

STIMULAN[®]

Bullet Mat & Introducer

Caution: Federal Law (USA) restricts this device
to sale by or on the order of a physician

Important Information for the Operating Surgeon

Instructions for Use

Number I.030 Rev 081805



(EN) ENGLISH

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 for single use only.

Not made from natural rubber latex.

Intended Uses:

For use with STIMULAN® Rapid Cure 20cc to produce either:

Bullet Size	7mm x 20mm	9mm x 20mm
Number of Bullets	32	24

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 technique and clean-air theatre.

Instructions for Use:

Follow the mixing instruction for STIMULAN® Rapid Cure 20cc. Use the bullet mat in place of the bead mat provided in the Stimulan Rapid Cure pack.

Prepare the STIMULAN® Rapid Cure and place the STIMULAN® paste on the area of the mat with the size of bullet required.

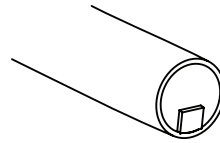
Use the paste applicator provided with the STIMULAN® Rapid Cure 20cc to fill the bullet cavities with the STIMULAN® paste. Once filled, lift the mat and then drop onto a solid surface to reduce trapped air bubbles. Remove excess material off the face of the mat. Allow the material to set, according to the STIMULAN® Rapid Cure instructions.

Once bullets are set they can be removed from the mat by flexing. Ensure the bullets remain in the sterile field.

Ream before insertion.

Bullet Diameter	Outside Diameter of Introducer	Minimum Reamed Diameter	End to end length
7mm	9mm	10mm	640mm
9mm	11mm	12mm	480mm

Ensure the retaining tab at the distal tip is as depicted.

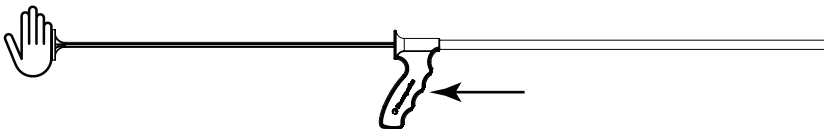


7mm bullets use the BLACK handled introducer.

9mm bullets use the SILVER handled introducer.

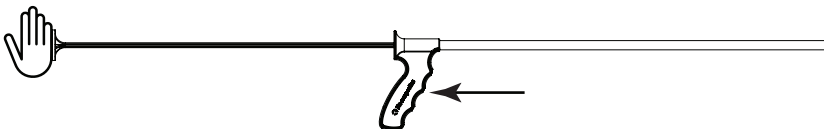
OPTION 1 (Load in situ):

1. Insert the obturator into the chosen introducer.
2. Insert the bullet introducer slowly into the surgical site.
3. Remove the obturator and introduce the first bullet.
4. Ensure the bullet is pushed to the distal tip of the introducer with the obturator. The obturator should be 20mm off the back face of the introducer. Remove the obturator.
5. Insert further bullets into the introducer to the level required to fill the void.
6. Apply a positive pressure onto the last bullet placed into the introducer using the obturator. Whilst maintaining a positive pressure, pull the introducer back along the obturator to leave the bullets in the surgical site.



OPTION 2 (Pre-load):

1. Insert Bullets into the introducer to the level required to fill the void.
2. Transfer the pre-loaded introducer horizontally to the surgical site.
3. Insert the introducer slowly into the surgical site.
4. Insert the obturator into the introducer and apply a positive pressure onto the last bullet placed into the introducer using the obturator. Whilst maintaining a positive pressure, pull the introducer back along the obturator to leave the bullets in the surgical site.



Discard all components

STIMULAN[®] is manufactured by
Bullet Mat & Introducer



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