Summit Medical

Helping to improve the survivorship of orthopaedic implants

Summit Medical Cementation Product Guide

HiVac™ Bowl
HiVac™ 7
HiVac™ Multimix
MiniMix™
Summit Medical Pulsed Lavage

www.summit-medical.com

We keep patients moving

As a trusted cementation partner to the top 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 design and market a crystal clear mixing system so you can see you have a good mix.

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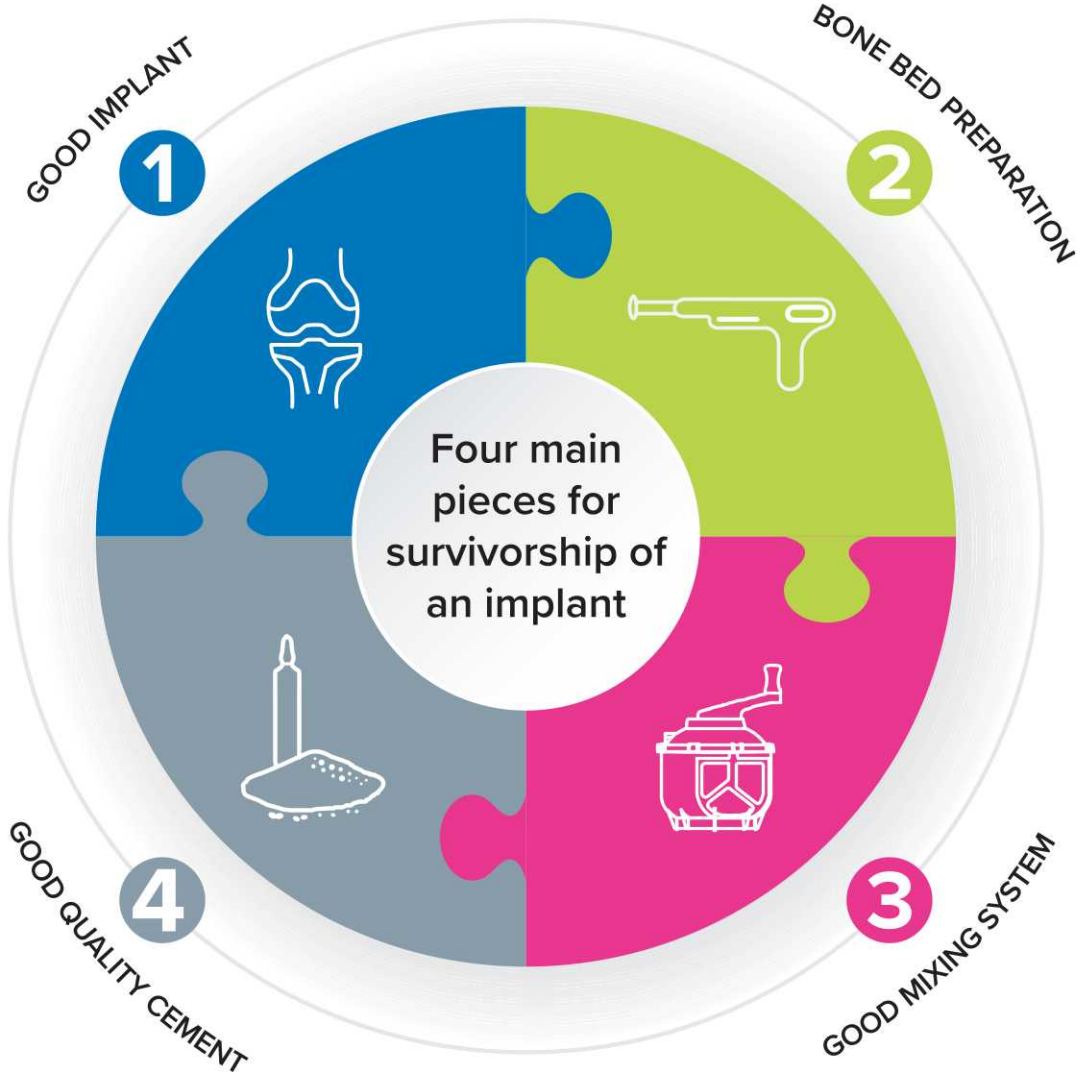
What is needed for long-term survivorship?

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 harden 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 waiting 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 can further decrease exposure to MMA fumes[3].

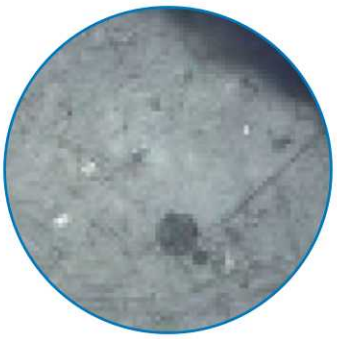
The main reason for vacuum cement mixing is to produce a bone cement that is able to withstand load transfer and physical forces that it is going to be subjected to over the lifetime of the implant. Aseptic loosening has been the dominant reason behind the need for revisions[1]. Vacuum mixing has been proven to significantly enhance the strength, creep resistance and fatigue properties of the cement[4].

IS HERE AN OPTIMUM RANGE FOR VACUUM MIXING?

There is an optimum vacuum range 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 the cement. The vacuum range of 550mmHg (±15) is an effective level of vacuum, that can facilitate the effective mixing of bone cement by reducing the porosity and enhancing the mechanical properties.

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 an effective porosity and enhanced mechanical properties[4].
2. Cement fatigue life is key[5] – use a system with proven fatigue life properties.
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 the Educational Brochure 'Principles of Bone Cement Mixing & Application'

HiVac™ Bowl

MIX WITH CLARITY

HiVac™ Bowl is a bone cement mixing and delivery device that allows effective mixing, under a monial vacuum of 550mmHg (±15mmHg).

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

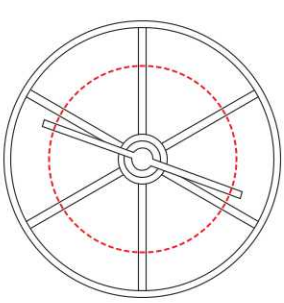
HiVac™ Bowl is provided with a specially designed spatula that precisely matches the bowl interior profile and helps minimise cement waste. Each spatula is fitted with a disposable curette that can be used to remove excess cement from critical surfaces.

HIVAC™ BOWL

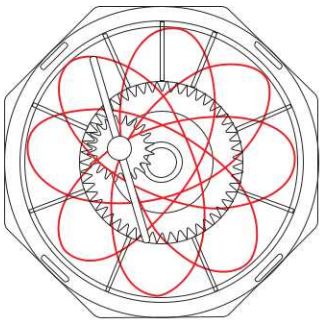
Our HiVac™ Bowl has been designed with a high clarity material, offering the clinician a clear view of the cement during mixing.

HIGH VOLUME CAPACITY

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



Fixed Axis



Rotational Axis

HiVac™ 7

MIX WITH CLARITY

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

CLEAR MIXING TUBE

HiVac™ 7 features a clear tube permitting a clear view of the cement during mixing.

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.

FEMORAL PRESSURISER

- Good pressurisation is proven to improve longevity of implant[7].
- Suitable for a wide range of femur sizes.
- Shaped to fit with 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 effective porosity, ensuring a good quality 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[3].

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[6].

VACUUM LEVEL OF 550MMHG (±15MMHG)

Allows PMMA bone cement to be mixed at an effective level of porosity[4] 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, ideally 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®

Summit Medical Pulsed Lavage

EFFECTIVE IRRIGATION AND DEBRIDEMENT

A fully disposable Summit Medical Pulsed Lavage system for cleaning wounds, removing dirt, necrotic tissue and debris during orthopaedic surgery. Preparing the bone bed during arthroplasty is an important element of modern cementing technique, and improves fixation strength and reducing revision rates.

STERILE AND DISPOSABLE

Simplifies operation planning and eliminates the need for sterilisation.

BUILT-IN BATTERY PACK

Avoids extra cables and improves workspace.
Also available with external battery pack.

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.

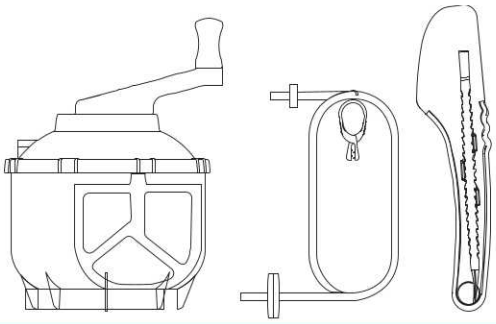
2 SPEED SETTINGS

High or low speed for user choice.

LOCKING CLAMPS

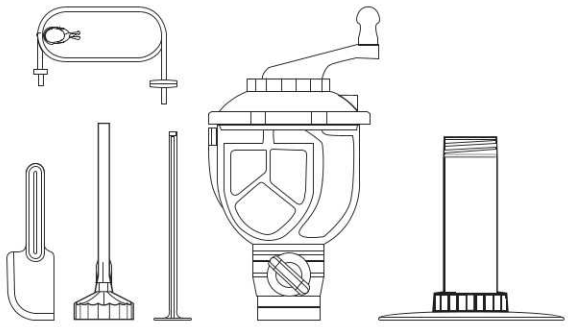
To prevent leakage of fluids.

Product Ordering Information



HiVac Bowl

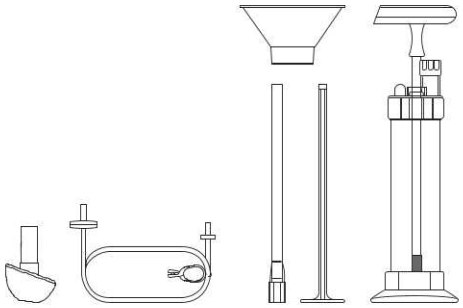
B713	Single Pack (suitable for a 120g MV mix)	QTY/BOX 15
B713PP	Non-sterile	QTY/BOX 30



HiVac Multimix

For use with gun H749F

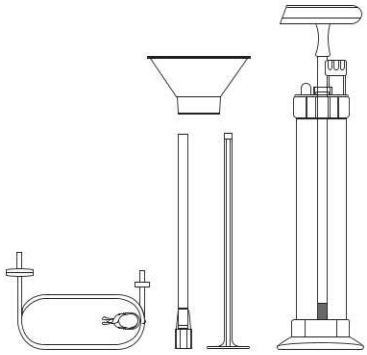
T100	Triple-mix pack (suitable for a 120g MV mix)	QTY/BOX 6



HiVac 7

For use with gun H759

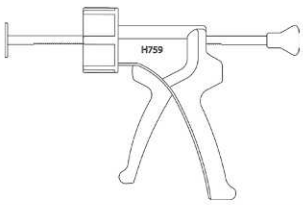
CP701	HiVac-7 Syringe (with pressuriser) (suitable for a 80g mix)	QTY/BOX 10
C701	HiVac-7 Syringe (without pressuriser) (suitable for a 80g mix)	QTY/BOX 10
C701PP	Non-sterile	QTY/BOX 20



HiVac 7

For use with gun H759L

C703	Triple-mix pack (suitable for a 120g HV mix)	QTY/BOX 5
C703PP	Non-sterile	QTY/BOX 15



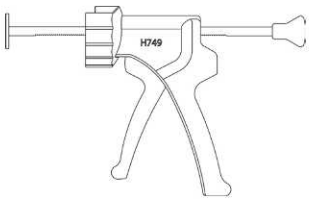
HiVac7 Bone Cement Delivery Gun

For use with C701 & CP701

H759	QTY/BOX 1

For use with C703

H759L (Long)	QTY/BOX 1



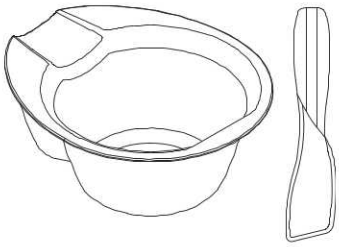
MultiMix Bone Cement Delivery Gun

For use with T100

H749F	QTY/BOX 1

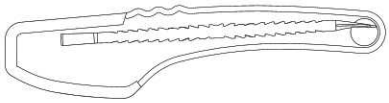
All syringe mixers come with 12mm nozzle as standard.

Product Ordering Information



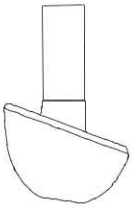
Summit Open Bowl

B710 QTY/BOX 30



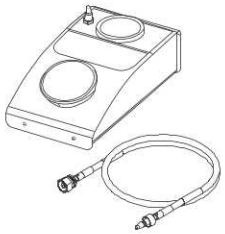
Spatula & Curette Pack

SC01 QTY/BOX 40



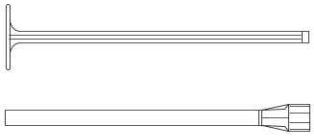
Femoral Cement Pressuriser

P721 QTY/BOX 10



Vacuum Foot Pump

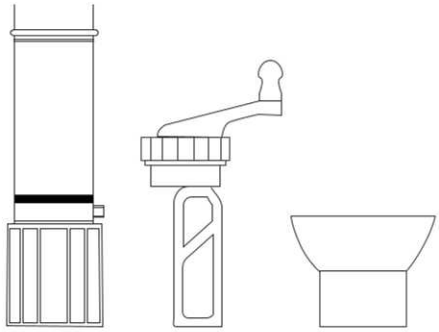
H550 QTY/BOX 1



9mm Nozzle with Extruder

For use with T100, CP701, C701, C703

N700 QTY/BOX 20



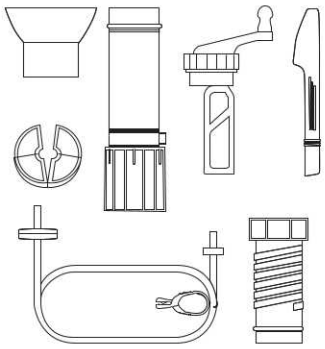
MiniMix Small Port with Luer Lock

Sterile:

SMLV QTY/BOX 10

Non-sterile:

MMS1-NS QTY/BOX 50



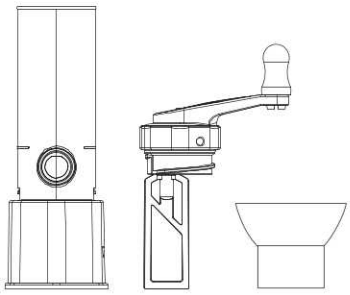
MiniMix Medium Port

Sterile:

SMMM1 QTY/BOX 10

Non-sterile:

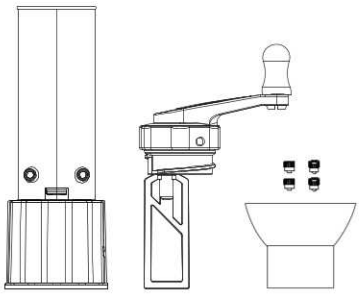
132892 QTY/BOX 50



MiniMix Large Port with Luer Lock

Non-sterile:

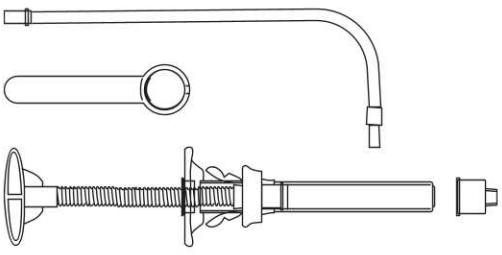
MML1-NS QTY/BOX 50



MiniMix 4 Port (small)

Non-sterile:

CMM4-NS QTY/BOX 30

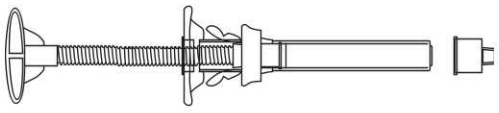


MiniMix Delivery Syringe with Catheter

SMDS1C QTY/BOX 10

Non-sterile:

MDS1C-NS QTY/BOX 50

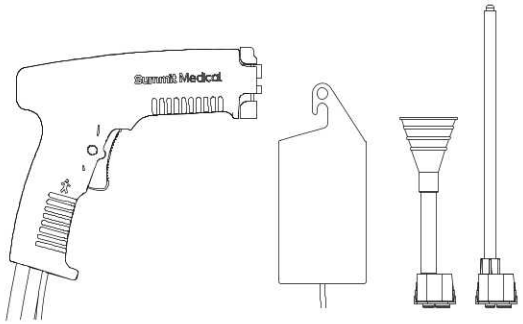


MiniMix Delivery Syringe

Non-sterile:

MDS1-NS QTY/BOX 50

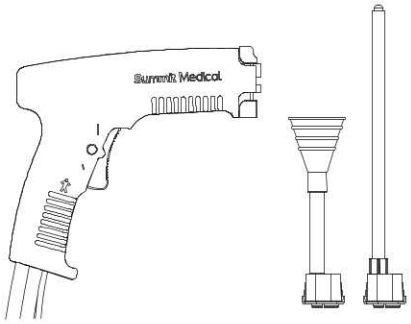
Product Ordering Information



Pulsed Lavage with External Battery Pack

Fan Spray Nozzle and Long Nozzle

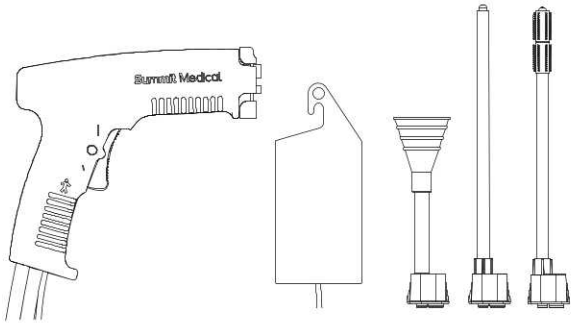
WZ-WDS-01 QTY/BOX 5



Pulsed Lavage with Built-In Battery Pack

Fan Spray Nozzle and Long Nozzle

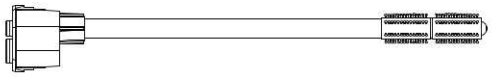
WZ-WPL-01 QTY/BOX 5



Pulsed Lavage with External Battery Pack

Fan Spray Nozzle, Long Nozzle and Femoral Brush tip

WZ-WDS-07 QTY/BOX 5



Single Packed Sterile Femoral Brush Tip

WZ-PT-03 QTY/BOX 5

Here at Summit Medical, we believe in being responsive to the needs of our customers and business partners, in the ever changing dynamic market place.

That is why we are always listening to feedback, to allow us to be flexible and adaptable, so we can stay one step ahead of the competition and offer the best in class solutions for the most important customers... the patients!

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.

> **“It is not the strongest of the species that survives, nor the most intelligent. It is the one most adaptable to change.”**
>
> - Charles Darwin

Notes

[1] National Joint Registry 19th Annual Report 2022

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: U.Schlegel, M. Sturm, V. Ewerbeck & S. Breusch. Efficacy of vacuum bone cement mixing systems in reducing methylmetharylate fume exposure. Comparison of 7 different mixing devices and hand mixing.

REF 4: Eveleigh 2001, Mixing Systems and the effects of vacuum mixing on bone cement.

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: D. Churchill, PhD; S Incavo, MD; J. Uroskie, MD; and B. Beynnon, PhD , Femoral stem insertion generates high bone cement pressurization .

Summit Medical Limited

Bourton Industrial Park
Bourton on the Water
Gloucestershire
GL54 2HQ
United Kingdom

Tel: +44 (0)1451 821311
Email: info@summit-medical.co.uk

www.summit-medical.co.uk

Distributed by:

Summit Medical

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