STIMULAN® power to transform™



Infection is a costly and complicated burden

Surgical site infections (SSI) account for nearly a quarter of hospital-acquired infections and cost up to \$10 billion annually in direct medical expenses.¹

Identifying the microorganisms

that cause SSI for each indication is essential to ensure the appropriate

antibiotic and treatment strategies*

Rates of procedural failure due to infection²⁻⁶



Distribution of microorganisms causing SSI⁷



Perfect partner for cases with an infected site

STIMULAN is a truly absorbable calcium sulfate, specifically designed to complement your dead space management.⁸

Can be placed directly into infected and non-infected bone voids and defects

Choosing an innovative void management device to work alongside your infection management strategy is key to:

- minimizing avoidable complications
- ✓ improving outcomes
- ✓ reducing costs

Calcium sulfate, uniquely recrystallized for consistent and reliable performance in the presence of infection

"The economic benefits are significant... the cost of a recurrent infection is hundreds of thousands of dollars relative to a product that is a few hundred dollars"

Dr. John Xenos

See the difference in your cases

STIMULAN can be used in cases with an infected site to fill a bone void or defect created by a cyst, tumor, traumatic injury or osteomyelitis.



Infected subtrochanteric fracture⁹

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.



Osteomyelitis caused by group B *Streptococcus* and MRSA¹⁰

Patient presented with: drainage issues 1 year after pilon fracture repair and then 2 weeks after hardware removal.

Outcome: 6 months after treatment the patient was fully weight-bearing and without restrictions on activity – with complete absorption of STIMULAN.





Bilateral high energy femoral fractures¹¹

Patient presented with: right open comminuted distal femoral fracture and tibial plateau fracture, and left closed comminuted femoral shaft fracture.

Outcome: complete absorption of **STIMULAN** and healing of the femoral defect after 4 months. At 1 year, patient was fully independently ambulatory with no pain.



Open calcaneus fracture infected with MRSA¹⁰

Patient presented with: infected, MRSA positive non-union and hardware failure 6 months after treatment for an open calcaneus fracture.

Outcome: at 13 months the absorption of STIMULAN was complete, the patient was weight-bearing and without sign of infection – amputation was avoided.

"It saves the hospital money as it decreases the hospital readmission rate"

Dr. Jorge Casas-Gánem

Uniquely engineered for the precision and control you demand every time

STIMULAN is a pharmaceuticalgrade calcium sulfate with a unique crystal structure that has tightly controlled properties.⁸

- ✓ controlled purity
- ✓ hydrophilic
- ✓ no hydroxyapatite

Only **STIMULAN** undergoes a proprietary DRy26[°] recrystallization method which consists of 26 steps over 6 weeks and results in its consistent and reliable performance.¹²

- ✓ truly absorbable
- absorbs at an optimal rate
- ✓ no third body damage

"It's very reproducible... I get the same outcomes time and time again"

Dr. Herrick Siegel



Every detail considered for your success

The high standards demanded for STIMULAN ensure any ingredients that increase the opportunity for infection are eliminated. This gives STIMULAN its characteristics for high biocompatibility.

 no hydroxyapatite, insoluble impurities or PMMA debris – leaves no nidus for infection.¹³⁻¹⁸



Truly absorbable and totally synthetic calcium sulfate — absorbs at an optimal rate⁸







11 weeks





6 months

15 months

Post-operative

8



STIMULAN – mixes with liquid

Competitor calcium sulfate — repels liquid

No third body damage to articulating surfaces^{19, 20}

Less scratching than competitor calcium sulfate.²¹



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

 $S\,T\,I\,M\,U\,L\,A\,N$ does not damage total knee replacements when trapped between the articulating surfaces of the implant.

Flexibility at your fingertips

Every part of STIMULAN is optimized to work around the clinical and surgical demands of the individual patient. Whatever the time, shape, accessibility or size constraints, STIMULAN gives you a way to adapt to each case.



STIMULAN Rapid Cure

For faster setting times



STIMULAN Kit

More time to sculpt or inject

No challenge too large or small

STIMULAN includes a range of pack sizes which enable you to mix and match to any void size.

The mini 3cc pack size and combination bead and bullet mat were designed for smaller void volumes.

- \checkmark versatile application
- ✓ full range of bead and bullet sizes
- ✓ reduce waste



The combination bead and bullet mat is only available with the 3cc pack size

Choice of formats



Bead mat available with STIMULAN Rapid Cure and STIMULAN Kit



Syringe available with $S\,T\,I\,M\,U\,L\,A\,N$ Kit

Hard to reach defect?

STIMULAN Bullet Mat and Introducer

Streamlined, flexible design that simplifies the delivery of STIMULAN for deep defects.



Unrivaled evidence and expertise bring confidence

With our industry-leading knowledge, dedication and experience, you can be sure that the high level of consistency you demand in your cases will be met.

Peer-reviewed papers, presentations and posters



"... happier with this product than anything I've used in the last 30 years" Dr. Richard Biama

Case study

Courtesy of Mr. Hemant K. Sharma

Consultant Orthopaedic Surgeon, Hull, UK

Clinical particulars

35-year-old male involved in a road traffic accident suffered multiple injuries and subtrochanteric fracture of left femur. This was nailed, but subsequently, he developed infection and drainage from both proximal and distal locking screw areas. He went to theatre multiple times and developed wound approx. 15cm on the proximal lateral thigh, which was treated with VAC.

He presented a year later with discharging wound proximally and distally.

Treatment

The femoral nail was removed, followed by reaming of the femoral canal and washout procedure. 40cc of **STIMULAN** beads were placed in the intramedullary canal. Cultures revealed infection to be *Staphylococcus aureus*. Antibiotics were administered to treat the infection.

Outcome

2.5 months' post-operatively x-rays showed almost complete absorption of the STIMULAN beads and at 7 months there was complete healing of the non-union.

At 1 year follow-up, the patient remains infection free, walking with no pain.





Pre-operative x-ray showing non-union



CT – 2 months



2.5 months



1 year

STIMULAN[®]

Case study

Courtesy of Dr. Daniel Schlatterer

Orthopaedic Surgeon, Atlanta, GA, USA

Clinical particulars

73-year-old female with osteomyelitis caused by group B *Streptococcus* and MRSA infection. Presented with exposed hardware and post-operative drainage issues, 1 year after pilon fracture repair and subsequently 2 weeks after removal of all hardware.

Treatment

Hardware removal and repeat debridement on the medial side of the ankle resulted in a large dead space which was managed using STIMULAN paste. Antibiotics were administered to treat the infection.

Outcome

6 months after treatment the patient was free from infection, fully weight-bearing and without restrictions on activity - with complete absorption of STIMULAN paste.





Presentation





1 month



6 months





15 months

Case study

Courtesy of Dr. Lawrence X. Webb

Orthopaedic Surgeon, Macon, GA, USA

Clinical particulars

50-year-old female presented with bilateral high-energy fractures due to a motor vehicle accident with prolonged extrication. The patient suffered from right open comminuted distal femoral fracture and tibial plateau fracture and left closed comminuted femoral shaft fracture.

Treatment

Day 1: Irrigation and debridement of the right femur was carried out along with placement of a large external fixator bridge for temporary stabilization. The left femur was stabilized using a retrograde IM nail locked statically with screws.

Day 3: The external fixator bridge was removed and open reduction internal fixation was performed on the distal right femur. **STIMULAN**, cancellous allograft and demineralized bone were used to fill a significant bone deficit just above the femoral condyles. Antibiotic treatment was provided to prevent infection. Open reduction internal fixation was carried out for the tibial plateau fracture supplemented with the use of cancellous allograft.

Outcome

4 months after treatment STIMULAN had absorbed and there was complete healing of the femoral defect.

At 1 year follow-up the patient was fully independently ambulatory with a normal gait, normal range of motion and no pain.







Day 1 – Post-operative Left leg



4 months – Right leg





1 year – Right leg



Day 1 – Post-operative Right leg



Day 3 – Post-operative Right leg



1 year – Left leg

Case study

Courtesy of Dr. Daniel Schlatterer

Orthopaedic Surgeon, Atlanta, GA, USA

Clinical particulars

40-year-old male sustained an open calcaneus fracture after a 20 foot fall. Initial surgery was an irrigation and debridement with definitive fixation 10 days after injury. 6 months later patient presented with an infected non-union and hardware failure. Cultures were positive for MRSA.

Treatment - Stage 1

Hardware removal, debridement of grossly infected bone and soft tissues. **STIMULAN** was used to fill the resulting dead space. I.V. antibiotics for 8 weeks.

Outcome - Stage 1

Infection eradicated, soft tissues healed, infectious lab studies normal (1 month after I.V. antibiotics completed). Foot suitable for correction of proximal migration of calcaneus (soft tissue releases) and subtalar fusion.

Treatment - Stage 2

Subtalar fusion procedure performed. **STIMULAN** was used again to fill the remaining dead space in and around the talus and calcaneus (image with **STIMULAN** at the fusion stage not included). I.V. antibiotics restarted as prophylaxis. 2 months later hardware removed again due to positive blood cultures. Calcaneus cultures were negative however the PICC line catheter tip was culture positive. A new PICC line was placed followed by another 8 weeks of I.V. antibiotics.

Outcome - Stage 2

This patient is now weight-bearing as tolerated and clinically no signs of infection. Infection in open calcaneus fractures is common and in some series amputation rates exceed 50%. For this patient a 2 stage approach was utilized to treat the infected non-union. Removal of hardware and aggressive debridement of the bone. The dead space was managed with **STIMULAN**.



Presentation



Post-operative - Stage 1



Stage 1 complete



13 months after subtalar fusion, 11 months after hardware removal

Case study

Courtesy of Dr. Robert J. Wetzel

Orthopaedic Surgeon, Cleveland, OH, USA

Clinical particulars

31-year-old female with metabolic bone disease who sustained a displaced right femoral neck fracture and a left femoral neck stress fracture after a low-energy fall. Initial surgery included ORIF with a sliding hip screw construct on the right side and placement of a prophylactic sliding hip screw on the left side to prevent fracture completion and displacement. She presented 6 months later with a left sided deep infection, non-union of her stress fracture and persistent pain.

Treatment - Stage 1

The sliding hip screw was removed from the left femur and multiple meticulous excisional debridements were performed. 20cc of **STIMULAN** paste was injected into the proximal femur bone void. Bacterial cultures revealed *Propionibacterium Acnes*. Antibiotic treatment was administered based on the sensitivities of the organism and I.V. antibiotics were administered for 6 weeks following surgery.

Treatment - Stage 2

At 6 weeks, autologous bone graft and 10cc of STIMULAN paste were placed at the femoral neck non-union site. Internal fixation was performed with a blade plate device.

Outcome

6 weeks after stage 1 treatment, the patient was free from infection with complete absorption of STIMULAN paste. 4 months after stage 2 treatment, the non-union site appeared to be healed with no hardware failure and complete absorption of STIMULAN. Imaging at 1 year after stage 2 treatment confirmed consolidation at the non-union site and stable hardware.

The patient developed heterotopic ossification in her vastus lateralis due to multiple debridement surgeries to treat her infection and extensile distal dissection required to place the blade plate. The heterotopic ossification was asymptomatic and did not require further treatment. At 2 years, the patient is ambulating without an assisted device and remains infection and pain free.



Initial post-operative





Stage 1 – post-operative



Stage 2 – 4 months





Stage 2 – 2 years

Overview

STIMULAN Rapid Cure

Paste volume	Bead volume	In the pack	Order code
Зсс	7сс	 Powder and solution Mixing bowl Spatula Paste applicator Combination bead and bullet mat 	620-003
5cc	12cc	 Powder and solution Mixing bowl Spatula Paste applicator Bead mat 	620-005
10cc	25cc		620-010
20сс	50cc	 Powder and solution Mixing bowl Spatula Paste applicator 2 x bead mats 	620-020

STIMULAN Kit

Paste volume	Bead volume	In the pack	Order code
5cc	10cc	 Powder and solution Spatula Paste applicator Bead mat Syringe and extension tube 	600-005
10cc	20cc		600-010

STIMULAN Bullet Mat and Introducer

Bullet dimensions	Reamed diameter	In the pack	Order code
7mm x 20mm	10mm reamed diameter (minimum)	• Bullet mat • 7mm (black) inserter • 9mm (silver) inserter • Obturator	660-001
9mm x 20mm	12mm reamed diameter (minimum)		

References: 1. Shea, K.G., Styhl, A.C., King, H.A., et al., Surgical Site Infection Reduction Program: Challenges and Opportunities. J Pediatr Orthop, 2015. 35(5 Suppl 1): S51-4. 2. Thiele, K., Perka, C.C., Matziolis, G., et al., Current failure mechanisms after knee arthroptasty have changed: Polyethylene wear is tess common in revision surgery. J Bone Joint Surg Am, 2015. 97: 715-20. 3. Marsh J.L., Smith S.T., Do T.T., External fixation and limited internal fixation for complex fracture of the tibial plateau. J Bone Joint Surg Am, 1995 May;77(5):661-73. 4. Gustilo, R.B., Anderson, J.T., Prevention of infection in the treatment of one thousand and twenty-five open fractures of long bones: retrospective and prospective analyses. J Bone Joint Surg Am, 1976. 58: 453-8. 5. Ramo, B.A., Roberts, D.W., MD, Tuason, D., et al., Surgical Site Infections After Posterior Spinal Fusion for Neuromuscular Scoliosis. J Bone Joint Surg Am. 2014. 96: 2038-48. 6. Hobizal, K.B., Wukich, D.K., Diabetic foot infections: current concept review. Diabetic Foot Ankle, 2012. 3: 10.3402/ dfa.v301.18409. 7. Public Health England. Surveillance of surgical site infections in NH5 hospitals in England, 2017 to 2018, December 2018. Available at: https://www.gov.uk/government/publications/surgical-site-infections-sis-usrveillance-nhs-hospitals-in-england – Last accessed: December 2019. 8. Biocomposites, STIMULAN Instructions for use. 9. Biocomposites, Data on file, Dr. Webb. 12. Cooper, J.J., Method of producing surgical grade calcium sulphate: Patent 1999. 13. Somasundaram, K., Huber, C.P., Babu, V., et al., Proximal humeral fractures: the role of calcium sulphate augmentation and extended dettoid splitting approach in internal fixation using locking plates. Injury, 2013. 44(4): 481-7. 14. Lei D., Zhanzhong, M., Huaikuo, Y., et al., Treatment of Dista Radius Bone Defects with Injectable Calcium Sulphate Cernent. In: Bone Grafting, A., Zorzi, Editor. 2012, InTech. p. 125-134. 15. Lei, D., Jing, L., Yang-yong, S., Calcium sulfate versus calcium

The Biocomposites Companion

Your essential guide to making the most of STIMULAN – all in one straightforward app.

Our accessible app provides all the information you need to meet different clinical demands when using **STIMULAN**. From surgeons' tips to how-to videos, this is the expert support tool you need, right at your fingertips.





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POWER TO TRANSFORM™

- Perfect partner for cases with an infected site⁸
- Unique DRy26[®] recrystallization method for consistent and reliable performance¹²
- No hydroxyapatite, insoluble impurities or PMMA debris¹³⁻¹⁹
- 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 35 years' experience and an unrivaled dedication to quality, the products we research, engineer and manufacture are at the forefront of calcium technology.

Find out more at biocomposites.com

For indications, contraindications, warnings and precautions see Instructions for Use. Concurrent use of locally administered antibiotics may affect setting time.

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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