Baxter

Actifuse

BONE GRAFT SUBSTITUTE

THE ADVANTAGE

MORE BONE LESS TIME[*1]

*In a preclinical model comparing ACTIFUSE Bone Graft Substitute (SiCaP) 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. Preclinical data. Results may not correlate to performance in humans.

UNIQUE DELIVERY METHODS **DESIGNED FOR YOU**

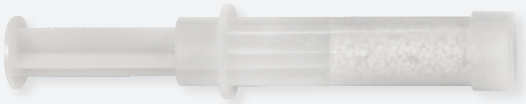
ACTIFUSE Bone Graft Substitute products are designed to be used alone. They can be mixed with sterile saline/water, autologous blood or bone marrow aspirate at the discretion of the surgeon but this may affect handling.

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.

Actifuse ABX
BONE GRAFT SUBSTITUTE



READY TO USE
A sculptable form of **ACTIFUSE** Bone Graft Substitute in a preloaded syringe, ready to use upon opening.[2]

Actifuse MIS System
BONE GRAFT SUBSTITUTE

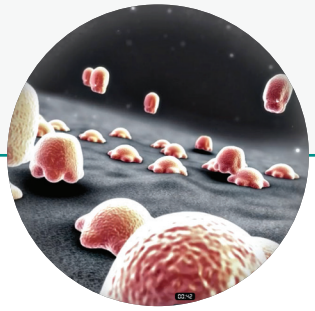
ENHANCED CONTROL
Ergonomic handle and specially engineered trigger enables one-handed delivery of a controlled amount of **ACTIFUSE** ABX Bone Graft Substitute.

TARGETED DELIVERY
Tip is designed to enable access to difficult to reach surgical sites.

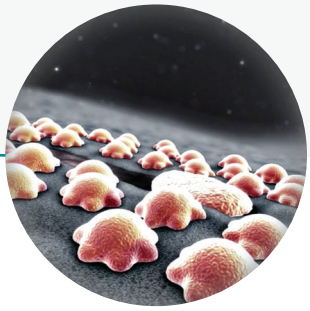
Si Substitution: Negative Surface Charge*6

Increased Protein Adsorption and Cell Attachment*7

Accelerated Bone Formation*1



Natural Remodeling and Graft Resorption*1



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

COMPARISON TO ILIAC CREST

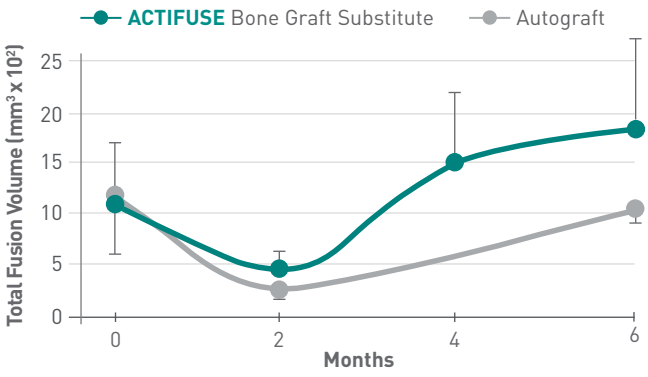
ACTIFUSE Bone Graft Substitute has shown similar fusion rates in comparison to iliac crest in both a clinically relevant ovine PLF model*3 as well as in a retrospective human study (vs historical controls).4

COMPARISON TO 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

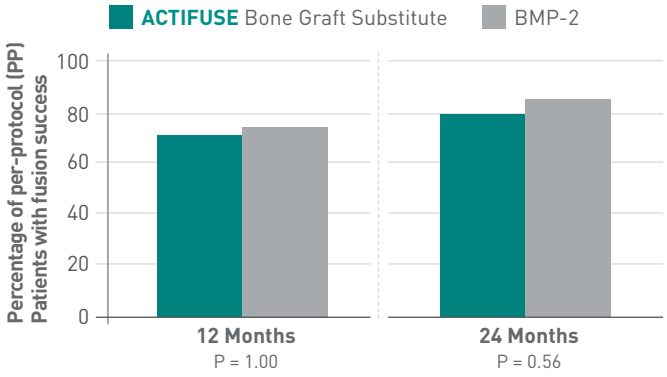
COMPARISON TO AUTOGRAFT

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 et al., 2007

FUSION SUCCESS



Adapted from Coughlan et. al 2018

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

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, large 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

ACTIFUSE INDICATIONS FOR USE

ACTIFUSE 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 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.

CONTRAINDICATIONS

ACTIFUSE is not designed or sold for any use except as indicated. Do not use ACTIFUSE in the presence of any contraindication. ACTIFUSE is contraindicated where the device is intended as structural support in the skeletal system. ACTIFUSE has not been cleared for use in vertebroplasty.

Other conditions representing contraindications include:

- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- hypercalcemia, abnormal calcium metabolism
- existing acute or chronic infections, especially at the site of the operation
- inflammatory bone disease such as osteomyelitis
- malignant tumors
- severely impaired renal function.

WARNINGS

ACTIFUSE is not intended for load-bearing uses. It is important to ensure that the area where ACTIFUSE has been implanted be properly secured mechanically with rigid fixation to strengthen the surroundings. 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 ACTIFUSE on patients with the following conditions is unknown:

- documented renal disease
- metabolic bone disease
- pregnancy and nursing
- radiation bone therapy
- long-term infection
- cardiovascular disease precluding elective surgery.

The effect of ACTIFUSE in pediatric patients is not known. Isolated cases of transient postoperative fever and inflammatory reaction, in the absence of infection have been reported from clinical experience in pediatric cases harboring large Juvenile Bone Cysts. This side effect had no impact on the therapeutic outcome. A causal relationship was not confirmed but it also cannot be fully excluded. The effect of mixing ACTIFUSE with substances other than sterile saline/water, autologous blood or bone marrow aspirate is unknown.

Rx only. For safe and proper use of this device, please refer to the full Instructions for Use

For questions or ordering information, go to www.advancedsurgery.baxter.com or contact your local Baxter representative.

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, Mostert AK, et al. A Prospective, Randomized, Multicenter Study Comparing Silicated Calcium Phosphate versus BMP-2 Synthetic Bone Graft in Posterolateral Instrumented Lumbar Fusion for Degenerative Spinal Disorders. Spine (Phila Pa 1976). 2018;43(15):E860-E868.

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