



# STIMULAN<sup>®</sup> Competitive Environment

In-person training for Canada Distributor Sales Representatives

# Training objectives

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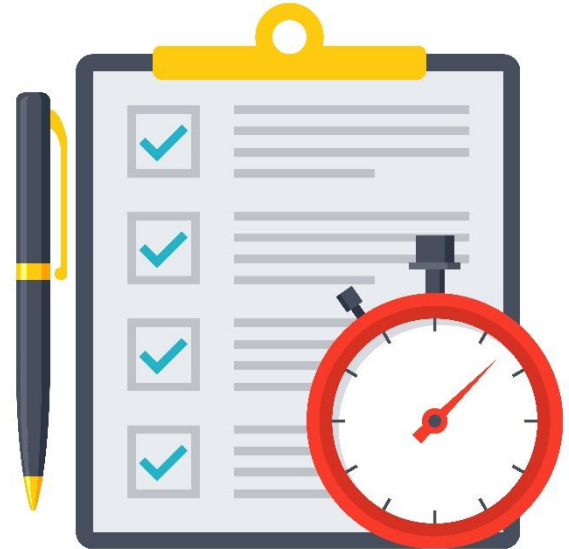
At the end of this 20 minute training session you will:

- Know who the key competitors are for S T I M U L A N in the infection market
- Understand the key characteristics of their products and positioning
- Be aware of their strengths and weaknesses relative to S T I M U L A N
- Know which differentiating factors to focus on in conversations with your surgeons
- Have an action plan for increasing S T I M U L A N sales

# Agenda

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- Infection market
- Competitor differentiation summary
- Product profiles:
  - Collatamp® G
  - OSTEOSSET® T
  - Cerament® G
  - STIMULAN
- Increase STIMULAN sales



# Infection market

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## Medical device suppliers are now focusing on infection as a growth opportunity

- Hospitals are under increased scrutiny to provide high quality care, reduce patient readmissions and lower treatment costs
  - There is a growing willingness by surgeons to discuss their infection challenges
  - There is a greater sensitivity to the cost impact of managing infection in patients
- Surgeons are willing to consider absorbable medical devices
- These devices can be segmented into products that are:
  - Supplied with antibiotics
  - Not supplied with antibiotics

# Competitor differentiation summary<sup>19-25</sup>

Product Name	Formats	Supplied with antibiotics	Elution Rate	Fully Absorbed	Claimed Absorption Rate	Drainage rates	STIMULAN Key points of differentiation
STIMULAN	3 bead sizes, paste, injection	No	Above MIC for 42 days when antibiotics are added	Yes	Approx. 30-60 days (4 - 8 weeks)	0-3.2%	N/A
Collatamp® G	3 collagen sponge sizes	Yes - Gentamicin	Above MIC for 7 days	Yes	1 - 7 weeks	Unknown	<ul style="list-style-type: none"> <li>• Flexible formats</li> <li>• May be mixed with antibiotics</li> <li>• Optimal absorption rate – leaves no nidus for infection</li> </ul>
OSTEOSET® T	1 pellet size	Yes - Tobramycin	Above MIC for 28 days	May not fully absorb	4 - 8 weeks	23-50%	<ul style="list-style-type: none"> <li>• Flexible formats</li> <li>• May be mixed with antibiotics</li> <li>• Purity – no impurities as not mined CaSO<sub>4</sub></li> <li>• Fully absorbs</li> <li>• Low levels of drainage</li> <li>• No third body damage</li> </ul>
Cerament® G	Moldable paste, beads	Yes - Gentamicin	Above MIC for 28 days	May not fully absorb	6 - 12 months	Unknown	<ul style="list-style-type: none"> <li>• Flexible formats – includes universal bead mat</li> <li>• May be mixed with antibiotics</li> <li>• Fully absorbs – no insoluble HA impurities</li> <li>• No third body damage</li> </ul>

# Product profiles

# Collatamp G – Aralez<sup>®</sup> Pharmaceuticals Inc., EUSA Pharma<sup>®</sup> EU

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## Indication & absorption rate<sup>1,2</sup>

- Indicated for local haemostasis of capillary, parenchymatous and seeping haemorrhages in areas with a high risk of infection
- Claims to absorb within 1-7 weeks

## Composition<sup>1</sup>

- 2.8mg renatured type-1 bovine collagen per cm<sup>2</sup>
- 2.0mg gentamicin sulfate per cm<sup>2</sup>

## Formats, sizing and dosage<sup>1,2</sup>

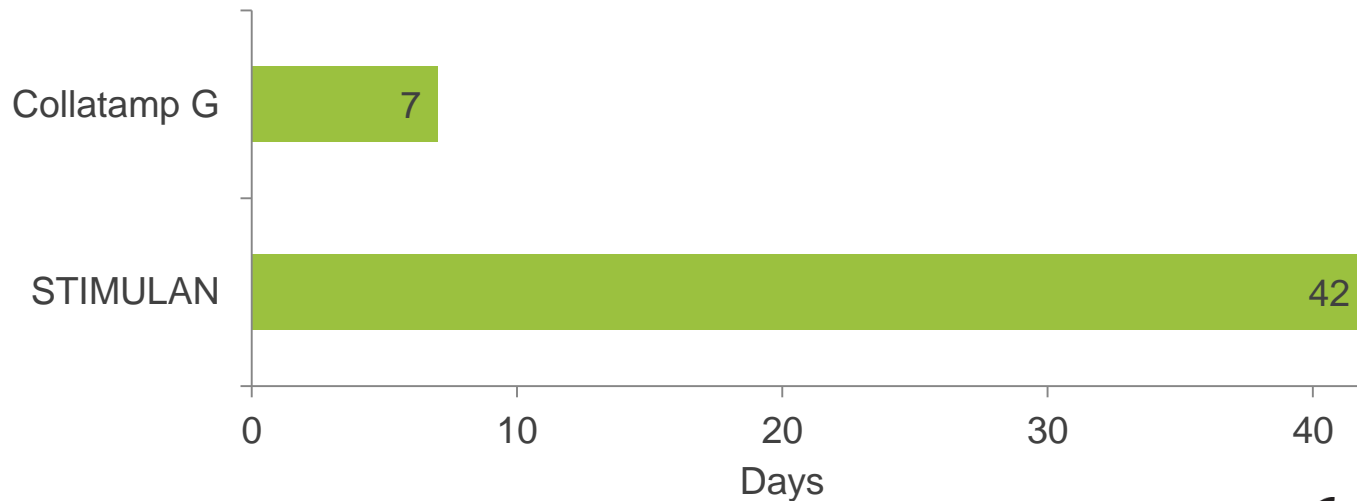
- Collagen sponge
- Available in 5x5x0.5cm, 10x10x0.5cm and 5x20x0.5cm sizes
- Each size contains 200mg gentamicin sulfate
- May be cut to desired size, rolled to fit into small incisions and sutured in place

# Collatamp G

## Elution<sup>2</sup>

- Local dose of 600mg gentamicin stays above MIC for ~ 7 days
- Gentamicin is released by a combination of diffusion and natural enzymatic breakdown of the collagen matrix
- The matrix is fully absorbed within 1-7 weeks according to implant location

Gentamicin Levels Remaining Above MIC in Days





# Collatamp G

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## Take away points<sup>1-8</sup>

- Supplied (pre-loaded) with gentamicin only – no Gram-positive coverage
- Should be placed dry on a dry surgical site
- Nidus for infection – 7 week absorption time but only above MIC for 7 days
- Short term elution – 7 days max but may be faster in a wet environment
- Lack of effectiveness in preventing infections and high re-infection rates reported in literature

# OSTEOSET T - Wright Medical™

## Indication & absorption rate<sup>9,10</sup>

- Bone void filler that may be used at infected sites
- Claims to absorb within 4-8 weeks

## Composition<sup>9-12</sup>

- OSTEOSET
  - 98.5% surgical grade (mined) calcium sulfate
  - 1.5% stearic acid
- Antibiotic added to form OSTEOSET T
  - 4% tobramycin sulfate by weight

## Formats, sizing and setting times<sup>9,10</sup>

- 4.8mm pellets
- Pellet injector available
- Available in 5, 10 and 20cc vials



# OSTEOSET T

## Manufacturing<sup>11,12</sup>

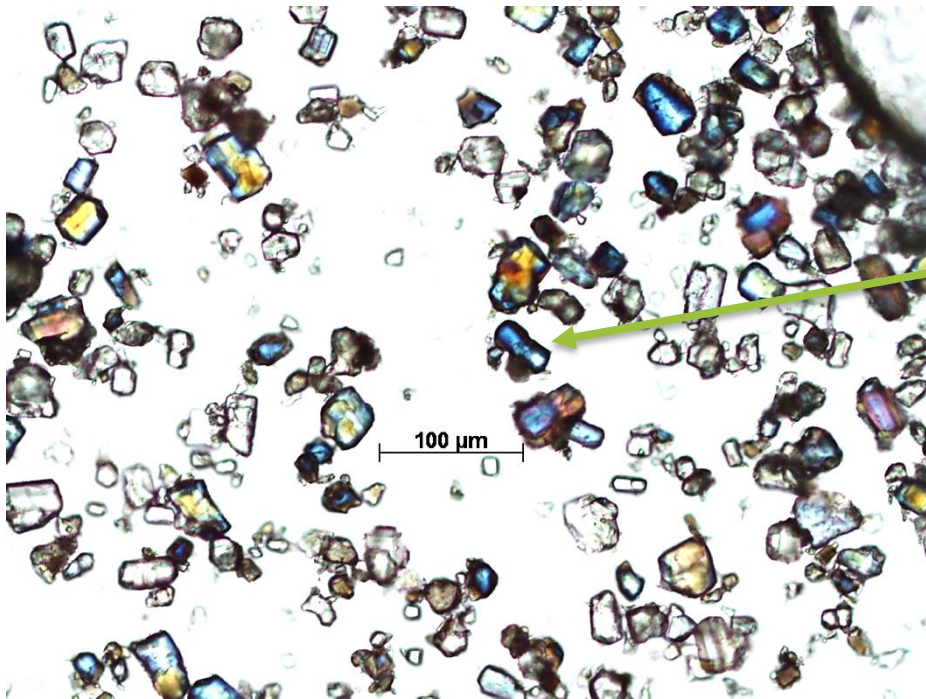


- OSTEOSET is manufactured from mined calcium sulfate
- The patents, technology, and process of producing OSTEOSET were acquired from the United States Gypsum Corporation
- Proprietary manufacturing methods are used to produce a consistent, high-quality material with **minimal lot-to-lot variation in chemical and material properties**
- OSTEOSET is composed of only 98.5% calcium sulfate

OSTEOSET	CaSO <sub>4</sub> (98.5%)	CaSO <sub>4</sub> · ½H <sub>2</sub> O (98%+) CaCO <sub>3</sub> · MgCO <sub>3</sub> (0.5%) CaCO <sub>3</sub> (0.3%) Aggregate (0.3%)
	Calcium Stearate (1.5%)	

# OSTEOSET T

## Microscopic analysis of purity<sup>17</sup>



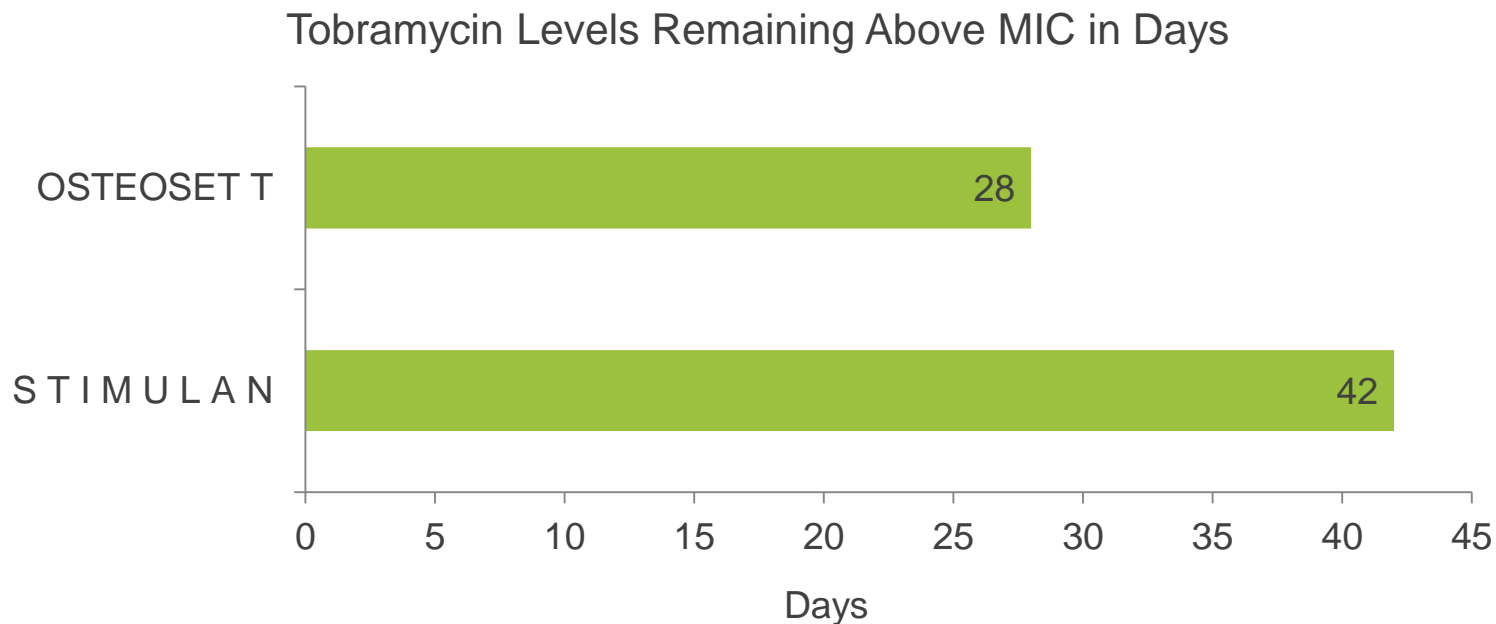
Insoluble crystalline impurities

OSTEOSET residue

# OSTEOSET T

## Elution<sup>9</sup>

- Local dose of tobramycin stays above MIC for 22 days *in vitro* and 28 days *in vivo*
- Maximum elution occurs within the first day and steadily declines



# OSTEOSET T

## Take away points<sup>9-12,17-26</sup>

- Calcium sulfate component is mined
- Contains non-absorbable impurities and may not fully absorb
- May cause third body damage
- Supplied (pre-loaded) with tobramycin only
- Maximum elution occurs over the first day and rapidly declines
- High wound complication rates reported in literature
- Drainage rates range from 23-50%



# Cerament G – Bonesupport<sup>®</sup>

## Indication & absorption rate<sup>13,14</sup>

- Bone graft substitute indicated to fill bony voids or gaps in the skeletal system
- Claims to absorb within 6-12 months

## Composition<sup>13</sup>

- Cerament
  - 40% hydroxyapatite and 60% calcium sulfate
- Antibiotic added to form Cerament G
  - 17.5mg/ml gentamicin
- Mixing liquid
  - 9mg/ml of sodium chloride mixing liquid

## Formats, sizing and setting times<sup>13,15,16</sup>

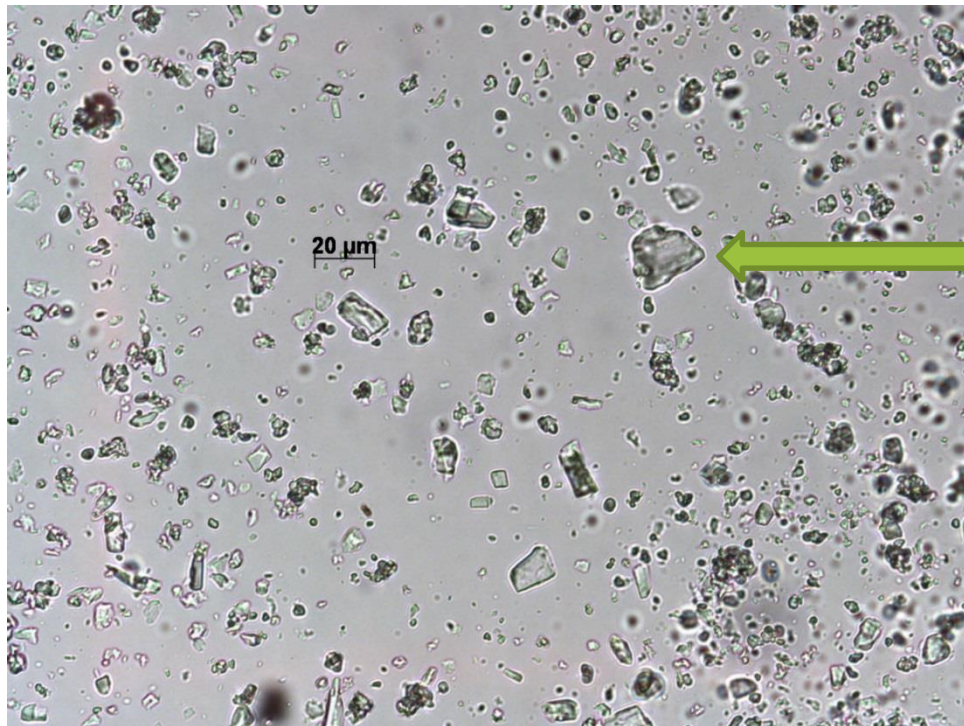
- Moldable paste, beads
- Available in 5ml and 10ml kits
- Sets within 20 minutes of mixing





# Cerament G

## Microscopic analysis of purity<sup>17</sup>



Insoluble “embedded”  
HA impurities

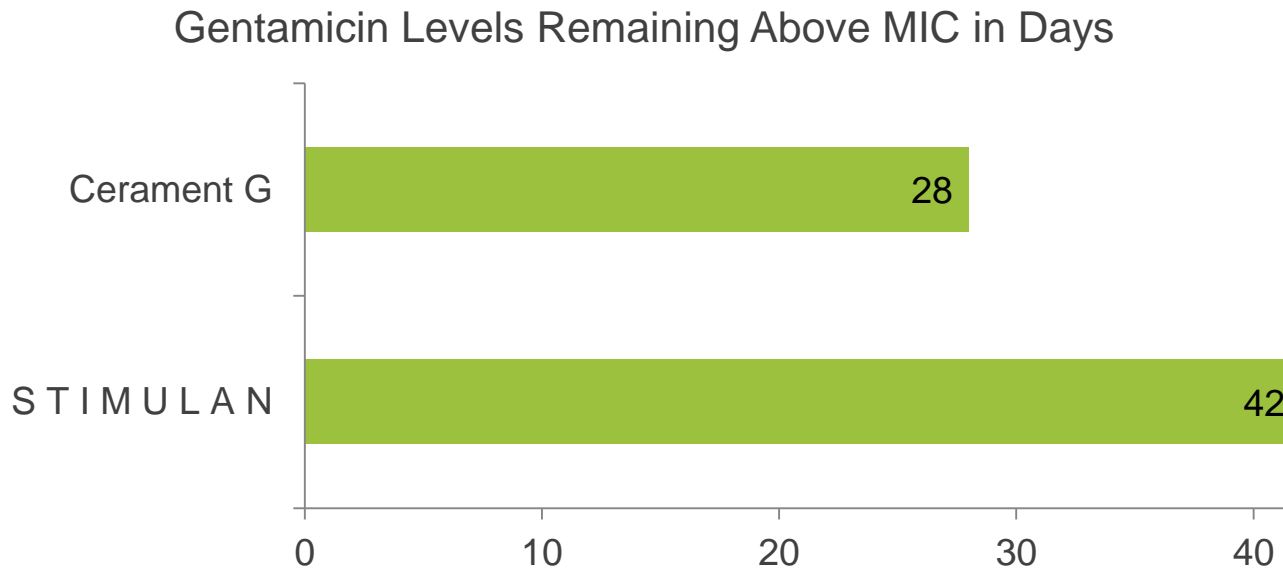
Microscopic analysis showing the 40% of HA remaining after calcium sulfate is dissolved.



# Cerament G

## Elution<sup>15,17</sup>

- Releases a high localized concentration of gentamicin directly to the surgical site
- Local dose of 175mg gentamicin stays above MIC for  $\approx$  28 days
- Antibiotic elution is not surface area dependent: injected, beads or molded



# Cerament G

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## Take away points<sup>13,15,17</sup>

- Not indicated for use in infected sites
- Includes gentamicin only – no gram-positive coverage
- Gentamicin is only added to prevent the device from being colonized with gentamicin sensitive microorganisms
- HA has a slow/incomplete absorption rate (evidence suggests that Cerament residual material remains visible on x-ray two years post-op)
- HA can cause a long-term nidus for infection
- Precaution to avoid intra-articular use
- Long setting times
- No bead mat provided

# STIMULAN - Biocomposites

## Indication and absorption rate<sup>17,27-29</sup>

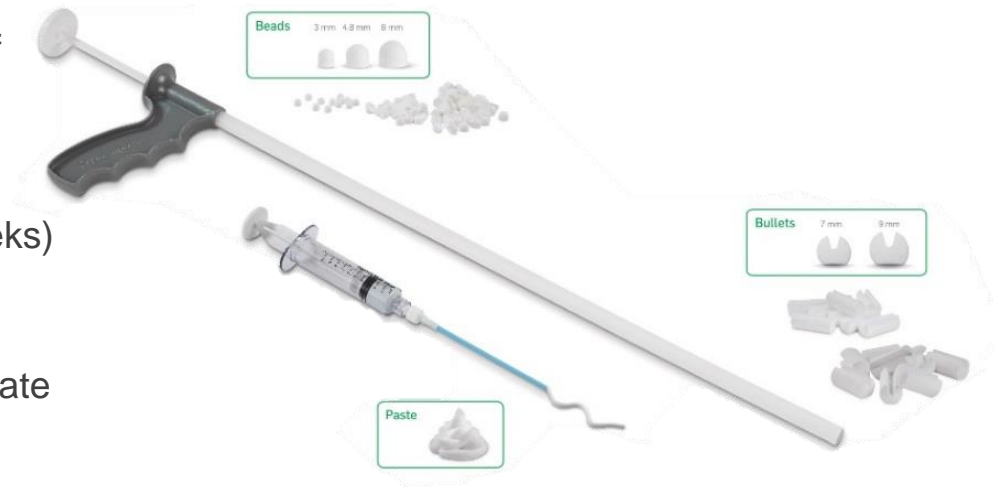
- Approved for placement directly at site of infection in bone voids and defects
- May be mixed with antibiotics
- Fully absorbs within 30-60 days (4-8 weeks)

## Composition<sup>17,27-29</sup>

- 100% pharmaceutical-grade calcium sulfate
- Sterile water

## Formats, sizing and setting times<sup>17,27-29</sup>

- 3 bead sizes, 2 bullet sizes, paste, injection
- STIMULAN Rapid Cure: 5cc, 10cc & 20cc sizes; sets in approximately 4 minutes
- STIMULAN Kit: 5cc & 10cc sizes; sets in approximately 8 minutes
- Included universal bead mat can be used to create 3, 4.8 and 6mm beads
- Bullet mat available to create 7 and 9mm bullets



# What makes STIMULAN different?

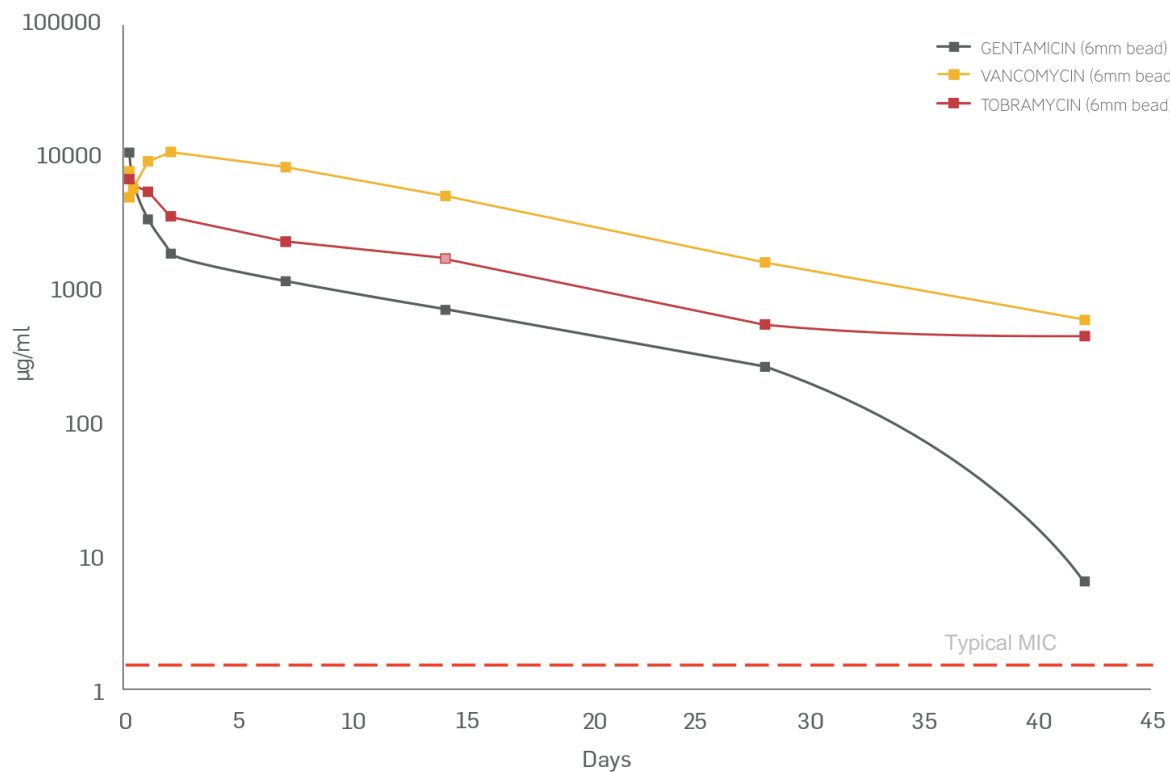
DRy26™ recrystallization method<sup>27</sup>



# STIMULAN

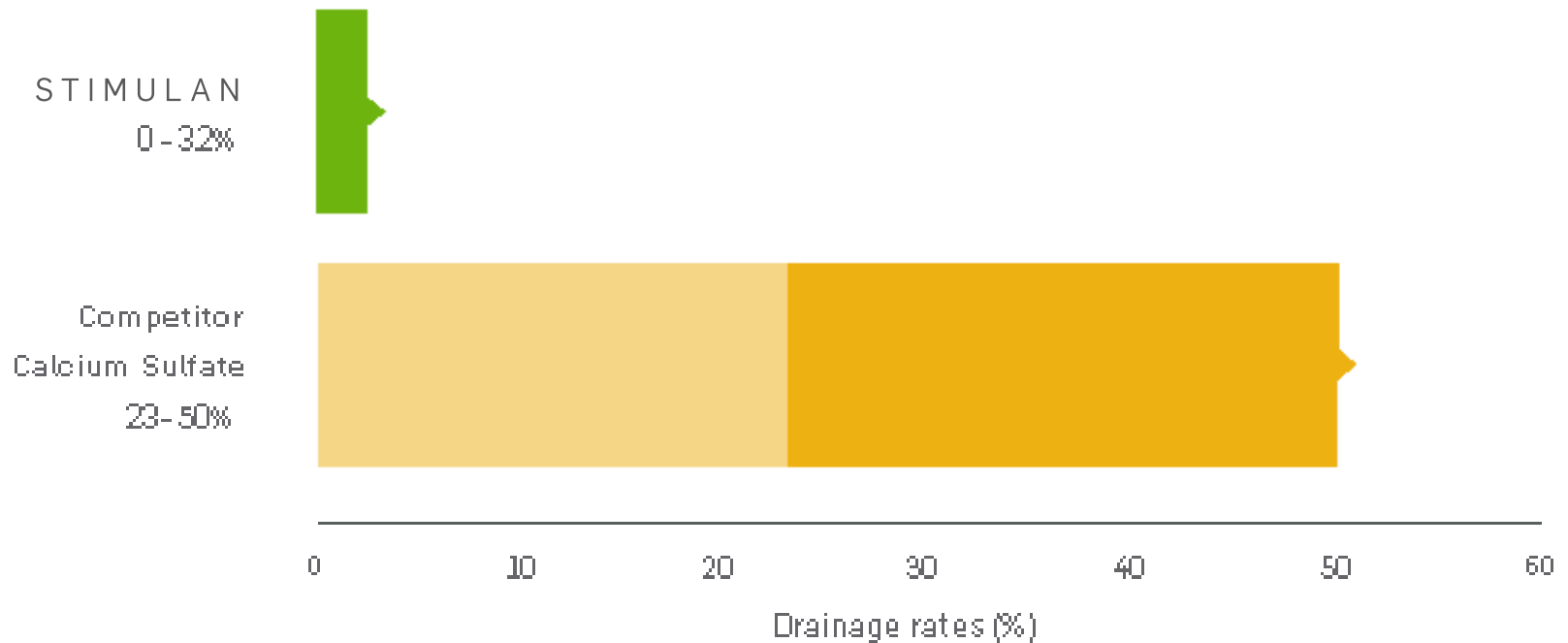
## Antibiotic elution from STIMULAN Rapid Cure<sup>22,30,31</sup>

- Elution of gentamicin, vancomycin and tobramycin from STIMULAN beads remains over MIC and MBC for 42 days



# STIMULAN

Low levels of drainage<sup>20-26</sup>



# STIMULAN

## Take away points <sup>17,27-29, 31-33</sup>

- Controlled purity
- Uniquely engineered through our DRy26 recrystallization method
- Hydrophilic
- Easily mixed with liquid, powder and heat sensitive antibiotics
- Predictable elution profile
- Optimal absorption profile
- Low levels of drainage
- No third body damage
- Used in over 30,000 cases per year
  - Biocomposites offers a comprehensive network of specialists, expert sales representatives and surgeons already using S T I M U L A N to support our customers and hospitals



# Increase STIMULAN sales

## Strategies and Resources



# How do we increase STIMULAN sales?

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## Key strategies to increase sales

- Understand what makes STIMULAN different
- Establish STIMULAN as a benchmark product
- Educate surgeons that competitor products are not equal substitutes
- Emphasize the importance of results over low prices
- Negative results will cost hospitals additional money
- React quickly
- Perform in-services
- Know what resources to draw on to help you sell STIMULAN



# Resources to help you sell STIMULAN

## Useful resources

- Comprehensive marketing materials & website
- Distributor Hub & training information
- Large surgeon following
- Surgeon testimonials
- Evidence-based medicine
- Company dedication to innovation, research & resources
- Information Request process



# STIMULAN competitive environment

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Find out more at **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. 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 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, EP 18275044.8, US 15/933936, CN 108619579A

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# STIMULAN competitive environment

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# STIMULAN competitive environment

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