Summit Medical

Helping to improve the survivorship of orthopaedic implants

Summit Medical Cementation Product Guide

HiVac™ Bowl

HiVac™ 7

HiVac™ Multimix

Minimix™

HiVac™ Mix In Syringe

Osron™ Pulse Lavage

Summit Medical Surgical

www.summit-medical.co.uk

We keep patients moving

As a trusted cementation partner to three of the top four global orthopaedic leaders, we instil confidence and offer simplicity to healthcare professionals treating complex clinical challenges.

Through decades of research and development, our products are a preferred choice for orthopaedic surgeons globally.

Interesting fact: Summit Medical were first to market a crystal clear mixing system so you can see you have a good mix.

WHAT IS NEEDED FOR IMPLANT SURVIVORSHIP?

The skill of the surgeon and the quality of the implant are not the only key factors in ensuring a successful joint replacement. The perioperative practitioner is a vital link in the chain.

Good quality bone cement is essential for long-term implant survival, and the role of the theatre nurse in preparing that cement is vitally important. Cement mantle failure is the primary cause of aseptic loosening which is the most common indication for hip revision[1]. With the population getting older and staying active for longer, the survival rate of joint replacements is becoming even more important.

WHAT IS BONE CEMENT?

Bone cement is made from Polymethyl methacrylate (PMMA) which is usually supplied in combination to hospitals as a sachet of polymer powder and a glass ampoule of monomer liquid.

BONE CEMENT MIXING

When using bone cement in theatre it is important to understand the distinct phases that occur when the powder and liquid are mixed together, known as the polymerisation process.

The polymerisation process indicates to the user when the cement is ready to be placed and the length of time it then requires to set.

Although this process has four distinct phases, the length of each phase can vary from cement to cement. The four distinct phases are:

1. MIXING PHASE

The time to fully integrate the powder and liquid together.

2. WAITING PHASE

The time to achieve a suitable viscosity so that it can be handled without sticking to gloves. This time can be used to load the cement into the delivery device.

3. WORKING PHASE

The time during which the cement can be applied and the prosthesis implanted. The implant must be in place before the end of the working phase.

4. SETTING PHASE

The time for the cement to harder and set completely.

WHY DO CEMENTS VARY DURING THE MIXING PROCESS?

There are several factors that can contribute to the variation in behaviour of bone cement seen during the polymerisation process. A few of the factors include:

COMPOSITION – Can be influenced by the use of different copolymers, different powder-liquid ratio and the manufacturing or sterilisation process of the cement.

VISCOSITY – High viscosity cement is relatively thick (dough like), and loses its stickiness quickly making the working phase longer whereas medium/low viscosity cement is more runny (liquid) and keeps its stickiness longer but has a shorter working phase.

TEMPERATURE – Higher temperatures speed up the process reducing the mixing phase and working time.

HUMIDITY – Higher humidity accelerates all the phases of the polymerisation process, whereas a dry atmosphere could lengthen the process[2].

THE IMPORTANCE OF VACUUM MIXING

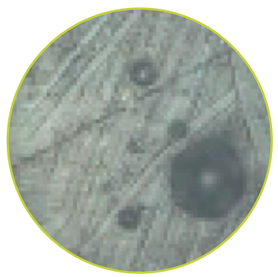
The original reason for vacuum mixing bone cement was to reduce the exposure to MMA fumes. Although excessive exposure to concentrated vapours may cause toxic side effects, the use of modern day fume extraction units used in operating theatres reduces the level of exposure from cement mixing to well within the Health & Safety Executive guidelines. In addition, using a vacuum mixing device with charcoal filters can further decrease exposure to MMA fumes[3].

The main reason for vacuum cement mixing is to produce a bone cement that is able to withstand load transfer and physical forces that it is going to be subjected to over the lifetime of the implant. Since 1999, aseptic loosening has been the dominant reason behind the need for revisions[4]. Vacuum mixing has been proven to significantly enhance the strength, creep resistance and fatigue properties of the cement. This is particularly the case when cement is mixed at around 550mmHg of vacuum, which has been found to be optimal.[4]

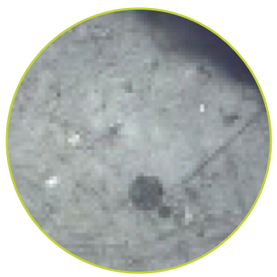
IS THERE AN OPTIMUM WAY TO VACUUM MIX?

There is an optimum vacuum level that cement should be mixed at to enhance the mechanical properties of bone cement. If the vacuum level is too low then the cement will contain high levels of porosity, but if the vacuum level is too high, the bone cement is subject to high excessive thermal shrinkage that could cause cracking in the cement. The optimum vacuum level is 550mmHg[4].
Using a well-designed mixing system can also help to achieve consistency. A simple and easy-to-follow mixing technique reduces the variability of hand mixes, and provides confidence in the quality of a reproducible mix.

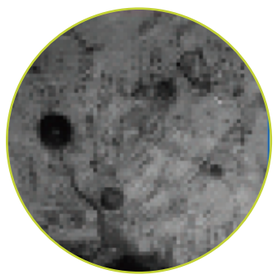
Radiographs of cement mixed in the same device at different vacuum levels[4].



Vacuum=0mmHg
no cracks



Vacuum=550mmHg
no cracks



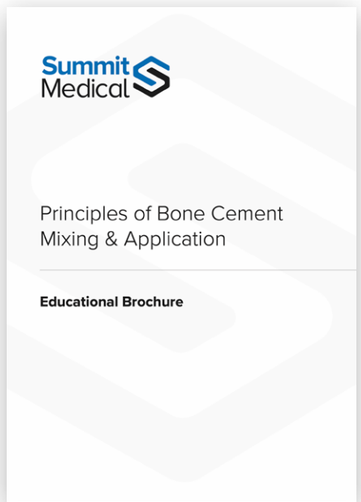
Vacuum=650mmHg
cracks seen

GETTING THE MOST FROM MODERN CEMENTATION TECHNIQUE

Correct mixing and application of bone cement is key to successful implant survival. Cemented implants are heavily loaded in the body, which represents a significant challenge to the implanted bone cement.

The key points to consider are:

1. Use a vacuum mixing system that operates at around 550mmHg to get optimal porosity and enhanced mechanical properties[4].
2. Cement fatigue life is key – use a system with proven fatigue life properties[5].
3. When syringe mixing, use a device with a repeatable mechanical action that requires minimal operator skill to avoid poor mixes.
4. When bowl mixing, use a rotational axis design for enhanced mix quality and reproducibility[6].
5. Monitor the storage temperature of the cement and operating room temperature.
6. If theatre temperature is different to normal, communicate the differences in working time to the surgical team.
7. Use a clock to carefully monitor the mixing phases.
8. Use a vacuum mixing device with a charcoal filter to reduce fume levels to within COSHH guidelines, preferably one that is not picked up during use.
9. Perioperative staff need to be familiar with the system that they use – do they need additional training?
10. The above should be used in conjunction with the other key elements of modern cementation technique to maximise long term results.



For more in depth information please refer to our Principles of bone cement mixing and application, educational brochure.

HiVac™ Bowl

MIX WITH CLARITY

HiVac™ Bowl is a bone cement mixing device that uses a vacuum level of 550mmHg for optimal porosity ensuring a good quality cement mix[1].

UNIQUE GEARED ROTATIONAL AXIS MIX

Mixer design has been found to significantly influence the quality of cement[4] and a significantly better mix quality can be achieved with a rotational axis device compared to hand mixing or a fixed axis device.

SHAPED SPATULA AND CURETTE

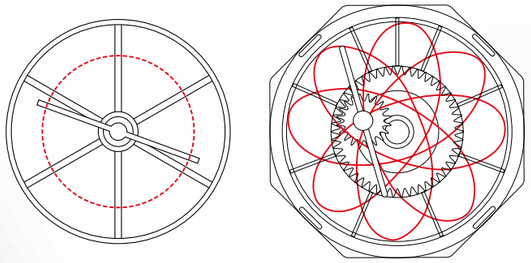
HiVac™ Bowl is provided with a specially designed spatula that precisely matches the bowl interior profile and helps minimise cement waste.
Each spatula is fitted with a disposable curette that can be used to remove excess cement from critical surfaces.

CLEAR MIXING CHAMBER

Allows the user a clear view of the cement during mixing offering peace of mind to the user as mix quality can be visually assessed prior to delivery.

HIGH VOLUME CAPACITY

Bowl allows mixing of 40g to 120g of all types of cement.



Fixed Axis

Rotational Axis

HiVac™ 7

MIX WITH CLARITY

Easy to use HiVac™ 7 helps theatre staff to produce high quality cement; critical to long-term joint survivorship.

SIMPLE, EASY TO USE

HiVac™7 combines excellent ergonomics with a positive feel as the cement is delivered. HiVac™7 has few components and is simple to assemble.

CLEAR MIXING TUBE

HiVac™7 features a clear tube permitting a clear view of the cement during mixing.
This offers peace of mind to the user as mix quality can be visually assessed prior to delivery.

COLOURED MIXING ROD SNAP POINT

The coloured indicator shows the user the end stroke position to avoid any potential compacted cement powder at the lid section. It also ensures that after mixing the rod snap point is easily identifiable.

VACUUM MIXING AND CHARCOAL FILTER

Once the cement components have been added HiVac™7 limits fumes to a level significantly lower than HSE guidelines[3].

FEMORAL PRESSURISER

- Good pressurisation is proven to improve longevity of implant[7].
- Suitable for all sizes of femur; minimal stockholding, maximum convenience.
- Easy to fit.
- Minimal femoral intrusion.
- The extension collar can be selected by the user to allow use where a deeper location is required.
- Latex-Free and Phthalate-Free.

HiVac™ Multimix

BONE CEMENT MIXING AND DELIVERY

HiVac™ Multimix is a low and medium viscosity bone cement mixing device and delivery system that uses a vacuum level of 550mmHg for optimal porosity, ensuring a good quality cement mix.

UNIQUE GEARED ROTATIONAL AXIS MIX

The primary paddle produces a high quality, reproducable cement mix.

CONTRA-ROTATING PADDLE

The secondary paddle counter rotates in relation to the primary mixing paddle, scraping the side of the bowl and feeding the cement down into the delivery syringe on cement transfer.

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 (up to 120g) of low and medium viscosity cement can be mixed and delivered.

NARROW DELIVERY SYRINGE

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

CLOSED SYSTEM WITH CHARCOAL FILTER

Reduces MMA fumes in theatre to levels significantly below those set out in the HSE guidelines[8].

Minimix™

BONE CEMENT AND BONE SUBSTITUTE MIXING

Minimix™(LV) has been designed to mix *40g or less of PMMA bone cement or bone substitute materials, to support hip resurfacing, unicondylar knees, vertebroplasty, bone void filling and small joints procedures.

The product is available as MINIMIX LV to mix low viscosity bone cement or as MINIMIX to mix low to high viscosity bone cement. Either product can be used in combination with the MINIMIX delivery syringe for precision delivery.

ROTATIONAL AXIS MIXING

MINIMIX has a geared rotational axis mixing mechanism to ensure a high quality mix[1].

VACUUM LEVEL OF 550MMHG

Allows PMMA bone cement to be mixed at optimal levels of porosity[1] to maximise the mechanical properties of the cement.

TRANSFER VALVE

To allow the mixed material to be cleanly and precisely transferred into the delivery device or prosthesis. MINIMIX LV has a luer lock transfer valve, and MINIMIX has an 8mm open bore transfer valve. The MINIMIX delivery syringe can be connected to either product.

10ML PRECISION SYRINGE

The delivery syringe can be pushed for quick ejection, or screwed for more accurate delivery. The syringe has a 10cc capacity, ideal suited to assist with vertebroplasty or small joint surgery.

200MM CATHETER WITH 90 DEGREE BEND

Used with the delivery syringe, the catheter is ideal for vertebroplasty procedures, allowing the operator to inject the material whilst outside the X-ray field.

*20g Simplex®

HiVac™ Mix In Syringe

BONE CEMENT MIXING AND DELIVERY

HiVac™ Mix In Syringe is a bone cement mixing and delivery device that uses a vacuum level of 550mmHg for optimal porosity ensuring a good quality cement mix[4].

UNIQUE MECHANICAL MIXING
Produces a high quality mix of cement, reducing dependency on operator skill.

OPERATING VACUUM LEVEL OF 550MMHG
Uses a vacuum level of 550mmHg for optimal porosity ensuring a good quality cement mix[4].

HIGH CLARITY MATERIAL
Allows the mixing process to be viewed from any position.

COMBINATION HIP PACK OPTION
HIVAC SYRINGE for the femur and HIVAC BOWL for the acetabulum in one convenient pack.

CLOSED SYSTEM WITH CHARCOAL FILTER
Reduces MMA fumes in theatre to levels significantly below those set out in the HSE guidelines[3].

Osron™ Pulse Lavage

EFFECTIVE IRRIGATION AND DEBRIDEMENT

OSRON™ is a fully disposable pulsed lavage system for effective irrigation and debridement during orthopaedic surgery. Preparing the bone bed during arthroplasty is an important element of modern cementing technique, and improves fixation strength for longer survival of implants.

STERILE AND DISPOSABLE
Simplifies operation planning and eliminates the need for sterilisation.

BUILT-IN BATTERY PACK
Avoids extra cables and improves workspace.

BUILT-IN LED LIGHT
Allows for improved visibility.

POWERFUL PRESSURE
For effective debridement.

OPTIMAL SUCTION
To clear waste material.

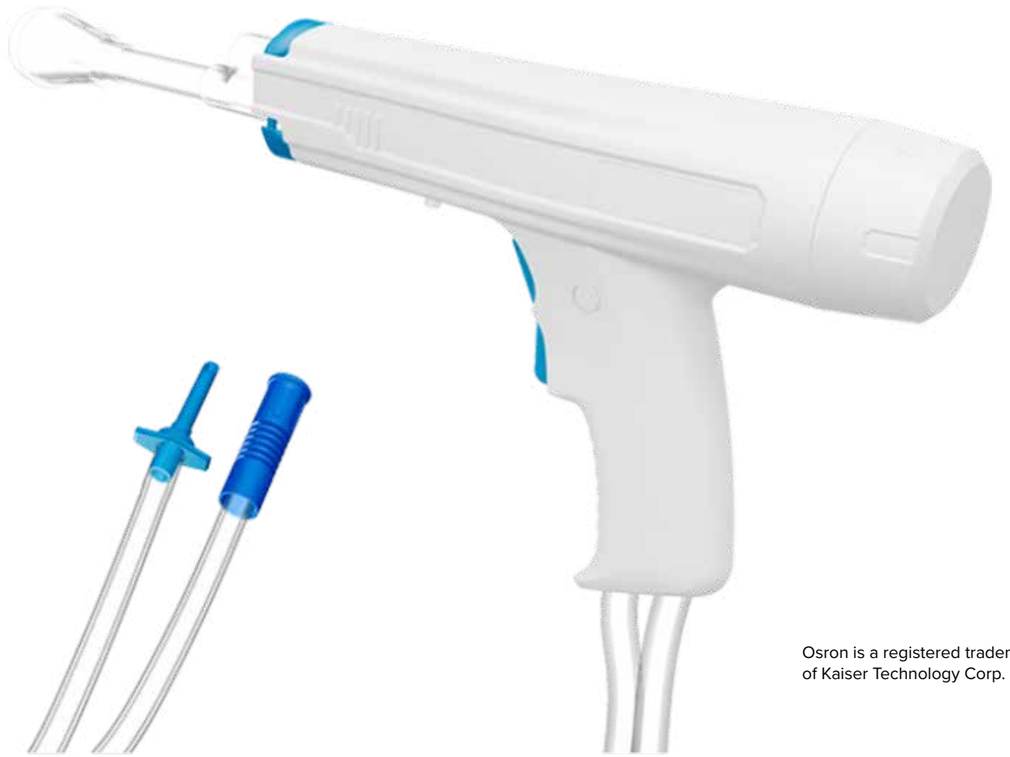
SHORT & LONG NOZZLE
Both supplied in pack for hip or knee surgery.

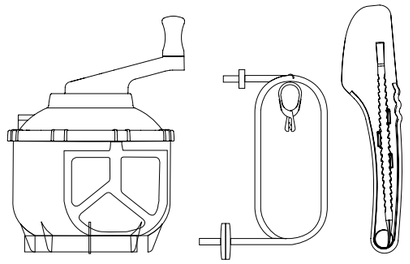
SECURE LOCKING RING
Easy to attach and secure the nozzle of choice.

2 SPEED SETTINGS
High or low speed for user choice.

3M TUBE LENGTH
For easy attachment to the irrigation solution and suction system.

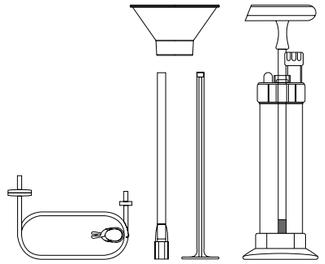
LOCKING CLAMPS
To prevent leakage of fluids.





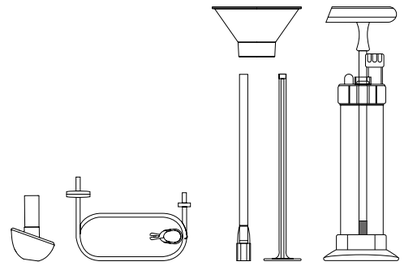
HiVac Bowl Pack

B713	Single Pack	QTY/BOX 15
B714	Double Pack	QTY/BOX 10



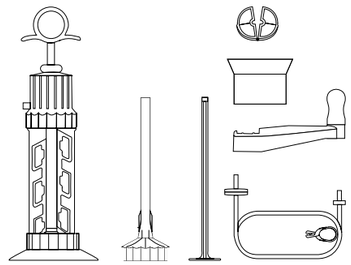
HiVac 7 Application

C701	Single Pack	QTY/BOX 10
C702	Double Pack	QTY/BOX 10
C703	Triple Pack	QTY/BOX 5



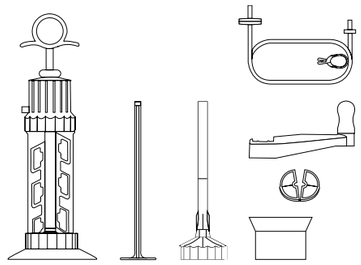
Hivac 7 with Femoral Pressuriser

CP701	Single Pack	QTY/BOX 10
CP702	Double Pack	QTY/BOX 10



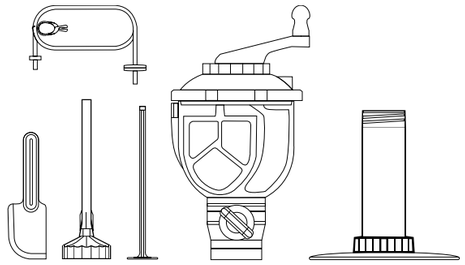
Hivac Syringe Application Pack

S717W	Single Pack	QTY/BOX 10
S718W	Double Pack	QTY/BOX 10



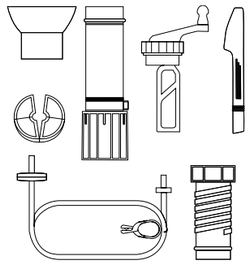
Hivac Syringe (with snap off nozzle)

S727	Single Pack	QTY/BOX 10
S728	Double Pack	QTY/BOX 10



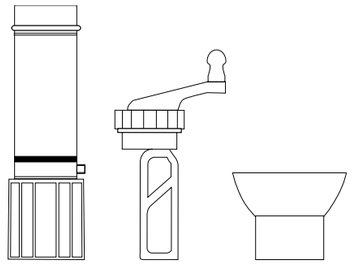
Hivac Multimix

T100 QTY/BOX 6



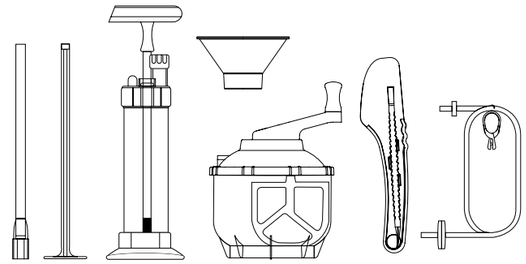
Minimix

SMMM1 QTY/BOX 10



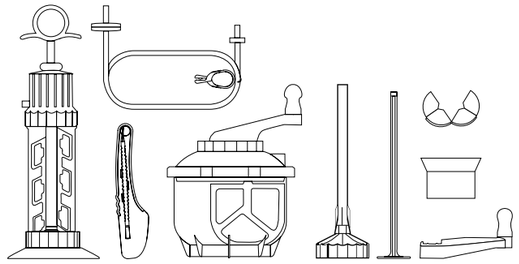
Minimix LV

SMLV QTY/BOX 10



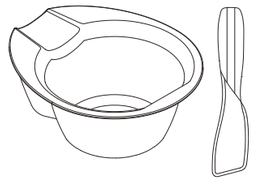
Combination Hip Pack

CB900 QTY/BOX 5



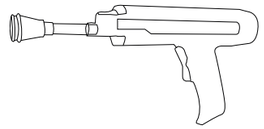
Hivac Combination Hip Pack

SB722 QTY/BOX 5



Summit Open Bowl

B710 QTY/BOX 30

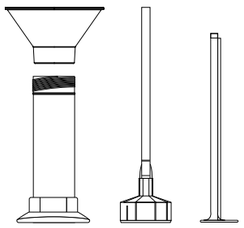


Osron Pulse Lavage with LED Light

PL2500LED QTY/BOX 10

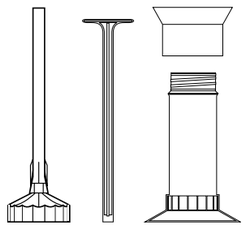
Coaxial Canal Brush Tip

BT04Z QTY/BOX 10



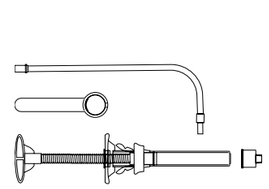
HiVac7 Syringe Pack

C800 QTY/BOX 20



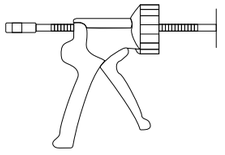
Syringe Pack

S720 QTY/BOX 20



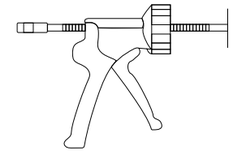
MiniMix Delivery Syringe

SMDS1C QTY/BOX 10



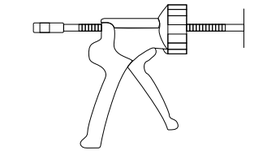
MultiMix Bone Cement Delivery Gun

H749 QTY/BOX 1



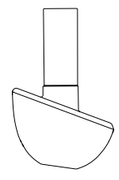
HiVac7 Bone Cement Delivery Gun

H759 QTY/BOX 1



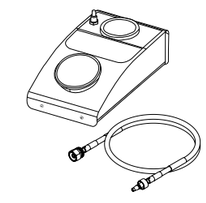
Mix In Syringe Bone Cement Delivery Gun

H719 QTY/BOX 1



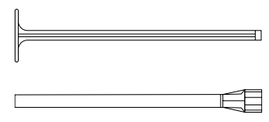
Femoral Cement Pressuriser

P721 QTY/BOX 10



Vaccum Foot Pump

H550 QTY/BOX 1



8.5mm Nozzle

N700 QTY/BOX 20

Founded in 1984, Summit Medical Group Ltd is a global leader in the provision of quality medical products, trusted by clinicians, physicians, hospitals and patients; manufactured in the UK, with a commitment to innovation, service and quality.

Summit Medical utilises highly skilled and advanced manufacturing techniques that meet the changing demands in global healthcare.

Ref 1: Nicholas A. Bedard MD, John J. Callaghan MD, Michael D. Stefl MD, Steve S. Liu MD Published online: 20 August 2014 The Association of Bone and Joint Surgeons 2014 Systematic Review of Literature of Cemented Femoral Components: What Is the Durability at Minimum 20 Years Followup?

Ref 2: Jung-Ro Yoon, MD, Young-Rok Ko, MD, Young-Soo Shin, MD* Effect of shape on bone cement polymerization time in knee joint replacement surgery* Correspondence: Young-Soo Shin, Department of Orthopedic Surgery, Veterans Health Service Medical Center, 61 Jinhwangdoro-gil, Gangdong-Gu, Seoul, 134-791.

Ref 3: EH40/2005 Workplace exposure limits Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended) EH40/2005 (Fourth Edition 2020)

Ref 4: Dunne N.J. Orr J.F, Mushipe M.T, Eveleigh R.J, 2002. The relationship between porosity and fatigue characteristics of bone cement. Biomaterials 24, 238-245, 2003.

Ref 5: Eveleigh R J, Dunne N J, Mushipe M T, Orr J F, Beverland D E, The fatigue life of bone cement: how it is affected by mixer design, vacuum level and user technique. Journal of Advanced Perioperative Care, Vol 1 No 1April 2002.

Ref 6: Kurdy NMG, Hodgkinson JP and Haynes R, 1996. Acrylic bone-cement: influence of mixer design and unmixed powder. J Arthroplasty, 11 (7), 813-819.

Ref 7: Malchau H, Herberts P, Sšderman P & OdŽn A, Update from the Swedish National Hip Arthroplasty Registry 1979-1998, 2000

Ref 8: Cary R, Morris L, Cocker J, Groves J and Ogunbiyi A, 1995. Methylmethacrylate: Criteria Document for an occupational exposure limit. Health and Safety Executive.

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