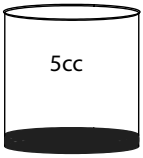
STIMULAN®
Kit

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.008 Rev 081831



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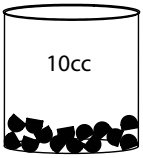
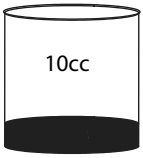


Paste Volume

3mm **Beads**
4.8mm **Beads**
6mm **Beads**



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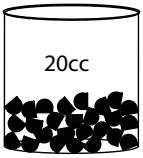

Paste Volume

3mm **Beads**
4.8mm **Beads**
6mm **Beads**

(US) UNITED STATES

STIMULAN® for use in the presence of Infection

PRODUCT DESCRIPTION AND MATERIALS

STIMULAN® Kit provided sterile for single patient use. STIMULAN® Kit contains calcium sulfate powder and mixing solution in pre-measured quantities so that when mixed together in a sterile mixing bowl, the resultant paste is to be injected or digitally packed into open bone void/gap to set in situ or placed into the mould provided, the mixture sets to form beads. The biodegradable, radiopaque beads are resorbed in approximately 30 – 60 days when used in accordance with the device labelling.

STIMULAN® Kit is manufactured from synthetic implant grade calcium sulfate dihydrate ($CaSO_4.2H_2O$) that resorbs and is replaced with bone during the healing process. Also, as the bone void filler beads are biodegradable and biocompatible, they may be used at an infected site. Not made with natural rubber latex.

INTENDED USES

To fill bone void or defect.

INDICATIONS FOR USE

STIMULAN® Kit 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® Kit is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., extremities, pelvis, and posterolateral spine). STIMULAN® Kit provides a bone graft substitute that resorbs and is replaced with bone during the healing process. STIMULAN® Kit 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 tumour
- osteomyelitis
- traumatic injury

CONTRAINDICATIONS

- filling of defects which are intrinsic to the stability of the bony structure
- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative bone disease
- pregnancy
- uncooperative patient who can't or won't follow post-operative instructions including individuals who abuse drugs or alcohol.
- hypercalcaemia
- renal compromised patients

WARNINGS AND PRECAUTIONS

The device is for single use only and must not be reused. Do not resterilise the device. Do not use beyond expiration date on the label. Do not use if product package shows signs of tampering or damage.

Do not add other substances to the device. Adding other substances may alter the safety and effectiveness of this product. 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 the site following implantation. Avoid overfilling the bone void or pressurising 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. The patient should be advised to report any related pain, swelling, fever or unusual incidences. The patient is to be cautioned to govern activities and protect the surgical site from unreasonable stresses and follow the instructions of the physician with respect to follow-up care and treatment. The patient is to be warned of surgical risks and made aware of possible adverse effects. Concurrent use of locally administered antibiotics may affect the setting time.

ADVERSE EFFECTS

Injection of the paste material is associated with the potential to pressurise material in a closed void, which could result in fat embolisation and/or embolisation of the device material into the blood stream. Peripheral neuropathies have been reported following surgery. Sub-clinical nerve damage occurs more frequently, possibly the result of surgical trauma. Material sensitivity/allergic reactions in patients following surgery have been rarely reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to, or during the healing process. Infection can lead to failure/removal of the void filler. Adverse effects may include but are not limited to: wound complications including hematoma, site drainage, bone fracture, infection and other complications that are possible with any surgery, fracture or extrusion of the bone void filler, with or without particulate debris generation, deformity of the bone at the site and incomplete or lack of osseous ingrowth into bone void as is possible with any bone void filler.

STERILISATION
When sterilisation dot is red product has been gamma irradiated.

Unless opened or damaged, the product is supplied sterile within a double pack. Check all packaging for punctures or other damage. Sterilisation of components is by gamma radiation to achieve a Sterility Assurance Level (SAL) of 10^{-6}. When removing the product, appropriate aseptic procedures must be observed. **Resterilisation of the product is prohibited.**

INSTRUCTIONS FOR USE
Open outer packaging using standard aseptic "non touch" technique to avoid contact with contents. Aseptic personnel only must handle the inner pack.
Do not add any additional substances to the paste. Use only the mixing solutions provided. Using alternative mixing solutions and/or adding other substances to the mixture may alter the setting time significantly. Some substances such as bone marrow and blood will prevent the paste from setting.

MIXING INSTRUCTIONS
BEAD FORMATION
To obtain paste suitable for bead formation, the following steps should be used:-

1. Empty powder into a sterile mixing bowl.
2. Add mixing solution from large tube provided.
3. Mix thoroughly until a smooth paste is formed (approximately 30 seconds). DO NOT over mix. STIMULAN® Kit has a working time of 1 - 2 minutes and will set approximately 8 minutes after mixing.
4. Select the size of bead required and apply a uniform layer of paste onto the bead mat provided. Use the paste applicator to ensure complete filling of each bead cavity.
   Note: 10cc STIMULAN® Kit will fill all of the 3mm or the 4.8mm or the 6mm cavities in the bead mat.
5. Allow paste to set undisturbed for at least 15 minutes after mixing. Flex bead mat to release beads.
6. Before implanting the beads, it is recommended that the structural integrity is checked by compressing the bead between thumb and index finger.

INJECTABLE PASTE
To obtain a paste suitable for controlled injection, the following steps should be used:-

1. Empty powder into a sterile mixing bowl.
2. Add mixing solution from both tubes.
3. Mix thoroughly until a smooth paste is formed (approximately 30 seconds). DO NOT over mix.
4. Introduce into the syringe quickly. STIMULAN® Kit is now ready to place into the bony void. STIMULAN® Kit starts to set 2 to 3 minutes after mixing.
5. Allow digitally packed or injected paste to set undisturbed for at least 15 minutes after mixing and prior to closure.

NOTE: Apply the material as a paste only to a dry field.

SURGICAL TECHNIQUE

- Accurate diagnosis of any bone cyst is an essential pre-requisite.
- Expose the bone defect. Raise a window of cortical bone with attached muscle or soft tissue where possible. Alternatively raise periosteum without dissection in the extraperiosteal plane. Decortication is to be preferred by sharp osteotome to raise small slivers of bone attached to the deep surface of periosteum.
- In the case of a cyst, evacuate by curette or preferably a high-speed burr. A dental mirror or arthroscope improves clearance of all unwanted tissue by improving visualisation.
- Lavage the prepared bone graft site with a saline solution until a healthy vascular surface is developed on all sides. Beads should not be crushed, shaved or cut.
- Determine the size of the bone void by filling from a syringe of saline. The bone defect should then be gently packed with STIMULAN® Kit beads or paste.
- Avoid overfilling the bone void or compressing the defect site. Remove any excess paste from the defect site while the material is still workable prior to setting. Do not disrupt the paste while it is setting.
- When implanting the material as a paste, the operating surgeon must ensure a dry (bloodless) field.
- Cover the opening of the bone void with the preserved cortical bone window and/or healthy periosteum or other soft tissues.
- It is of benefit to create a separate micro environment deep to the periosteum. Clean the wound in layers without tension, using standard closure techniques.
- Discard any unused STIMULAN® Kit material and mixing tools.

For additional information contact your Biocomposites representative or customer service at the address provided.

STIMULAN® Kit is manufactured by

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