

STIMULAN®

Bullet Mat and Introducer

Internal product launch guide for EU

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 moulds long bullets with a groove down one side to reduce the risk of pressurising the defect site. The streamlined, flexible Introducer can be inserted deep into the reamed canal or void area and the obturator enables you to push bullets into the surgical site.

Instructions for Use Summary

Description

- The **STIMULAN Bullet Mat and Introducer** include 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-sterilise.
- Do not implant the instrument system.
- Do not use if packaging is damaged or has been tampered with.
- Do not use beyond expiry date.

Sterilisation

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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Results of early clinical experiences

Early clinical experiences

- A total of 9 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** were 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 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.



See video

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early clinical
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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.

Product
pricing

Product pricing

List price:	£350
Floor price:	£250

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Frequently Asked Questions

Compiled from early clinical experiences

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?

No, 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 pressurising 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 are 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. Neither the Bullet Mat nor the Introducer are made with natural rubber latex.

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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 has not been assessed by a European medicines Competent Authority and is considered off-label usage of the medicinal product and of the device. 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 I204599 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, GB1704688.9