

STIMULAN[®] Frequently Asked Questions

for Distributors (USA)

February 2020

FAQs

What is STIMULAN indicated for?

STIMULAN is the perfect partner for cases with an infected site. It can be used in the presence of infection and is indicated for use to fill a bone void or defect of the skeletal system created by surgery, a cyst, a tumor, osteomyelitis or traumatic injury. STIMULAN is indicated only for bony voids or defects/gaps that are not intrinsic to the stability of the bony structure. STIMULAN paste can be digitally packed into the bone void to set in-situ, or molded into solid implants that are to be gently packed into the defect.

What is STIMULAN contraindicated for?

Contraindications for STIMULAN can be found in the IFU. These include contraindications for filling defects which are intrinsic to the stability of the bony structure, renal compromised patients, hypercalcaemia, severe vascular or neurological disease, uncontrolled diabetes, pregnancy, severe degenerative bone disease and uncooperative patients who can't or won't follow post operative instructions including individuals who abuse alcohol or drugs.

What supporting data do you have for STIMULAN?

Biocomposites has a variety of data ranging from pre-clinical laboratory testing, animal model data and clinical data. Biocomposites also has numerous case studies available that provide an overview of the use of STIMULAN in various clinical applications. Biocomposites would be happy to provide you with case studies for the clinical applications that you are most interested in.

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Who is using STIMULAN and in which hospitals?

STIMULAN is used in over 50,000 cases a year in a wide range of different indications. Biocomposites would be happy to introduce you to an appropriate surgeon if you would like to have a peer-to-peer conversation.

How long does STIMULAN take to absorb?

STIMULAN is absorbed in approximately 30-60 days (4-8 weeks) when used in accordance with the device labeling. Contributing factors are surgical site, quantity used and patient health.

Does STIMULAN damage articulating surfaces on joint prosthesis?

This is an area of ongoing research, but wear testing indicates that STIMULAN does not significantly scratch implant grade cobalt chrome and does not lead to increased wear of high density polyethylene components. Wear testing also shows that STIMULAN causes fewer scratches to cobalt chrome than PMMA and competitor calcium sulfates. Biocomposites has produced a white paper on the influence of third body damage to articulating surfaces with bone void fillers which can be viewed on the Biocomposites Distributor Hub.

Will STIMULAN cause heterotopic ossification if implanted in soft tissue?

STIMULAN is an osteoconductive material and is not osteoinductive or osteogenic in nature. Biocomposites has published a range of clinical data indicating a minimal risk of heterotopic ossification when implanted in or adjacent to soft tissue.

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Will STIMULAN grow bone in osteomyelitic or infected non-union cases?

We do have clinical evidence that STIMULAN is remodelled into bone when placed at an infected site following thorough debridement and removal of necrotic tissue. Biocomposites would be happy to provide you with the case studies that demonstrate this for the indication you are interested in.

Can STIMULAN be applied to a wet field?

It is recommended that STIMULAN paste be applied where surrounding bone is healthy and vascular but not actively bleeding at the time of insertion. When implanted as a paste, do not irrigate the site following implantation.

What is DRy26®?

Each and every synthesis of STIMULAN undergoes a 26 step process that starts with pharmaceutical grade precursors and takes over 6 weeks to reach maturity. We have named this our DRy26 methodology.

What is the compressive strength of STIMULAN?

STIMULAN Kit/Rapid Cure have been shown to have a 'wet' compressive strength (as set at implantation time) of 21 MPa. This helps maintain bead integrity immediately following bead placement. The compressive strength reduces rapidly as STIMULAN is absorbed.

FAQs

What is the powder weight of STIMULAN Rapid Cure per cc of paste volume?

The powder weight of STIMULAN Rapid Cure per cc of paste volume is:

PRODUCT	PASTE VOLUME	BEAD VOLUME	POWDER WEIGHT
STIMULAN® Rapid Cure Rapid setting paste with individual bead kit	3cc	7cc	6.3g
	5cc	12cc	9.5g
	10cc	25cc	19.0g
	20cc	50cc	38.0g

What volume and size of beads can be prepared using the STIMULAN Rapid Cure bead mat?

The STIMULAN Rapid Cure bead mat can be used to prepare 3mm, 4.8mm or 6mm hemispherical beads. A 10cc pack of STIMULAN Rapid Cure will yield 25cc of bead volume.

How many beads can be made from the different sections of the STIMULAN Rapid Cure bead mat using a 10cc pack?

3.0mm BEADS	4.8mm BEADS	6.0mm BEADS
560	150	95

FAQs

What volume and size of bullets can be prepared using the STIMULAN bullet mat?

The STIMULAN bullet mat can be used to prepare 7mm and 9mm bullets. Each bullet is 20mm in length. A 20cc pack will yield 50cc of bullet volume.

How many bullets can be made from the different sections of the STIMULAN bullet mat using a 20cc pack?

7.0mm BULLETS	9.0mm BULLETS
32	24

What is the end-to-end length if all bullets in the mat are used?

The end-to-end length refers to the cumulative length if all bullets are used. If all of the 7mm bullets are used, the total end-to-end length of the bullets is 640mm. If all 9mm bullets are used, the total end-to-end length of the bullets is 480mm. The end-to-end length does not correlate to the length of the introducer.

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How many STIMULAN beads can be made from each bead section of the new combination bead and bullet mat when using a 3cc pack size?

3.0mm BEADS	4.8mm BEADS	6.0mm BEADS
230	68	39

How many STIMULAN bullets can be made from each bullet section of the new combination bead and bullet mat when using a 3cc pack size?

7.0mm BULLETS		9.0mm BULLETS	
STANDARD LENGTH (20mm)	DOUBLE LENGTH (40mm)	STANDARD LENGTH (20mm)	DOUBLE LENGTH (40mm)
6	3	4	2

What volume of STIMULAN beads can be prepared with the new combination bead and bullet mat when using a 3cc pack size?

Filling one section of the combination bead and bullet mat using a 3cc pack will yield 7cc of bead volume.

What procedures should I target with STIMULAN Rapid Cure 3cc?

The STIMULAN Rapid Cure 3cc pack size is commonly used in procedures with smaller void volumes, such as diabetic foot osteomyelitis, amputations, osteotomies, distal tibia fractures, posterolateral spine and high-risk primary hip and knee reconstructive procedures.

FAQs

What are the working and setting times of STIMULAN?

When mixed with the liquid provided STIMULAN has the following setting times:

- STIMULAN Rapid Cure has a 1-2 minute working time and will set ~ 4 minutes after mixing. Following mixing and application onto the bead or bullet mat, allow to set undisturbed for at least 8 minutes prior to release from bead/bullet mat.
- STIMULAN Kit (beads and bullets) have a working time of 1-2 minutes and will set in approximately 8 minutes after mixing. Following mixing and application onto the bead/bullet mat, allow to set undisturbed for at least 15 minutes prior to release from bead/bullet mat.
- STIMULAN Kit (injectable paste) has a 30 second working time prior to injection and begins to set 2-3 minutes after mixing. Following mixing and application, allow paste to set undisturbed for at least 15 minutes prior to closure.

Can I mix antibiotics with STIMULAN?

STIMULAN is not currently FDA cleared/approved to be mixed with antibiotics. Specific questions relating to off label/physician directed use should be sent to the Biocomposites' Compliance Department via the Unsolicited Request Process.

Can I substitute other mixing solutions or add additional solution when preparing STIMULAN Rapid Cure?

You should only use the mixing solution 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.

FAQs

Is there an increased risk of hypercalcaemia when using large quantities of STIMULAN?

There have been a small number of reported cases of hypercalcaemia in patients where STIMULAN has been used. Vancomycin and aminoglycoside antibiotics are known to be nephrotoxic. Implantation of STIMULAN beads with locally administered vancomycin or aminoglycoside antibiotics may result in elevated serum calcium levels. These levels may be increased further in the absence of adequate kidney function and/or dehydration which may result in an increased risk of hypercalcaemia.

In laboratory *in-vitro* trials, Biocomposites has found that large amounts of vancomycin (hydrochloride) with STIMULAN may cause the beads to dissolve faster. This increased rate of dissolution of STIMULAN beads may potentially elevate serum calcium levels which may lead to an increased risk of hypercalcaemia. This would be more likely with patients who are dehydrated or have impaired kidney function.

Uncontrolled diabetes and renal compromised patients.

The kidneys regulate the amount of fluid and various salts in the body, helping to control blood pressure. Kidney disease or nephropathy can happen to anyone but is more common in patients with diabetes and develops very slowly, over many years. It is most common in people who have had the condition for over 20 years. About 1 in 3 people with diabetes may go on to develop nephropathy, although as treatment improves fewer people are affected.

<https://www.diabetes.org.uk/kidneys>

Can surgeons use STIMULAN when the patient has a known sulfonamide allergy?

The Instructions for Use does not contraindicate STIMULAN for sulfa allergies.

FAQs

Can wound drainage occur with the use of STIMULAN?

Wound drainage is possible with any implanted material and may be attributed to several factors including patient health and surgical methods. To reduce the risk of drainage ensure complete soft tissue coverage and/or containment is achieved.

Why is there so little drainage associated with STIMULAN?

STIMULAN is a pharmaceutical-grade, synthetic calcium sulfate. The physical and chemical properties are tightly controlled during manufacturing to ensure optimal purity, hydrophilicity and physiological pH. The absence of impurities in STIMULAN may be associated with reduced drainage rates when compared to naturally occurring mineral sources of calcium sulfate.

What potential adverse effects may be associated with the implantation of STIMULAN?

Adverse effects for STIMULAN can be found in the IFU. These 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.

What should I do if my surgeon experiences an adverse event?

In this case the event should be reported as per the hospital policy and reported to the Compliance Department, Biocomposites Inc.

FAQs

Can STIMULAN cause an adverse soft tissue response?

As part of a recent study by the University of New South Wales Australia, soft tissue inflammatory response to implanted STIMULAN was determined. The study describes a novel small animal model to investigate dead-space management in muscle tissue¹. Results from histology and serological analysis indicated no significant unusual inflammatory response to the implanted materials.

Reference:

1. Oliver, R.A., et al., Development of a Novel Model for the Assessment of Dead-Space Management in Soft Tissue. PLoS ONE, 2015. 10(8): p. e0136514.

What should I do if my surgeon requires technical or clinical information or peer-to-peer communication?

Information requested by the surgeon or their medical team should be directed to your Field Marketing Specialist (FMS) or Regional Manager (RM).

FAQs

How does STIMULAN compare to Cerament®?

STIMULAN is indicated for infected sites and is fully absorbable. Cerament is contraindicated for infected sites and does not fully absorb. Cerament does not have a fast set product and does not provide a mat for molding beads.

How does STIMULAN compare to Calcigen® S?

STIMULAN is indicated for infected sites and is fully absorbable. Calcigen S is contraindicated for active infection and does not fully absorb. Calcigen S does not have a fast set product and contains 1/2 less product per volume when compared to STIMULAN.

How does STIMULAN compare to OsteoBoost®?

STIMULAN is indicated for infected sites and is fully absorbable. OsteoBoost is contraindicated for infected sites and does not fully absorb. OsteoBoost does not have a fast set product and contains 1/2 less product volume per cc when compared to STIMULAN.

How does STIMULAN compare to Osteoset®?

STIMULAN is indicated for infected sites and is fully absorbable. Osteoset is cleared for infected sites but contains nonabsorbable impurities that may not fully absorb and can cause third body damage. A bead mat is included but it is not universal.

How does STIMULAN compare to Synthecure™?

STIMULAN is indicated for infected sites and is fully absorbable. Synthecure is cleared for infected sites and fully absorbs, although our tests show that Synthecure has a higher porosity and a much faster degradation rate than STIMULAN.

How does STIMULAN compare to InterSep®?

STIMULAN is indicated for infected sites and is fully absorbable. InterSep is cleared for infected sites and fully absorbs, although our tests show that InterSep has a much faster degradation rate than STIMULAN.

FAQs

Why should I choose STIMULAN over other lower priced calcium sulfates?

STIMULAN is a truly absorbable calcium sulfate that is uniquely recrystallized for consistent and reliable performance in the presence of infection.

When you need it – STIMULAN delivers every time:

- Controlled Purity – contains no traces of non-absorbable impurities
- Hydrophilic – mixes easily and quickly with liquid, and does not require pre-soaking
- Physiologic pH level - STIMULAN has a controlled physiologic pH for improved biocompatibility
- Truly absorbable – fully absorbs within 30-60 days (4-8 weeks)
- Low levels of drainage in clinical use
- No third body damage to articulating surfaces
- Case-by-case flexibility – it can be used in three bead sizes, two bullet sizes, as a paste or for injection

FAQs

For any other questions please contact your Biocomposites representative.

Company Confidential

This material is intended for use by Biocomposites' employees and their authorized representatives. This material is for informational purposes only, not for clinical application. Do not copy or distribute.

For indications, contraindications, warnings and precautions see Instructions for Use. Concurrent use of locally administered antibiotics may affect setting time.

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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