<b>₹</b> Biocomposites®		Analytical Report		
Document No:	20180603			
Author		Date:	Thursday, 31 May 2018	
Laboratories, Keele University Science Park, Keele, Staffordshire.				
Title:	Title: Degradation Analysis of Two Forms of Calcium Sulfate Bone Void Filler			

## **Study Summary**

Two samples of calcium sulfate bone void filler received. Investigate material degradation properties in solution.

Sample Name	Ref	Lot	Appearance	
Synthecure	20-125	RM118904	White Powder, clear liquid	
Stimulan Rapid Cure	620-005D	2018-03a	White Powder, clear liquid	

# **Analytical Methods and Results**

# **Sample Degradation Assay**

Investigate the rate of degradation of each material using a physiological solution. Total solution exchanged and replenished at 24 hour intervals.

# Method

10 6mm Bead samples of each material were weighed to 4 decimal places. Beads were saturated with Phosphate Buffered Saline (PBS) for 1 minute and saturated weight was recorded. Beads were placed into individual sealed containers of 10ml of 0.01M PBS solution and incubated at 37°C. Samples were removed from the solution at regular intervals, surface dried and weighed. At each interval, the PBS was replenished with fresh solution.

#### **Results**

Synthecure beads absorbed more PBS on soaking indicating a higher porosity.

### Table 1. Weight increase on soaking

	Lot Number	Average Initial Average		Average	Average Weight
		Weight of bead   Saturated weight   W		Weight	increase %
		(n=10)	of bead (n=10)	increase	
Synthecure	RM118901	0.1745g	0.1918g	0.0173g	9.914%
Stimulan Rapid	2018-03a	0.1800g	0.1858g	0.0058g	3.22%
Cure					

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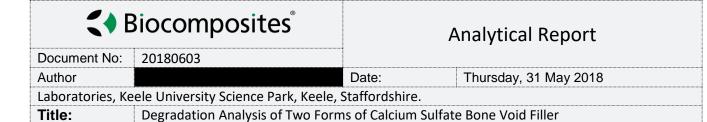


Table 2. Degradation rate data

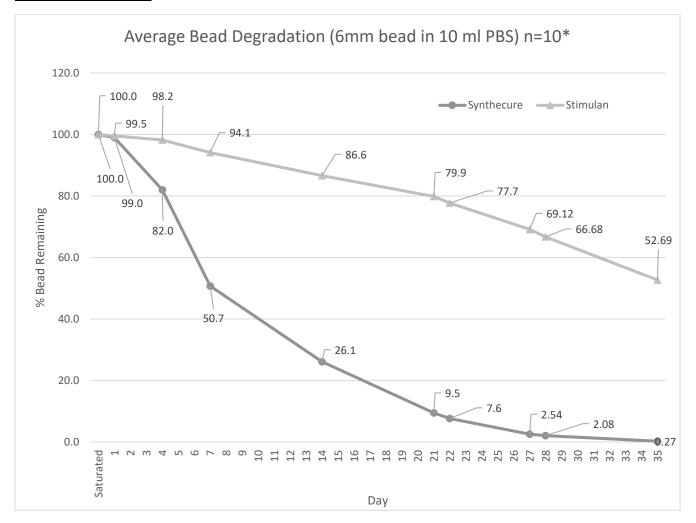
	% Bead Remaining		
	Synthecure	Stimulan Rapid	
		Cure	
Day	RM118901	2018-03a	
Saturated	100	100	
1	98.95	99.53	
4	81.99	98.2	
7	50.68	94.14	
14	26.103	86.56	
21	9.5	79.9	
28	2.08	66.68	
35	0.27	52.69	

# Fig 1. Example beads

Day 4 Bead Loss Synthecure -18% Stimulan -1.8%	Day 13 Bead Loss Synthecure - 70.23% Stimulan -11.76%	
Day 5 Bead Loss Synthecure -31% Stimulan -3.39%		
Day 6 Bead Loss Synthecure -41% Stimulan -4.47%		
Day 7 Bead Loss Synthecure -49% Stimulan -6%		

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Fig 2. Degradation rate



#### Conclusions

Synthecure beads degrade at a much higher rate than Stimulan Rapid Cure beads

The 9.9% increase in weight on soaking with PBS indicates a higher porosity.

\*Of the 10 bead samples of Synthecure, only 8 remained at the 14 day time point, 5 at the 21 day time point and two at the 35 day time point. All Synthecure samples had degraded by day 37.

All 10 samples remained for Stimulan at the 35 day time point.

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