

STIMULAN[®]

Bullet Mat and Introducer

Internal product launch guide

For internal use only, not for distribution.



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Bullet Mat and Introducer

Introduction

The innovative new **STIMULAN Bullet Mat and Introducer** simplify delivery into hard-to-reach defects. The Bullet Mat molds long bullets with a groove down one side to reduce the risk of pressurizing the defect site. The streamlined, flexible Introducer can be inserted deep into the void area and the obturator enables you to push bullets into the surgical site.

Product Clearance

The **STIMULAN Bullet Mat and Introducer** is an orthopaedic manual surgical instrument, and is exempt from premarket notification requirement. Class I devices are subject only to general controls and represent the lowest potential for harm. Examples of Class I devices include elastic bandages, examination gloves and hand-held surgical instruments.

Instructions for Use Summary

Description

- The **STIMULAN Bullet Mat and Introducer** includes a flexible mat for preparation of the **STIMULAN** bullets, a 7mm Introducer, a 9mm Introducer and an obturator.
- The device is single use only.
- The device is not made with natural rubber latex.

Intended Uses

For use with **STIMULAN** Rapid Cure 20cc to produce either: 32 bullets that are 7mm wide x 20mm long, or 24 bullets that are 9mm wide x 20mm long.

Warnings and Precautions

- Do not reuse.
- Do not re-sterilize.
- Do not implant the instrument system.
- Do not use if packaging is damaged or has been tampered with.
- Do not use beyond expiry date.

Sterilization

The **STIMULAN Bullet Mat and Introducer** are supplied sterile by gamma radiation. Use an aseptic non-touch technique and clean-air theatre.

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Preparation and Technique


Choose Bullet and Introducer sizes to suit surgical site


Bullet diameter	Outside diameter of Introducer	Minimum reamed diameter	End-to-end length	Order code
7mm	9mm (black handle)	10mm	640mm	660-001
9mm	11mm (silver handle)	12mm	480mm	


Prepare STIMULAN Rapid Cure 20cc

Use the mixing solution from the tube provided in the pack.
Do not add any other fluid. Replace the bead mat with the Bullet Mat.

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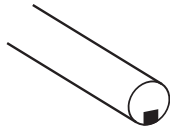
Empty **STIMULAN** Rapid Cure powder into the sterile mixing bowl provided
- 


Add mixing solution and mix thoroughly until a smooth paste is formed (approx. 30 secs)
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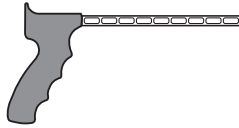
Apply to Bullet Mat immediately
- 

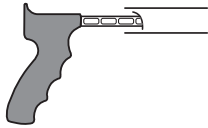
Allow paste to set undisturbed for at least 8 minutes after mixing. Flex Bullet Mat to release bullets


Technique for pre-loading and using the introducer

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Ensure retaining tab at the distal tip is as shown
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Remove obturator and insert bullets to level required to fill void
- 

Transfer pre-loaded Introducer to surgical site. Keep horizontal
- 

Insert Introducer slowly into surgical site
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Insert obturator and apply positive pressure. Maintain positive pressure and pull the Introducer back, leaving **STIMULAN** bullets inside the void

The IFU also includes a technique guide for loading the bullets in situ.

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Results of Pilot Cases

Summary of pilot

- A total of 9 pilot cases were completed.
- Surgeons who participated in trial cases: Dr. Lawrence X. Webb, Dr. Jorge Casas-Ganem, Dr. Joel Wells, Dr. Eric Miller, Dr. William McMaster, Dr. Chet Deshpande, and Dr. Herrick Siegel.
- The **STIMULAN Bullet Mat and Introducer** was used in procedures for infected joint revisions, infected tibial nail removal, and an infected hindfoot nail requiring ankle fusion.

Surgeon feedback

- Average ease of use & handling rating: 4.5 (ranking 1-5)
- Average frequency product will be used: somewhat (monthly)
- Product met customer expectations in all pilot cases.
- The pre-load technique was used in 8 of 9 cases.

Surgeon quotes

- It will be a useful tool – Dr. Lawrence X. Webb.
- When can we get more in the hospital? – Dr. Jorge Casas-Ganem.
- Very easy to use – Dr. Chet Deshpande.
- The bullets show up great on x-ray and you can see the notches – Dr. Eric Miller.

Case images

Infected Hindfoot nail case. Bullets were used in an ankle fusion.
Courtesy of Lawrence Webb MD.



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Results of Pilot Cases

Tips learned

- The Bullet Mat should be scraped to remove excess paste during preparation. This will help to ensure consistent bullet diameter and proper fit in the Introducer.
- Bullets should be completely set before loading into the Introducer.
- It is easiest to remove bullets from the mat individually, using a thumb.
- It is recommended to have the surgical technician hold their thumb over the back end of the Introducer when passing it to the surgeon to prevent bullets from spilling out.
- Ensure that the surgeon always secures the obturator when moving the Introducer.
- The number of bullets needed depends on the surgical case. Not all bullets will be used for every case. In the pilot, the most common bullet size was 7mm.
- If the Introducer tube is filled with bullets, the obturator will extend beyond the length of the tube.

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Selling Information

Product positioning

The **STIMULAN Bullet Mat and Introducer** were designed to provide surgeons with a simple method to deliver **STIMULAN** into hard-to-reach defects.

Unique selling features

- Bullets can be prepared in 7mm and 9mm diameters for varying void sizes.
- The Bullet Mat molds long bullets with a groove down one side to reduce the risk of pressurizing the defect site.
- The streamlined, flexible Introducer can be inserted deep into the void area and the obturator enables the surgeon to push the bullets into the surgical site.

Customer targets

- Reconstructive surgeons – Any orthopaedic surgeon who performs reconstructive revision procedures with hard-to-reach defects with or without infection.
- Trauma surgeons – Any trauma surgeon who requires a product for hard-to-reach defects with or without infection.

Order Code

660-001 (includes mold and introducers for 7mm and 9mm bullets)

Product pricing

List price:	\$1,200
Mandatory HCA price:	\$995
Target price:	\$895
Floor price:	\$695

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Frequently Asked Questions

Compiled from
pilot cases

What is the length of each bullet?

Each bullet is 20mm long.

How many bullets can be made using each side of the Bullet Mat?

The 7mm side of the mat makes 32 bullets and the 9mm side makes 24 bullets.

What volume of STIMULAN will fill up the Bullet Mat?

The Bullet Mat can fit up to 20cc of product, but the amount of STIMULAN needed depends on the individual surgical case.

What does 'end-to-end length' mean?

The end-to-end length refers to the cumulative length if all bullets from one side of the mat are used. For example, if you use all of the 7mm bullets (which are 20mm in length), the total end-to-end length of the bullets is 640mm. This length does not correlate to the length of the introducer.

Does the setting time of bullets differ from beads?

The setting time is equivalent for bullets and beads.

Can bullets and beads be used together?

Yes, but the Introducer should only be used to introduce bullets to the surgical site.

What are the grooves in the 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 are the STIMULAN Bullet Mat and Introducer commonly used for?

The STIMULAN Bullet Mat and Introducer is commonly used during revision joint and trauma cases.

What materials are the STIMULAN Bullet Mat and Introducer made from and are they latex free?

The Bullet Mat is made from medical grade silicone and the introducer tube is made from medical grade plastic. Both the Bullet Mat and Introducer are not made with natural rubber latex.

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Supporting Resources

The following resources are available on the Distributor Hub:

- STIMULAN Bullet Mat and Introducer flyer
- Instructions for Use (IFU)
- Latex declaration
- Technique video

[Distributor Hub login](#)

For indications, contraindications, warnings and precautions see Instructions for Use. Concurrent use of locally administered antibiotics may affect setting time. This flyer 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. ©2016, Biocomposites and Stimulan are registered trademarks of Biocomposites Ltd. All rights reserved. No unauthorized copying, reproduction, distributing or re-publication is allowed unless prior written permission is granted to the owner, Biocomposites Ltd. 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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