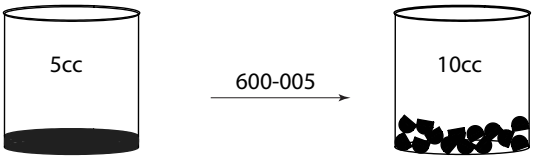
STIMULAN®
Kit

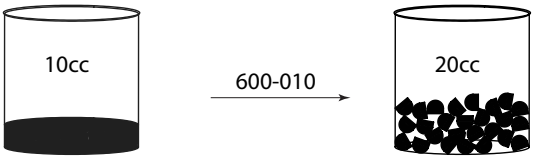
Instructions for Use

Number I.008
Rev 102033



Paste Volume

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



Paste Volume

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

Ref Code	Description	Size	UDI-DI Number
600-005	Stimulan Kit	5cc	15060155710119
600-010	Stimulan Kit	10cc	15060155710126

Sample Type	Average Days to Complete Dissolution ±SD (n=10)
Stimulan Kit	30.5 ± 3.0
Stimulan Kit Vancomycin	26.5 ± 2.9
Stimulan Kit Gentamicin	37.7 ± 8.3
Stimulan Kit Tobramycin	17 ± 3.1

Contents

(EN) ENGLISH

STIMULAN® for use in the presence of Infection

PRODUCT DESCRIPTION
STIMULAN® Kit is calcium sulfate powder and aqueous mixing solution supplied in pre-measured quantities. When mixed, the resultant paste may be
implanted into open voids/gaps of the musculoskeletal system to set in situ or placed in the bead mould mat provided to form beads for implantation.
STIMULAN® Kit is biodegradable and is absorbed by the body in approximately 30 to 60 days. Accessories are provided for the preparation and use of STIMULAN® Kit. STIMULAN® Kit, accessories and packaging are not made from natural rubber latex. STIMULAN® is non-metallic and non-magnetic and poses no known hazards in all Magnetic Resonance environments. The characteristics of STIMULAN® Kit make it suitable as a carrier material for substances such as antibiotics.

INTENDED USES
Calcium matrix for bone and soft tissue implantation

INDICATIONS FOR USE
STIMULAN® Kit is intended for use as a bone / soft tissue 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 absorbs 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 voids, defects or gaps created by:
- surgery
- a cyst
- a tumour
- osteomyelitis
- traumatic injury

CONTRAINDICATIONS
- Filling of defects that are intrinsic to the stability of the bony structure
- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Uncooperative patients who can't or won't follow post-operative instructions, including those that abuse drugs or alcohol
- Hypercalcemia

WARNINGS
- Device performance characteristics may be affected by failing to follow indications, contraindications, warnings, precautions or
instructions for use
- Concurrent use of other substances may affect bone formation, absorption rate and/or setting time.
- Rapid absorption may result in elevated serum calcium levels
- Implantation into patients with a calcium metabolism disorder (including renal compromised patients) may exacerbate symptoms associated with hypercalcemia and/or renal injury and require intervention
- The device has not been studied in paediatric populations
- Do not implant in the cranium where there is risk of contact with cerebrospinal fluid (CSF) or dura mater
- Single use. Do not resterilise. Reuse may result in contamination and/or transmission of disease and/or inconsistent setting characteristics
- Sterile. Do not use beyond expiry date
- Avoid contact with chemicals (e.g. alcohol) in the clinical setting

PRECAUTIONS
- This prescription device is for use by suitably qualified Healthcare Professionals only according to its intended use
- It is at the treating physician's discretion to determine the best course of care based on individual patient's needs, taking into account the indications, contraindications, warnings, precautions and possible adverse effects.
- Ensure surrounding bone is healthy and vascular but not actively bleeding at time of insertion
- Do not irrigate the site following implantation
- Beads should not be crushed, shaved or cut to prevent debris restricting pores of the device
- Avoid overfilling or pressurising the defect site (e.g. when injecting) due to risk of migration and/or embolization of fat into the bloodstream
- Ensure adequate tissue coverage and/or containment is achieved as incomplete or inadequate soft tissue coverage may result in migration
and/or serous exudate
- Dispose of unused, soiled or explanted product as contaminated clinical waste

POSSIBLE ADVERSE EFFECTS
- Inadequate or incomplete bone formation may occur
- Material sensitivity/allergic reactions may occur
- Heterotopic ossification may occur
- Device migration may occur and result in wound drainage
- Embolism may occur if injecting the device
- Renal failure may occur due to concurrent therapies and/or the patient's medical condition, including implantation into patients who have, or are at risk of, impaired renal function
- Hypercalcemia, infection and seroma are associated risks
- Known risks and potential adverse effects associated with general surgical procedures may also occur

PATIENT INFORMATION

- The patient is to be cautioned to protect the surgical site from unreasonable stresses and to follow the instructions for follow-up care to reduce risk of device migration during the healing period
- The patient is to be made aware of risks and possible adverse effects and to report any such effects, fever or unexpected incidents

STORAGE

Store in a cool, dry place away from direct sunlight and other sources of heat

STERILISATION

- Sterile unless packaging is damaged or opened, check before use
- Indicator dot on packaging turns from yellow to red to indicate product has been exposed to radiation for sterilisation. Only use product if red
- Double pack to allow aseptic presentation.

PREPARATION AND USE

Select size required according to defect or clinical need. Double packed for aseptic presentation. Circulating (non-scrubbed) practitioner to open outer pack and allow the scrubbed practitioner to take the inner pack by grasping or using forceps. Scrubbed practitioner to open inner pack within the sterile field. Prepare STIMULAN® Kit per surgical requirements. The concurrent use of antibiotics is at the discretion of the physician. Apply STIMULAN® Kit according to preferred surgical technique.

BEAD FORMATION

1. Empty powder into a sterile mixing bowl.
2. Add mixing solution from the large tube provided. If mixing with antibiotic in liquid form add 5ml per 10cc dose. Refer to warning concurrent use.
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 to confirm that the bead has set before implantation.

INJECTABLE PASTE

1. Empty powder into the 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 surgical site. STIMULAN® Kit starts to set 2 to 3 minutes after mixing.
5. Allow injected paste to set undisturbed for at least 15 minutes after mixing and prior to closure.

WARNING

Concurrent use of locally administered antibiotics may affect the setting time, absorption characteristics and/or bone formation. Antibiotics may affect the setting time as exemplified below for 10cc of STIMULAN® Kit.
Only the antibiotics shown can be added and the combination with other antibiotics shall be avoided.

It is the surgeon/healthcare professional's responsibility to give due consideration to the details contained in the medicinal product marketing authorisation in deciding whether it is appropriate for the patient under his/her care. The relevant Summary of Product Characteristics (SmPc) must be consulted. The type and dose of medicinal substance should also be assessed according to the individual patient's clinical circumstances.

Data based on 10cc Stimulan Kit for a given quantity of antibiotic. Supplier shown in parenthesis, other sources may vary.

For additional information contact your Biocomposites representative or distributor.

Single powders added to Stimulan powder plus mixing solution provided

Substance (supplier)	Quantity	Expected Set Time (min)
Vancomycin (Flynn Pharma)	1000mg	5-10 min

Single Liquids added to Stimulan powder instead of mixing solution provided

Substance (supplier)	Quantity	Expected Set Time (min)
Gentamicin (Amdipharm)	240mg in 6ml solution	10-20 min
Tobramycin (Alloga)	240mg in 6ml solution	10-20 min

STIMULAN® Kit is manufactured by

Biocomposites CE 0123

Biocomposites Ltd, Keele Science Park, Keele, Staffordshire, ST5 5NL, England
Tel +44 (0) 1782 338580 Fax +44 (0) 1782 338599
Email: info@biocomposites.com Web: www.biocomposites.com

Biocomposites Inc, PO Box 2692, Wilmington, NC 28402, USA
Tel +1 (910) 350 8015 Fax +1 (910) 350 8072
Email: infous@biocomposites.com Web: www.biocomposites.com

Biocomposites (Shanghai)Ltd, 上海市恒丰路436号环智国际大厦704室
电话: +86 (0) 21 6380 2385 电传: +86 (0) 21 6380 5827
电子信箱:infochina@biocomposites.com www.biocomposites.com

Australian Sponsor.
Emergo Australia, Level 20, Tower II, Darling Park
201 Sussex Street, Sydney, NSW 2000, Australia