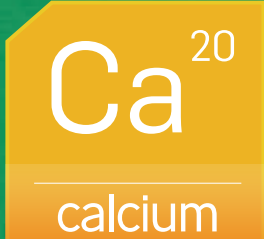




STIMULAN[®]

Introduction and Preparation Guide for Canadian Healthcare Professionals

Biocomposites

bringing  to life[®]

- Innovative approaches to infection management strategies
- Singular focus on calcium compound technologies
- Deep expertise
- Dedicated to quality
- Based in Keele, UK – with companies in the USA and China, and a presence in Canada and India

Aim of the training course

This training course will

- ✓ Introduce you to S T I M U L A N, the perfect partner for your infection management strategy
- ✓ Show you how to prepare S T I M U L A N Rapid Cure ready for use



STIMULAN

Treatment goals

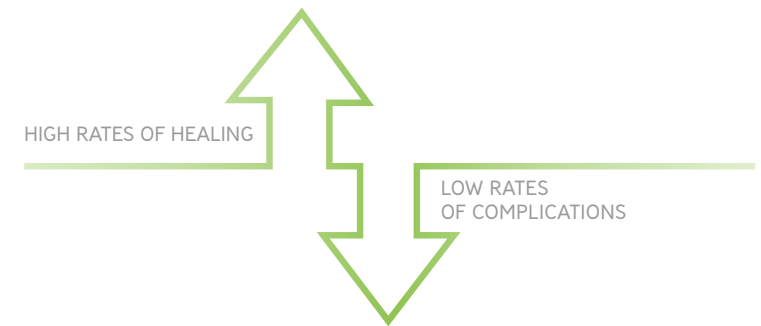
- ✓ Provide a novel and innovative solution to infected or high risk patients
- ✓ Provide a clinically superior treatment alternative for periprosthetic joint infection, infected non-unions and osteomyelitis
- ✓ Minimize avoidable complications
- ✓ Improve patient outcomes and decrease hospital readmissions
- ✓ Improve treatments while decreasing overall treatment cost

STIMULAN

Perfect partner for your infection management strategy

STIMULAN is a truly absorbable calcium sulfate, specifically designed to complement your dead space and infection management strategies.¹

- ✓ Approved for placement directly at the site of infection
- ✓ May be mixed with antibiotics



Calcium sulfate, uniquely recrystallized to transform outcomes in the presence of infection^{1,2}

STIMULAN

Recrystallized for improved clinical performance

STIMULAN is a pharmaceutical-grade calcium sulfate with a unique crystal structure and properties.¹⁻³

- ✓ Controlled purity
- ✓ Easily mixed with liquid, powder and heat-sensitive antibiotics

Only STIMULAN undergoes a patented recrystallization process that starts with pharmaceutical-grade reagents and results in its consistent and reliable performance.¹⁻³

- ✓ Predictable elution profile
- ✓ Truly absorbable at an optimal rate
- ✓ Low levels of drainage



STIMULAN

What is STIMULAN indicated for?

- ✓ STIMULAN is the perfect partner for your infection management strategy
- ✓ It is intended for use as a bone void filler for voids or gaps and can be used at an infected site
- ✓ It is indicated for use in musculoskeletal defects created by surgery, a cyst, a tumor, osteomyelitis or traumatic injury
- ✓ STIMULAN is not intended to provide structural support during the healing process

STIMULAN

Transforming outcomes in infected non-unions, osteomyelitis and periprosthetic joint infection⁴



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.

STIMULAN

Transforming outcomes in infected non-unions, osteomyelitis and periprosthetic joint infection⁵



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.

STIMULAN

Transforming outcomes in infected non-unions, osteomyelitis and periprosthetic joint infection⁶



TRANSFORM INFECTED REVISION ARTHROPLASTY^{6*}

Patient presented with: Recurrent periprosthetic infection after complex hinged total knee replacement (TKR).

Outcome: 7 months' post-operatively, the infection remained controlled and the bone had consolidated. 2 years' post-operatively, no recurrence of infection had occurred.

STIMULAN

Case-by-case flexibility

- ✓ Can be used in three bead sizes, as a paste or for injection
- ✓ Quick and easy to prepare

PRODUCT	PASTE VOLUME	BEAD VOLUME	SETTING TIMES
STIMULAN _{Kit} Fully injectable paste with individual bead kit	5cc	10cc	8 minutes approx.
	10cc	20cc	
STIMULAN _{Rapid Cure} Rapid setting paste with individual bead kit	5cc	12cc	4 minutes approx.
	10cc	25cc	
	20cc	50cc	

How to prepare STIMULAN Rapid Cure



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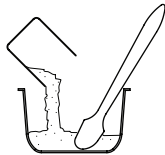
STIMULAN

PREPARATION GUIDE FOR STIMULAN Rapid Cure

Mixing solution provided

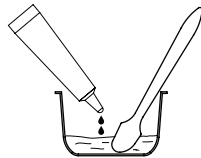
Use the mixing solution from the tube provided in the pack. Do not add any other fluid.

1



Empty **STIMULAN**
Rapid Cure powder
into the sterile mixing
bowl provided

2



Add mixing solution and
mix thoroughly until a
smooth paste is formed
(approx. 30 secs)

3



Apply to bead
mat immediately



Allow paste to set
undisturbed for at least
8 minutes. Flex bead mat
to release beads.

STIMULAN

Warning: Concurrent use of locally administered antibiotics may affect the setting time as exemplified in the following slides for 10cc of **STIMULAN** Rapid Cure. The mixing of antibiotics with the **STIMULAN** Rapid Cure device is considered off-label usage of the medicinal product. To do so is at the professional risk of the surgeon/healthcare professional.

STIMULAN

Combination of powder and liquid antibiotics

If using liquid antibiotics, the mixing solution provided in the pack should not be used.

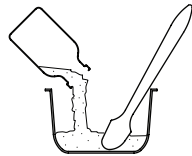
Vancomycin* (powder) 1g and gentamicin* (liquid) 240mg

DO NOT USE MIXING SOLUTION PROVIDED

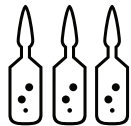


1g vancomycin powder

1



Add vancomycin powder to **STIMULAN** Rapid Cure powder and mix



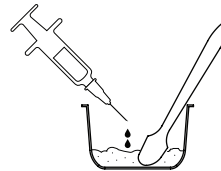
3x 80mg ampoules gentamicin liquid (6ml)

2



Measure 6ml gentamicin liquid into syringe

3



Add 6ml gentamicin liquid to pre-mixed **STIMULAN** Rapid Cure and vancomycin powders and mix for 30 secs

4



Apply to bead mat immediately



Sets in 3-5 minutes

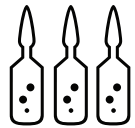
STIMULAN

Vancomycin* (powder) 1g and tobramycin* (liquid) 240mg

DO NOT USE MIXING SOLUTION PROVIDED

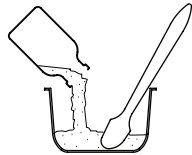


1g vancomycin powder



3x 80mg ampoules tobramycin liquid (6ml)

1



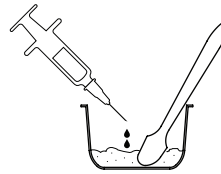
Add vancomycin powder to **STIMULAN** Rapid Cure powder and mix

2



Measure 6ml tobramycin liquid into syringe

3



Add 6ml tobramycin liquid to pre-mixed **STIMULAN** Rapid Cure and vancomycin powders and mix for 30 secs

4



Apply to bead mat immediately



Sets in 4-7 minutes

STIMULAN

Powdered antibiotics

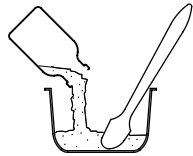
The mixing solution provided in the pack should be used. Do not add any other fluids.

Vancomycin* (powder) 1g



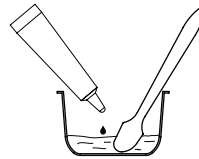
1g vancomycin
powder

1



Add vancomycin powder
to **STIMULAN** Rapid
Cure powder and mix

2



Add **STIMULAN**
Rapid Cure mixing
solution and mix for
30 secs

3



Apply to bead
mat immediately



Sets in
2-5 minutes

STIMULAN

Powdered antibiotics with extended setting times

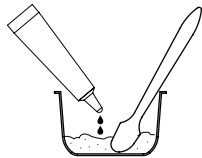
Some antibiotics may delay the setting time significantly. This technique ensures a faster set time.

Tobramycin* (powder) 1.2g



1.2g tobramycin
powder

1



Add mixing solution
to **STIMULAN**
Rapid Cure powder.
Mix for 40 secs

2



Add tobramycin powder
to **STIMULAN**
Rapid Cure powder
and mix for 30 secs

3



Apply to bead
mat immediately



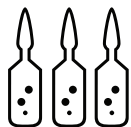
Sets in
10-20 minutes

STIMULAN

Liquid antibiotics

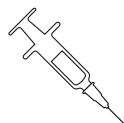
If using liquid antibiotics, the mixing solution provided in the pack should not be used.

Gentamicin* (liquid) 240mg DO NOT USE MIXING SOLUTION PROVIDED



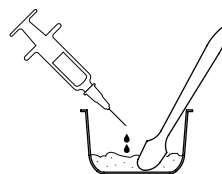
3x 80mg ampoules
gentamicin liquid (6ml)

1



Measure 6ml gentamicin
liquid into syringe

2



Add 6ml gentamicin liquid to
STIMULAN Rapid Cure
powder and mix for 30 secs

3



Apply to bead
mat immediately



Sets in
3-5 minutes

STIMULAN

Tobramycin* (liquid) 240mg DO NOT USE MIXING SOLUTION PROVIDED



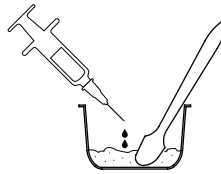
3x 80mg ampoules
tobramycin liquid (6ml)

1



Measure 6ml tobramycin
liquid into syringe

2

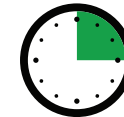


Add 6ml tobramycin liquid to
STIMULAN Rapid Cure
powder and mix for 30 secs

3



Apply to bead
mat immediately



Sets in
5-15 minutes

Find out more at biocomposites.com

References:

1. Biocomposites Ltd, STIMULAN, Instructions for Use
2. McPherson, E.J., M.V. Dipane, and S.M. Sherif, Dissolvable Antibiotic Beads in Treatment of Periprosthetic Joint Infection and Revision Arthroplasty. The Use of Synthetic Pure Calcium Sulfate (Stimulan®) Impregnated with Vancomycin & Tobramycin. Reconstructive Review, 2013. 3(1): p. 32-43.
3. Cooper, J.J., Method of producing surgical grade calcium sulphate, patent GB2367552; EP 1204599 B1; US 6780391. 1999.
4. Biocomposites, Data on file, Mr Jogia.
5. Biocomposites, Data on file, Mr Sharma.
6. Biocomposites, Data on file, Mr Norrish.

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 is considered off-label usage of the medicinal product. To do so is at the professional risk of the surgeon / healthcare professional.

This presentation 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
Patents pending: GB1502655.2, EP 16154210.5, US 15/040075, CN 201610089710.5, US 15/288328.

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