# Synthetic Backfill Bioimplant

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**Caution: U.S. Federal Law restricts this product to sale by or on the order of a physician or hospital.**

RADIATION STERILIZED


SINGLE USE ONLY

℞ ONLY

DO NOT RESTERILIZE

## INSTRUCTIONS FOR USE

**IMPORTANT PRODUCT INFORMATION**
**Please read before use**

**ENGLISH**

**These instructions-for-use refer specifically to Synthetic Backfill Bioimplant**

### Description
The Synthetic Backfill Bioimplant is designed as a bone void filler, incorporating a collagen matrix enriched with hydroxyapatite (HA) and tri-calcium phosphate (TCP) granules, along with 45S5 bioactive glass granules. This implant utilizes biocompatible bovine fibrillar collagen and bioactive 45S5 glass particles. The granular composition includes 60 wt% HA and 40 wt% TCP, with the graft containing 20 wt% of 45S5 granules.
This device serves as a scaffold to facilitate new bone growth. A sequence of surface reactions on the granules leads to the creation of a calcium phosphate layer that closely mimics the composition and structure of bone mineral hydroxyapatite. This layer, along with the HA-TCP granules, forms an osteoconductive scaffold that supports the growth of the patient's new bone. As healing progresses, the graft material is gradually absorbed and transformed into new bone.

### Intended Use
The Synthetic Backfill Bioimplant is designed for application in bony voids or gaps within the skeletal system, such as in extremities, the pelvis, and the posterolateral spine. These osseous defects may either be surgically created or occur as a result of traumatic injury to the bone and do not inherently affect the stability of the bone structure. Throughout the healing process, the graft material is absorbed and subsequently replaced by new bone growth. In the posterolateral spine, the Synthetic Backfill Bioimplant must be utilized in conjunction with autogenous bone marrow aspirate and autograft.

### Contraindications
The Synthetic Backfill Bioimplant is exclusively marketed for its specified indications and should not be used for any other purpose. It is important to avoid using the Synthetic Backfill Bioimplant in the presence of any known contraindications.
This bioimplant is contraindicated in patients who have severe allergies that have previously resulted in anaphylaxis or who are known to be allergic to bovine collagen. It is also unsuitable for patients currently receiving desensitization injections to meat products, as these may contain bovine collagen. Additionally, its use is contraindicated in children and pregnant women, for fractures involving the epiphyseal plate, and in areas where there is significant vascular or neurological impairment near the graft site.

### Warnings
The Synthetic Backfill Bioimplant is sterilized using gamma irradiation. Always check the expiration date before use and do not use the product if the expiration date has passed. Do not use if the packaging is damaged, as this compromises the sterility of the contents.
This implant is intended for single use only. Re-sterilizing or re-using the device may result in loss of functionality or contamination.
Synthetic Backfill Bioimplant contains bovine collagen and is contraindicated in patients who are allergic to any bovine products, including but not limited to injectable collagen, collagen implants, hemostatic sponges, and collagen-based sutures, due to the risk of hypersensitivity reactions. Such reactions may include erythema, swelling, induration, and/or urticaria at the implantation sites.
The implant must be properly secured to prevent migration and should only be used in surgical settings where bone grafts are adequately contained.
Additionally, the Synthetic Backfill Bioimplant is not designed for load-bearing applications. It is crucial to ensure that the implantation site is mechanically stabilized using standard internal fixation techniques, as external stabilization alone is inadequate.

### Precautions
The safety and efficacy of the Synthetic Backfill Bioimplant have not been confirmed in patients suffering from pathological fractures due to severe degenerative bone diseases, pre-existing severe vascular or neurological conditions associated with uncontrolled diabetes, alcoholism, or other pathologies, or in those with clinically significant immune-mediated systemic diseases or bone diseases. Additionally, its safety in pregnant women and children has not been established.
The Synthetic Backfill Bioimplant is designed for use by surgeons experienced in bone grafting and internal fixation procedures. It is important to ensure that no direct load is placed on the implant and that the defect site is not overfilled.
Excessive pressurization of the defect site should be avoided as it may lead to fat embolization or embolization of the implant material into the bloodstream. Furthermore, over-pressurizing the implant can cause it to extrude beyond the intended application site and potentially damage surrounding tissues.

### Potential Adverse Reactions
Potential adverse reactions to the Synthetic Backfill Bioimplant may include, but are not limited to, complete resorption of the graft, malunion, pseudoarthrosis, hypersensitivity reactions, thrombophlebitis, embolism, loss of fixation, neurological complications, and site deformity. Similar to other orthopedic and grafting procedures, complications related to the wound such as hematoma, edema, swelling, fluid accumulation, tissue thinning, infection, and other surgical complications may also occur.

### Preoperative Procedure
In cases of an open fracture, it is crucial to perform initial debridement and manage the wound properly. Any infections should be treated, and sepsis must be eradicated before proceeding with the grafting procedure. Additionally, appropriate prophylactic antibiotics should be used as necessary.

### Surgical Procedure
All procedures should be conducted in the operating room under sterile conditions. Adhere to standard grafting practices with fixation. In the event of an open fracture, perform initial debridement and manage the wound accordingly. Take precautions to minimize periosteal stripping. The granules and strips may be hydrated using sterile water, blood, or bone marrow aspirate at approximately a 1:1 ratio. Allow the materials to rehydrate for three minutes.
For applications in the extremities, hydrate the granules and strips with sterile water and blood at a 1:1 ratio, allowing three minutes for rehydration. In the posterolateral spine, hydrate the graft material with bone marrow aspirate at a 1:1 ratio, then combine the hydrated graft with autograft bone also at a 1:1 ratio. Ensure that the defect site is filled as completely as possible to facilitate optimal outcomes.

### Storage Conditions
Recommended Storage Conditions: Maintain a temperature between 15-30˚C (59-86˚F) in a secure and dry environment. DO NOT FREEZE. AVOID EXPOSURE TO EXCESSIVE HEAT. The graft will rapidly lose functionality if subjected to temperatures exceeding 55˚C (131˚F).

### Shelf Life and Disposal
The expiration date is indicated on the label. DO NOT USE the Synthetic Backfill Bioimplant BEYOND THE EXPIRATION DATE. The packaging materials are recyclable. Any remaining materials should be disposed of along with other medical waste.

### Other Information
The Synthetic Backfill Bioimplant is a sterile bone graft substitute that is individually packaged in vials. The putty is pre-loaded into syringes, ready for injection. Each container is securely sealed within translucent double pouches and further enclosed in an additional box to ensure safe transport and storage. This product comes with an instructions-for-use leaflet and additional labels for patient documentation.

Manufactured by Berkeley Advanced Biomaterials, Berkeley, CA (USA).
**Note:** The physician is solely responsible for appropriately selecting patients, obtaining sufficient training, making informed decisions regarding the selection and placement of the graft, and determining the post-operative follow-up procedures. Should there be any complaints or if additional information about the product and its applications is needed, please contact Berkeley Advanced Biomaterials using the contact details provided on this leaflet.