ACTIFUSE FLOW Bone Graft Substitute

Product Code	Description
506005078076	Actifuse Flow 1.5 mL
506005078077	Actifuse Flow 3 mL
506005078078	Actifuse Flow 5 mL

Orthopedic Indication for ACTIFUSE FLOW Bone Graft Substitute

Actifuse Flow is a bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse Flow can be injected into bony voids or gaps of the skeletal system, i.e., extremities, pelvis, and spine, including use in posterolateral spinal fusion procedures with appropriate stabilizing hardware. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Important Risk Information for ACTIFUSE FLOW Bone Graft Substitute

ACTIFUSE FLOW is contraindicated where the device is intended as structural/load-bearing support in the skeletal system. ACTIFUSE FLOW is contraindicated for treatment of vertebral compression fractures.

Attempts should not be made to modify the size of the granules or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration.

The effect of mixing Actifuse Flow with substances other than sterile saline/water, autologous blood or bone marrow aspirate is unknown.

Rx Only. For safe and proper use please refer to full device Instructions for Use.

References:

1. Hing KA, et al. Comparative performance of three ceramic bone graft substitutes. Spine J. 2007; 7(4):475-490.
2. Actifuse Flow IFU
3. Hing KA, Revell PA, Smith N, Buckland T. Effect of silicon level on rate, quality and progression of bone healing within silicate-substituted porous hydroxyapatite scaffolds. Biomaterials. 2006;27(29):5014-5026.
4. Coathup MJ, Cai Q, Campion C, Buckland T, Blunn GW. 2013. The effect of particle size on the osteointegration of injectable silicate-substituted calcium phosphate bone substitute materials. J Biomed Mater Res Part B 2013:101B:902–910.
5. Blunn G, et al. "The Safety and Efficacy of Easyfill and Actifuse Injectable Putty." Preclinical Report.
6. Data on File

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One Baxter Parkway
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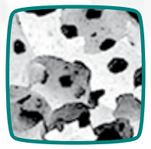
USMP/MG95/18-0005(1) 10/2018



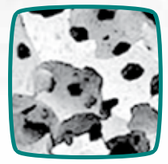
Actifuse Flow

Bone Graft Substitute

Silicate Substituted Calcium Phosphate

ACCELERATED BONE FORMATION[1*]

- Optimal Silicon Level
- More Surgical Options
- Ready To Use



Actifuse Flow

Bone Graft Substitute

Silicate Substituted Calcium Phosphate

Optimal Silicon Level for Bone Formation*

ACTIFUSE FLOW bone graft substitute is a bioactive, osteoconductive and osteostimulative silicate substituted synthetic bone graft substitute that provides for accelerated bone formation.[1,2,3*]

ACTIFUSE FLOW contains ACTIFUSE granules sized 90 to 500 µm, suspended in an aqueous gel carrier.[2] ACTIFUSE contains 0.8% silicon by weight, which in preclinical studies was shown to be optimal for bone formation.[3*]

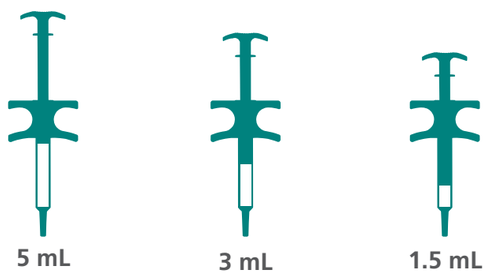
In a pre-clinical model, **ACTIFUSE FLOW** delivered similar bone growth to Actifuse Microgranules.[4,5*]

More Surgical Options

- **ACTIFUSE FLOW** is delivered directly from the syringe
- Compatible with small incisions and less invasive approaches
- Ideal for filling constrained defects and complex geometries

Ready To Use

- Does not require mixing or waiting
- Maintains consistency throughout surgery[6]
- Available in three convienient sizes:



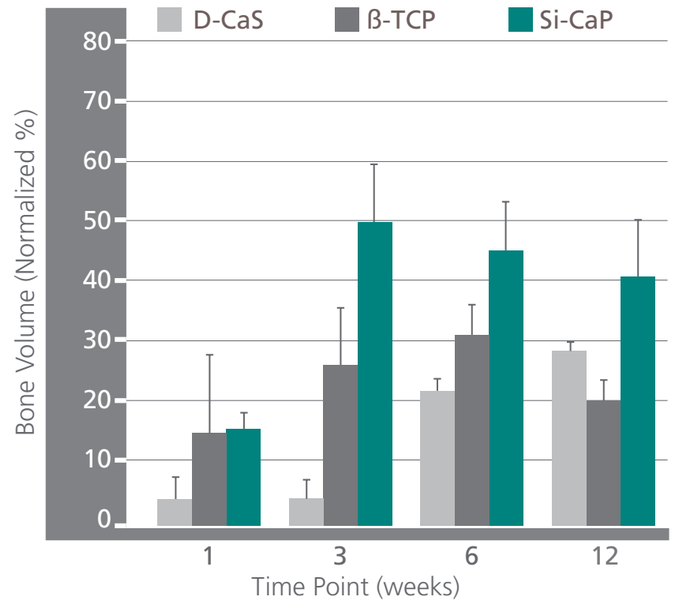
*Preclinical data. Results may not correlate to performance in humans.

Accelerated Bone Formation[1*]

In a preclinical model comparing ACTIFUSE Bone Graft Substitute to ß-TCP and dense calcium sulfate, ACTIFUSE Bone Graft Substitute treated animals had greater new normalized bone volume.*

Bone Volume

Variation in normalized volume of new bone within the various bone graft substitutes.



Adapted from Hing 2007.

*Preclinical data. Results may not correlate to performance in humans.

ACTIFUSE Flow has 80% Total Porosity[2]

Please see Important Risk Information at the end of this brochure.