

# Endurance<sup>®</sup>

COPOLYMER BONE CEMENT



A HERITAGE  
CEMENTED  
IN TIME

# ENDURANCE...CEMENTING EXCELLENCE IN ORTHOPAEDICS FOR NEARLY 40 YEARS

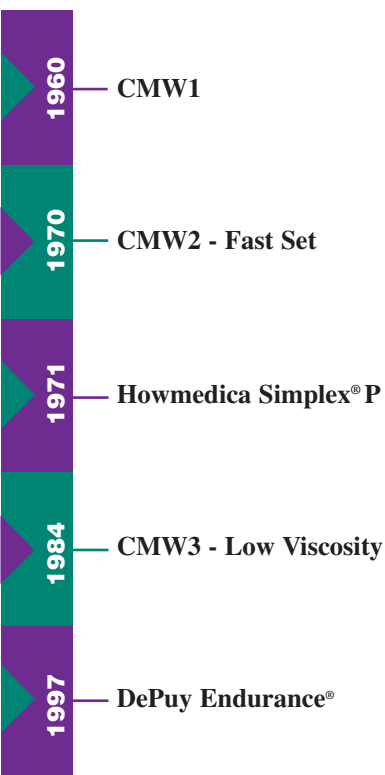
## A HERITAGE CEMENTED IN TIME

In 1994, DePuy continued its tradition of



performance and excellence in orthopaedics by acquiring CMW Laboratories. CMW is world renowned for its unprecedented years of

excellence in bone cement technology.



Sir John Charnley and CMW began working together in 1958 to develop bone cements exclusively for orthopaedic applications. Today, DePuy, the first name in orthopaedics, offers bone cements for a variety of orthopaedic surgical applications.

## PROVEN CLINICAL PERFORMANCE

DePuy CMW provides a strong portfolio of products with proven clinical performance. Used in over one million cemented arthroplasties, the documented clinical performance is unsurpassed.

Wroblewski et al., reported that 19 to 25 year “clinical results remained excellent” with the

DePuy CMW cement.<sup>1</sup> Other published

results, including Older, have

shown extensive clinical

studies documenting a 94

percent implant survivorship

at 10-12 years with

DePuy CMW cements.<sup>2</sup>



## PROVEN CHEMISTRY WITH PREFERRED HANDLING CHARACTERISTICS

With proven chemistry and an

unparalleled history of manufacturing

expertise, Endurance Bone Cement is the ideal choice

for modern cementing techniques. Strength, performance

and preferred handling characteristics make the

DePuy Endurance Bone Cement the “cement of choice”

for physicians around the world.

# **ENDURANCE® BONE CEMENT**

## **Medium Viscosity Bone Cement**

### **INDICATIONS FOR USE**

Endurance™ Bone Cement is indicated for the fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions and revision of previous arthroplasty.

### **CONTRAINDICATIONS**

Endurance Bone Cement is contraindicated in the presence of active or incompletely treated infection which could involve the site where the cement is applied.

### **WARNINGS**

Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements.

Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest. For this reason, patients should be monitored carefully for any change in blood pressure during and immediately following the application of the cement.

The surgeon should, by specific training and experience, be thoroughly familiar with the properties, handling characteristics and application of bone cements. Because the handling and curing characteristics of this cement vary with temperature and mixing technique, they are best determined by the surgeon's actual experience.

Because the liquid monomer is highly volatile and flammable, the operating room should be adequately ventilated to eliminate as much monomer vapor as possible. Ignition of monomer fumes caused by use of electrocautery devices in surgical sites near freshly implanted bone cements has been reported.

Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer, which may produce irritation of the respiratory tract, eyes and possibly the liver. Personnel wearing contact lenses should not be near or involved in mixing this bone cement.

### **PRECAUTIONS**

The liquid component has caused contact dermatitis in those handling and mixing it. Strict adherence to the instructions for mixing the powder and liquid components may reduce the incidence of this complication.

The liquid component is a powerful lipid solvent. This liquid component should not be allowed to come into contact with rubber or latex gloves. Wearing of a second pair of gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The mixed bone cement should not make contact with the gloved hand until the cement has acquired the consistency of dough. This usually occurs between 2 and 3 minutes after the liquid and powder components have been mixed.

Inadequate fixation or unanticipated postoperative events may affect the cement-bone interface and lead to micromotion of

cement against bone surface. Under these circumstances, a fibrous tissue layer may develop between the cement and the bone, and loosening of the prosthesis may occur. For this reason, long-term follow-up is advised for all patients on a regularly scheduled basis.

Polymerization of the bone cement is an exothermic reaction which occurs while the cement is hardening in situ. The released heat may damage bone or other tissue surrounding the implant.

Extrusion of the bone cement beyond the region of its intended application may occur.

The safety of bone cement in pregnant women or in children has not been established.

Ensure that the powder and liquid components to be mixed together have the same lot number, since the monomer and polymer components are individually formulated for each batch.

The product should not be used after the expiration date printed on the package.

The polymer component may be disposed of in a landfill. The liquid component can be evaporated under a well ventilated hood or absorbed by an inert material and transferred in a suitable container for deposition in a landfill.

### **ADVERSE REACTIONS**

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements include myocardial infarction, cardiac arrest, cerebrovascular accident and pulmonary embolism.

The most frequent adverse reactions reported with acrylic bone cements are transitory fall in blood pressure, thrombophlebitis, hemorrhage and hematoma, loosening or displacement of the prosthesis, superficial or deep wound infection, trochanteric bursitis and short-term cardiac conduction irregularities.

Other adverse reactions include heterotopic new bone formation and trochanteric separation.

Other potential adverse events reported for acrylic bone cements include: pyrexia due to an allergy to the bone cement; hematuria, dysuria, bladder fistula, and delayed sciatic nerve entrapment due to extrusion of the bone cement beyond the region of its intended application; and adhesions and stricture of the ileum due to the heat released during polymerization.

### **LIMIT OF USEFULNESS**

Current storage stability tests indicate that Endurance Bone Cement has a shelf-life of 3 years when stored below 25°C and protected from light.

### **CAUTION**

Federal Law (USA) restricts this device to sale by or on the order of a physician.

## ORDERING INFORMATION

	Catalog No.	Description
	5450-49-000	<b>Endurance Bone Cement 20g</b> (This package contains: 1 sterile bag with 20g of powder, 1 sterile ampoule containing 9.44g of liquid)
	5450-50-000	<b>Endurance Bone Cement 40g</b> (This package contains: 1 sterile bag with 40g of powder, 1 sterile ampoule containing 18.88g of liquid)
	5450-51-000	<b>Endurance Bone Cement 80g</b> (This package contains: 1 sterile bag with 80g of powder, 2 sterile ampoules containing 18.88g of liquid)
	5401-30-000	<b>Prism Vacuum Mixing Bowl, Single Mix</b>
	5401-31-000	<b>Prism Vacuum Mixing Bowl, Double Mix</b>
	5401-32-000	<b>Prism Foot Pump</b>
	5401-33-000	<b>Prism II Vacuum Mixing Cartridge System</b>
	5401-34-000	<b>Prism II Cement Injection Gun</b>
	5401-43-000	<b>Prism Syringe Set</b>
	5401-53-000	<b>Prism 8.5mm Diameter Nozzle/Extruder</b>
	5461-01-000	<b>Femoral Prep-Kit with Restrictors</b>
	5461-02-000	<b>Femoral Prep-Kit without Restrictors</b>
	5461-10-000	<b>Small Universal Restrictor</b>
	5461-12-000	<b>Large Universal Restrictor</b>
	5461-22-000	<b>Femoral Brush</b>
5461-26-000	<b>Femoral Pressurizer</b>	
5461-28-000	<b>Cup Curette</b>	
5461-30-000	<b>Spatula/Ring Curette</b>	
5402-06-000	<b>DePuy 6" Femoral Canal Sponge</b>	
5402-08-000	<b>DePuy 8" Femoral Canal Sponge</b>	
5402-09-000	<b>DePuy Acetabular Sponge</b>	

Simplex® P is a registered trademark of Pfizer Hospital Products Group, Inc., Rutherford, New Jersey.  
Endurance® is a registered trademark and Prism™ is a trademark of DePuy Orthopaedics, Inc.

### References:

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2. Older, J.: Low-Friction Arthroplasty of the Hip, *Clinical Orthopaedics and Related Research*, No. 211, October 1986, pp. 36-42.
3. Coutts, R.D.: Load Effect on Fatigue Test Failure of Palacos-R and Simplex P Bone Cements, *Abstract at The Hip Society Summer Meeting*, September 1996.
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8. Linder, L.: Boneloc® - The Christiansen Experience Revisited, *Acta Orthopaedica Scandinavia*, 1995; 66(3), pp. 205-206.
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10. Jefferiss, C.D. and Lee, A.J.: Thermal aspects of self-curing polymethylmethacrylate, *Journal of Bone and Joint Surgery (Br)*, 1975 Nov; 57(4), pp. 511-518.
11. CMW Test Report on Exotherm Temperatures
12. CMW Test Report on Reduced Air Volume in Powder



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