STIMULAN® Rapid Cure
STIMULAN® Kit

Calcium matrices for bone and soft tissue implantation

Patient Information

Biocomposites®

What is STIMULAN?

STIMULAN is a void filler for bone and soft tissue implantation. It is intended to fill voids, defects or gaps created by: surgery, a cyst, a tumour, bone infection (osteomyelitis), traumatic injury.

STIMULAN is intended to be gently packed into bony voids or gaps of the skeletal system (i.e. extremities, pelvis, and posterolateral spine). The characteristics of STIMULAN make it suitable as a carrier material for substances such as antibiotics.

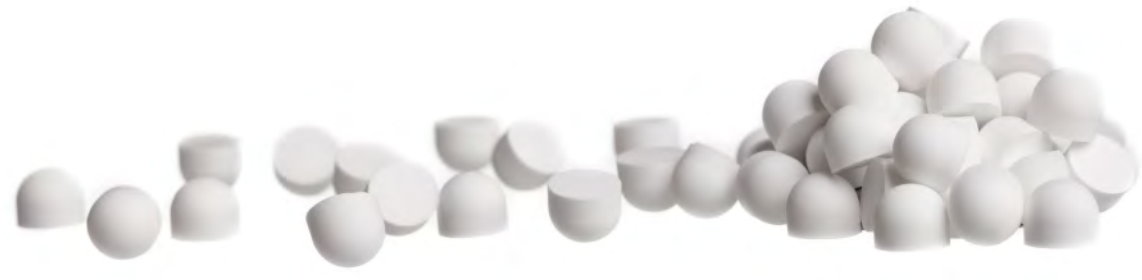
How does STIMULAN work?

STIMULAN provides a bone graft substitute that absorbs and is replaced with bone during the healing process. The intended user is a healthcare professional who is familiar with the intended use of the product and treatment of infected cases, such as an orthopaedic surgeon.

Your healthcare professional will determine the quantity implanted based on your surgical needs.

STIMULAN material

STIMULAN is provided as calcium sulfate powder and mixing solution (water) in pre-measured quantities so that when mixed together in a sterile mixing bowl, the resultant paste can be gently packed into open voids/gaps according to the Instructions for Use. The product can be used in the form of a bead or paste. STIMULAN is absorbed by the body within approximately 30 to 60 days following implantation, as such the device is single use and does not require maintenance or monitoring.



Other treatment options

Void fillers are used to fill and enhance biological repair of musculoskeletal defects when natural bone repair may be too slow or inadequate.

Autogenous bone graft is considered the 'gold standard', in which bone is taken from elsewhere in the patient's body; however, it is subject to limitations such as donor site morbidity and availability. Similar issues are seen with the use of allogeneic bone grafts, in which bone is taken from someone other than the patient, however this carries a greater risk of infection.

To overcome these problems, synthetic alternatives have been developed. STIMULAN is an example of such a synthetic alternative. It is recommended that the patient discuss any possible therapeutic alternatives with a healthcare professional who can take into consideration the individual patient's situation.

Residual risks and follow-up

This document is not intended to replace a consultation with your healthcare professional if needed.

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks below:

- Inadequate or incomplete bone formation may occur.
- Material sensitivity/allergic reactions may occur.
- Abnormal bone growth in non-skeletal tissues (Heterotopic ossification) may occur.
- Device migration may occur and result in wound drainage.
- Blood vessel blockage (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 fluid build-up (seroma) are associated risks.
- Known risks and potential adverse effects associated with general surgical procedures may also occur.

STIMULAN has no known risks due to interactions with other devices.

Device name and model number

Device name	Size	Reference code	UDI
STIMULAN Rapid Cure	5cc	620-005	15060155711024
STIMULAN Rapid Cure	10cc	620-010	15060155711031
STIMULAN Rapid Cure	20cc	620-020	15060155711048
STIMULAN Kit	5cc	600-005	15060155710119
STIMULAN Kit	10cc	600-010	15060155710126

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Adverse Events/incident reporting instruction
You should report serious events to Biocomposites at +44(0)1782 338580 (compliance@biocomposites.com) and the Competent Authority.

For indications, contraindications, warnings and precautions see Instructions for Use. Concurrent use of locally administered antibiotics may affect setting time, absorption characteristics and/or bone formation. It is the surgeon/healthcare professional's responsibility to give due consideration to the details 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 circumstance.

This brochure may include the use of STIMULAN or techniques that go beyond the current clearance/approval granted by the relevant regulatory authority.

Patents granted: GB2367552, EP 1204599 B1, US 6780391, EP 2594231 B1, US 8883063, CN ZL201210466117.X, GB2496710, EP 3058899 B1, US 10390954, US 10,588,748, CN ZL201610089710.5

Patents pending: GB1502655.2, GB1704688.9, EP 18275044.8, US 15/933936, CN 108619579A

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