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

Rates of procedural failure due to infection²⁻⁶

<table>
<thead>
<tr>
<th>Category</th>
<th>Rate</th>
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</thead>
<tbody>
<tr>
<td>Orthopaedics</td>
<td>up to 26%</td>
</tr>
<tr>
<td>Trauma</td>
<td>up to 45%</td>
</tr>
<tr>
<td>Spine</td>
<td>up to 24%</td>
</tr>
<tr>
<td>Foot and ankle</td>
<td>up to 40%</td>
</tr>
</tbody>
</table>

Distribution of microorganisms causing SSI⁷

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gram Negative</td>
<td>12%</td>
</tr>
<tr>
<td>Gram Positive</td>
<td>40%</td>
</tr>
<tr>
<td>Gram Negative / Gram Positive</td>
<td>42%</td>
</tr>
<tr>
<td>Other</td>
<td>6%</td>
</tr>
</tbody>
</table>

Identifying the microorganisms that cause SSI for each indication is essential to ensure the appropriate antibiotic and treatment strategies*
Perfect partner for cases with an infected site

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

*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

“**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

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

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 fracture

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 MRSA

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.
It saves the hospital money as it decreases the hospital readmission rate”

Dr. Jorge Casas-Gánem

Bilateral high energy femoral fractures

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 MRSA

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.
STIMULAN is a pharmaceutical-grade calcium sulfate with a unique crystal structure that has tightly controlled properties.

- **controlled purity**
- **physiologic pH level**
- **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.¹³

- **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.14-19

Truly absorbable and totally synthetic calcium sulfate — absorbs at an optimal rate\(^8\)
No third body damage to articulating surfaces

Less scratching than competitor calcium sulfate.

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

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.

Sets in 4 mins

STIMULAN Rapid Cure
For faster setting times

Sets in 8 mins

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.

Introducing the NEW mini 3cc pack size and combination bead and bullet mat for smaller void volumes.

✔ versatile application
✔ full range of bead and bullet sizes
✔ reduce waste

The new combination bead and bullet mat is only available with the 3cc pack size
Choice of formats

Beads 3mm 4.8mm 6mm Paste

Bead mat available with STIMULAN Rapid Cure and STIMULAN Kit

Syringe available with STIMULAN Kit

Hard to reach defect?

STIMULAN Bullet Mat and Introducer
Streamlined, flexible design that simplifies the delivery of STIMULAN for deep defects.

Long bullets with a groove down one side to reduce the risk of pressurizing the defect site

(See the inside back cover for further details and ordering codes)
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

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>382</td>
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<tr>
<td>Infection-related</td>
<td>254</td>
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<tr>
<td>Multiple-patient</td>
<td>196</td>
</tr>
<tr>
<td>Pathogen-specific</td>
<td>91</td>
</tr>
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</table>

With over 20 years of clinical experience and use in 50,000 new cases each year, STIMULAN continues to expand the possibilities for surgeons and patients through a commitment to innovation and consistently high levels of satisfaction.

“... 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.

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.
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.

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.
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.
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.
Case study

Courtesy of Dr. Motasem Refaat
Orthopaedic Surgeon, Fresno, CA, USA

Clinical particulars
26-year-old male with shotgun wound to the right shoulder presented with right distal open comminuted lateral third clavicle fracture with intact AC joint and large overlying skin defect. Fracture was grossly exposed with several free bony fragments. X-ray of right shoulder revealed multiple radiopaque foreign bodies surrounding the clavicle, superior chest and neck.

Treatment
Initial I.V. antibiotics were administered for 72 hours, fracture site was washed out at bedside and visible metal debris was removed. Irrigation and excisional debridement of subcutaneous tissue, skin, muscle and bone was completed. Metal debris and pieces of the patient’s shirt were removed from wound. A thorough washout was completed with repeat debridement from superficial to deep layers to ensure all possible debris was removed. STIMULAN beads were used to fill the bone deficit at the fracture site. Antibiotic treatment was provided to prevent infection as the wound was contaminated. A layered closure of the fascia was carried out to cover the bone. A primary closure of the skin was completed with little tension and a wound VAC was placed over the incision.

Outcome
Post-operative x-rays show partial absorption of STIMULAN beads at 1 month. Wound healing occurred 3 months after treatment, and at 6 months there was full consolidation of the clavicle fracture with complete absorption of STIMULAN beads. At 1 year, the patient remains infection free and without pain from remaining shotgun pellet debris.
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. 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.
### Overview

#### STIMULAN Rapid Cure

<table>
<thead>
<tr>
<th>Paste volume</th>
<th>Bead volume</th>
<th>In the pack</th>
<th>Order code</th>
</tr>
</thead>
</table>
| 3cc          | 7cc         | • 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        | • Powder and solution  
• Mixing bowl  
• Spatula  
• Paste applicator  
• Bead mat | 620-010 |
| 20cc         | 50cc        | • Powder and solution  
• Mixing bowl  
• Spatula  
• Paste applicator  
• 2 x bead mats | 620-020 |

#### STIMULAN Kit

<table>
<thead>
<tr>
<th>Paste volume</th>
<th>Bead volume</th>
<th>In the pack</th>
<th>Order code</th>
</tr>
</thead>
</table>
| 5cc          | 10cc        | • Powder and solution  
• Spatula  
• Paste applicator  
• Bead mat | 600-005 |
| 10cc         | 20cc        | • Syringe and extension tube | 600-010 |

#### STIMULAN Bullet Mat and Introducer

<table>
<thead>
<tr>
<th>Bullet dimensions</th>
<th>Reamed diameter (minimum)</th>
<th>In the pack</th>
<th>Order code</th>
</tr>
</thead>
</table>
| 7mm x 20mm        | 10mm reamed diameter      | • Bullet mat  
• 7mm (black) inserter  
• 9mm (silver) inserter  
• Obturator | 660-001 |
| 9mm x 20mm        | 12mm reamed diameter      |             |            |

### References

dfu.v3i0.18409.  
8. Biocomposites, STIMULAN Instructions for use.  
9. Biocomposites, Data on file, Mr. Sharma.  
10. Biocomposites, Data on file, Dr. Schlatterer.  
15. Lazarou, S.A., Drosdos, G.B., Okekeje, I.D., Correction of atrophic ulcer with calcium- 
STIMULAN®

POWER TO TRANSFORM™

- Perfect partner for cases with an infected site

- Unique DRy26® recrystallization method for consistent and reliable performance

- No hydroxyapatite, insoluble impurities or PMMA debris

- Provides case-by-case flexibility

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 unrivaled dedication to quality, the products we research, engineer and manufacture are at the forefront of calcium technology.

Find out more at biocomposites.com