Modern Cementing Technique

PALACOS® Bone Cement, ClearMix™ Vacuum Mixing System and Quick-Vac® Vacuum Mixing Bowl
Secure a Strong Bond and Optimal Interfaces between Implant-Cement and Cement-Bone

Modern Cementing Technique Knee (MCT Knee) is a concept within knee arthroplasty. This concept addresses implant loosening and the objective is to provide long term implant stability in knee arthroplasty. It is based on scientific data, findings by Zimmer Biomet and evidence-based techniques documented in the Swedish Hip Arthroplasty Register.

The crucial factors in knee arthroplasty to achieve long term implant stability are to secure a strong bond and optimal interfaces, both between implant-cement and cement-bone. To address the risk of de-bonding and thus loosening of the implant follow the established MCT concepts below:

### Implant-Cement Interface
- Deliver the cement with a cement gun, CementON® Tibial Mold and appropriate delivery devices, such as knee nozzles
- Apply bone cement to implant first, as early as possible (no waiting phase)
- Prevent implant-cement interface contamination by implementing a “no-touch” policy

### Bone Cement
- Use a bone cement with good mechanical and consistent handling properties
- Mix and collect the cement under vacuum to reduce cement porosity and to improve mechanical strength

### Cement-Bone Interface
- Perforate cancellous bone if dense or sclerotic
- Clean with high pressure pulsatile lavage repeatedly until clear fluid is received in the return line
- Deliver the cement with a cement gun and appropriate delivery devices, such as knee nozzles
- Deliver bone cement into tibial stem hole to achieve full cementation

*Bench test results not necessarily indicative of clinical performance.*
Implant - Cement Interface

General Clinical Problem in Knee Arthroplasty: Tibial Loosening
Tibial loosening between cement and implant is not limited to any particular cement brand or tibial component design. The overriding factor is the cementation technique.2*

- Knee revisions in US 2014 were projected to be 75,500 with an annual growth rate of 4.8%.29
- Aseptic loosening of cemented tibial components remain a major cause of failure. It is shown in literature to account for 24% of all knee revisions.1
- Micro motion at the implant-cement or cement-bone interface can generate wear particles.30

Cement Application
Optimized micro-mechanical interlock can be achieved with early applied bone cement to a non-contaminated implant surface.27*

*Tensile-Adhesion Strength of PALACOS® on 30 grit blast CoCr27*

<table>
<thead>
<tr>
<th>Contaminant</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Contaminant</td>
<td>2000</td>
<td>1800</td>
<td>1600</td>
<td>1400</td>
<td>1200</td>
<td>1000</td>
<td>800</td>
</tr>
<tr>
<td>PBS</td>
<td>1800</td>
<td>1600</td>
<td>1400</td>
<td>1200</td>
<td>1000</td>
<td>800</td>
<td>600</td>
</tr>
<tr>
<td>Blood</td>
<td>1400</td>
<td>1200</td>
<td>1000</td>
<td>800</td>
<td>600</td>
<td>400</td>
<td>200</td>
</tr>
<tr>
<td>Fat</td>
<td>1200</td>
<td>1000</td>
<td>800</td>
<td>600</td>
<td>400</td>
<td>200</td>
<td>0</td>
</tr>
</tbody>
</table>

*Lab test results not necessarily indicative of clinical performance.
Independent Study with Stryker Triathlon® Tibial Trays and Simplex® and PALACOS® Bone Cements2*

Lab Study by Aaron Kavanaugh, Thomas Schmalzried and Fabrizio Billi

Conclusions

• Under laboratory conditions, a clean tibial tray-cement interface is strong, but much stronger when the keel is cemented.

• Earlier application of the cement to metal increases bond strength while later application reduces bond strength.

• Fat contamination of the tibial tray-cement interface reduces bond strength, but application of cement to the underside of the tibial tray prior to insertion substantially mitigates this.

Implant-Cement Interface Solution

To achieve an optimized micro-mechanical interlock, apply the bone cement to implant first, as early as possible (no waiting phase), using the flat knee nozzle.

*Lab test results not necessarily indicative of clinical performance.
Bone Cement

PMMA bone cements fill the space between prostheses and bone, transmitting and evenly distributing loads. The main considerations are:

- Good mechanical properties
- Consistent handling properties
- Well-documented bone cement

Mixing Under Vacuum

Mixing under vacuum reduces both micro and macro pores.\(^8\) Deliver the cement with a cement gun and nozzle suitable for the application.\(^10,11\)

- Improved cement strength and fatigue life\(^7\)
- Lower risk of aseptic loosening due to cracks in the cement\(^7,10\)
- Delivery of reproducible results
- Less exposure to monomer fumes\(^11\)

\(^*\) Lab test results not necessarily indicative of clinical performance.
Cement - Bone Interface

**Delivery**

- A uniform, deep bone cement mantle provides for optimal fixation and stress distribution\(^{14,15}\)
- Application with a cement gun and an appropriate nozzle on both tibia and femur\(^{16-19}\)
- Delivery to a clean, dry bone bed following pulse lavage\(^7\)

**Pressurization**

- Increases penetration into the cancellous bone\(^{20}\)
- Improves interface between bone and cement\(^7^*\)

\(^*\) Lab test results not necessarily indicative of clinical performance.
PALACOS Bone Cement - the unique solution

Long term clinical success
Since its introduction in 1959, PALACOS cement stands the test of time with a clinical history of low revision risk.31

Excellent handling characteristics
PALACOS cement offers a quick mixing and dough-up time, and a consistent working time long enough not to feel hurried for implant application.

Optimized antibiotic release characteristics
With the addition of 0.5g Gentamicin, PALACOS R+G offers a broad spectrum of coverage and greater in vitro elution rates compared with other available cement brands containing twice the amount of antibiotics.*32-33

High visualization
The green color of PALACOS cement improves visualization compared to surrounding bone. PALACOS cement also offers excellent post-operative visualization on x-ray.

Viscosity for every application
When a high viscosity cement is not needed, PALACOS cement is offered in a low viscosity formulation - PALACOS LV and PALACOS LV+G. Using the same time-tested raw materials and its unique green color, these cements can be easily ejected from long, narrow nozzles.

*Bench test results not necessarily indicative of clinical performance.
ClearMix Vacuum Mixing System

High quality vacuum mixing
ClearMix is a high performing vacuum cartridge mixing and delivery system. It allows for a standardized mixing procedure when cement is mixed, resulting in a high quality bone cement. This vacuum mixing system can be used to mix all viscosities of PMMA bone cement.

Practical and easy to use
This easy to use system requires minimal assembly. The mixing rod has a colored indicator that identifies the snap point for breaking. In addition, the vacuum line is equipped with a visual vacuum indicator to ensure proper vacuum level is present before mixing.

Safer working environment
ClearMix Vacuum Mixing System meets modern safety standards and the high demands on mixing bone cement in the OR. By drawing the monomer fumes through special filters, the ClearMix System minimizes MMA exposure of the OR staff to a level significantly lower than OSHA and NIOSH guidelines.27

Clear viewing
Based on customer feedback, the clear tube is important as it allows them to see the bone cement during the mixing process.
ClearMix Vacuum Mixing System is available in two different sizes

The ClearMix Vacuum Mixing System is available as single/double for 40-80g bone cement and as triple for 120g bone cement.

Knee nozzles for improved cement interfaces

Zimmer Biomet provides knee nozzles for optimal delivery and pressurization of the bone cement.

* To be available Q2 2017
Quick-Vac Vacuum Mixing Bowl

**Vacuum mixing in a highly visible bowl**
The bowl allows excellent visibility and monitoring of the blending process.

**Orbiting paddle design optimizes radial coverage**
The paddle turns about one and a half paddle turns per crank turn. The rotating axis gives the paddle a pathway that constantly changes providing improved mixing versus a fixed axis bowl.

**Large capacity bowl**
The large capacity mixing bowl holds up to three 40 gram batches of any type bone cement.

**Contoured spatula makes cement removal easy**
The spatula design follows the contour of the bowl and allows for quick removal of the cement when ready for application.

**Tubing set incorporates charcoal filter and vacuum indicator**
The unique tubing set offers the user a reduction in monomer fumes as well as a visual indicator when to begin mixing.
## Ordering Information

<table>
<thead>
<tr>
<th>Product</th>
<th>Part Number</th>
<th>Description</th>
<th>Units/Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modern Cementing Technique</td>
<td>00111214001</td>
<td>PALACOS R 1X40</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>00111314001</td>
<td>PALACOS R+G 1X40 (with Gentamicin)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>00111814001</td>
<td>PALACOS LV 1X40</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>00111914001</td>
<td>PALACOS LV+G 1X40 (with Gentamicin)</td>
<td>1</td>
</tr>
</tbody>
</table>

### Bone Cement Mixing Systems

<table>
<thead>
<tr>
<th>Product</th>
<th>Part Number</th>
<th>Description</th>
<th>Units/Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>ClearMix Single/Double</td>
<td>414702</td>
<td>ClearMix Single/Double</td>
<td>10</td>
</tr>
<tr>
<td>ClearMix Triple</td>
<td>414703</td>
<td>ClearMix Triple</td>
<td>1</td>
</tr>
<tr>
<td>Nozzle Knee Flat*</td>
<td>4146</td>
<td>Nozzle Knee Flat*</td>
<td>5</td>
</tr>
<tr>
<td>23-Degree Pressurizing Nozzle and Knee Cementation Nozzle*</td>
<td>110031498</td>
<td>23-Degree Pressurizing Nozzle and Knee Cementation Nozzle*</td>
<td>5</td>
</tr>
<tr>
<td>ClearMix Delivery Gun</td>
<td>414700</td>
<td>ClearMix Delivery Gun</td>
<td>1</td>
</tr>
<tr>
<td>Quick-Vac Mixing Bowl**</td>
<td>00504900100</td>
<td>Quick-Vac Mixing Bowl**</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>00504900115</td>
<td>Quick-Vac Mixing Bowl**</td>
<td>15</td>
</tr>
<tr>
<td>Zimmer® Vacuum Foot Pump II-Air Connector</td>
<td>00504908600</td>
<td>Zimmer® Vacuum Foot Pump II-Air Connector</td>
<td>1</td>
</tr>
</tbody>
</table>

* To be available Q2 2017  **Note: An adapter is packaged with each mixing system for use with the pump
References


PALACOS® is a trademark of Heraeus Medical, GmbH, Germany. Under license from Heraeus Medical GmbH, Germany. Triathlon® and Simplex® are trademarks of Stryker Corporation or its affiliates.

For product information, including indications, contraindications, warnings, precautions, potential adverse events, and patient counseling information, see package insert and www.zimmerbiomet.com.

All content herein, is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to Zimmer Biomet or its affiliates unless otherwise indicated and must not be redistributed, duplicated or disclosed, in whole or in part without the express written consent of Zimmer Biomet.

This material is intended for health care professionals, the Zimmer Biomet sales force only and Zimmer Biomet employees. The distribution to any other recipient is prohibited.

©2017 Zimmer Biomet