

Competitor Fact Sheet: InterSep®



For Biocomposites' employees and authorized distributors internal use only.



Feature	STIMULAN®	InterSep® Exactech®
Composition	Powder: Pharmaceutical-grade CaSO_4 Mixing solution: Sterile water	Powder: Medical-grade CaSO_4 Mixing solution: Unknown aqueous solution ⁴
Cleared for infected sites	Yes ¹	Yes ⁴
Available sizes	Rapid Cure: 3cc, 5cc, 10cc, 20cc Kit: 5cc, 10cc	5cc, 10cc, 20cc
Product per volume	<ul style="list-style-type: none"> 3cc box = 6.3g powder 5cc box = 9.5g powder 10cc box = 19.0g powder 20cc box = 38.0g powder 	5cc box (7.7g powder): Contains 19% less powder than 5cc STIMULAN box ²
Setting options and times	Rapid Cure: 4 minutes Kit (Standard set): 8 minutes	Fast cure: 5 minutes ^{4, 5}
Formats	3 bead sizes, 2 bullet sizes, paste, injectable	3 bead sizes, paste, injectable ^{4, 5, 6}
Bead and bullet sizes	3.0mm, 4.8mm, 6.0mm beads 7.0mm, 9.0mm bullets	3.0mm, 4.5mm, 6.0mm beads ^{4, 5, 6}
Bead or bullet mat included	<ul style="list-style-type: none"> Universal bead mats are included in 5cc, 10cc and 20cc boxes A combination bead and bullet mat is included in the 3cc box A bullet mat and introducer system is available for order 	Double-sided bead mats included in each box ^{4, 5}
Impurities	No impurities ²	No impurities ⁷
Claimed absorption rate	4-8 weeks ¹	Not specified
Fully absorbs	Yes ¹	Yes ²

Feature	STIMULAN [®]	InterSep [®] Exactech [®]
pH	Physiologic ²	Extremely acidic ²
Hydrophilic or Hydrophobic	Hydrophilic ²	Hydrophilic ²
Degradation rate	Low ²	High ²
Third body damage	No third body damage to articulating surfaces ²	Not tested
Peer-reviewed evidence	382 ²	0
Key selling points and weaknesses	(+) Can be used at infected sites ¹ (+) Only STIMULAN undergoes a proprietary DRY26 [®] recrystallization method which consists of 26 steps over 6 weeks and results in its consistent and reliable performance ³ (+) Fully absorbs at an optimal rate ² (+) Standard set option available (+) Bullet format available (+) Physiologic pH ² (+) Contains more product per volume ² (+) Peer-reviewed evidence to support the use of STIMULAN ² (+) In-house product development, manufacturing, marketing and distribution (+) Comprehensive support network for our customers and hospitals (+) 50,000 cases per year ²	(+) Can be used at infected sites ⁴ (+) Claims to be equivalent to STIMULAN ⁸ (-) Degrades at a rapid rate ² (-) May absorb faster than STIMULAN ² (-) No standard set option available ^{4, 5, 6} (-) Extremely acidic pH (3.6-3.8) ² (-) Contains less product per volume ² (-) No data or publications to support efficacy (-) OEM product with separate companies covering R&D, manufacturing, marketing and distribution * (+) = competitor selling points (-) = competitor weaknesses

References:

1. Biocomposites Ltd, STIMULAN Instructions for Use.
2. Biocomposites, Data on file.
3. Cooper, J.J., Method of producing surgical grade calcium sulphate; Patent. 1999.
4. Exactech[®], Inc. InterSep[™] Calcium Sulfate Bone Void Filler Instructions for Use. 4I272 Rev. A.
5. Exactech[®], Inc. CEMENT Handling Technique. InterSep[®] Calcium Sulfate Bone Void Filler. 00-0000440 0719. 2019.
6. Exactech[®], Inc. InterSep[™] Calcium Sulfate Product Sheet. 715-08-10 0119.7. 2019.
7. Exactech[®], Inc. InterSep[®] Calcium Sulfate. Elemental Analysis of InterSep[®] vs Stimulan[®]. I2-0000640 I019. 2019.
8. Department of Health and Human Services 510(k) Summary Letter. K171161. DB-CSD. 2017.

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.

©2020, Biocomposites, STIMULAN, Bringing Calcium to Life, Power to Transform and DRY26 are trademarks/registered trademarks of Biocomposites Ltd. All rights reserved. No unauthorized copying, reproduction, distributing or republication is allowed unless prior written permission is granted by the owner, Biocomposites Ltd.

Patents granted: GB2367552, EP I204599 B1, US 6780391, EP 2594231 B1, US 88883063, CN ZL201210466117.X, GB2496710, EP 3058899 B1, US 10390954
 Patents pending: GB1502655.2, US I5/040075, CN 201610089710.5, GB1704688.9, EP I8275044.8, US I5/933936, CN I08619579A