

Explanation of Symbols



Do not use if package is damaged



Sterilized using irradiation



Do not re-use



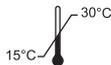
Caution. Consult the Instructions for Use



Use by Date



Prescription Only



Temperature Limit



Do not re-sterilize

This product is to be handled or implanted by trained qualified persons having read these Instructions for Use.



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SGF-037	Contents: 3.75 g
SGF-075	Contents: 7.5 g
SGF-150	Contents: 15 g

Instructions for Use

Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner)

IMPORTANT PRODUCT INFORMATION

Please read before use

A. General Information

Device Generic Name: Bioactive Bone Graft Device
Trade Name: SIGNAFUSE Putty



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B. Materials & Device Description

SIGNAFUSE Putty is a synthetic bone void filler device comprised of biphasic calcium phosphate (CaP) & bioactive glass (45S5) granules suspended in a resorbable alkylene oxide polymer (AOP) carrier. The device is considered bioactive based on in vitro studies that show apatite layer formation on the implant surface following immersion in simulated body fluid. These results have not been correlated to clinical performance.

C. Indications for Use

SIGNAFUSE Putty is a bone void filler device intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. SIGNAFUSE Putty is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities, pelvis, and posterolateral spine, and intervertebral disc space fusion procedures). SIGNAFUSE Putty can also be used with autograft as a bone graft extender in posterolateral spine. When used in intervertebral body fusion procedures, SIGNAFUSE Putty can be used on its own or as a bone graft extender, and with an intervertebral body fusion device cleared by FDA for use with a bone void filler. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.

D. Contraindications

SIGNAFUSE Putty is not designed or sold for any use except as indicated. Do not use SIGNAFUSE Putty in the presence of any contraindication. SIGNAFUSE Putty is contraindicated where the device is intended as structural support in the skeletal system. Other conditions representing contraindications include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- Hypercalcemia, abnormal calcium metabolism
- Necrosis at the recipient site
- Inflammatory bone disease such as osteomyelitis
- Malignant tumors
- Severely impaired renal function
- Intra-articular implantations

E. Warnings

SIGNAFUSE Putty is not intended for load-bearing uses. It is important to ensure that the area where SIGNAFUSE Putty 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 safety and effectiveness of SIGNAFUSE Putty on patients with the following conditions is unknown:

- Documented renal disease
- Metabolic bone disease
- Pregnant women
- Pediatric patients
- Radiation bone therapy
- Long-term infection
- Cardiovascular disease precluding elective surgery

F. Possible Complications

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

- Wound complications including hematoma, edema, swelling and fluid accumulation, adverse tissue reaction, bone fracture, infection and other complications that are possible with any surgery.
- Incomplete, or lack of, bone formation
- Delayed or non-union
- Fracture of the bone void filler with or without particulate formation
- Transient hypercalcemia
- Fracture of the newly formed bone

G. Precautions

- Content of package is STERILE by prior exposure to gamma irradiation unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded.
- The device is for SINGLE USE ONLY. DO NOT attempt to re-sterilize or reuse.
- SIGNAFUSE Putty is opaque to x-rays. This may mask areas under or above the implant on a radiograph.
- 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 SIGNAFUSE Putty and the host bone.
- DO NOT overfill the bony defect 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 may cause damage to the surrounding tissues.
- In the incidence of an open fracture, initial debridement and wound management should be performed. Exercise care to minimize periosteal stripping. Infections must be treated and sepsis eradicated prior to the graft procedure. Use prophylactic antibiotic coverage as appropriate.

H. Instructions for Use

All procedures should be performed under aseptic conditions.

1. Peel open pouch and remove syringe.
2. Remove protective cap from the syringe and extrude the material.
3. Crush implant to activate and mold as desired.
4. SIGNAFUSE Putty is designed to be use alone or mixed with autograft (1:1 ratio) at the discretion of the surgeon.
5. Secure the surgical site after implanting to prevent micro-motion 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 SIGNAFUSE Putty.

I. Storage Conditions

SIGNAFUSE should be stored in a secure, dry environment at ambient temperature. Do not expose to excessive heat for extended periods of time. Optimal storage conditions 15-30 °C (59-86 °F).

J. Shelf Life and Disposal

The expiration date is printed on the label. Do not use SIGNAFUSE after the expiration date. The contents of each pouch are sterile unless opened or damaged. Discard unused portion immediately after use.