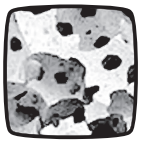

Actifuse MIS System

Bone Graft Substitute

Silicate Substituted Calcium Phosphate

INSTRUCTIONS FOR USE – IMPORTANT PRODUCT INFORMATION

Please read before use

Spinal / Orthopedic Applications

Product Description

Actifuse MIS System contains Actifuse ABX, an osteostimulatory, phase-pure, porous, silicate substituted calcium phosphate bone graft substitute. Actifuse contains 0.8% silicon by weight, similar levels to those identified in naturally-growing bone. Calcium phosphate bone graft substitutes have been the topic of extensive clinical studies for several decades. Actifuse MIS System is safe and has excellent biocompatibility. The interconnected macro- and micro-porous structure and enhanced surface chemistry of Actifuse MIS System encourages the rapid formation of host bone and the growth of capillary blood vessels throughout the network of interconnecting pores. Actifuse is osteostimulatory based upon *in vitro* studies that show that cellular responses, such as metabolic activity and proliferation, are accelerated when compared to an identical material that did not contain 0.8% silicon by weight. After it is implanted, Actifuse undergoes physiologicallyl-mediated resorption and is replaced by natural bone. Actifuse has a resorption time that lies between the least soluble pure Hydroxyapatite and the most soluble form of tricalcium phosphate.

Actifuse MIS System is supplied prepackaged in 7.5ml volumes and contains Actifuse granules, with 80% (±2.5%) porosity and a granule size range of 1–2 mm, suspended in an aqueous gel carrier. **Actifuse MIS System does not set in-situ following implantation. Actifuse MIS System does not contain antibiotics.** The bioactive and osteostimulatory nature of Actifuse has not been correlated with human clinical experience.

Indications For Use

Actifuse MIS System 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 MIS System 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 MIS System is not designed or sold for any use except as indicated. Do not use Actifuse MIS System in the presence of any contraindication. Actifuse MIS System is contraindicated where the device is intended as structural support in the skeletal system. Actifuse MIS System 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 MIS System is not intended for load-bearing uses. It is important to ensure that the area where Actifuse MIS System 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 MIS System 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 MIS System 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 MIS System with substances other than sterile saline/water, autologous blood or bone marrow aspirate is unknown.**

Possible Complications

Successful results may not be achieved in every surgical case. Reoperation to remove or replace an implant may be required due to specific medical conditions or device failure. Possible adverse effects may include but are not limited to:

- wound complications including hematoma, edema, swelling and fluid accumulation, tissue thinning, bone fracture, infection, and other complications that are possible with any surgery
- fracture of the implant with or without generation of particulate debris
- bone deformity at the site
- delayed or non-union
- transient hypercalcemia.

Precautions

Content of package is STERILE by prior exposure to gamma radiation unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded.
Actifuse MIS System is opaque to x-rays. This may mask areas under or above the implant on a radiograph.
Additional mixing containers and stirrers must be sterilized before use.
The graft must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained.
Fully fill the bony defect ensuring maximal contact between Actifuse MIS System and the host bone.
Do not overfill or attempt to pressurize the bony defect site, as this may lead to extrusion of the product beyond the site of its intended application and damage to the surrounding tissues, or may lead to fat embolization or embolization of the product into the bloodstream.
Dosage is for SINGLE USE ONLY. Do not attempt to re-sterilize or re-use.

Instructions for use:

Open both outer (non-sterile) and inner (sterile) packaging.
Step A. Remove plug from bayonet fitting of cartridge (1). Attach filled cartridge to applicator with bayonet fitting (2) by locating bayonet tangs and twisting clockwise (3) so that marks on cartridge and applicator are aligned. Remove cap (4) from cartridge end.
Step B. Depress handle (5) to express Actifuse MIS System from the cartridge.
Implant. Actifuse MIS System is designed to be used alone. Actifuse MIS System can be mixed with sterile saline/water, autologous blood or bone marrow aspirate at the discretion of the surgeon but this may affect handling. Secure the surgical site after implanting to prevent micromotion and implant migration. When excess fluid is present at the surgical field, the surgeon may use cauterization, suction, and application of bone wax (if needed) to reduce bleeding. If the material is not positioned satisfactorily, remove the implant and start over with a new package of Actifuse MIS System.
To load another cartridge:
Step C. Depress handle (6) and hold while withdrawing plunger (7).
Step D. Remove empty cartridge by twisting anticlockwise (8) and dispose of properly.

Storage, Shelf Life and Disposal

Product should be stored between 10-70% Relative Humidity and 5-25˚C (40-77˚F). The expiration date is printed on the label. DO NOT USE ACTIFUSE MIS SYSTEM AFTER THE EXPIRATION DATE. No special disposal is necessary.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician or hospital.
Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of Actifuse MIS System, and for the choice of post-operative follow-up procedures rests entirely with the physician.

Manufactured by: ApaTech Ltd. 370 Centennial Avenue, Centennial Park, Elstree, Hertfordshire, WD6 3TJ, UK
ApaTech Ltd. is an affiliate of Baxter Healthcare Corporation.
Distributed by: Baxter Healthcare Corporation, Westlake Village, CA 91362, USA Tel: 866-652-0700 (toll-free) 508-543-0700

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Actifuse MIS System

Bone Graft Substitute

Silicate Substituted Calcium Phosphate

INSTRUCTIONS FOR USE – IMPORTANT PRODUCT INFORMATION

Please read before use

Periodontal / Oral / Craniomaxillofacial Applications

Product Description

Actifuse MIS System contains Actifuse ABX, an osteostimulatory, phase-pure, porous, silicate substituted calcium phosphate bone graft substitute. Actifuse contains 0.8% silicon by weight, similar levels to those identified in naturally-growing bone. Calcium phosphate bone graft substitutes have been the topic of extensive clinical studies for several decades. Actifuse MIS System is safe and has excellent biocompatibility. The interconnected macro- and micro-porous structure and enhanced surface chemistry of Actifuse MIS System encourages the rapid formation of host bone and the growth of capillary blood vessels throughout the network of interconnecting pores. Actifuse is osteostimulatory based upon *in vitro* studies that show that cellular responses, such as metabolic activity and proliferation, are accelerated when compared to an identical material that did not contain 0.8% silicon by weight. After it is implanted, Actifuse undergoes physiologically-mediated resorption and is replaced by natural bone. Actifuse has a resorption time that lies between the least soluble pure Hydroxyapatite and the most soluble form of tricalcium phosphate.

Actifuse MIS System is supplied prepackaged in 7.5ml volumes and contains Actifuse granules, with 80% (±2.5%) porosity and a granule size range of 1–2 mm, suspended in an aqueous gel carrier. Actifuse MIS System Bone Graft Substitute is intended for placement into open bony voids or osseous defects. **Actifuse MIS System does not set in-situ following implantation. Actifuse MIS System does not contain antibiotics.** The bioactive and osteostimulatory nature of Actifuse has not been correlated with human clinical experience.

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Indications For Use

Actifuse MIS System is a synthetic bone grafting material intended to fill, augment, and/or reconstruct maxillofacial osseous bone defects, including periodontal, oral, and craniomaxillofacial applications. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a synthetic bone grafting material that resorbs and is replaced by bone during the healing process.

Contraindications

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

Actifuse MIS System is not intended to be used in direct contact with the brain.

Other conditions representing contraindications include:

- severe vascular or neurological disease
- uncontrolled diabetes
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- uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- hypercalcemia, abnormal calcium metabolism
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