

# Distributor Representative Training (Canada)

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Introduction to Biocomposites and  
**STIMULAN**

# Training objectives

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At the end of this session you will have the knowledge to:

- Speak confidently about Biocomposites and S T I M U L A N.
- Discuss the cost of infection and sell the value of S T I M U L A N.
- Demonstrate how S T I M U L A N has the power to transform outcomes.
- Sell S T I M U L A N compliantly and address unsolicited requests.
- Expand your business.
- Properly manage new accounts.
- Utilize resources to assist your selling practices.

# Training agenda

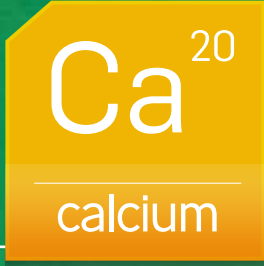
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- Introduction to Biocomposites.
- Musculoskeletal Infection.
- Selling S T I M U L A N.
- Antibiotic Mixing Guidelines.
- Power to Transform Outcomes.
- Account Management.
- Why Should I Sell S T I M U L A N?
- Useful Resources.



# Introduction to Biocomposites

# Biocomposites<sup>®</sup>

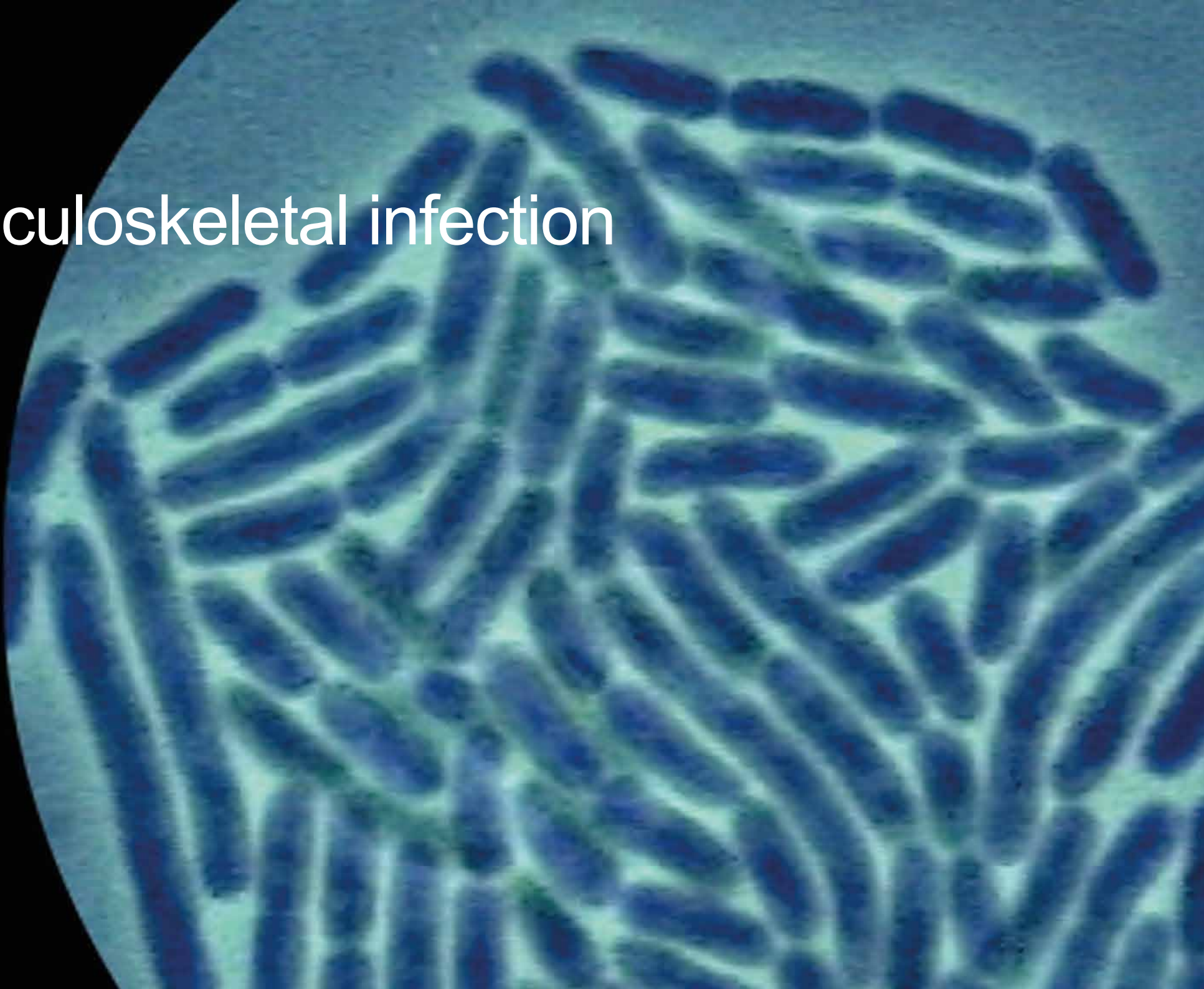
bringing  to life<sup>™</sup>

- Innovative approaches to infection management
- 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





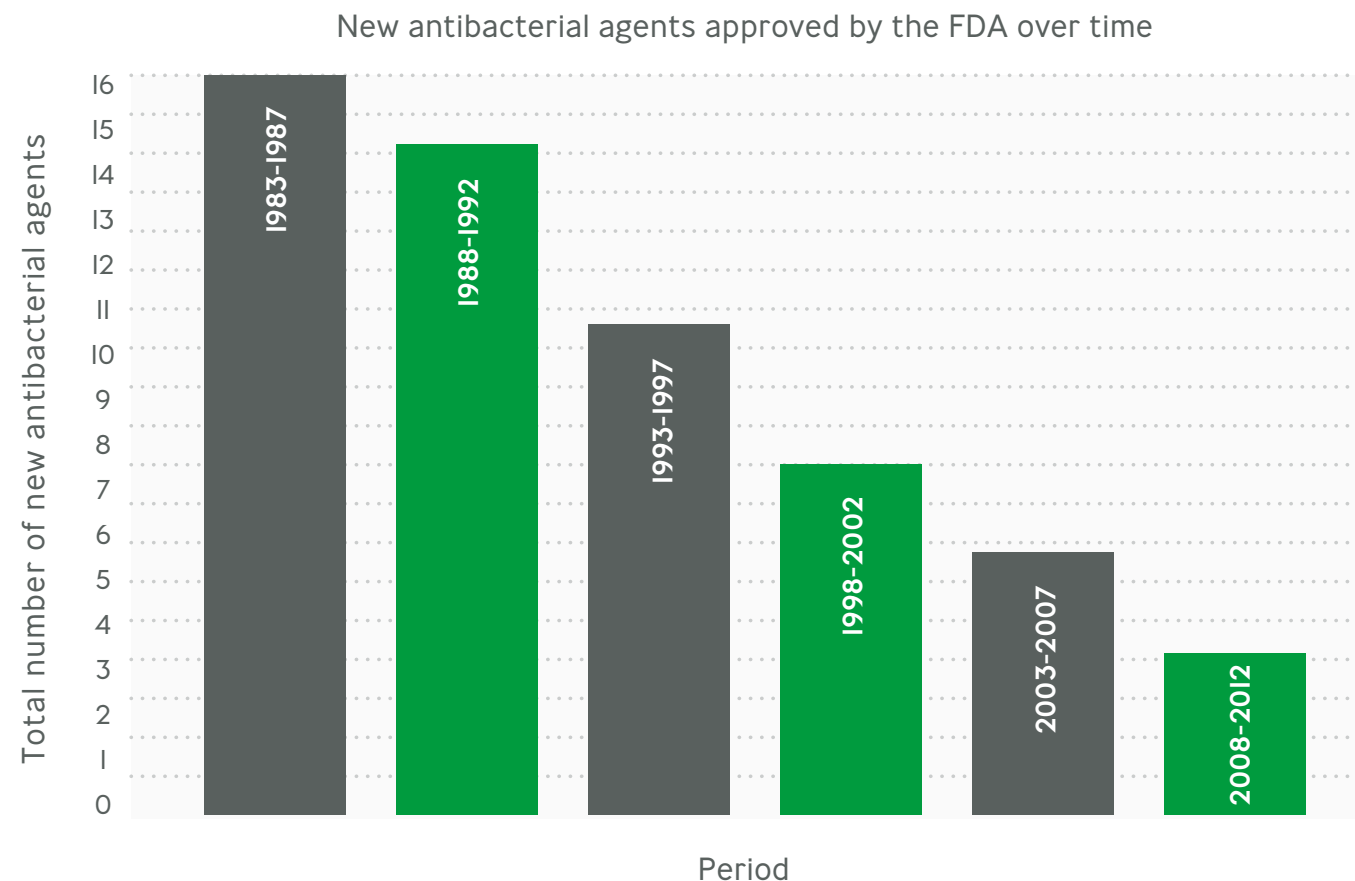
# Musculoskeletal infection



# Musculoskeletal infection

Musculoskeletal infections are one of the biggest healthcare challenges in the 21st century

- Rapid growth of antibiotic-resistant strains and biofilms continues to outpace the development of new antibiotics and antibiotic strategies. <sup>1,12</sup>





# Musculoskeletal infection

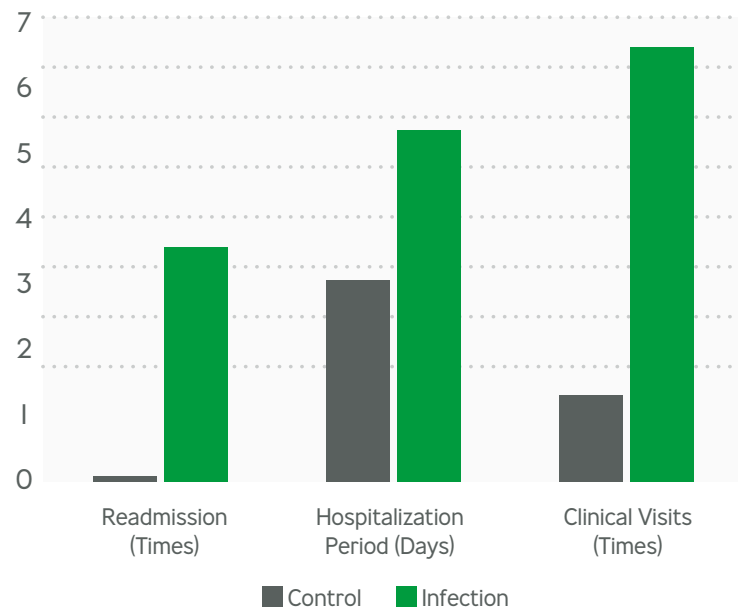
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Musculoskeletal infections are one of the biggest healthcare challenges of the 21<sup>st</sup> century

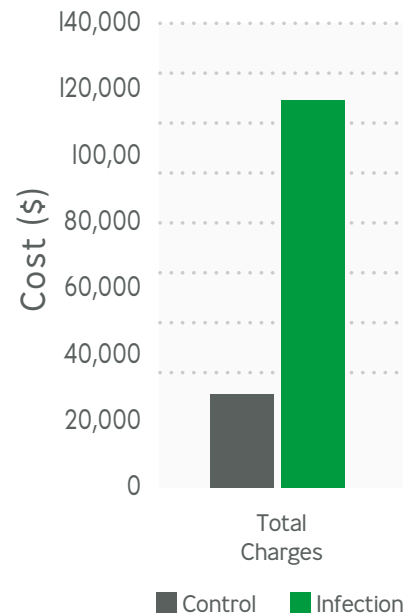
- 50-60% of all hospital acquired infections are caused by antibiotic-resistant bacteria. <sup>2</sup>
- Hospital acquired infections average US\$9.8B in the U.S. and US\$32.5B worldwide. <sup>2</sup>
- Average hospital cost per patient can increase from US\$32K to US\$185K when an infection is present.<sup>2</sup>
- Orthopedic SSI's prolong total hospital stays by a median of 2 weeks per patient, approximately double re-hospitalization rates and increase healthcare costs by 300%. <sup>3</sup>

# Musculoskeletal infection

A 2007 - 2011 study measured the economic impact of PJI following TKA compared to an uninfected control group<sup>4</sup>



Hospital & clinic visits



Total costs, hospital bed & operating room charges

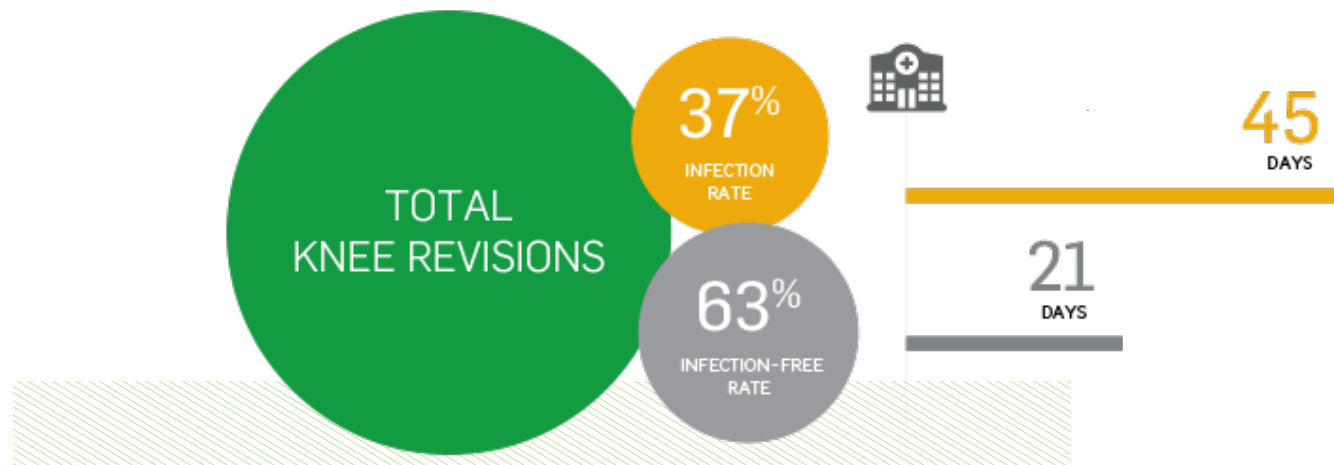
- Increased readmissions for patients with PJI.
- Longer hospitalization periods for patients with PJI.
- Higher number of clinical visits for patients with PJI.
- Higher costs for patients with PJI.

# Musculoskeletal infection

A major cause of arthroplasty failure, PJI often leads to prolonged antibiotic therapy and higher costs.<sup>5</sup>

## Knee

- 1% of primaries result in infection with 8% going on to have a revision.
- 37% of knee revisions result in infection and lead to an average 24 days additional stay in hospital.
- Treatment costs dramatically rise from an average cost per patient of £6,266 for a primary, to £16,437 for a primary and revision and £29,747 for a primary and infection after revision.



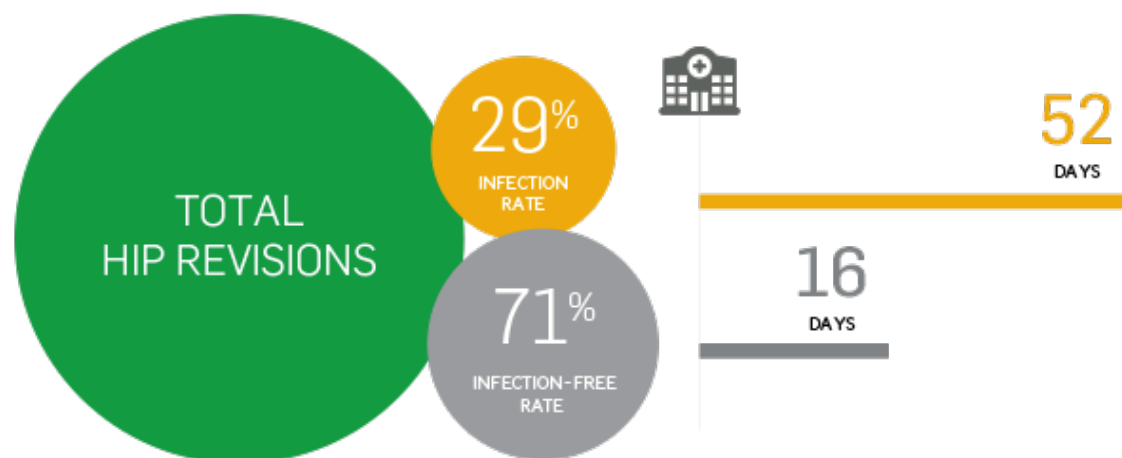
Average length of hospital stay following primary and joint revision (UK)

# Musculoskeletal infection

A major cause of arthroplasty failure, PJI often leads to prolonged antibiotic therapy and higher costs.<sup>5</sup>

## Hip

- 1% of primaries result in infection with 13% going on to have a revision.
- 29% of hip revisions result in infection and lead to an average 36 days additional stay in hospital.
- Treatment costs dramatically rise from an average cost per patient of £5,764 for a primary, to £16,239 for a primary and revision and £28,538 for a primary and infection after revision.



Average length of hospital stay following primary and joint revision (UK)

# Musculoskeletal infection

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## 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.
- Help with antibiotic stewardship.



# STIMULAN

POWER TO TRANSFORM OUTCOMES



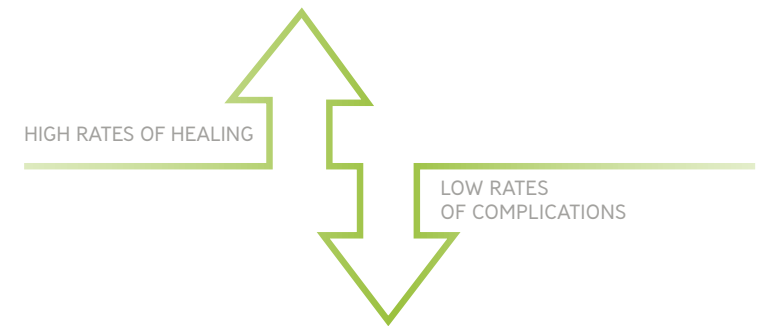
# STIMULAN<sup>®</sup>

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## Perfect partner for your infection management strategy

STIMULAN<sup>®</sup> is a truly absorbable calcium sulfate, specifically designed to complement your dead space and infection management strategies.<sup>6</sup>

- ✓ approved for placement directly at the site of infection in bone and soft tissue.
- ✓ may be mixed with antibiotics to protect the device from colonization by bacteria.\*



*Calcium sulfate, uniquely recrystallized to transform outcomes in the presence of infection.*<sup>6,7</sup>

# STIMULAN<sup>®</sup>

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## Recrystallized for consistent and reliable performance

STIMULAN is a pharmaceutical-grade calcium sulfate with a unique crystal structure and properties.<sup>8,9</sup>

- ✓ 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.<sup>6,9-15</sup>

- ✓ predictable elution profile.
- ✓ truly absorbable at an optimal rate.
- ✓ low levels of drainage.

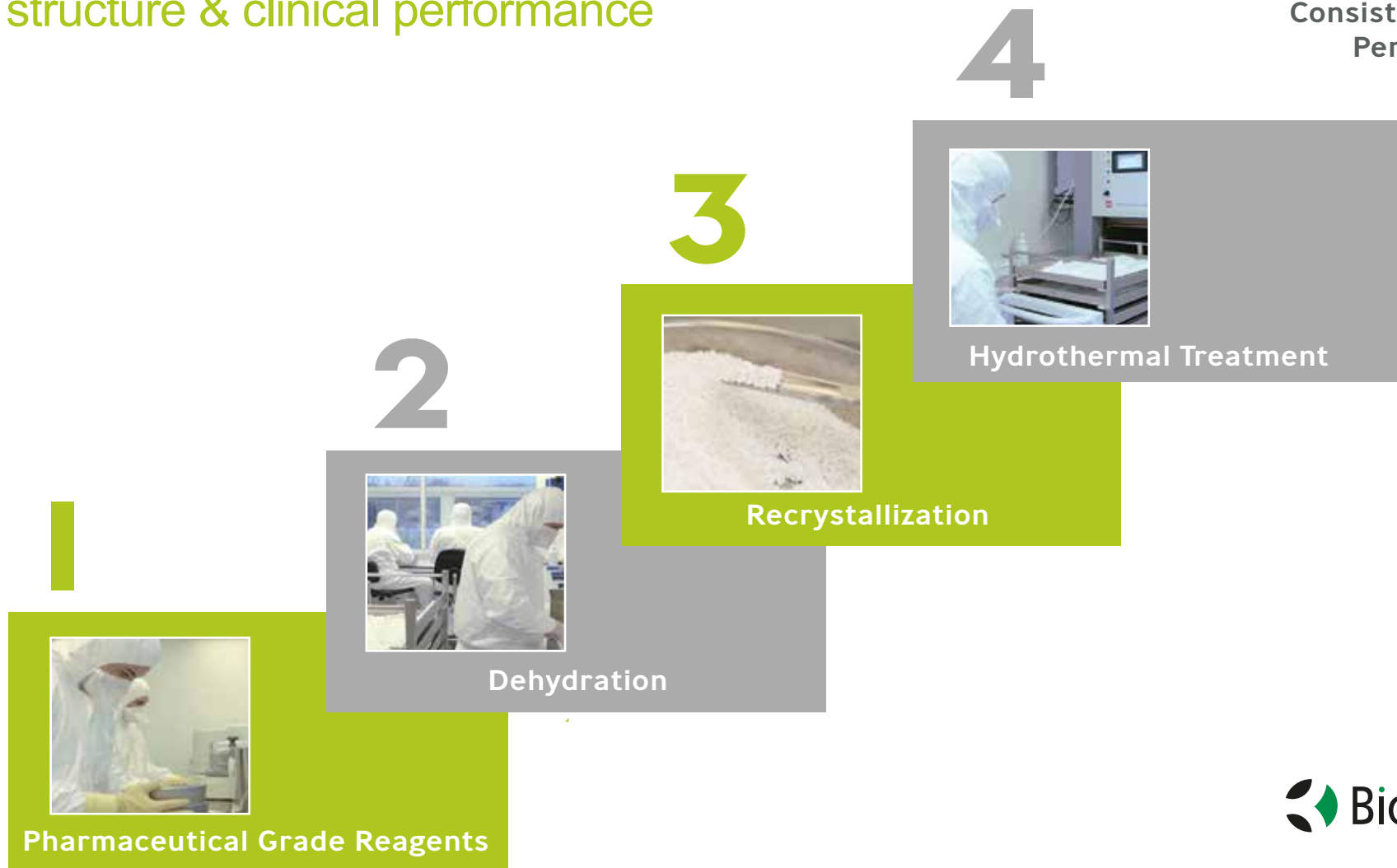


# STIMULAN<sup>®</sup>

Recrystallized for a unique crystal structure & clinical performance

STIMULAN

Consistent & Reliable  
Performance

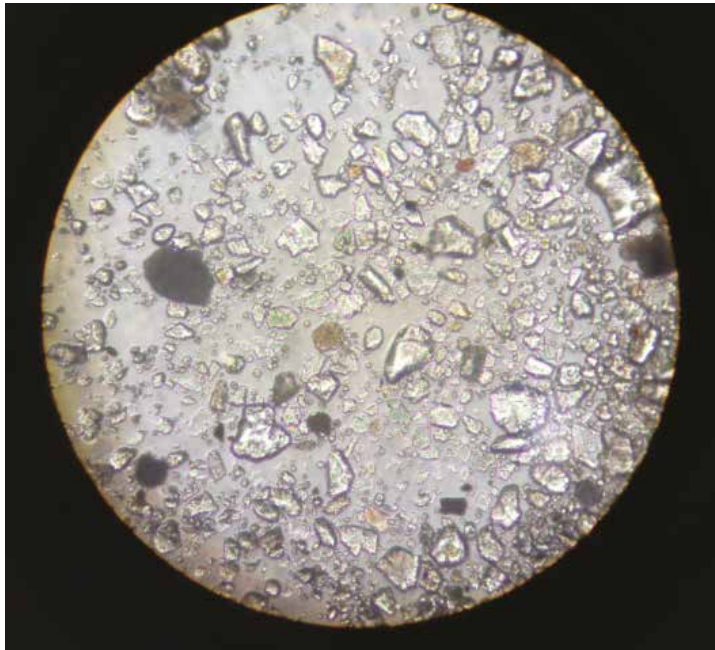


# STIMULAN<sup>®</sup>

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## Controlled purity

Impurities isolated from a competing calcium sulfate (10g powder)



Residual earth impurities left when the calcium sulfate is dissolved  
(microscope image)

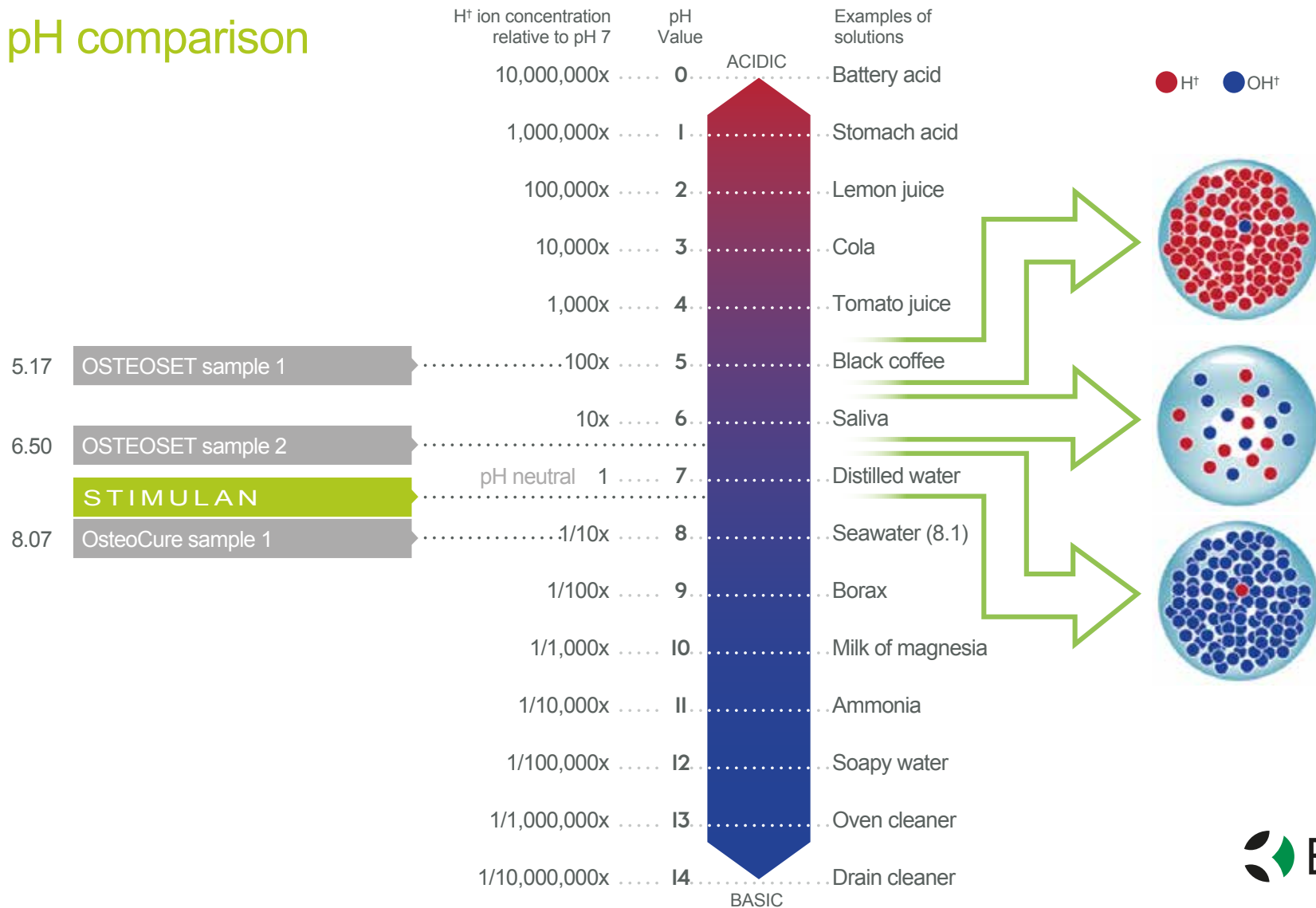


Crystalline earth impurity



# STIMULAN<sup>®</sup>

## pH comparison



# STIMULAN<sup>®</sup>

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Hydrophilic for fast, easy mixing

No soaking required.



STIMULAN - Mixes with liquid



Competing calcium sulfate repels liquid

# STIMULAN<sup>®</sup>

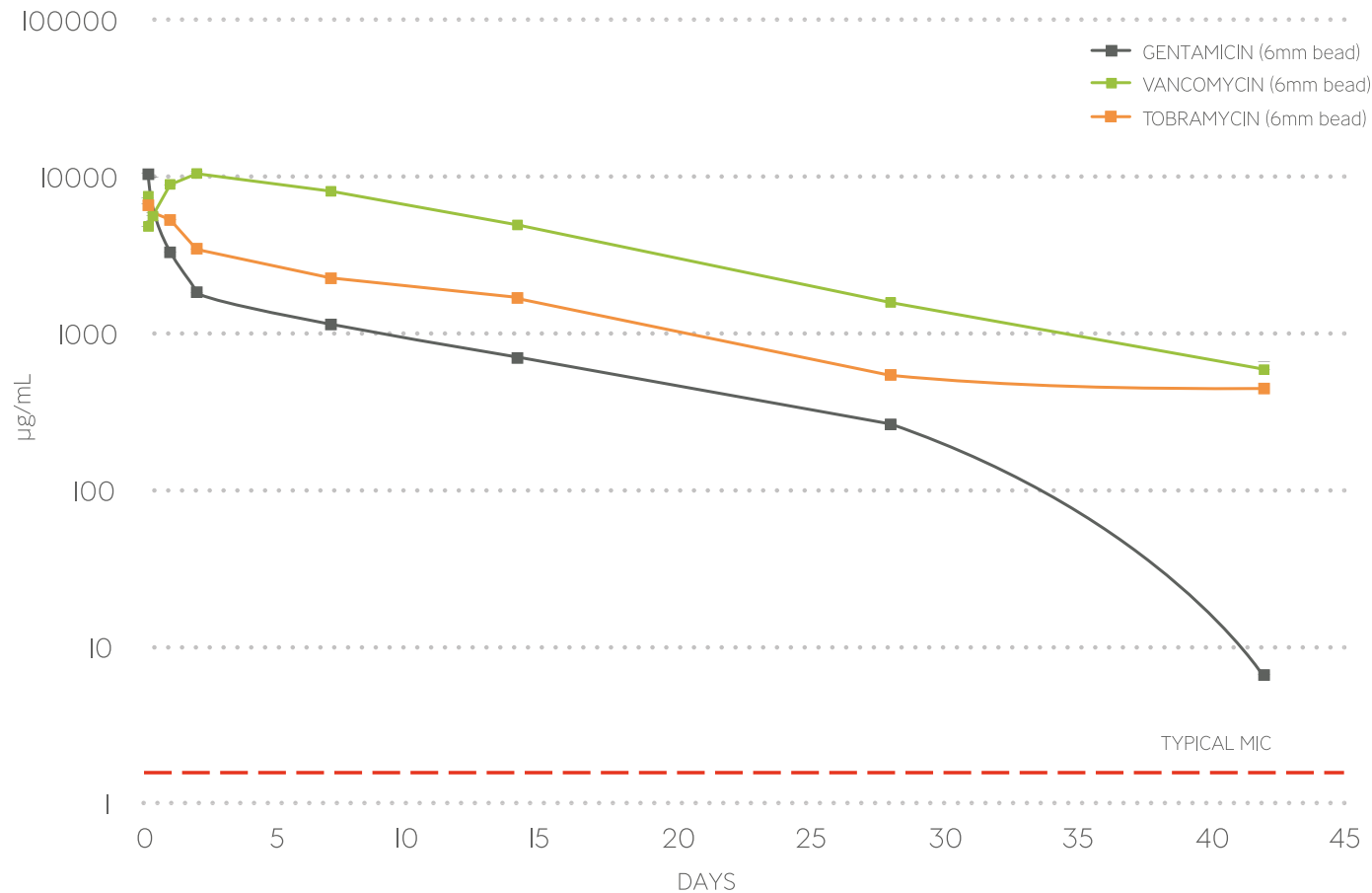
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OSTEOSET hydrophobic demonstration video



# STIMULAN<sup>®</sup>

## Antibiotic elution from STIMULAN Rapid Cure<sup>®15</sup>



# STIMULAN<sup>®</sup>

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Truly absorbable and totally synthetic calcium sulfate – absorbs at an optimal rate<sup>6</sup>

Leaves no nidus for infection.



Post-operative



1 month



11 weeks



6 months

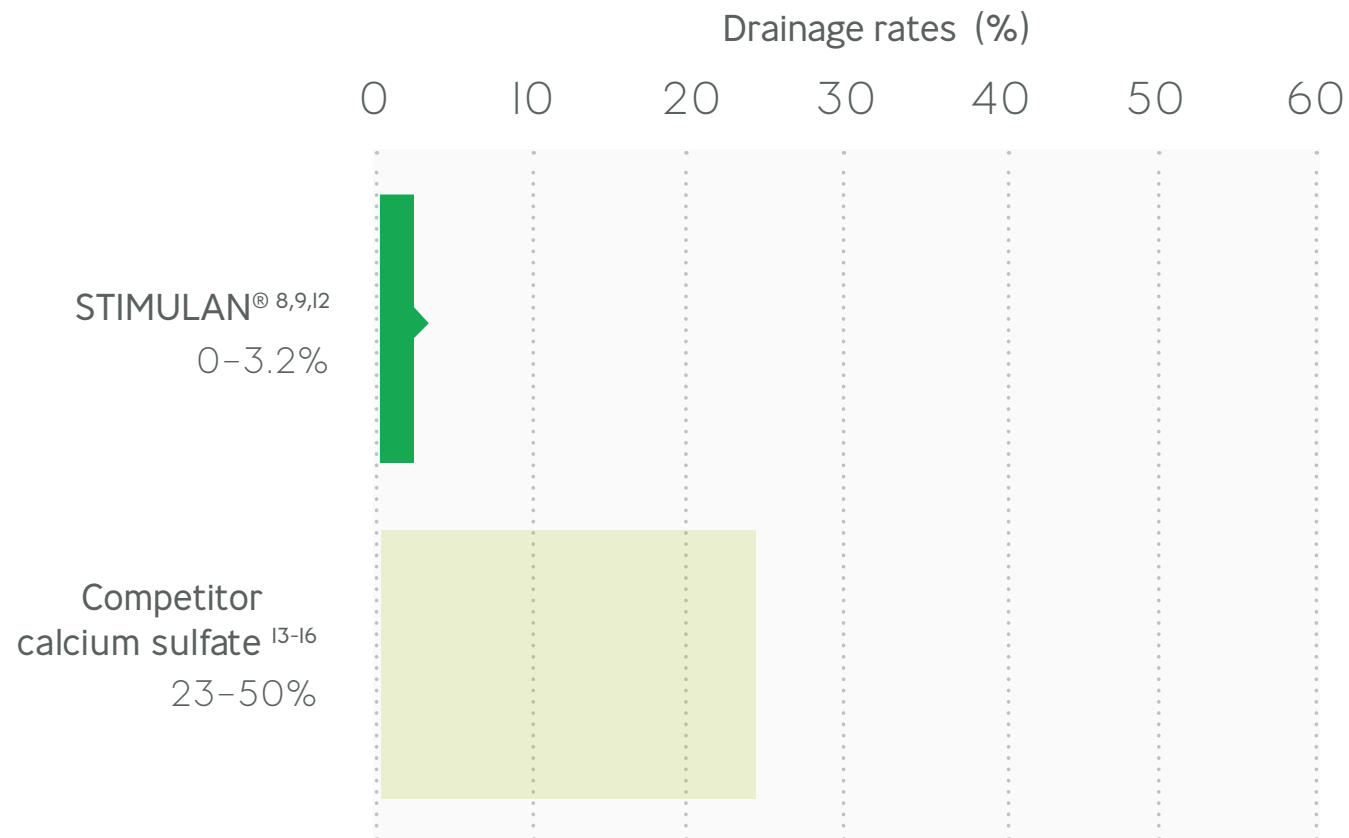


15 months



# STIMULAN<sup>®</sup>

Low levels of drainage <sup>7,8,16-20</sup>



# STIMULAN<sup>®</sup>

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No third body damage to articulating surfaces<sup>21</sup>

Stereomicroscope images (x63) of a cobalt chrome plate following damage simulation with third body particles trapped between it and an articulating UHMWPE pin



STIMULAN



PMMA



Positive Control

# STIMULAN<sup>®</sup>

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Less scratching than competitor calcium sulfate<sup>21</sup>

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<sup>®</sup>

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## Case-by-case flexibility

- Can be used in three sizes of bead, as a paste or for injection.
- Optimizes packing in bone and soft tissue.
- Its hydrophilic properties and options of rapid or standard setting times make it quick and easy if mixed with one or more antibiotics.\*



# STIMULAN®

## Flexible formats to optimize dead space management

STIMULAN®	PASTE VOLUME	BEAD VOLUME	BEAD SIZES	SETTING TIMES
<b>STIMULAN® Kit</b> Fully injectable paste with individual bead kit	5 cc	10 cc	3.0 mm	Approx. 8 minutes
	10 cc	20 cc	4.8 mm	
			6.0 mm	
<b>STIMULAN® Rapid Cure</b> Rapid setting paste with individual bead kit	5 cc	12 cc	3.0 mm	Approx. 4 minutes
	10 cc	25 cc	4.8 mm	
	20cc	50cc	6.0 mm	

Bead Mat included. Can be used to produce all bead sizes.



# Antibiotic Mixing Guidelines



# Antibiotic Mixing Guidelines

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## Antibiotic mixing guidelines for S T I M U L A N Rapid Cure

- The treating physician is responsible for deciding the type and quantity of antibiotic used.
- Guidelines are based on 10cc of S T I M U L A N Rapid Cure powder that is prepared as beads.
- The timings shown reflect the point at which the beads are set sufficiently to be removed easily from the bead mat. Before implanting the beads, it is recommended that the structural integrity is checked by compressing the bead between thumb and index finger.
- Refer to Instructions for Use for indications, contraindications, warnings and precautions.

# Antibiotic Mixing Guidelines

## POWDERED ANTIBIOTICS

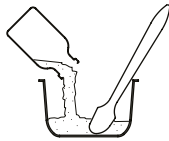
**CAUTION:** The mixing solution provided in the pack should be used. Do **not** add any other fluid.

### 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 seconds

③



Apply to bead mat  
immediately



Sets in  
3-5 minutes

## POWDERED ANTIBIOTICS WITH EXTENDED SETTING TIMES

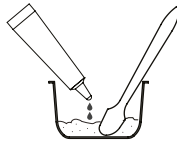
**CAUTION:** Some antibiotics may delay the setting time significantly. The following technique ensures a faster set time.

### Tobramycin\* (powder) 1.2g



1.2g  
tobramycin powder

①



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

②



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

③



Apply to bead mat  
immediately



Sets in  
10-20 minutes

# Antibiotic Mixing Guidelines

## LIQUID ANTIBIOTICS

**CAUTION:** When using liquid antibiotics, the mixing solution provided in the pack should **not** be used and should be discarded.

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



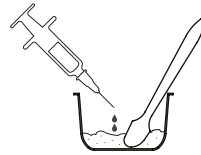
3 x 80mg ampoules  
**gentamicin** liquid (6ml)

①



Measure 6ml **gentamicin**  
liquid into syringe

②



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

③



Apply to bead mat  
immediately



Sets in  
3-5 minutes

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



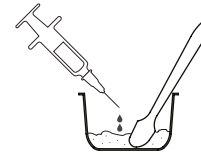
3 x 80mg ampoules  
**tobramycin** liquid (6ml)

①



Measure 6ml **tobramycin**  
liquid into syringe

②



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

③



Apply to bead mat  
immediately



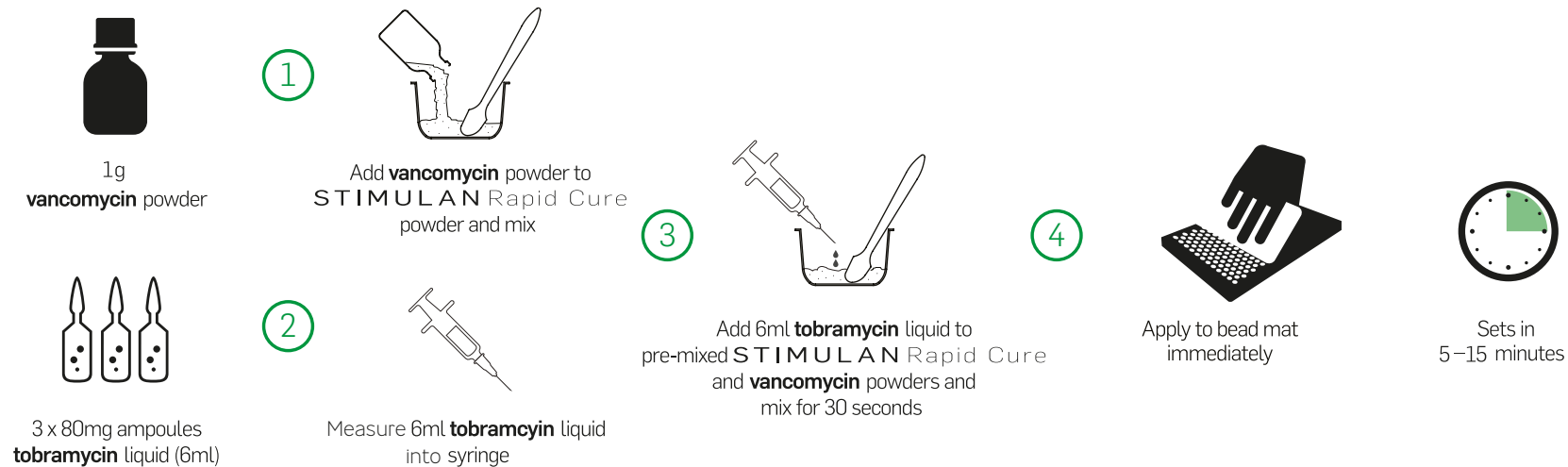
Sets in  
5-15 minutes

# Antibiotic Mixing Guidelines

## COMBINATION OF **POWDER** AND **LIQUID** ANTIBIOTICS

**CAUTION:** When using liquid antibiotics, the mixing solution provided in the pack should **not** be used and should be discarded.

Vancomycin\* (powder) 1g and tobramycin\* (liquid) 240mg DO NOT USE MIXING SOLUTION PROVIDED



# How to prepare STIMULAN Rapid Cure



# STIMULAN

POWER TO TRANSFORM OUTCOMES





# Power to Transform Outcomes

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## Target audience

- Total Joint Surgeons.
- Trauma Surgeons.
- Foot & Ankle Surgeons
- Podiatrists.





# Power to Transform Outcomes

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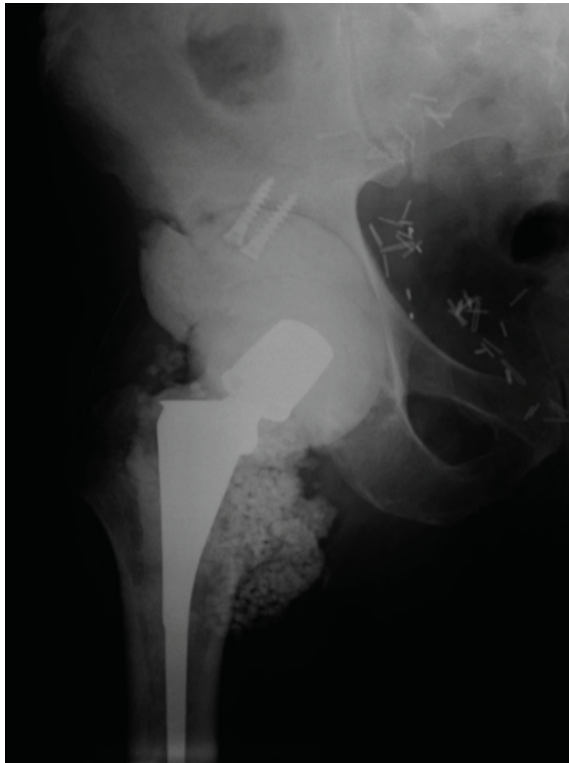
## What applications can I sell S T I M U L A N for?

- Total joint reconstructive procedures:
  - THA & TKA revisions with PJI .
- Trauma procedures:
  - Infected non-unions.
  - Osteomyelitis.
  - Fractures.
  - Infected hardware removal.
- Foot & ankle / podiatry procedures:
  - Osteomyelitis.
  - Fractures.

# Power to Transform Outcomes

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## Periprosthetic joint infection with S T I M U L A N beads



S T I M U L A N beads  
used in THA and TKA  
revisions.

# Power to Transform Outcomes

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## Transforming outcomes in an infected hip

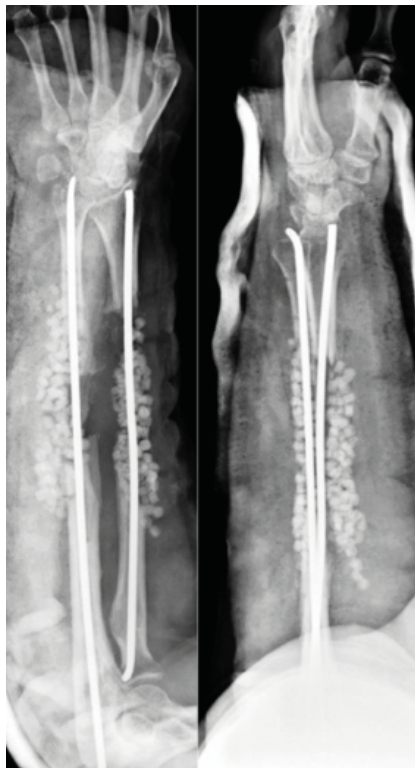


STIMULAN beads used in a Girdlestone procedure.

# Power to Transform Outcomes

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## Infected non-unions with S T I M U L A N beads



Non-union of the  
radius and ulna



Long bone  
non-union

# Power to Transform Outcomes

## Long bone osteomyelitis with S T I M U L A N paste

Case 1



S T I M U L A N injected as a paste  
for a tibia fracture

Case 2



S T I M U L A N injected as a paste  
to fill an IM canal

# Power to Transform

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## Femoral infection with S T I M U L A N beads



S T I M U L A N beads used to fill infected femoral defect.

# Power to Transform Outcomes

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## Infected non-unions with S T I M U L A N paste



S T I M U L A N injected as a paste for a femoral non-union



# Power to Transform Outcomes

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## Osteomyelitis with S T I M U L A N beads



Osteomyelitis of the calcaneus



Lower extremity osteomyelitis



Charcot joint disease



# Power to Transform Outcomes

## Use of **STIMULAN** beads in an infected non-union

Case study courtesy of Mr Hemant K Sharma, Hull Royal Infirmary & Castle Hill Hospital, England



Pre-operative x-ray  
showing non-union



Post-operative  
x-ray and CT



2 months



2.5 months



1 year

# Power to Transform Outcomes

## Use of **STIMULAN** for infected revision arthroplasty

Case study courtesy of Mr Ramasubramanian Dharmarajan, North Cumbria University Hospitals, UK



Presentation



First stage - Post-operative



Second stage -  
Post-operative



Second stage -  
Post-operative

# Power to Transform Outcomes

## Use of **STIMULAN** paste for osteomyelitis

Case study courtesy of Dr Daniel Schlatterer, Atlanta Medical Center, Atlanta, GA



Presentation



Post-operative



1 month



11 weeks



6 months



15 months

# Power to Transform Outcomes

Use of **STIMULAN** beads in an infected non-union  
Case study courtesy of Dr Daniel Schlatterer, Atlanta Medical Center, Atlanta, GA



Presentation



Post-operative 1<sup>st</sup> stage treatment



Outcome at 4 months

# Power to Transform Outcomes

Use of **STIMULAN** beads in an infected non-union  
Case study courtesy of Dr Daniel Schlatterer, Atlanta Medical Center, Atlanta, GA



Post-operative 2<sup>nd</sup> stage  
treatment



6 months after subtalar fusion,  
4 months after hardware removal



13 months after subtalar fusion,  
11 months after hardware removal

# Power to Transform Outcomes

## Use of **STIMULAN** for osteomyelitis in diabetic foot

Case study courtesy of Mr Robert Morley, Buxton Hospital, UK



Presentation



Post-operative  
- 17 days



Post-operative  
- 3 months



Post-operative  
- 3 months

# Power to Transform Outcomes

Use of **STIMULAN** for osteomyelitis in diabetic foot  
Case study courtesy of Mr Jogia, University Hospitals of Leicester, UK



Presentation



Post-operative



2 weeks



16 months



# Account Management



# Account Management

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## Overview

- Biocomposites (Wilmington office) is registered with Health Canada to allow for import to Canada.
- STIMULAN and geneX paste, putty and ds are approved by Health Canada.
- Hospitals currently purchase products directly from Biocomposites.
- Biocomposites receives a PO from the hospital.
- Product is shipped and billed by Wilmington.
- Biocomposites does not currently consign products at hospitals - future probability.
- Biocomposites does not currently consign products to distributors - future probability.

# Why Should I Sell STIMULAN?



# Why Should I Sell S T I M U L A N ?

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- Monetary rewards.
- Build and expand your business.
- Access to competitor surgeons.
- Sell within your current call pattern.
- Provide value to your customers.





# Useful Resources



# Useful Resources

## Distributor Hub

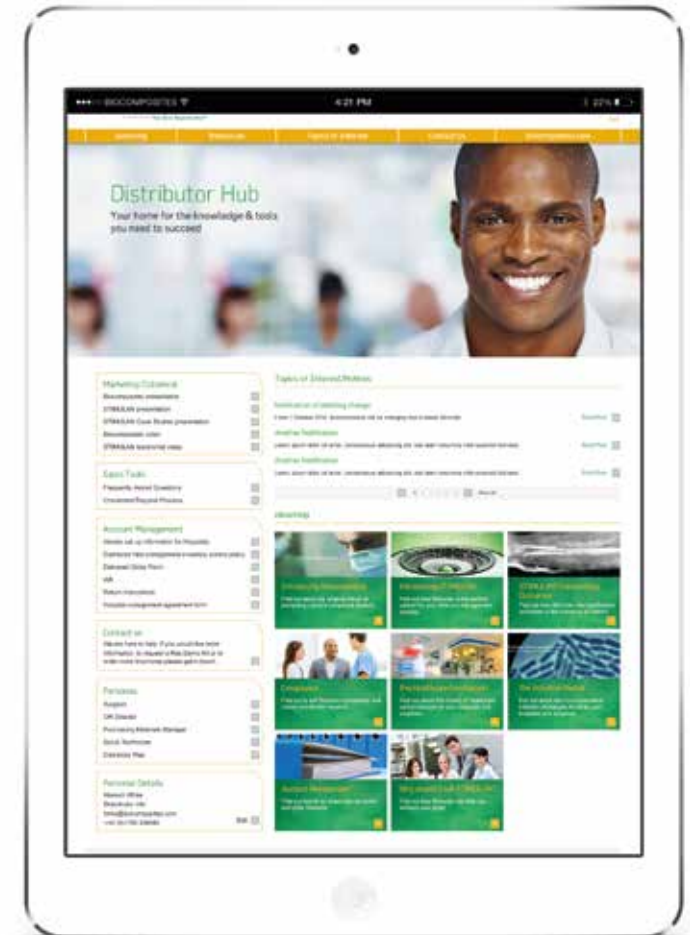
- Access training presentations.
- Biocomposites and STIMULAN customer presentations.
- Useful articles.
- Case studies.
- Useful forms for account management.
- Mixing videos.

## Biocomposites website

- Interactive website.
- Contains product information specific to relevant clinical specialties.
- Provides an overview of Biocomposites.

## Marketing collateral materials

- Printed brochures.
- Demo kits.
- Videos.



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## Testimonial video



# STIMULAN<sup>®</sup>

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Find out more at [biocomposites.com](http://biocomposites.com)

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

\*The treating physician is responsible for deciding the type and quantity of antibiotic used.

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 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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