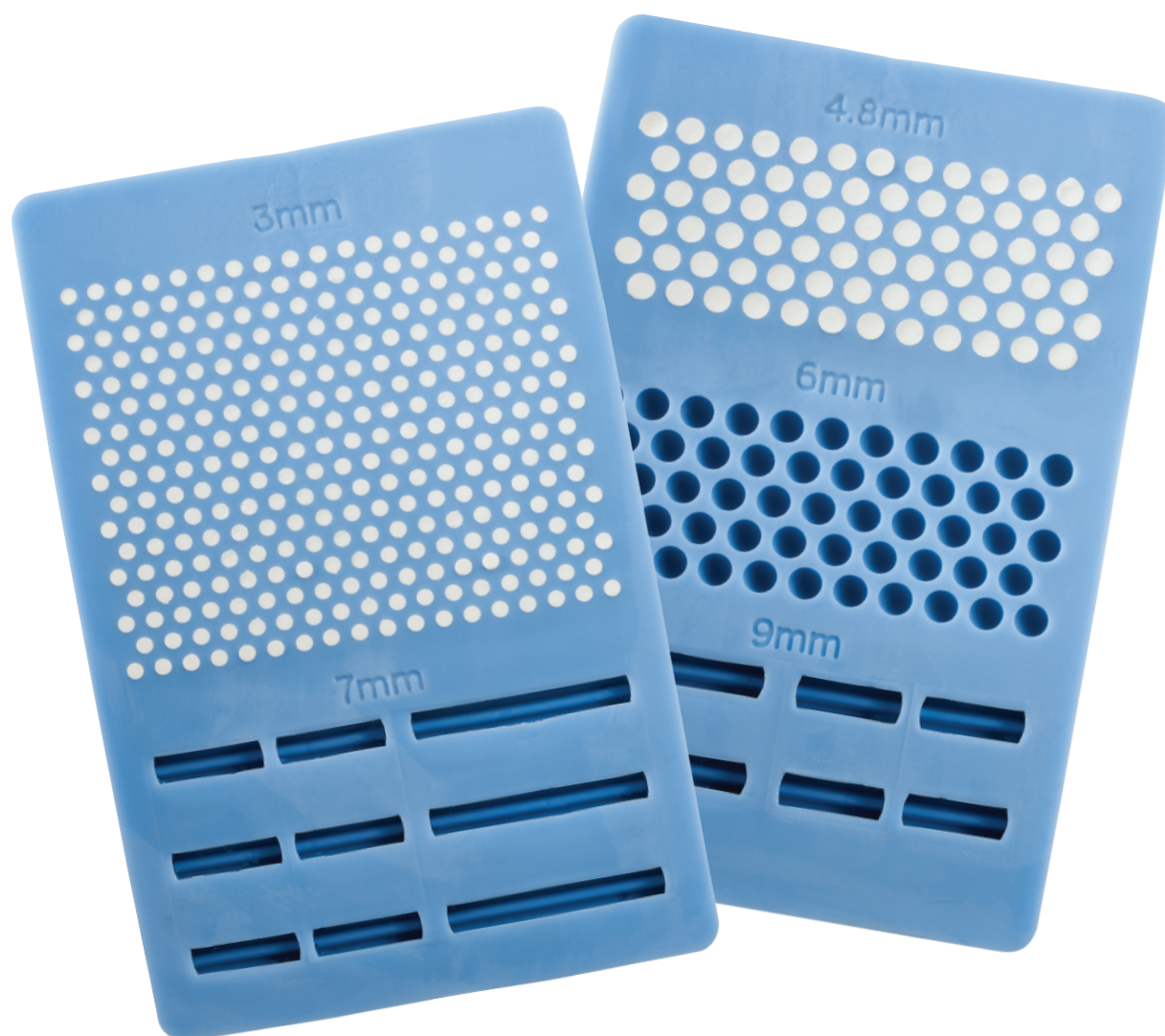


STIMULAN[®]

Rapid Cure 3cc

Product launch guide

For internal use only. Not for distribution.



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Rapid Cure 3cc

Introduction

The **STIMULAN Rapid Cure 3cc** product builds on the pedigree and performance of the STIMULAN line to enable you to mix and match to any void size. Launched exclusively in the USA, the new mini 3cc pack size is supplied with a combination bead and bullet mat for smaller void volumes.

Instructions for Use Summary

Indications for Use

- STIMULAN Rapid Cure is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure
- These osseous defects may be surgically created or created from traumatic injury to the bone
- STIMULAN Rapid Cure is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., extremities, pelvis, and posterolateral spine)
- STIMULAN Rapid Cure provides a bone graft substitute that resorbs and is replaced with bone during the healing process
- STIMULAN Rapid Cure is biodegradable and biocompatible and may be used at an infected site

To fill a bone void or defect created by:

- Surgery
- A cyst
- A tumor
- Osteomyelitis
- Traumatic injury

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Instructions for Use Summary

Contraindications (see IFU for full list)

- Filling of defects which are intrinsic to the stability of the bony structure
- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Hypercalcaemia

Warnings and Precautions (see IFU for full list)

- The device is for single use and must not be reused
- The device must be implanted where surrounding bone is healthy and vascular but not actively bleeding at time of insertion
- Do not use for bony voids in the cranium, due to the potential risk of contact with cerebrospinal fluid (CSF) or dura mater
- Do not irrigate site following implantation
- Avoid overfilling the bone void or pressurizing the treatment site. Incomplete or inadequate soft tissue coverage may result in device migration and/or effusion or serous exudate
- Do not implant unless adequate tissue coverage and/or containment can be achieved

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Selling Information

Product positioning

With 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 new mini 3cc pack size and combination bead and bullet mat were designed with smaller void volumes in mind.

Key sales messages

1. Versatile application

The STIMULAN Rapid Cure 3cc product can be used across a range of surgical applications, including:

- Diabetic foot osteomyelitis
- Amputations
- Osteotomies
- Distal tibia fractures
- Posterolateral spine procedures
- High-risk primary hip and knee reconstructive procedures

2. Full range of bead and bullet sizes

The STIMULAN Rapid Cure 3cc pack size and combination bead and bullet mat can be used to create 3.0mm, 4.8mm and 6.0mm beads, along with 7.0mm and 9.0mm standard and double length bullets for varying void sizes.

3. Reduce waste

The 3cc pack size reduces the likelihood of product waste for smaller void volumes.

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Selling Information

Customer targets

- Foot & ankle surgeons
- Podiatrists
- Orthopaedic reconstructive surgeons
- Trauma surgeons
- Spine surgeons
- Existing STIMULAN users
- Non-STIMULAN users:
 - Not used because current pack size is too large
 - Not used because price point is too high
 - Potential new users

Product Information

STIMULAN Rapid Cure 3cc pack contents:

- 3cc STIMULAN Rapid Cure powder
- 2ml mixing liquid
- Spatula
- Paste applicator
- Combination bead and bullet mat

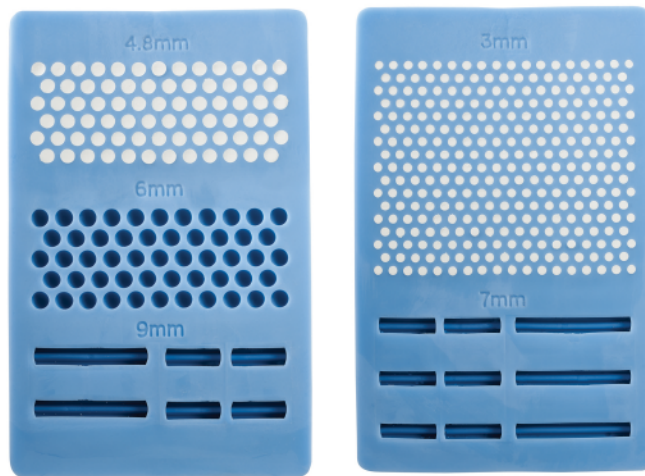
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Product Information

A 3cc pack will produce:

Description	Diameter	Length	Number beads/bullets created
Beads	3.0mm	N/A	298
	4.8mm		75
	6.0mm		53
Standard length bullets	7.0mm	20mm	6
	9.0mm		4
Double length bullets	7.0mm	40mm	3
	9.0mm		2



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Ordering Information

Product	Paste Volume	Bead Volume	Order Code	List Price
STIMULAN Rapid Cure 3cc	3cc	7cc	620-003	\$995

Consignment

3cc STIMULAN Rapid Cure pack sizes are available for consignment.

Demo Mat

The combination bead and bullet mat for the new STIMULAN Rapid Cure 3cc product is available to order from the Biocomposites' Wilmington office. A demo mat will be provided to each RM/FMS. They are not available to sales reps.

Please refer to the STIMULAN IFU for preparation instructions.

Hospital Contracts

Each hospital will have a procedure to allow new products to be used. Contact contracts@biocomposites.com if you want to know if a hospital has an existing contract with Biocomposites.

Our hospital contracts typically include a 'new product or new technology' clause that allows a new product to be added to an existing contract with hospital approval. New products may also have to be added through contract renewal. Examples for each scenario are shown below:

Hospital – existing contract:

- Biocomposites' Regional Manager (RM) to gain verbal/email agreement from hospital procurement to add new pack size and price to contract.
- RM informs the Biocomposites' Contracts Department of the needed amendment.
- Biocomposites' Contract Department will contact the hospital Contracts Department to add the product by amendment; where signatures by both parties are required.

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Hospital Contracts

Hospital – contract renewal:

- Biocomposites' Contracts Department will advise the RM when contract renewal is due.
- RM discusses renewal with hospital procurement and agrees to the addition of the product and price.
- Biocomposites' Contracts Department will add the product to the renewal contract before it is sent to the hospital.

Distributor Contracts

Amendments will be required to distributor contracts. RM should discuss the new product addition with the Distributor Principal. RM can then advise the Contracts Department to send out contract amendment to them for execution.

Frequently Asked Questions

How many STIMULAN beads can be made from each bead section of the new combination bead and bullet mat when using a 3cc pack size?

3.0mm Beads	4.8mm Beads	6.0mm Beads
298	75	53

How many STIMULAN bullets can be made from each bullet section of the new combination bead and bullet mat when using a 3cc pack size?

7.0mm Bullets		9.0mm Bullets	
Standard Length (20mm)	Double Length (40mm)	Standard Length (20mm)	Double Length (40mm)
6	3	4	2

What is the difference in length between a standard and double length bullet?

The standard length bullet is 20mm long and the double length bullet is 40mm long.

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Frequently Asked Questions

What volume of STIMULAN beads can be prepared with the new combination bead and bullet mat when using a 3cc pack size?

Filling one section of the combination bead and bullet mat using a 3cc pack will yield 7cc of bead volume.

Is the setting time different for STIMULAN beads and bullets?

The setting time is equivalent for beads and bullets.

What are the grooves in the STIMULAN bullets for?

The groove that extends down the side of each bullet helps to reduce the risk of pressurizing the defect site and also increases the surface area of the individual bullet.

What procedures should I target with STIMULAN Rapid Cure 3cc?

The STIMULAN Rapid Cure 3cc pack size is commonly used in procedures with smaller void volumes, such as diabetic foot osteomyelitis, amputations, osteotomies, distal tibia fractures, posterolateral spine and high-risk primary hip and knee reconstructive procedures.

Supporting Resources

The following resources are available on the Distributor Hub website and/or app:

- STIMULAN brochure
- STIMULAN conference flyer
- STIMULAN clinical presentation
- STIMULAN FAQs document
- STIMULAN e-learning (training) modules
- STIMULAN Instructions for use
- Publication library

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Actions to be Taken

The following actions should now be taken:

1. Secure approval for STIMULAN Rapid Cure 3cc in your target hospitals.
2. Work with your hospitals to add STIMULAN Rapid Cure 3cc to their contracts.
3. Develop a distribution plan to review with your AVP.
4. Work with the Biocomposites' Contracts Department to add STIMULAN Rapid Cure 3cc to your distributor contracts.

References

- STIMULAN Instructions for Use (IFU)
- Data on file

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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Patents granted: GB2367552, EP I204599 BI, US 678039I, EP 259423I BI, US 88883063, CN ZL20I2I0466II7.X, GB24967I0, EP 3058899 BI, US I0390954

Patents pending: GBI502655.2, US I5/I040075, CN 20I6I00897I0.5, GBI704688.9, EP I8275044.8, US I5/I933936, CN I086I9579A

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