

- 1 Malchau H, Herberts P, Soderman P and Oden A, 2000. Update from the Swedish National Hip Arthroplasty Registry 1979-1998. Scientific exhibit AAOS, March 15-19, Orlando, Florida, USA.
- 2 James SP, Jasty M, Davies J, Piehler H and Harris WH, 1992. A fractographic investigation of MMA bone cement focussing on the relationship between porosity reduction and increased fatigue life. J Biomechanical Materials Res, 26, 651-662
- 3 Paul, 1976. Approaches to design; Force actions transmitted by joints in the human body. Proc R Soc Lond B, 192, 163-172
- 4 Schmalzried TP, Szuszczewicz ES, Northfield MS, Akizuki KH, Belcher and Amstutz HC, 1998. Quantitive assessment of walking activity after total hip or knee replacement. J Bone Surgery, 80A (1), 54-59
- 5 Jasty M, Maloney WJ, and Bragdon CR, 1991. The initiation of failure in cemented femoral components of hip arthroplasties. J Bone & Joint Surgery, 73B, 551-558.
- 6 Topoleski LDT, Ducheyne P and Cuckler JM, 1990. A fractographic analysis of in vivo polymethylmethacrylate bone cement failure mechanisms. J Biomed Materials Res, 24, 145-154

Code	Description	Boxed
T100	Single HiVac™ MultiMix	6
H749F	MultiMix Cement Gun	1
C701	Single HiVac™7 pack	10
C702	Double HiVac™7 pack	10
C703	HiVac™7 Triple Mix single pack	5
C800	HiVac™7 Delivery Syringe	20
CB900	HiVac™7 Combination Hip Pack	5
S717	Single HiVac™ Syringe	10
S718	Double HiVac™ Syringe	10
S727	Single HiVac™ Syringe (snap off nozzle version)	10
S728	Double HiVac™ Syringe (snap off nozzle version)	10
SB722	HiVac™ Combination Hip Pack	5
H550	HiVac™ Footpump	1
H719	Syringe Cement Delivery Gun	1
H759	HiVac™7 Cement Delivery Gun	1
H759L	HiVac™7 Cement Delivery Gun - Triple Mix	1

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**HiVac**<sup>™</sup> MultiMix Bone Cement Mixing and Delivery System

Effective, Progressive, Innovative



S U M M I T M E D I C A L



# HiVac™ MultiMix

## Bone Cement Mixing and Delivery System Mixes up to 3 x 40g of low viscosity cement

Research suggests that the quality of the cement mix is critical in achieving long-term joint survival.

Bone cement must be able to withstand the high and complex loading that it is subjected to through the lifetime of the implant.

"75% of revisions are caused by aseptic loosening" [1] and "mechanical failure of the cement mantle is the most common cause of aseptic loosening" [2]

During walking hip joint force exceeds 4 times body weight and this is applied cyclically [3].

Patients with hip/knee replacements take on average 5000 steps per day [4] and these conditions can lead to mechanical failure of the cement mantle [5] and [6]. Therefore the mechanical properties of the cement should be optimised to prevent failure.

Figure 1 shows that the HiVac™ MultiMix produces cement with enhanced Compressive and Bending strength compared to other commercially available systems. In addition Figure 2 shows that bending modulus is also enhanced with the MultiMix product.

To further enhance the mechanical properties of the cement it needs to be mixed under optimal vacuum levels. If the vacuum level is too low then the cement will contain high levels of porosity, but if too high excessive thermal shrinkage can create cracking in the cement mantle. The HiVac™ range operates at 550mmHg, which has been proven to provide an optimal balance between the two.

Exposure to MMA fumes is a concern of many that work in the vicinity of bone cement mixing. HSE recommend a maximum exposure for these fumes of 100ppm during a 15 minute exposure. The HiVac™ range uses charcoal filters that reduce fume exposure down to levels that are only a small fraction of these guideline limits. Fig 4.

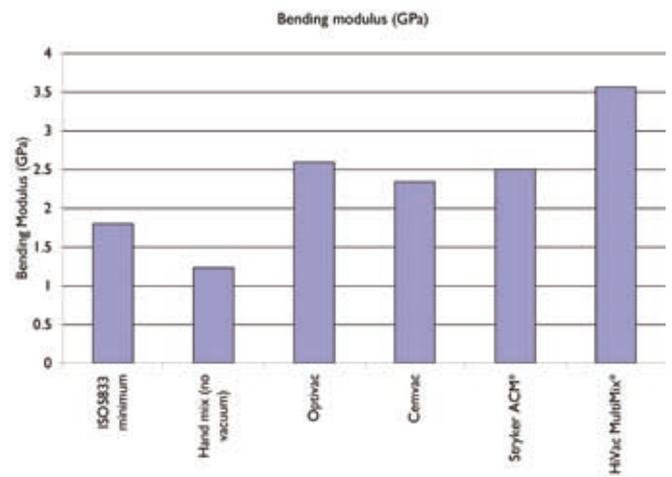


Figure 2 – Testing conducted by RAPRA Technology Ltd, 1999, 2001 (Palacos cement). \* Queens University Belfast, 2004 (Simplex cement)



Vacuum=0mmHg no cracks      Vacuum=550mmHg no cracks      Vacuum=650mmHg cracks seen

Figure 3 - Dunne NJ, and Orr JF, 2001. The effects of porosity on acrylic bone cement shrinkage after polymerisation. European Society for Biomaterials 2001 conference, 12th/14th Sep, London, UK

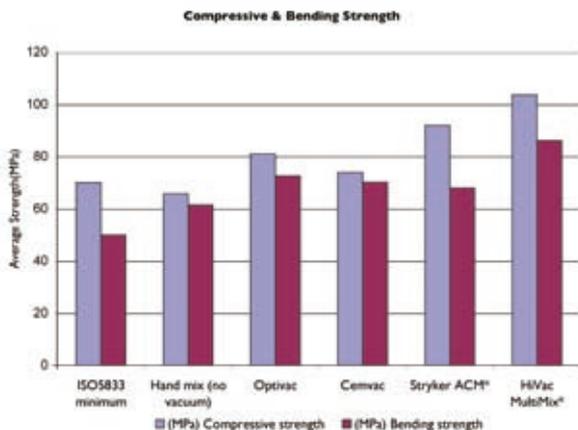


Figure 1 – Testing conducted by RAPRA Technology Ltd, 1999, 2001 (Palacos cement). \* Queens University Belfast, 2004 (Simplex cement)

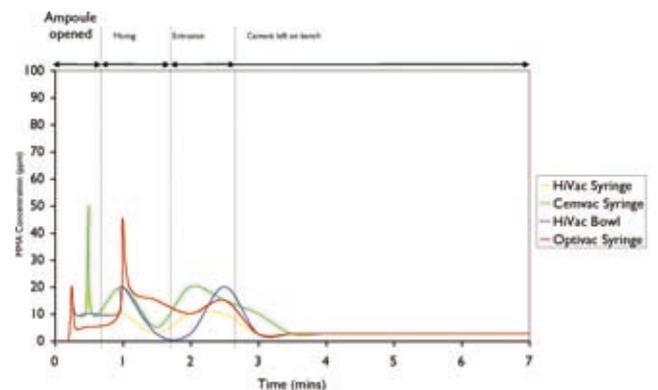


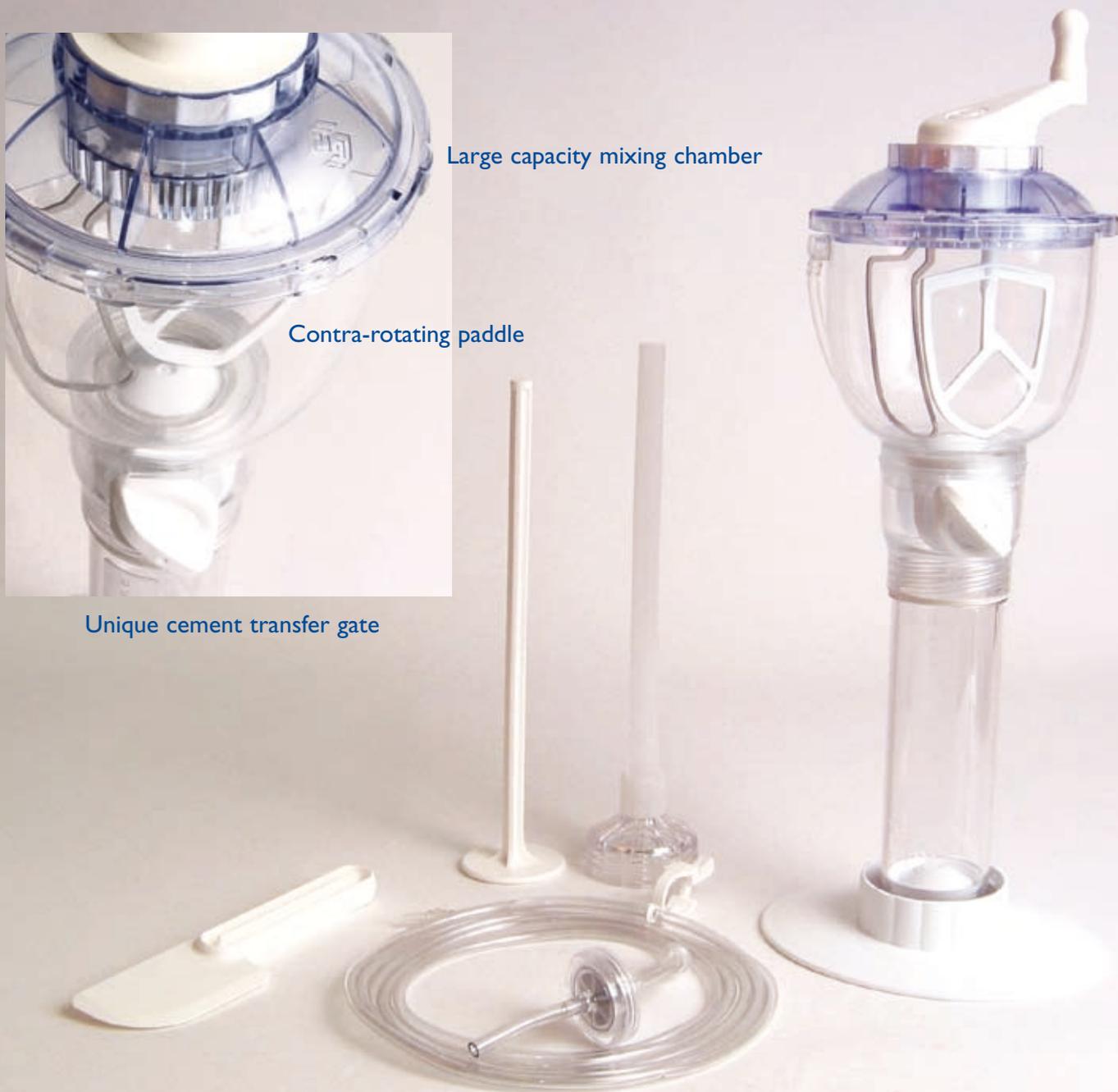
Figure 4 – Testing conducted by Vapour Management Systems, Plymouth, 2001. Note: HiVac™ MultiMix uses the same charcoal filter as the HiVac™ Bowl & HiVac™ Syringe



Large capacity mixing chamber

Contra-rotating paddle

Unique cement transfer gate



- **Unique geared rotational axis mixing mechanism**

The primary paddle produces a reproducibly high quality mix of cement

- **Contra-rotating paddle**

The secondary paddle counter rotates in relation to the primary mixing paddle, scraping the side of the bowl and feeding cement back into the path of the primary mixing paddle. This produces reproducibly high quality mixes of low viscosity cement reducing dependency on operator skill

- **Unique cement transfer gate**

Allows simple, safe and clean transfer of cement from the mixing chamber to the delivery syringe

- **Large capacity mixing chamber**

A single, double or triple mix of low viscosity cement can be mixed and delivered

- **Narrow delivery syringe & efficient ratchet delivery gun**

Allows for greater “feel” on delivery and the opportunity to generate high cement pressure during pressurisation

- **Operating vacuum level of 550mmHg**

Allows cement to be mixed at optimal levels of porosity to maximise the mechanical properties of the cement – see fig 1, 2 & 3 opposite. Equalised vacuum between mixing chamber and delivery syringe allowing smooth cement transfer and minimal air inclusion.

- **Closed system using charcoal / microbiological filter**

Reduces MMA fumes in theatre to levels significantly below those set out in the HSE guidelines

- **Few components / simple to use design**

Easy to use system

- **High clarity material**

Allows the mixing process to be viewed from any position

- **Latex free product**

Provides protection against potential latex allergy for nursing staff and patients

- **PVC Free packaging**

Helps minimise environmental pollution