

STIMULAN[®]

POWER TO TRANSFORM OUTCOMES[™]



STIMULAN[®]

Perfect partner for your infection management strategy

In contrast to today's growing economic and performance challenges, **STIMULAN** has been shown to transform outcomes and reduce associated costs of care across a wide range of settings.^{1,2}

STIMULAN is a truly absorbable calcium sulfate, specifically designed to complement your dead space and infection management strategies.³

- ✓ Approved for placement directly at the site of infection



Calcium sulfate, uniquely recrystallised to transform outcomes in the presence of infection^{7,8}

STIMULAN can transform outcomes in infected non-unions, osteomyelitis and periprosthetic joint infection⁴⁻⁶



TRANSFORM OSTEOMYELITIS IN DIABETIC FOOT^{4*}

Patient presented with: Persistent osteomyelitis and interphalangeal joint destruction of left hallux. He was already receiving treatment for Charcot arthropathy to his right foot.

Outcome: 2 weeks post-operatively the toe reduced in size. At the 16 month x-ray the patient was infection free and amputation had been avoided. **STIMULAN** was seen to have completely absorbed at 4 months.



TRANSFORM INFECTED TRAUMA^{5*}

Patient presented with: Infected femoral nail and non-union of left femur with persistent discharging wounds proximally and distally.

Outcome: At 7 months' follow-up there was complete healing of the non-union and at 1 year patient remains infection free, walking with no pain.



TRANSFORM INFECTED REVISION ARTHROPLASTY^{6*}

Patient presented with: Infected total knee replacement 2 years after primary procedure.

Outcome: At 1-year follow-up the patient remains infection free and is under regular follow-up.

STIMULAN[®]

Recrystallised for improved clinical performance

STIMULAN is a pharmaceutical-grade calcium sulfate with a unique crystal structure and properties.⁷

- ✓ Controlled purity
- ✓ Physiologic pH level
- ✓ Hydrophilicity

Only STIMULAN undergoes a patented recrystallisation process that starts with pharmaceutical-grade reagents and results in its consistent and reliable performance.^{3,7-13}

- ✓ Truly absorbable at an optimal rate
- ✓ No third body damage
- ✓ Low levels of drainage

Truly absorbable and totally synthetic calcium sulfate – absorbs at an optimal rate^{3,12}

Leaves no nidus for infection



Post-operative



1 month



11 weeks



6 months



No third body damage to articulating surfaces¹²

Less scratching than competitor calcium sulfate

Microscope images (x6.5) of a cobalt chrome plate following damage simulation (360,000 cycles) with third body particles trapped between it and an articulating UHMWPE pin



STIMULAN



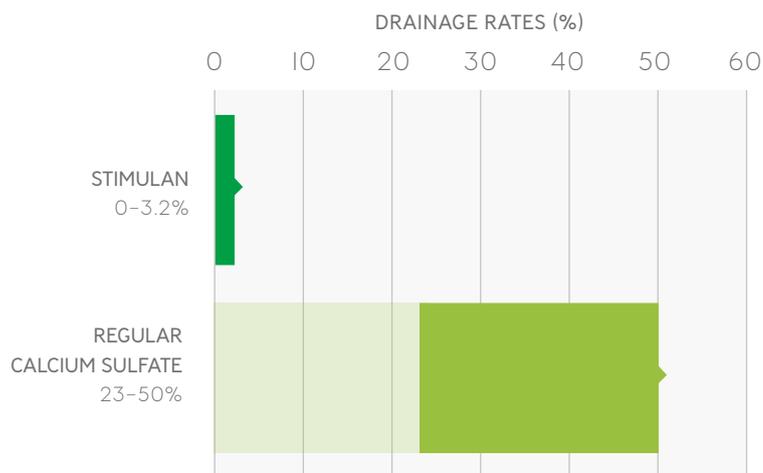
Competitor calcium sulfate



Control

STIMULAN does not damage total knee replacements when trapped between the articulating surfaces of the implant.

Low levels of drainage^{8,9,13-17}



STIMULAN®

Case-by-case flexibility

Can be used in three sizes of bead, as a paste or for injection, **STIMULAN** optimises packing in bone and soft tissue. Its hydrophilic properties and options of rapid or standard setting times make it quick and easy to prepare – helping you to adapt to each case as is merited.



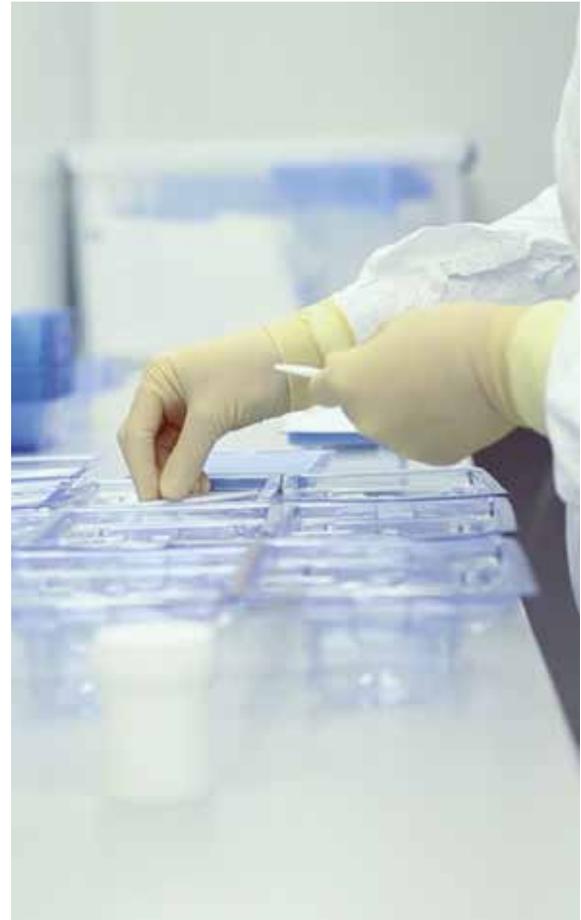
Flexible formats to optimise dead space management

PRODUCT	PASTE VOLUME	BEAD VOLUME	SETTING TIMES	ORDER CODES
STIMULAN Rapid Cure Rapid setting paste with individual bead kit	5cc	12cc	4 minutes approx.	620-005
	10cc	25cc		620-010
	20cc	50cc		620-020
STIMULAN Kit Fully injectable paste with individual bead kit	5cc	10cc	8 minutes approx.	600-005
	10cc	20cc		600-010

STIMULAN®

POWER TO TRANSFORM OUTCOMES

- ✓ Perfect partner for your infection management strategy³
- ✓ Recrystallised to give a unique crystal structure and clinical performance^{7,8}
- ✓ Provides case-by-case flexibility



All Biocomposites' products are engineered, manufactured and shipped from our facilities in Keele, UK.

At Biocomposites, we are proud to be driving improved outcomes across a wide range of clinical applications for patients and surgeons. Our team of specialists is singularly focused on the development of innovative calcium compounds for surgical use. With over 30 years' experience and an unrivalled dedication to quality, the products we research, engineer and manufacture are at the forefront of calcium technology.

References: **1.** Lei D *et al.* Treatment of distal radius bone defects with injectable calcium sulfate cement. In: Zorzi A, ed. Bone Grafting, InTech (2012). **2.** Somasundaram K *et al.* Proximal humeral fractures: The role of calcium sulfate augmentation and extended deltoid splitting approach in internal fixation using locking plates. *Injury* 2013;44:481-7. **3.** Biocomposites Ltd, STIMULAN Instructions for Use. **4.** Data on File, Mr Jogia. **5.** Data on File, Mr Sharma. **6.** Data on File, Mr Dharmarajan. **7.** Cooper JJ. Method of producing surgical grade calcium sulphate. 1999. **8.** McPherson EJ. Dissolvable antibiotic beads in treatment of periprosthetic joint infection - the use of synthetic pure calcium sulfate (Stimulan®) impregnated with vancomycin and tobramycin. Presented at: Oxford Bone Infection Conference (OBIC) 2012. **9.** McPherson EJ *et al.* Dissolvable antibiotic beads in treatment of periprosthetic joint infection and revision arthroplasty. The use of synthetic pure calcium sulfate (Stimulan®) impregnated with vancomycin and tobramycin. *Reconstructive Review* 2013;3:32-43. **10.** Cierny G, DiPasquale D. Comparing OsteoSet and Stimulan as antibiotic-loaded, calcium sulfate beads in the management of musculoskeletal infection. Presented at: Musculoskeletal Infection Society of North America 2009. **11.** Kallala R, Nizam I, Haddad F. Outcomes following use of antibiotic-eluting, absorbable, calcium sulfate beads in revision hip and knee surgery for periprosthetic infection. Presented at: International Society for Technology in Arthroplasty 2013. **12.** Data on file. **13.** Gauland C. The use of antibiotic impregnated, implanted synthetic calcium sulfate tablets in the treatment of soft tissue, vancomycin resistant enterococcus infections. Presented at: Wound Healing Society 2011. **14.** Borrelli J *et al.* Treatment of nonunions and osseous defects with bone graft and calcium sulfate. *Clin Orthop Relat Res* 2003;245-54. **15.** Helgeson MD *et al.* Antibiotic-impregnated calcium sulfate use in combat-related open fractures. *Orthopedics* 2009;32:323. **16.** McKee MD *et al.* The use of an antibiotic-impregnated, osteoconductive, bioabsorbable bone substitute in the treatment of infected long bone defects: Early results of a prospective trial. *J Orthop Trauma* 2002;16:622-7. **17.** Noor S *et al.* The use OsteoSet-T in the treatment of chronic osteomyelitis of the tibia following exogenous trauma: A review of 22 patients at a regional trauma centre. *Bone Joint J* 2013;95-B:4.

For indications, contraindications, warnings and precautions see Instructions for Use.

The treating physician is responsible for deciding the type and quantity of antibiotic used. Concurrent use of locally administered antibiotics may affect setting time.

The mixing of antibiotics with the STIMULAN Kit / STIMULAN Rapid Cure device has not been assessed by a European medicines Competent Authority and is considered off-label usage of the medicinal product. To do so is at the professional risk of the surgeon / healthcare professional.

This brochure may include the use of STIMULAN or techniques that go beyond the current clearance / approval granted by the relevant regulatory authority. Please contact your local representative for further information.

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Patents granted: GB2367552, EP 1204599 B1, US 6780391, EP 2594231 B1, US 8883063, CN ZL201210466117.X, GB2496710, EP 3058899 B1

Patents pending: GB1502655.2, US 15/040075, CN 201610089710.5, US 15/288328, GB1704688.9

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