BONE CEMENT
History, Performance, and Choice
The Bone Cementing Story
Started with DePuy Synthes Companies…

CMW Laboratories, now part of DePuy Synthes Companies, was a pioneer in manufacturing bone cement for modern orthopaedic procedures. DePuy Synthes has been designing and manufacturing bone cement for over 50 years and offers a bone cement portfolio with the longest clinical history in total joint arthroplasty.

In 1958, Sir John Charnley pioneered the use of bone cement in hip surgery, starting with the treatment of hip fractures with Nu-Life dental cement manufactured by CMW Laboratories.¹ The Charnley low-frictional arthroplasty was introduced into routine clinical practice in 1962² and the use of cement was critical in its success.² CMW Laboratories supported the efforts of Sir John Charnley to advance the technique and began the commercial manufacture of bone cement for Total Joint Arthroplasty (TJA) in 1966. CMW Laboratories was acquired by DePuy Orthopaedics in 1994 and became part of the DePuy Synthes Companies in 2012. The heritage of the original CMW™ Bone Cements is now part of DePuy Synthes’ product portfolio, which has grown to include the SMARTSET® Bone Cements. For over 50 years, DePuy Synthes has partnered with surgeons to provide clinical solutions to optimize patient care.

DePuy Synthes works with surgeons to provide a wide range of clinical solutions for their patients. The comprehensive portfolio of cements and mixing systems available today reflects that dedication.
CEMENTING HISTORY

1958  Sir John Charnley used Nu-Life acrylic cement for the first time in hip fracture surgery¹

1962  Sir John Charnley’s Low Friction Arthroplasty Procedure was introduced into routine clinical practice²

1964  Sir John Charnley began collaborating with CMW Laboratories (now part of DePuy Synthes Companies) on a non-pigmented cement with no additives¹

1966  CMW Laboratories (now part of DePuy Synthes Companies) began commercial manufacture of the first bone cement indicated for total joint arthroplasty; this successful formulation is the basis for DePuy CMW™ 1 Bone Cement

1984  CMW 1 Radiopaque Bone Cement, CMW™ 2, and CMW™ 3 Bone Cements introduced (later branded as DePuy CMW 1, DePuy CMW 2, and DePuy CMW 3 Bone Cements)

1991  CMW 1 Bone Cement, and CMW 3 Bone Cement with Gentamicin introduced in Europe (later branded as DePuy CMW 1 and DePuy CMW 3 Gentamicin Bone Cements)

1996  ENDURANCE™ Bone Cement introduced in Europe (Gamma irradiated)

1997  ENDURANCE Bone Cement introduced in US (Gamma irradiated) later branded to SMARTSET® MV ENDURANCE Bone Cement in 2005

2003  SMARTSET® HV Bone Cement approved for sale in US and Europe
SMARTSET® GHV Gentamicin Bone Cement introduced in Europe
DePuy CMW 1 Gentamicin Bone Cement approved for sale in the US

2004  SMARTSET® GMV ENDURANCE Gentamicin Bone Cement and SMARTSET GHV Gentamicin Bone Cement cleared by the FDA for second stage of a two stage revision total joint arthroplasty after the initial infection has been cleared

2006  DePuy CMW 2 Gentamicin Bone Cement and DePuy CMW 3 Gentamicin Bone Cement approved for sale in the US

2008  SMARTSET® MV Bone Cement and SMARTSET GMV Gentamicin Bone Cement (ETO Sterilized) introduced in the US
DePuy Synthes’ portfolio of cements has evolved from finely tuned chemical formulations and manufacturing processes in order to fit the needs of orthopaedic surgery. These combined elements impart excellent fatigue strength, antibiotic elution, and handling properties.\textsuperscript{3,4,5}

**FATIGUE LIFE**

Optimum mechanical strength of bone cement is essential in joint replacement if the load bearing capacity of the joint is to be retained. During normal daily activities the cement mantle surrounding knee implants is subjected to complex tensile and compressive stresses. Having a bone cement with a high fatigue strength is therefore very important to the performance of a bone cement.

Fatigue life is measured in laboratory testing. ASTM standard F2118 provides a protocol to characterize acrylic bone cements using standardized methods. The test is designed to compare the fatigue lifetime of different bone cement formulations. Independent laboratory testing to ASTM F2118 of commercially available antibiotic bone cements showed that DePuy Synthes Bone Cements outperform their direct competitors.\textsuperscript{5} The Weibull median number of fatigue stress cycles is accepted methodology for comparing fatigue performance. Table 1 shows the median Weibull results for comparative fatigue testing of commercially available antibiotic bone cements and clearly shows that SMARTSET GHV Gentamicin Bone Cement has greater fatigue strength than Palacos\textsuperscript{®} R+G Gentamicin bone cement (Zimmer\textsuperscript{®}) and Cobalt\textsuperscript{TM} HV Gentamicin bone cement (Biomet\textsuperscript{®}) and SMARTSET GMV Gentamicin Bone Cement has greater fatigue strength than Simplex\textsuperscript{®} P Tobramycin bone cement (Stryker\textsuperscript{®}).\textsuperscript{3,5}
Fatigue life is influenced by a variety of factors, one of which is the method of sterilization. SMARTSET MV Bone Cement and GMV Gentamicin Bone Cement and SMARTSET HV Bone Cement and GHV Gentamicin Bone Cements are sterilized with ETO which preserves the molecular weight of the polymer chains. This leads to improved fatigue strength over cements that are Gamma sterilized. Simplex\textsuperscript{®} P bone cement is sterilized by Gamma radiation which leads to the degradation of polymer chains and reduced fatigue life. The careful design of the DePuy Synthes' Bone Cement portfolio in conjunction with sterilization method result in an offering of bone cements with favorable fatigue properties in comparison to other marketed bone cements as shown in Table 1.

### Table 1

Lewis G. (2012). Comparative fatigue performance of commercially available antibiotic loaded PMMA bone cements. United Kingdom Society for Biomaterials. All testing was performed on antibiotic loaded cements. *In vitro* or bench top testing may not be indicative of clinical performance.
ANTIBIOTIC ELUTION

Antibiotic elution from bone cement is a critical feature. The antibiotic release characteristics of a bone cement are based on the hydrophilic properties of their polymer components. DePuy Synthes’ Bone Cements have been formulated to deliver excellent antibiotic elution profiles.

Gentamicin has long been the preferred choice for inclusion in antibiotic bone cements. The gentamicin used in DePuy Synthes’ Bone Cements has been selected to optimize drug release and maintain mechanical properties like fatigue strength. DePuy Synthes’ Antibiotic Bone Cements are pre-blended with 1 gram active gentamicin per 40 gram pack. This process ensures even distribution of the antibiotic in the polymer resulting in a consistent antibiotic release profile. In vitro tests show that SMARTSET GMV Gentamicin Bone Cement has a higher initial burst release of antibiotic than Simplex® P Tobramycin bone cement (Stryker®) (Table 2). Additionally, SMARTSET GMV Gentamicin Bone Cement has higher cumulative antibiotic release than Stryker® Simplex® P bone cement with tobramycin (Table 3).

SMARTSET GMV Gentamicin Bone Cement and SMARTSET GHV Gentamicin Bone Cement are indicated for use in the second stage of a two stage revision total joint arthroplasty after the initial infection has been cleared.

Comparative Antibiotic Elution Between SMARTSET GMV Gentamicin Bone Cement and Simplex® P With Tobramycin Bone Cement

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<th>Time (Days)</th>
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<tr>
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Table 2
Cumulative Antibiotic Release from PMMA Bone Cements, SMARTSET GMV Gentamicin Bone Cement and Simplex® P With Tobramycin Bone Cement


**Table 3**
DePuy Synthes has the most comprehensive bone cement portfolio on the market today. The portfolio of bone cement products has been designed with surgeon needs in mind. While other companies may offer cements of only one viscosity, DePuy Synthes offers a variety of cement options. The nuances of clinical practice vary by surgeon and the portfolio of cements offered by DePuy Synthes is designed so surgeons with different preferences can make product choices based on their specific technique.

For high-viscosity needs, choose SMARTSET HV Bone Cement. For medium-viscosity needs, choose SMARTSET MV Bone Cement. For fast setting needs, choose DePuy CMW 2 Bone Cements.

INDICATIONS
SMARTSET GMV Gentamicin, SMARTSET GHV Gentamicin, DePuy CMW 1 Gentamicin and DePuy CMW 2 Gentamicin Antibiotic Bone Cements are indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.
# ORDERING INFORMATION

## PRODUCT LIST

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<th>Cat. No.</th>
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<td>3122-040</td>
<td>SMARTSET MV, 40g</td>
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## MIXING SYSTEMS

- 5401-98-000 SMARTMIX® Tower Cartridge
- 5401-76-501 SMARTMIX® CTS Bowl
- 5401-37-000 SMARTMIX® Open Mixing Bowl
- 5401-39-000 SMARTMIX® Mini
- 83-1615 SMARTMIX® Cemvac® Cartridge Mixing System
References:


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Limited Warranty and Disclaimer: DePuy Synthes Joint Reconstruction products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.