Patient Information Leaflet

ACTIFUSE ABX, ACTIFUSE MIS, ACTIFUSE Shape

Description of Device and its Intended Purpose

ACTIFUSE is a synthetic bone graft. It is an implantable medical device that consists of porous silicate substituted calcium phosphate (similar to the composition of human bones). A bone graft is a material that acts as a filler or support for new bone growth and is used in patients undergoing surgeries to repair diseased or damaged bones.

ACTIFUSE is intended to fill bony voids or gaps of the skeletal system and may be used mixed with bone materials taken from the patient's own body as a bone graft extender. ACTIFUSE promotes bone formation and accelerates the body's own bone repair response producing bone throughout the graft.

ACTIFUSE is intended to be used only by trained surgeons during an operation. Your surgeon may choose to use ACTIFUSE in surgical procedures such as spinal fusion and small void filling in bones. ACTIFUSE is not intended to bear weight in the skeletal system, so ACTIFUSE may be used with supporting instrumentation such as cage or screw fixation devices.

ACTIFUSE is 100% synthetic and does not contain any biological materials or natural proteins. After implantation, ACTIFUSE is absorbed by the body and is replaced with bone as part of your own natural healing process.

ACTIFUSE is available in a range of product types and sizes as shown below:

PRODUCT NAME	PRODUCT CODE
ACTIFUSE ABX 1.5mL	506005078059
ACTIFUSE ABX 2.5mL	506005078047
ACTIFUSE ABX 5.0mL	506005078048
ACTIFUSE ABX 10.0mL	506005078049
ACTIFUSE ABX 20.0mL	506005078057
ACTIFUSE MIS 7.5mL (cartridge + applicator)	506005078069
ACTIFUSE MIS 7.5mL (refill cartridge)	506005078071
ACTIFUSE Shape Small Cylinder 9mm, 1.6mL	506005078061
ACTIFUSE Shape Medium Cylinder 15mm, 2.6mL	506005078063
ACTIFUSE Shape Large Cylinder 45mm, 8.0mL	506005078065
ACTIFUSE Shape Large Strip 90mmx25mmx7mm, 15mL	506005078067

ACTIFUSE range products all have ACTIFUSE granules, but they are mixed with different types of supporting materials to provide the surgeon different handling properties or may be supplied in a pre-loaded applicator.

Risk Information

ACTIFUSE is fully synthetic, so there is no risk of disease transmission. If your surgeon is considering using ACTIFUSE, they have determined that the benefits of using it outweigh the risks.

Tell your surgeon about your medication, lifestyle, willingness to follow post-operation instructions and/or physical attributes, and any on-going diseases, as these may compromise clinical outcome.

ACTIFUSE should be used as indicated. Tell your surgeon if you have the following conditions: severe vascular or neurological disease, uncontrolled diabetes, severe degenerative disease, if you cannot or will not follow post-operative instruction, drugs and/or alcohol abuse, higher than normal level of calcium in your blood, abnormal calcium metabolism, existing acute or chronic infections (especially at the site of the operation), inflammatory bone disease, cancer, and severely impaired renal function.

Same as with any bone graft surgery, undesirable side effects may happen after ACTIFUSE implantation. Possible undesirable side effects may include but are not limited to:

- wound complications, including bruise, swelling and fluid build-up, tissue thinning, bone fracture, infection, and other surgical complications
- fracture of the implant with or without creating small pieces
- bone deformity at the site
- delayed bone healing or lack of bone repair
- temporary high blood calcium levels.

Successful results may not be achieved for every surgical case due to differences in patient condition and surgical technique. Additional operations to remove or replace an implant may be required due to certain patient-specific medical conditions or device failure.

Post-Surgery

ACTIFUSE resorbs and is replaced with bone during your healing process.

Based on the type of surgical procedure performed, your surgeon will provide you with instructions on how to take care of yourself after your surgery and any restrictions on activities.

Contact your surgeon if you believe you are experiencing side-effects related to the device. This document is not intended to replace consultation with your surgeon if needed.

Serious incidents and adverse events should be reported to Baxter Healthcare Pty Ltd by calling 1800 BAXTER (1800 229 837) or sending an email to ANZ_Product_Safety@baxter.com, and to the Therapeutic Goods Administration on the following site: www.tga.gov.au.

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Sponsor name and address
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