

Joint Replacements

Trauma

Spine

Micro Implants

Orthobiologics

Instruments

Interventional Pain

Navigation

Endoscopy

Communications

Patient Handling Equipment

EMS Equipment

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Product Range

Simplex® Bone Cement now comes with a choice of two antibiotic options

- Antibiotic Simplex® with Tobramycin and
- Antibiotic Simplex® with Erythromycin and Colistin

Full Dose

Cat. No. 6197-1-010

Antibiotic Simplex® Bone Cement Radiopaque

Ten box dispenser carton.

Each box containing:

1 STERILE packet containing 41g sterile powder including 1g Tobramycin (as Sulphate) USP

1 STERILE ampoule containing 20ml of sterile liquid

6197-1-010



Half Dose

Cat. No. 6197-5-010

Antibiotic Simplex® Bone Cement Radiopaque

Ten box dispenser carton.

Each box containing:

1 STERILE packet containing 20.5g sterile powder including 0.5g Tobramycin

(as Sulphate) USP

1 STERILE ampoule containing 10ml of sterile liquid

6197-5-010



Full Dose

Cat. No. 6196-9-010 Antibiotic Simplex® with Erythromycin and Colistin

Ten box dispenser carton.

Each box containing:

1 STERILE packet containing 41g sterile powder including 0.5g Erythromycin (as glucoheptonate) and 3,000,000 I.U. Colistin sulphomethate sodium Ph.Eur.

1 STERILE ampoule containing 20ml of sterile liquid

6196-9-010



Joint Replacements

Simplex® Antibiotic

Radiopaque Bone Cement

with Tobramycin
with Erythromycin and Colistin



Antibiotic Simplex® with Tobramycin

The Issues

- To combat potential deep wound infection in the immediate post-operative period.
- To maintain the bone cement's integrity ensuring there is no loss of strength due to the addition of antibiotics.
- To create a strong bone-cement-implant composite. Independent studies^{1,2,3} have shown that Antibiotic Simplex® has the same excellent strength properties as Simplex® P.

Infection Control

The problem of infection associated with total joint replacement has been reduced by both increased surgical experience and improved surgical conditions, however, deep infection remains a problem. Studies using antibiotic-loaded cement have clearly shown success in containing the rate of deep infection.⁴

The Facts

Simplex® P has been proven in independent studies to have optimal

- Fatigue Strength^{13,14}
- Compressive Strength¹⁵
- Shear Strength¹⁶
- Creep¹⁷
- Penetration into Bone¹⁶

Over 20 million units of Simplex® have been supplied for implantation since 1960, which along with more than 255 published papers and references has led to Simplex® being recognised as one of the most researched, studied and tested orthopaedic product in the world.

Antibiotic Simplex® has a history spanning more than two decades and can show a proven broad spectrum of antibiotic coverage combined with unrivalled cement strength.

With the launch of Antibiotic Simplex® containing Tobramycin the clinical options have now been increased to offer more choice to those wishing to capitalise on the superior mechanical and handling characteristics of Simplex® bone cement.

Antibiotic Simplex®

with Tobramycin

Effective release characteristics

An antibiotic chosen for use with bone cement must elute from the cement at high enough levels to provide antibacterial protection during the initial 72 hours after implantation whilst remaining at safe, non-toxic levels in the serum and urine.

To provide this effective release, the antibiotic must be able to withstand the heat generated by polymerisation.

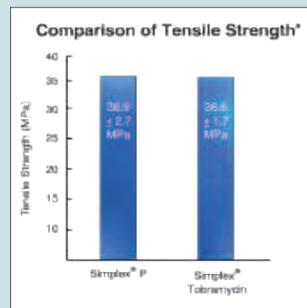
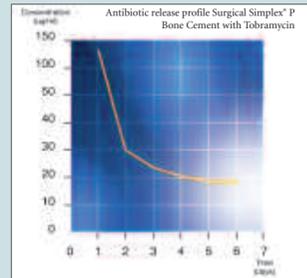
Safe for clinical use

Tobramycin has been proven to be both heat stable and non-toxic. More than 20 years of surgical clinical use has shown that Tobramycin is not prone to causing sensitivity in patients.^{3,6}

“Tobramycin powder elutes from acrylic bone cement at very high levels. We also find very low serum Tobramycin levels at any given moment. Tobramycin impregnated acrylic cement is safe and effectively establishes bactericidal levels of antibiotic at the site of the implant.”⁷

Optimal strength

Tobramycin does not negatively impact the strength of Surgical Simplex® P ^{2,3,8} unlike some other cement brands, in which the strength of the bone cement is adversely affected by the addition of Gentamicin.¹

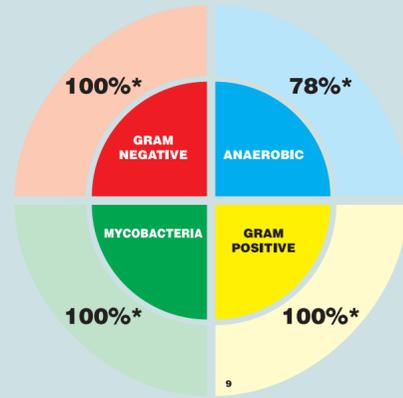


Broad spectrum protection

Tobramycin is a broad spectrum antibiotic which has been extensively used in total joint replacement for more than two decades. It has been recognised as an antibiotic of choice for 70% of U.S. surgeons.¹⁰

In a study by Scott et al⁹ Antibiotic Simplex® with Tobramycin was found to have activity against not only gram positive and gram negative aerobic organisms but also a significant number of anaerobes and mycobacterium.

Studies have shown that Antibiotic Simplex® with Tobramycin is especially effective against *S. Aureus* and *S. Epidermidis*, the two bacteria found most often in joint deep sepsis.^{11,12}



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Antibiotic Simplex®

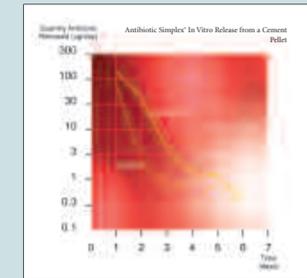
with Erythromycin and Colistin

Tried and tested

The combination of Erythromycin and Colistin, two tried and tested drugs, effectively combat deep wound infecting organisms during the vital time, within 72 hours of the operation. Any subsequent infection risks can then be identified and treated by the surgeon with an appropriate specific antibiotic. After this period the release of Erythromycin and Colistin are minimal. This further supports the continued mechanical integrity of Antibiotic Simplex® Cement.

The small amount of Colistin in the cement combined with both the short release time and localised delivery minimises the possibility of any toxic effects.

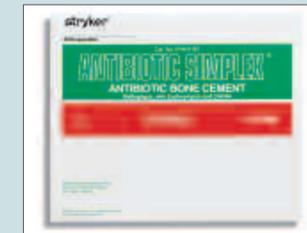
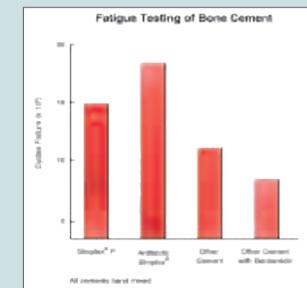
In this application Erythromycin has been shown to be a non toxic drug and lacks tendency to produce hypersensitivity.



Optimal strength

Independent studies³ have shown that there is no significant reduction in fatigue properties with the addition of Erythromycin and Colistin to Simplex® P.

This is not the case for all cement brands.¹



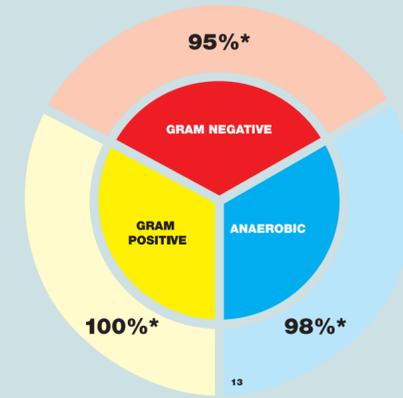
Clinically proven

Rosenthal et al¹³ found that in this application, the combination of Erythromycin and Colistin is effective not only against gram +ve and gram -ve organisms but also has activity against anaerobic organisms.

This broad spectrum of activity ensures wide security against post-operative infections and has proven extremely successful in clinical use.

“786 fresh and revision standard total hip arthroplasties were performed with the combined Colistin-Erythromycin bone-cement mixture. The wound infection rate was 0.4% (3 of 786).”¹⁴

Antibiotic Simplex® Cement’s broad spectrum of activity and excellent strength properties are demonstrated by countless successful surgical operations over a 25 year period.



* This chart shows the spectrum of antibiotic cover which may be provided by Antibiotic Simplex® with Tobramycin.

Please note that the figures given are the results of comparative tests within the study referenced above⁹ and that these results should NOT be assumed to apply to ALL gram positive, gram negative, anaerobic, aerobic, or mycobacteria.

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