The information contained in this document is intended for healthcare professionals only.
Now with Tobramycin!

The Perfect Blend of Confidence and Performance

- **Simplex™ P Bone Cement** – the #1 Bone Cement
  - Unmatched strength and handling
  - Uncompromising clinical success

- **Now Pre-blended with Tobramycin** – the #1 Antibiotic of Choice

Stryker
Howmedica
OSTEONICS
**Blending Experience and Science**

For over 40 years, Simplex™ P Bone Cement has earned the trust and confidence of tens of thousands of surgeons. **With over 18 million doses implanted,** no other bone cement can match the experience of Simplex™ P Bone Cement. Hundreds of articles in respected, peer-reviewed journals confirm the outstanding performance of Simplex™ P Bone Cement.

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**Cement Confidence and Performance**

**In One Box**

At the heart of this illustrious history is the science behind the success of Simplex™ P Bone Cement – a unique chemical composition that has become the orthopaedic standard by which other bone cements are measured:

- 75% methylmethacrylate-styrene copolymer
- 15% polymethylmethacrylate
- 10% barium sulfate

Simplex™ P Bone Cement provides the right ingredients in the right formula, balancing unrivaled strength with consistent handling for dependable intraoperative and long-term clinical results.

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1958
Simplex™ C Cement introduced in Europe.

1962
Simplex™ P Bone Cement introduced in Europe.

1971
Simplex™ P Bone Cement first to receive FDA approval in US for total hip arthroplasty.

1973
Simplex™ P Bone Cement approved for total knee arthroplasty in US.

1975
Simplex™ P Antibiotic Bone Cement with Erythramycin and Colistin introduced in Europe.

1976
Simplex™ P Bone Cement* approved for use in pathological fractures and general prosthetic fixation.

2000
Simplex™ P Bone Cement with Tobramycin introduced in Europe.

2003
Simplex™ P Bone Cement with Tobramycin introduced in US.

*See package insert for full prescribing information.
**Blending Preference and Consistency**

Tobramycin is the antibiotic-of-choice for more than 75% of orthopaedic surgeons in the US\(^1\) for several important reasons:

- Ability to withstand exothermic temperatures of polymerizing cement
- Low allergy potential versus cephalosporins\(^2\)
- Excellent safety profile
- Proven elution from Simplex™ P Bone Cement\(^3,4,5\)
- Broad spectrum antibiotic
- Used safely for over 20 years in orthopaedics\(^6,7\)

With pre-blended Simplex™ P Bone Cement with Tobramycin, surgeons can be confident that the tobramycin is being optimally delivered to the patient. Commercial blending also ensures that the tobramycin is evenly distributed throughout the mixture, and that the mixture is consistently smooth.
Blending Efficiency and Convenience

In one step, Simplex™ P Bone Cement with Tobramycin gives surgeons the strength of Simplex™ P Bone Cement plus the convenience of tobramycin – without the delay, hassle, or potential inconsistencies associated with mixing intraoperatively.

Cement Strength and Handling

In One Step

Simplex™ P Bone Cement with Tobramycin is indicated for the fixation of prostheses to living bone in the second stage of a two-stage revision for total joint arthroplasty. It is manufactured, blended, and tested to ensure optimal consistency of the mixture, which is comprised of 40g of Simplex™ P Bone Cement powder plus 1g of tobramycin.

The liquid monomer portion of Simplex™ P Bone Cement is unchanged, maintaining the original Simplex™ P Bone Cement formula. As a result, the superior mechanical properties surgeons expect with Simplex™ P Bone Cement are inherent in Simplex™ P Bone Cement with Tobramycin.

The proprietary formula and manufacturing process of Simplex™ P Bone Cement impart excellent viscosity characteristics, which result in superior fatigue¹⁸,¹⁹ and shear strength.¹⁰ Unlike high-viscosity bone cements, Simplex™ P Bone Cement penetrates deeper into cancellous bone for consistent fixation performance.¹⁰ The controlled addition of tobramycin powder does not alter the unsurpassed mechanical properties of Simplex™ P Bone Cement.¹¹,¹²
Shear Strength at Cement-to-Bone Interface (MPa)

“Tests prove Simplex™ P withstands nearly 20% more shear stress at the cement-to-bone interface as Palacos®.”¹⁰

Fatigue Cycles to Failure

Tested at 20MPa* and 3 cycles/second.

“Internal mechanical testing confirms that fatigue strength is unaffected by the addition of 1g. tobramycin.”¹⁵

Handling Properties

“The handling properties of Simplex™ P with Tobramycin are unchanged from those of Simplex™ P Bone Cement.”¹⁵

The Perfect Blend of Confidence and Performance

*Note: 1 MPa (megapascal) = 145psi.
**Blending Control and Capability**

When antibiotics are blended with bone cement, serum levels are controlled by the degree of antibiotic release.

**Cement Safety and Results**

**In One Product**

Tobramycin elutes from Simplex™ P Bone Cement and is concentrated locally. Low serum levels are maintained, minimizing the potential for toxicity and associated adverse side effects. In pre-clinical and clinical studies with Simplex™ P Bone Cement with Tobramycin, systemic tobramycin levels remained well below the toxic threshold.4,13,14

**The Perfect Blend of Confidence and Performance**

Simplex™ P Bone Cement with Tobramycin is the perfect blend – offering surgeons the confidence of their number-one bone cement plus their first-choice antibiotic. For experience, strength, consistency, and dependability, no other bone cement comes close to Simplex™ P Bone Cement with Tobramycin.
Clinical Elution from Simplex™ P Bone Cement with Tobramycin

Simplex™ P Bone Cement with Tobramycin vs. Palacos® with Gentamicin Release

The Perfect Blend of Confidence and Performance
The most reliable, predictable, and trusted bone cement.

The Perfect Blend of Confidence and Performance

References

15. Data on file at Howmedica Osteonics