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Actifuse

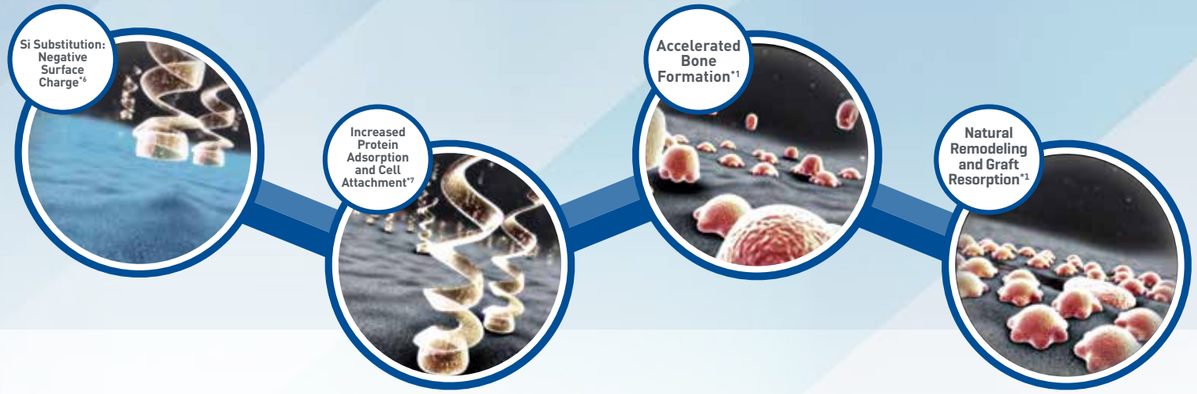
BONE GRAFT SUBSTITUTE

More bone,
Less time[*1]

*In a preclinical model comparing ACTIFUSE Bone Graft Substitute to ß-TCP at 3, 6 and 12 weeks, ACTIFUSE Bone Graft Substitute treated animals had greater new normalized bone volume than ß-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 ß-TCP and dense calcium sulfate.*1

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

Actifuse MIS System
BONE GRAFT SUBSTITUTE

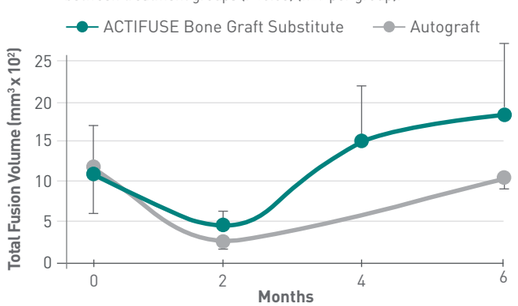
Enhanced Control
Ergonomic handle and specially engineered trigger enables one-handed delivery of a controlled amount of ACTIFUSE ABX.

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

Comparison to Iliac Crest

Actifuse Bone Graft Substitute has shown similiar 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

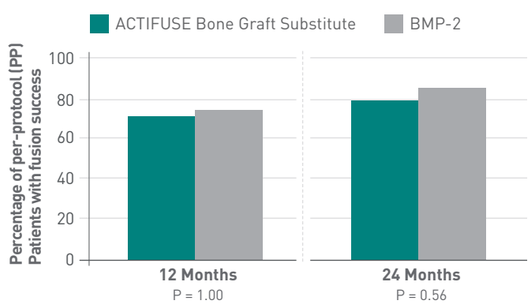


Adapted from Wheeler 2007.

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-2[8].

Fusion Success



Adapted from Coughlan et. al 2018

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	506005078062	506005078064	506005078066	506005078068

ACTIFUSE ABX

A sculptable synthetic bone graft substitute designed as a standalone product ready to use upon opening[2]

Product Size	1.5 mL	2.5 mL	5 mL	10 mL	20 mL
Product Number	506005078060	506005078050	506005078051	506005078052	506005078058

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	506005078070	506005078072

Orthopedic Indication for ACTIFUSE Bone Graft Substitute

ACTIFUSE Bone Graft substitute 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 Bone Graft substitute is indicated to be packed gently 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 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 for Contraindications, Warnings, and Precautions.

For questions or ordering information, please contact your Baxter representative.
www.advancedsurgery.baxter.com

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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