ACTIFUSE MIS System

Product Code	Description	Product Size
506005078070	Applicator and Cartridge	7.5 mL
506005078072	Refill Cartridge	7.5 mL

Orthopedic Indication for ACTIFUSE Bone Graft Substitute

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.

Important Risk Information for ACTIFUSE Bone Graft Substitute

ACTIFUSE is contraindicated where the device is intended as structural/load-bearing support in the skeletal system. ACTIFUSE 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.

References:

1. Actifuse MIS System IFU. Apatech, 25011; October 2009.
2. 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;27:5014-5026.

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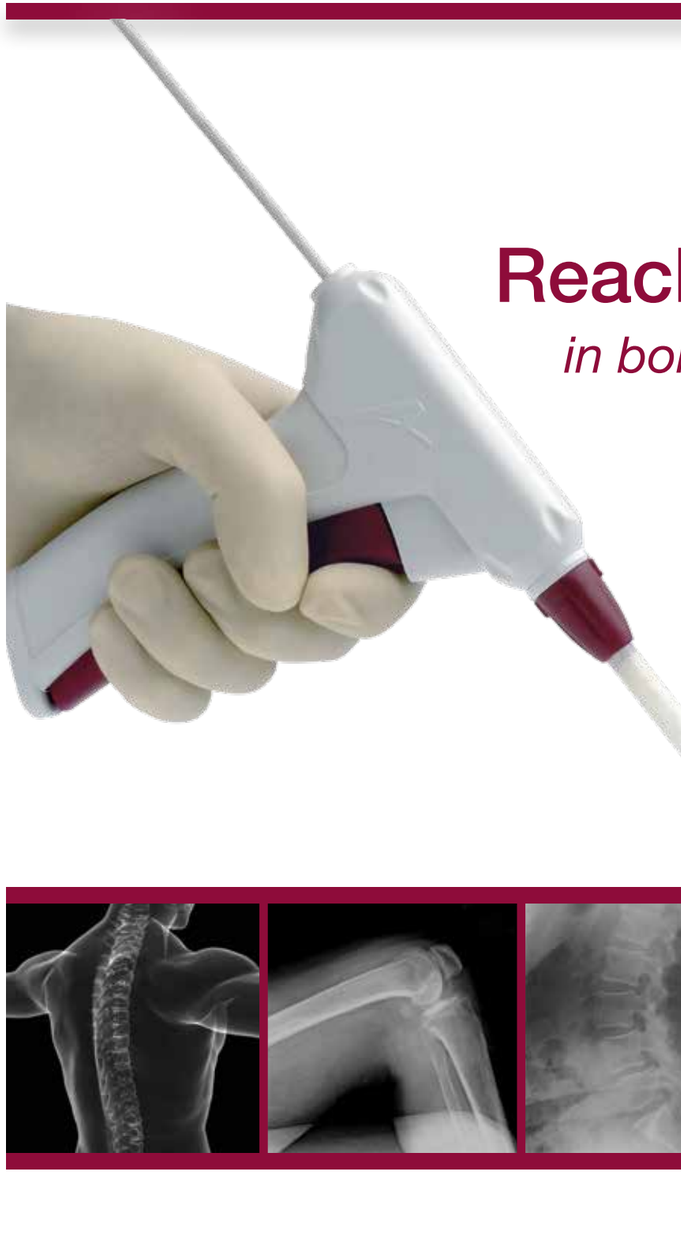
Actifuse
Bone Graft Substitute
Silicate Substituted Calcium Phosphate

MIS System



Reaching new levels
in bone grafting

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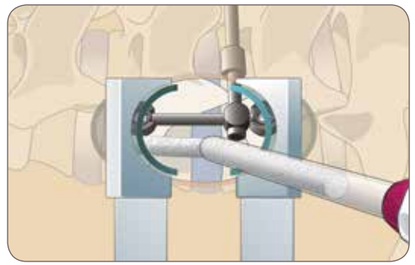
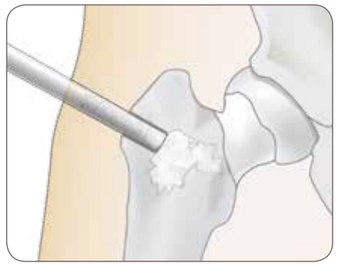
ACTIFUSE MIS System is designed to assist the surgeon who wants a simple, ready-to-use bone grafting system for open and minimally invasive procedures. The system combines extended reach, controlled delivery and precise bone graft placement in a specially designed applicator with **ACTIFUSE** ABX.

▸ **Extended Reach** ▸ **Controlled Delivery** ▸ **Precise Placement**

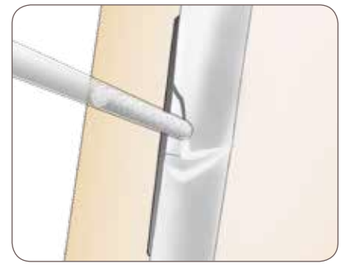
Applications in a Variety of Spinal and Orthopaedic Procedures



Posterolateral Fusion



Bone Void Filling



Fracture Repair

Designed for Ease of Use

- Transparent cartridge for visualization.
- Simple bayonet fitting for quick cartridge attachment.
- Textured grip for use in wet environments.
- Refill cartridges when additional volume is required.

Cartridge	
Working Length	200 mm
Outside Diameter	8 mm
Fill Volume	7.5 mL
Delivery Volume	
• Full Squeeze	0.5 mL
• Half Squeeze	0.2 mL

Optimal Silicon Level*[2]

» 0.8 wt% silicon shown to be optimal for accelerated bone formation.

» BGS samples were implanted into the lower femur of rabbits with surgically created osseous defects (4.8 ± 0.3 mm diameter, 6-7 mm length).

» The sample size was n=4 per implant time point.

» Histomorphometry, using point counting, was used to determine the normalized bone volume percentage.

» For the 0.8 wt% silicon group, there was a statistically significant increase in bone volume from Week 3 to 12 ($p<0.05$) and from Week 6 to 12 ($p<0.005$).

Adapted from Hing 2006.

Please see Indication and detailed Important Risk Information on the back of this brochure.

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