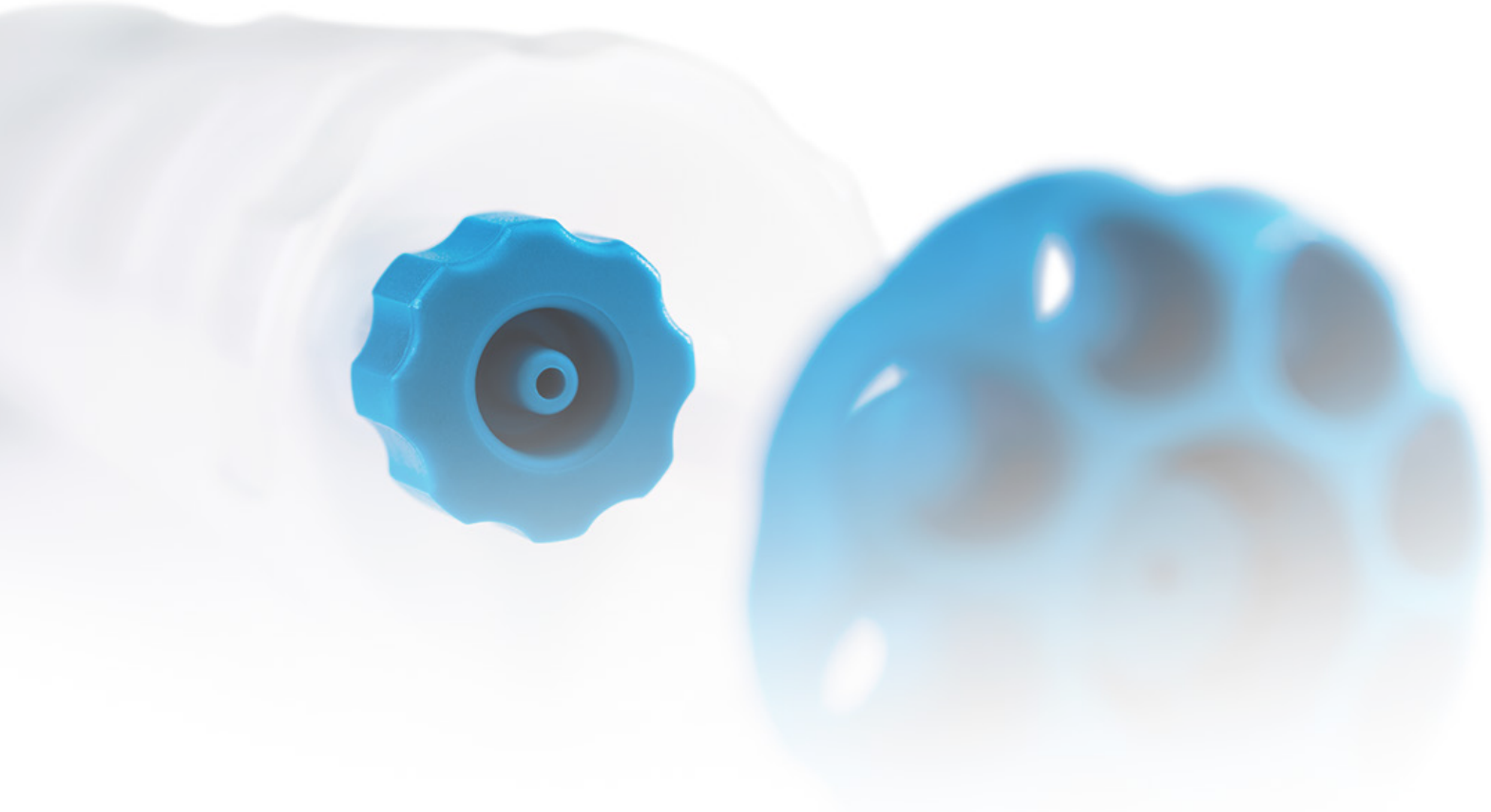


Femoral pressurizer
(1 included in the Optivac M,
Optivac Hip Set and Optivac Hip+ Set)



Acetabular Press

Mixing and Collection Under Vacuum

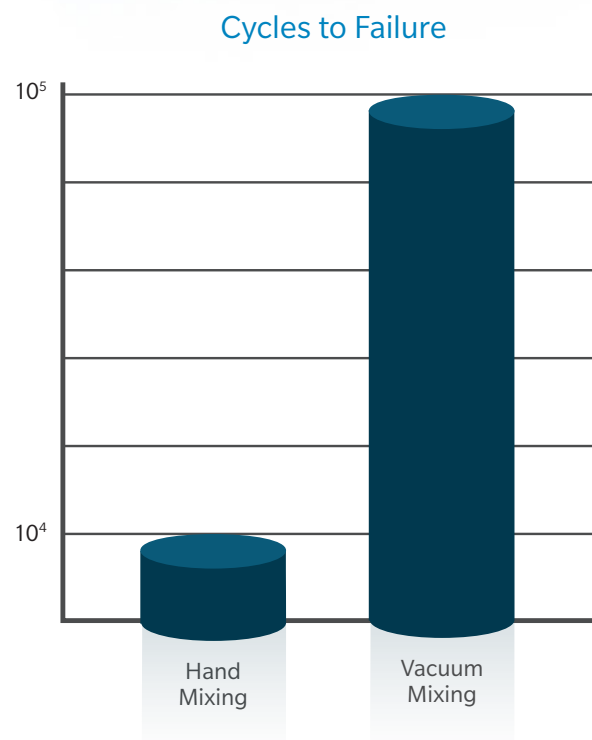


Minimized Porosity and Improved Mechanical Strength

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.



The fatigue life improves 10 times with vacuum mixing compared to hand mixing³⁴

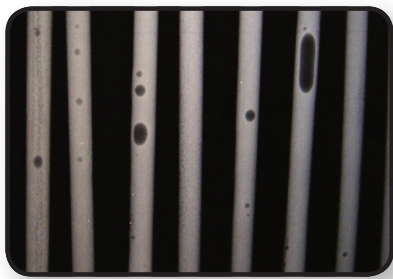
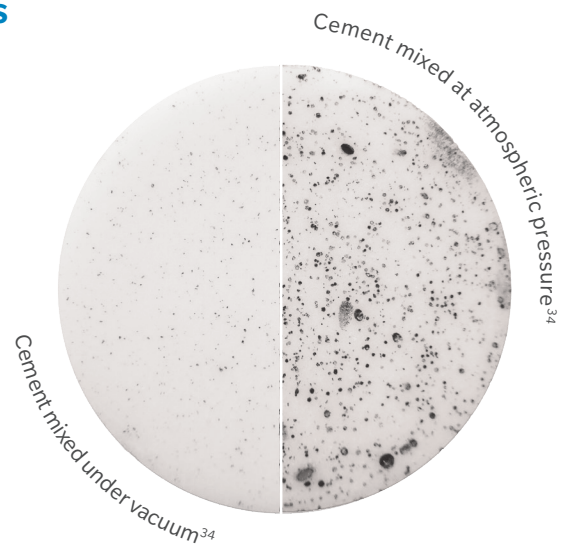
Mixing and Collection Under Vacuum Reduces Both Macropores and Micropores^{10,14}

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

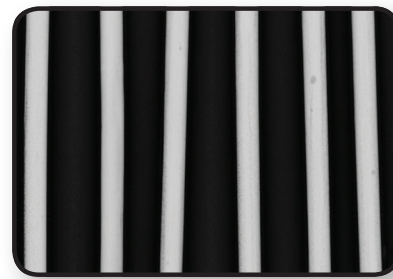
1. Macropores, with a pore diameter of more than 1.0 mm.¹⁴
2. Micropores, with a pore diameter of 0.1–1 mm.¹⁴

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

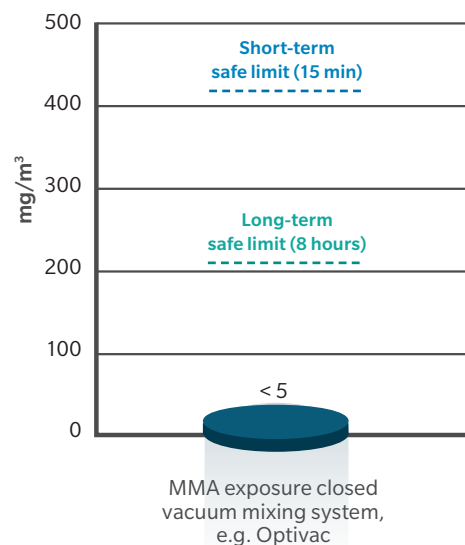
The Optivac system meets modern safety standards and the high demands of mixing bone cement. Bone cement in the Optivac system is mixed and delivered in the same cartridge, preventing direct contact of the user with the bone cement.

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

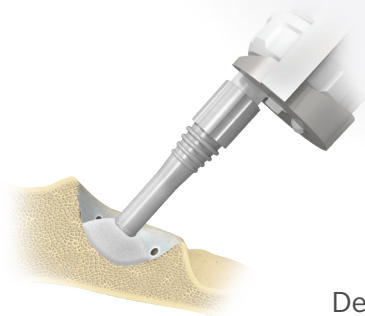
MMA Exposure Levels



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

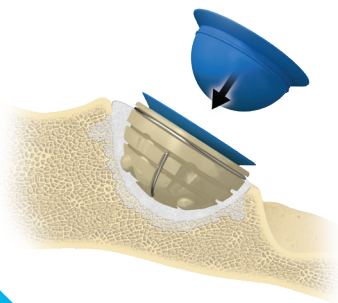
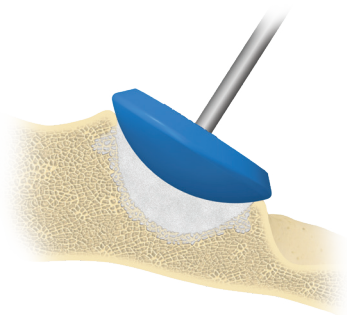
Delivery of Bone Cement

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

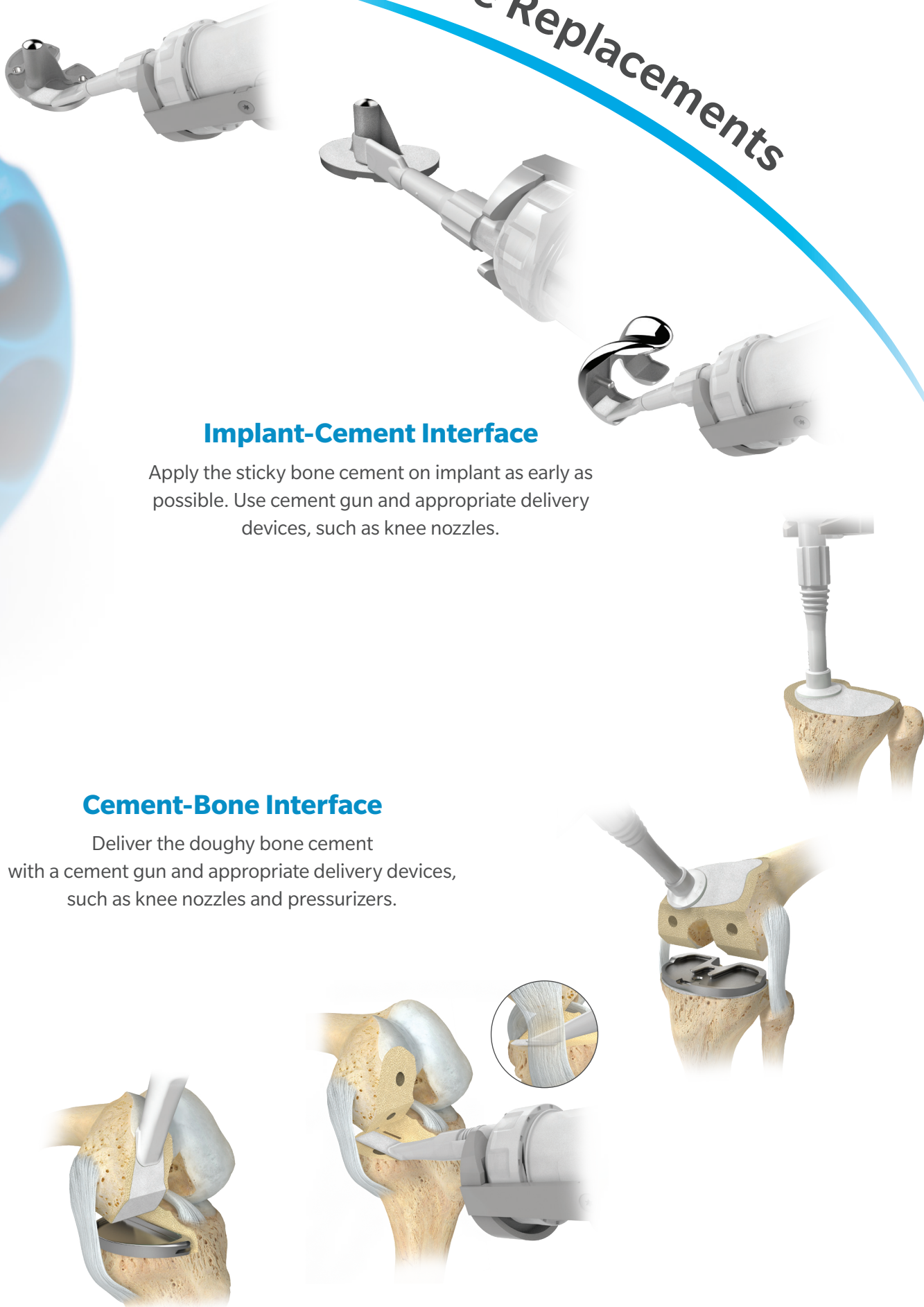
Knee Replacements

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.

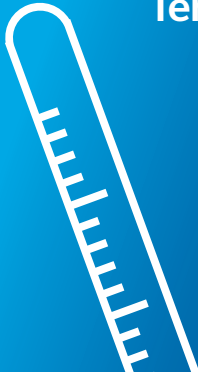
Cement-Bone Interface

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

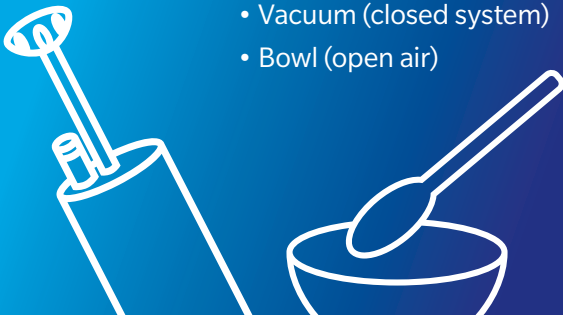
Time



- 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

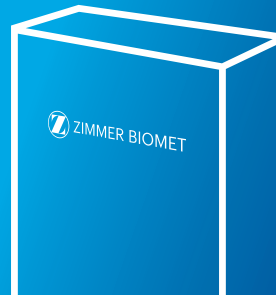
Mixing Method



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

Read relevant information*

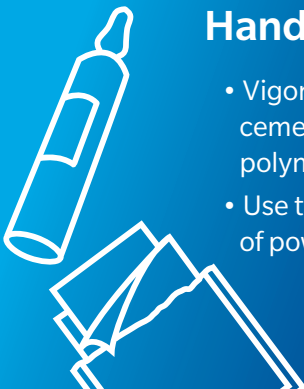
Type of Cement



- 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 monomer

* See Product Instructions for Use

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






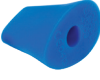

Product	Description	Part Number	Units/Box
	Optigun™	4193	1
	Optigun Ratchet	4195	1

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

References

1. Malchau H, et al. Prognosis of Total Hip Replacement. The National Hip Arthroplasty Register: 9-11, 1996.
2. Malchau H, et al. The Swedish Total Hip Replacement Register. *The Journal of Bone and Joint Surgery*. 84A: 2-20, 2002.
3. Breusch S, et al. Optimal Cementing Technique - The Evidence: What is Modern Cementing Technique? In: The Well-Cemented Total Hip Arthroplasty. Chapter 6.1. Springer Verlag 2005.
4. Swedish Hip Arthroplasty Register. Annual Report 1998.
5. Kalteis T, et al. An experimental comparison of different devices for pulsatile high-pressure lavage and their relevance to cement intrusion into cancellous bone. *Archives of Orthopaedic and Trauma Surgery*. 127(10):873-7, 2007.
6. Breusch SJ, et al. Pulmonary Embolism in Cemented Total Hip Arthroplasty. The Well-Cemented Total Hip Arthroplasty. Heidelberg. 320-31, 2005.
7. Breusch SJ, et al. Lavage technique in total hip arthroplasty: jet lavage produces better cement penetration than syringe lavage in the proximal femur. *The Journal of Arthroplasty*. 15(7):921-927, 2000.
8. Kühn, K-D. Properties of Bone Cement: What is Bone Cement? In: The Well-Cemented Total Hip Arthroplasty. Chapter 3.1. Springer Verlag 2005.
9. Breusch SJ. Cementing techniques in Total Hip Replacement: factors influencing survival of femoral components. In: Bone Cements and Cementing Technique; Walenkamp GHIM, Murray DW (eds) Berlin, Heidelberg, Springer Verlag 2001.
10. Wang J-S, et al. Porosity of bone cement reduced by mixing and collecting under vacuum. *Acta Orthopaedica Scandinavica*. 64 (2): 143-146, 1993.*
11. Wang J-S, et al. Bone Cement Porosity in Vacuum Mixing Systems, Bone Cements and Cementing Technique. Walenkamp, Murray (Eds). Springer Verlag 2001.*
12. Dunne N-J, et al. Influence of the mixing techniques on the physical properties of acrylic bone cement. *Biomaterials*. 22: 1819-1826, 2001.*
13. Wilkinson JM, et al. Effect of mixing technique on the Properties of Acrylic Bone-Cement. *The Journal of Arthroplasty*. 15:663-667, 2000.*
14. Lewis G. Properties of Acrylic Bone Cement: State of the Art Review. *Journal of Biomedical Materials Research*. 38(2):155-82, 1997.*
15. Reading AD, et al. A Comparison of 2 Modern Femoral Cementing Techniques: Analysis by Cement-bone Interface Pressure Measurements, Computerized Image Analysis, and Static Mechanical Testing. *The Journal of Arthroplasty*. 15(4):479-87, 2000.
16. Jørgensen P. B., et al. Equivalent hip stem fixation by Hi-Fatigue G and Palacos R + G bone cement: a randomized radiostereometric controlled trial of 52 patients with 2 years' follow-up. *Acta Orthopaedica*. Accepted 2019-02-08.
17. Tanner, K.E. Test report. Fatigue testing of four bone cements for aap Biomaterials GmbH & Co. University of Glasgow. 24 Oct, 2007.*
18. Havelin LI, et al. Prosepective Studies of the Hip Prostheses and Cements. A presentation of the Norwegian Arthroplasty Register 1987-1999. Scientific Exhibition presented at the 67th Annual Meeting of the American Academy of Orthopaedic Surgeons, March 15-19, 2000, Orlando, USA.
19. Data on file at Osartis. Report no. 1004-03FBA1701 Comparison of Gentamicin release.*
20. Parvizi J, et al. Efficacy of antibiotic-impregnated cement in total hip replacement. A meta-analysis. *Acta Orthopaedica*. 79(3): 335-341, 2008.
21. Report from SP Technical Research Institute of Sweden. Airborne Methyl Methacrylate Monomer During the use of Different Bone Cement Mixing Systems. Aug 13, 2007.*
22. Schlegel UJ, et al. Pre-packed vacuum Bone cement mixing systems. A further step in reducing methylmethacrylate exposure in surgery. *Annals of Occupational Hygiene*. June 30: 1-7, 2010.*
23. Murphy B.P, et al. On the magnitude and variability of the fatigue strength of acrylic bone cement. *International Journal of Fatigue*. 22(85): 864, 2000.*
24. Kühn K-D. Bone Cements, Up-to-Date Comparison of Physical and Chemical Properties of Commercial Materials. Springer Verlag: Berlin. 234, 2000.
25. Benjamin J, et al. Cementing technique and the effects of bleeding. *The Journal of Bone and Joint Surgery*. 69B(4): 620-624, 1987.
26. Malchau H, et al. Prognosis of Total Hip Replacement. Scientific Exhibition presented at the 67th Annual Meeting of the American Academy of Orthopaedic Surgeons. March 15-19, 2000.
27. Espehaug, B, et al. Antibiotics Prophylaxis in Total Hip Arthroplasty. *Journal of Bone and Joint Surgery*. 79(4):590-595, 1997.
28. Buchholz H.W., et al. Über die Depotwirkung einiger Antibiotika bei Vermischung mit dem Kunstharz Palacos. (Timed release of some antibiotics in admixture to the artificial resin Palacos). *Chirurg*. 40: 511-515, 1970.
29. Wahlig H, et al. Über die Freisetzung von Gentamicin aus Polymethylmethacrylat. I. Experimentelle Untersuchungen in vitro. (Release of Gentamicin from Polymethyl Methacrylate. I Experimental in vitro tests). *Langenbecks Arch. Chir*. 331: 169-192, 1972.*
30. Wahlig H, et al. Über die Freisetzung von Gentamicin aus Polymethylmethacrylat. II. Experimentelle Untersuchungen in vivo. (Release of Gentamicin from Polymethyl Methacrylate. II Experimental in vivo tests). *Langenbecks Arch. Chir*. 331: 193-212, 1972.
31. Scheerlinck T, et al. Cement mantle thickness does not influence serum or local gentamicin concentrations in hybrid total hip arthroplasty: a randomised controlled trial. *HIP International*. Jul;28(4):415-421, 2018.
32. Wang J-S, et al. Is there any difference between vacuum mixing systems in reducing bone cement porosity? *Journal of Biomedical Materials Research*. 33(2): 115-8, 1996.*
33. Mau H, et al. Comparison of various vacuum mixing systems and bone cements as regard reliability, porosity and bending strength. *Acta Orthopaedica Scandinavica*. 75(2): 160-172, 2004.*
34. Graph based on Lidgren L, et al. Bone cement improved by vacuum mixing and chilling. *Acta Orthopaedica Scandinavica*. 57, 27-32, 1987.*
35. EH40/2005 Workplace exposure limits, ISBN 0-7176-2977-5.

* Laboratory test results not necessarily indicative of clinical performance.

All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to Zimmer Biomet or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of Zimmer Biomet.

This material is intended for health care professionals. Distribution to any other recipient is prohibited.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

Check for country product clearances and reference product specific instructions for use. Not for distribution in France.

Hi-Fatigue is a trademark of OSARTIS GmbH.

Palacos® is a registered trademark of Heraeus Medical GmbH.

Simplex® is a registered trademark of Stryker or its affiliates.

©2019 Zimmer Biomet



ZIMMER BIOMET

Your progress. Our promise.®