

Baxter

Actifuse

BONE GRAFT SUBSTITUTE



More bone,
Less time^{*1}

*In a preclinical model comparing ACTIFUSE Bone Graft Substitute to β -TCP at 3, 6 and 12 weeks, ACTIFUSE Bone Graft Substitute treated animals had greater new normalized bone volume than β -TCP treated animals.

Unique Delivery Methods Designed For You

Actifuse products are designed to be used alone.
They can be mixed with sterile saline/water, autologous blood or bone marrow aspirate at the discretion of the surgeon but this may affect handling.



Actifuse Shape BONE GRAFT SUBSTITUTE



Irrigation Resistance
Remains resistant to irrigation.^{*5}



Malleable Consistency
Ensures the ability to address the unique contours of each defect.



Significantly MORE CELLS

attach to ACTIFUSE Bone Graft Substitute than calcium phosphate.^{*7}

0.8 wt% chemically bound

silicon shown to be optimal for accelerated bone formation.^{*6}

GREATER new cell-mediated bone volume

in a preclinical model compared to β -TCP and dense calcium sulfate.^{*1}

*As demonstrated in an animal model. Results may not correlate to performance in humans.



Actifuse ABX BONE GRAFT SUBSTITUTE

A sculptable form of ACTIFUSE in a preloaded syringe, ready to use upon opening.²

Actifuse MIS System BONE GRAFT SUBSTITUTE



Enhanced Control
Ergonomic handle and specially engineered trigger enables one-handed delivery of a controlled amount of ACTIFUSE ABX.



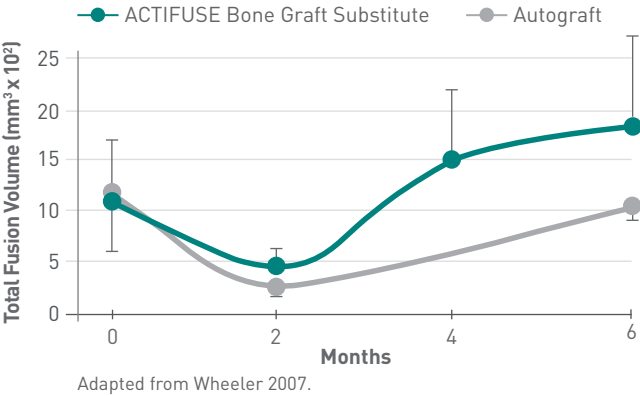
Targeted Delivery
Tip is designed to enable access to difficult to reach surgical sites.



Comparison to Iliac Crest

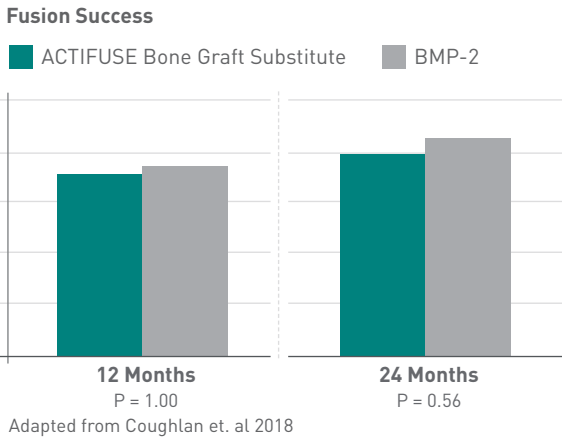
Actifuse Bone Graft Substitute has shown similar fusion rates in comparison to iliac crest in both a clinically relevant ovine PLF model^{*3} as well as in a retrospective human study (vs historical controls).⁴

Comparison to Autograft
Quantitative CT demonstrates total fusion volume against time in a preclinical ovine PLF model. No statistical differences were detected between treatment groups (P<0.05) (n=9 per group).^{*3}



Comparison to BMP-2

Actifuse Bone Graft Substitute was safe and well tolerated in patients with degenerative spinal disorders requiring posterolateral fusion (PLF) and provided fusion rates similar to BMP-2⁸.



ACTIFUSE Shape

Distinctive moldability and versatility allowing the unique contours of each defect to be addressed.

Product Size	1.6 mL, small cylinder	2.6 mL, medium cylinder	8 mL, medium cylinder	15.8 mL, large strip
Product Number	506005078061	506005078063	506005078065	506005078067

ACTIFUSE ABX

A sculptable synthetic bone graft substitute designed as a standalone product ready to use upon opening²

Product Size	1.5 mL	2.5 mL	5 mL	10 mL
Product Number	506005078059	506005078047	506005078048	506005078049

ACTIFUSE MIS System

A ready-to-use applicator and cartridge designed for controlled delivery during minimally invasive procedures
The MIS applicator cartridge is preloaded with ACTIFUSE ABX

Product Size	Applicator and Cartridge 7.5 mL	Refill Cartridge 7.5 mL
Product Number	506005078069	506005078071

Important Risk Information for ACTIFUSE Bone Graft Substitute

ACTIFUSE Bone Graft Substitute is contraindicated where the device is intended as structural/load-bearing support in the skeletal system.
ACTIFUSE Bone Graft Substitute has not been cleared for use in vertebroplasty.

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 Bone Graft Substitute 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 and for Contraindications, Warnings, and Precautions.

Indications for ACTIFUSE Bone Graft Substitute

Bone graft substitutes are intended to be used in place of cortico-cancellous or cancellous allograft or autograft bone.
The mechanical environment for such uses experience either low load requirements or compression.

Typical surgical applications for bone graft substitutes are:

Small void filling, e.g. after removal of a small bone tumour or following bone fracture reduction or in osteotomies.

Spinal fusion, where a cage or screw fixation device is used to relieve the graft site from physiological loads.

It is not intended to be used in place of cortical strut allograft bone where high tensile, torsion and/or bending strength are required. The products are used by orthopaedic surgeons in place of allograft bone (bone from humans stored in bone banks).

**For questions or ordering information, please contact the product distributor:
Australian Allografts**

Advancing the art of healing

1. Hing KA, Wilson LF, Buckland T. Comparative performance of three ceramic bone graft substitutes. Spine J. 2007; 7(4):475-490.
2. ACTIFUSE Bone Graft Substitute Instructions for Use.
3. Wheeler DL, Jenis LG, Kovach ME, Marini J, Turner AS. Efficacy of silicated calcium phosphate graft in posterolateral lumbar fusion in sheep. Spine J. 2007; 7(3):308-317.
4. Jenis LG, Banco RJ. Efficacy of silicate-substituted calcium phosphate ceramic in posterolateral instrumented lumbar fusion. Spine (Phila Pa 1976). 2010;35(20):E1058-E1063.
5. Scaffold Content and Resistance to Irrigation of Several Bone Graft Substitute Materials, Campion. Data on file, Baxter Healthcare Corporation.
6. 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.
7. Guth, K, Campion C, Buckland T, Hing KA. Effect of silicate-substitution on attachment and early development of human osteoblast-like cells seeded on microporous hydroxyapatite discs. Adv Eng Mater. 2010;12(4):B77-B82.
8. Coughlan M, Davies M, Mosert AK, Nanda D, Willems PC, Rosenberg G, Ferch R. SPINE. 2018;43(15):E860-E868.

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