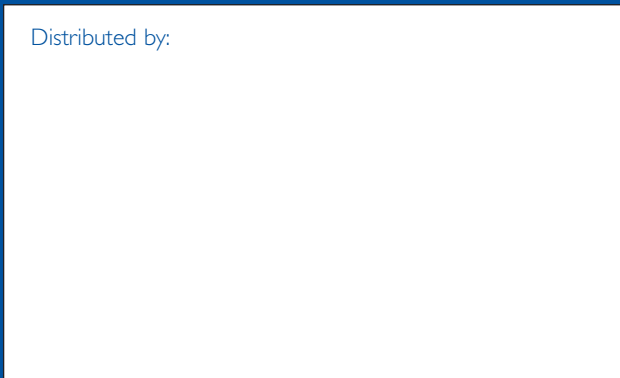


- 1 Kurdy NMG, Hodgkinson JP and Haynes R, 1996. Acrylic bone-cement; influence of mixer design and unmixed powder. J Arthroplasty, 11 (7). 813-819
- 2 Cary R, Morris L, Cocker J, Groves J and Ogunbiyi A, 1995. Methylmethacrylate: Criteria Document for an occupational exposure limit. Health and Safety Executive.

Code	Description	Boxed
SMMMI	Bone Cement / Substitute Mixing System for medium & low viscosity material	10
SMLV	Bone Cement / Substitute Mixing System with luer lock for low viscosity material	10
SMDSIC	10cc Precision Delivery Syringe	10



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 CMDCAS Certificate No. FM 77186
 BS EN ISO 13485:2001



MiniMix™ Bone Cement & Bone Substitute Mixing

Effective, Progressive, Innovative



SUMMIT MEDICAL



MiniMix™ Bone Cement & Bone Substitute Mixing

Mixing of 40g* or less of PMMA bone cement or bone substitute materials *(20g Simplex®)

MiniMix™ has been designed to support the following applications

- Hip Resurfacing
- Unicondular knees
- Vertebroplasty
- Bone void filling
- Small joints

The specific aim of the MiniMix™ systems are to ensure not only a homogenous, reproducible mix, but importantly for the user a quick and effective transfer of the material into a delivery device or prosthesis. The design allows for effective mixing of either bone cements or bone substitute materials meeting the needs of Orthopaedic Surgeons and Interventional Radiologists.

Mixer design has been found to significantly influence the quality of cement [1], Fig 1.

This paper shows significantly better PMMA mix quality from a rotational axis device compared to that created by hand mixing or a fixed axis system. The Summit Medical MiniMix™ design includes a rotational axis mechanism to reduce unmixed powder.

To further enhance the strength of bone 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, Fig 2. The Summit Medical MiniMix™ has a vacuum option functioning at 550mmHg, which has been proven to provide an optimal balance between the two.

Exposure to methylmethacrylate (MMA) fumes is a concern of many people who work in the vicinity of bone cement mixing. Health and Safety Executive (HSE) guidelines recommend a maximum exposure for these fumes of 100ppm during a 15-minute period [2]. The Summit Medical MiniMix™ includes the option of a lineset with an integral filter, which reduces fume levels to a small fraction of these guideline limits. Fig 3 shows how the same filter system on the Summit HiVac™ Bowl maintains fume levels below the 15-minute exposure guideline of 100ppm.

% unmixed powder per unit area

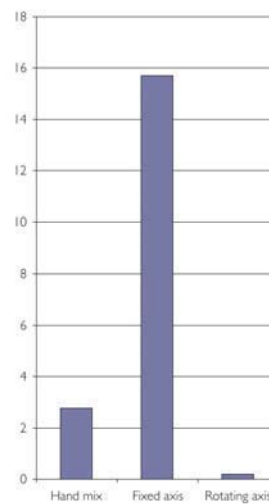


Figure 1 – Kurdy NMG, Hodgkinson JP and Haynes R, 1996. Acrylic bone cement; influence of mixer design and unmixed powder. J Arthroplasty, 11(7), 813-819

Magnification x16



Vacuum=0mmHg
no cracks

Vacuum=550mmHg
no cracks

Vacuum=650mmHg
cracks seen

Figure 2 – 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 Sept, London, UK

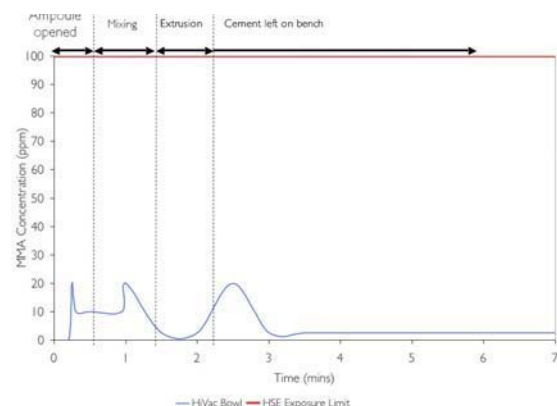


Figure 3 – Testing conducted by Vapour Management Systems, Plymouth, 2001

* Simplex is a registered trademark of the Stryker Corporation.



MiniMix™ Precision Delivery Syringe

MiniMix™ LV

MiniMix™

MiniMix™ / MiniMix™ LV

- **Patented geared rotational axis mixing mechanism**
Ensures a reproducibly high quality mix, significantly better than fixed axis or hand mixing – see figure 1.
- **Unique material transfer valve**
Allows the mixed material to be cleanly and precisely transferred into the delivery device or prosthesis.
- **8mm open bore or Luer Lock transfer interface options**
8mm open bore allows the mixed material to be easily transferred into hip resurfacing femoral components
Luer lock interface allows transfer of the material into standard syringes of varying sizes.
- **Vacuum level of 550mmHg**
Allows PMMA cement to be mixed at optimal levels of porosity to maximise the mechanical properties of the cement.
- **Charcoal / microbiological filter**
Reduces MMA fumes in theatre to levels significantly below those set out in the HSE guidelines.
- **Latex free product**
Provides protection against potential latex allergy for nursing staff and patients.
- **PVC free packaging**
Helps minimise environmental pollution.
- **Few components / simple to use design**

MiniMix™ Precision Delivery Syringe

- **10cc delivery capacity**
Ideally suited to assist with vertebroplasty or small joint surgery.
- **Push and screw application modes**
To prime the catheter or eject material quickly, the plunger is pushed forward. For slower more accurate delivery, the screw mechanism is engaged allowing precise control over the delivery rate. Reversing the screw direction will halt the material delivery.
- **Handle attachment**
Increases control and aids accurate delivery.
- **200mm catheter with 90 degree bend and Luer lock connection**
Specially designed to assist with vertebroplasty procedures allowing the operator to inject the material whilst outside of the X-ray field.
Luer lock allows secure fixing to the delivery syringe and injection needle. The catheter can be cut to required length for use on small joints.
- **Latex free product**
Provides protection against potential latex allergy for nursing staff and patients.
- **PVC free packaging**
Helps minimise environmental pollution.
- **Few components / simple to use design**